IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

RETRACTABLE TECHNOLOGIES, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Civil Action No. 6:08-CV-120
	§	
OCCUPATIONAL & MEDICAL	§	
INNOVATIONS, LTD.,	§	Jury Trial Demanded
	§	
Defendant.	§	

FIRST AMENDED COMPLAINT

Plaintiff Retractable Technologies, Inc. ("Retractable") files this First Amended Complaint for patent infringement and related causes of action against Defendant Occupational & Medical Innovations, Ltd. ("OMI"), in support of which Retractable alleges as follows.

I. THE PARTIES

1. Retractable is a Texas corporation having a principal place of business in Little Elm, Collin County, Texas.
2. OMI is an Australian corporation having a principal place of business at Unit 1/12 Booran Drive, Slacks Creek, Queensland 4127, Australia, and having a sales agent, TriAxis Medical Solutions, with a principal place of business at 4197 Honor Drive, Frisco, Collin County, Texas.

II. JURISDICTION AND VENUE

3. The Court has general jurisdiction and specific personal jurisdiction over OMI based upon the facts and acts described below, including but not limited to the acts discussed in paragraphs 19-25. OMI is engaged in business in Texas and this lawsuit arises out of its business contacts in Texas. It does not maintain a regular place of business in Texas and is

not required by statute to designate or maintain a registered agent for service of process in Texas. OMI may be served with process through the Secretary of State under the Texas Long Arm Statute, Tex. Civ. Prac. & Rem. Code §17.041, et seq. This Court has personal jurisdiction over OMI under the Texas Long Arm Statute because it is doing business within Texas within the meaning of that statute.

4. The Court has subject matter jurisdiction under at least the following: 15 U.S.C. 1125(a); 28 U.S.C. §§1331, 1332(a)(2), 1338 and 1367, and 35 U.S.C. §281.

5. The amount in controversy is over $75,000.

6. Venue in this federal judicial district is proper under at least the following: 28 U.S.C. §§1400(b) and 1391(d).

III. INTRODUCTION

7. Retractable brings this action against OMI because OMI is now selling in the United States safety syringes that infringe Retractable's United States Patents and that are being manufactured in China by the same business entity that manufactures syringes for Retractable. In addition to patent infringement, OMI has illegally competed with Retractable through theft of confidential information, intentional interference with contracts and by engaging in false advertising that wrongfully disparages and mischaracterizes Retractable's products and makes false allegations regarding the source of origin of OMI's safety syringe products that are now being offered for sale in the United States.

IV. FACTUAL BACKGROUND

Retractable's Patented Safety Syringes

8. Retractable is a small, publicly owned Texas company manufacturing a revolutionary safer alternative to traditional needles and syringes. In the early 1990s, founder Thomas Shaw

developed and patented a new safety syringe that is marketed by Retractable under the name "VanishPoint®." Development of the new safety syringe was initially funded by two Small Business Innovation Research ("SBIR") grants received from the National Institute on Drug Abuse, a division of the National Institutes of Health ("NIH"). The VanishPoint® syringe offers reliable protection against the spread of potentially deadly blood-borne pathogens due to syringe reuse or due to accidental needle-stick injuries, and does not require the user to take any additional steps to render the syringe safe. The VanishPoint® syringe automatically retracts the needle back inside the syringe body when the plunger is fully depressed after it has delivered medicine into a patient. There is virtually no chance for a nurse or doctor to be accidentally stuck by a needle that has been in contact with a patient's blood as the needle is no longer exposed after an injection has been given. Because the nurse or doctor only needs to push the syringe plunger completely to retract the needle, the VanishPoint® is designed to require no separate action to retract the needle. When the syringe is used as designed, the needle will retract as the nurse or doctor finishes injecting medicine into the patient. This is referred to as a passive safety device as opposed to an active device that requires the user to take affirmative action to engage it. Retractable also manufactures retracting safety insulin syringes, retracting safety blood collection devices, and safety intravenous catheters.

9. Retractable's VanishPoint® syringes are manufactured in plants located in Little Elm, Texas and in China, and are being offered for sale in countries throughout the world. Retractable's products are made in China by Double Dove Group Co. Ltd. ("Double Dove"), an entity that was under a contract (hereinafter "Manufacturing Agreement") prohibiting Double Dove from manufacturing retractable syringes for any party other than Retractable and from using or disclosing information developed with respect to Retractable's syringes other than for the

manufacture of Retractable's VanishPoint® syringes. Retractable disclosed its valuable confidential information and trade secrets to Double Dove under confidentiality provisions that remain in effect in order to enable Double Dove to manufacture the VanishPoint® syringes. Retractable's confidential information and trade secrets cannot be easily and properly acquired or duplicated by others.

10. Clinical acceptance of the VanishPoint® syringes has been demonstrated by the placement of approximately four million units in U.S. governmental facilities and almost 500 million units in the global marketplace. Retractable is the only U.S. manufacturer of syringes that has supplied retractable syringes for use in the President's $15 billion AIDS relief program for African nations**.** The new safety syringe and Retractable have been featured in major news publications and on CBS' *60 Minutes*.

11. In 2003, Frost & Sullivan, an international business research and consulting firm, named Retractable as the recipient of its Product Quality Leadership Award for developing, manufacturing and marketing the VanishPoint® line of automated retraction safety needle devices. Frost & Sullivan found that the VanishPoint® product line represented a major improvement over other retractable syringes then on the market. Amit Bohora, a Frost & Sullivan industry analyst, stated, "VanishPoint® devices are clearly the gold standard in retractable syringes." Retractable has been recognized as a superior safety product by independent rating agencies, studies and scholarly reviews, and polls and questionnaires of nurses and doctors.

OMI Illegally Gains Access to Retractable's Confidential Information

12. Retractable's confidential information was generated by Double Dove with respect to Retractable's VanishPoint® retractable syringes under the Manufacturing Agreement. This

includes various testing and analysis that is required by the FDA in order to allow a syringe product to be marketed in the United States. Pursuant to the Manufacturing Agreement, this information is highly sensitive and is considered Retractable's confidential information. This additional Retractable confidential information is not generally known outside of Retractable and Double Dove. Because this information has great value to Retractable, significant measures are taken by Retractable and are required to be taken by Double Dove to ensure that this information remains confidential. This information is the result of substantial time, effort and expense by and/or on behalf of Retractable and gives Retractable a substantial business advantage over other competitors who do not know or use it.

13. OMI entered into an agreement with China Medical Group, a subsidiary of Double Dove, in October of 2003 to manufacture retractable syringes for OMI.

14. On information and belief, OMI was aware of the restrictions on Double Dove as a result of Double Dove's Manufacturing Agreement with Retractable and the prohibition against Double Dove's contracting with OMI. Nevertheless, OMI received Retractable's confidential information.

15. Upon information and belief, OMI was aware that it was receiving Retractable confidential information in breach of the Manufacturing Agreement between Retractable and Double Dove.

16. On information and belief, at the time it contracted with Double Dove, through China Medical Group, Defendant OMI had its own retractable syringe design. However, that design could not be manufactured at significant volumes. From 2004 through 2006, OMI periodically reported to the Australian Stock Exchange that it was still having problems manufacturing syringes in commercial quantities. OMI even admitted in its 2004 annual

chairman's address that "[T]he idea of a research and development company with less than 20 employees (few, if any with process manufacturing experience), attempting to take three complex products into mass manufacture in a foreign Country is simply overly ambitious." OMI did not have a retractable syringe on the market until some time in 2007.

17. On information and belief, Double Dove, using Retractable's confidential information and trade secrets, assisted Defendant OMI in redesigning its retractable syringes during this period so that they worked and could be manufactured in significant volumes.

18. On information and belief, the current OMI retractable syringes incorporate and are the result of the wrongful use of Retractable confidential information by OMI. On August 13, 2007 OMI announced that it had demonstrated its retractable syringes for a potential distributor in the United States.

19. On March 6, 2008, OMI announced publicly that OMI had appointed Cardinal Health as a North American distributor, that the guaranteed minimum order quantities under the distributorship agreement will approximate USD $4.3 million in calendar 2008, that approximately 25% of the revenue is anticipated to be booked by March 31, 2008, that all production tooling has been validated and large quantity production runs have been successfully completed during Cardinal Health's auditing process (with quality meeting all FDA validation and regulatory requirements), that the syringes are packaged and branded with the Cardinal Health logo, that meticulous and conclusive design and regulatory approvals to complete the artwork and packaging for the Cardinal Health Private Label for the OMI syringe has been finalized and signed off, that the required "Certificate of Completion of Supplier Audit" has been received from Cardinal Health's Shanghai office, that syringe manufacture is in full production and completion of Cardinal Health's initial

stocking order ("ISO") is expected by the end of March 2008 with additional orders expected soon thereafter, that delivery of the ISO as each run passes OMI's batch testing has begun and the first shipments of the ISO have been received into Cardinal Health's U.S. warehouse, with revenue booked accordingly, that OMI anticipates approximately USD $1 million of the committed calendar 2008 orders will be booked by March 31, 2008, that OMI anticipates receipting cash flow from these sales in March 2008, that OMI confirms its earlier advice that syringe sales into North America under the Cardinal Health distribution agreement will increase top line revenue by a minimum of USD $4.3 million in calendar 2008, and that more than 50% of the revenue increase will be booked by June 30, 2008.

20. On Thursday, March 27, 2008, Kevin Kohler, Regional Sales Manager for Retractable, was present at and made a presentation at a meeting held in Austin, Texas at the Texas Department of State Health Services ("DSHS") for the purpose of promoting continued sales of Retractable's products, including VanishPoint® syringes having retractable needles, to that state agency. Retractable has been selling VanishPoint® retractable syringes and other products to DSHS for a number of years, and currently sells to DSHS through McKesson, another national distributor of medical products. On information and belief, DSHS holds this meeting annually for the purpose of reviewing medical products currently being purchased by, or being offered for sale to, the agency. Products purchased by the agency are shipped initially to its distribution facility in Austin and then redistributed by the agency to its various field offices throughout the state.

21. Also present at the March 27, 2008 meeting in Austin, Texas, and making a presentation to the agency were Fred Kratz, President of TriAxis Medical Solutions, of Frisco, Collin

County, Texas, representing OMI, and Rhonda Conklin, Sales Representative for Physician Products and Services for Cardinal Health, who offices in San Antonio, Texas.

22. While waiting to begin his presentation, Mr. Kohler began conversing with Mr. Kratz and Ms. Conklin, who showed him a new syringe product that they were offering for sale to the agency at the meeting. Mr. Kohler was permitted to handle one of the syringes, open the package, inspect and activate the syringe. The syringe had a retractable needle and was identified with markings for Cardinal Health. Mr. Kohler asked for and received business cards from Mr. Kratz and Ms. Conklin.

23. On information and belief, the OMI/Cardinal syringe Mr. Kohler examined is one of the syringes having retractable needles that have recently been touted by OMI as being the syringes currently being shipped from OMI's Chinese manufacturer (related to Double Dove) to the U.S. for distribution through Cardinal Health.

24. On information and belief, OMI, through its distributors, sales representatives and/or agents Cardinal Health and TriAxis Medical solutions, offered its syringes having retractable needles for sale in the State of Texas and to the Texas Department of State Health Services in Austin, Texas, at least as early as March 27, 2008.

OMI Engages in False Advertising

25. In November 2007, OMI displayed its retractable syringe products and accompanying sales literature to attendees at an international trade show, *Medica 2007*, held in Dusseldorf, Germany. This trade show was attended by consumers of such medical products in the United States. On information and belief, OMI distributed at the tradeshow and has otherwise distributed to customers and prospective customers for its retractable syringes in the United States a brochure titled "*OMI Safety Syringe.*" A copy of the brochure is attached as Exhibit C to this First Amended Complaint.

26. The brochure "*OMI Safety Syringe"* directs the reader's attention to the "KEY BENEFITS" section of the brochure and to the accompanying graph titled "Waste Space Comparison – 3mL Syringe." The brochure purportedly compares the waste space volume ("WSV") of OMI's Safety Syringe to that of the VanishPoint® syringe as currently marketed by Retractable. The graph shows the WSV of the OMI syringe to be 0.016 mL and the WSV of the VanishPoint® syringe to be 0.143 mL. The graph further states: "Source: University test results. December 2006 document #0791."

27. Contrary to the statements made in the "*OMI Safety Syringe"* brochure, the VanishPoint® syringes marketed by Retractable for more than the past five (5) years have had a WSV that is significantly lower than that stated in the brochure, that complies with ISO standards, and that is directly comparable to the WSV stated for the OMI safety syringe.

28. In December 2007, through legal counsel, Retractable requested by letter from OMI a complete copy of the December 2006 university test results mentioned in the "*OMI Safety Syringe"* brochure and any related report (including but not limited to document #0791), identification of the name and location of the university that performed the test, identification of each principal investigator who supervised the subject test, identification of each person who contributed to or prepared the report, and identification of the source (other than Retractable) of the particular VanishPoint® syringes that were tested. Despite the written request, OMI failed to provide Retractable with any explanation and refused to provide any such information to Retractable.

29. On information and belief, OMI received a 2004 Australian Design Award for a syringe having a retractable needle. On information and belief, the OMI syringe that won the 2004 Australian Design Award was never manufactured and sold commercially anywhere in the

world. However, OMI has repeatedly and persistently maintained that the safety syringes it is now marketing in the United States received that award. On information and belief, such representations have been made on OMI's website, in public releases of information on behalf of OMI in promoting its business and the sale of its stock, and in promoting sales of its safety syringe products to customers in the United States.

30. On information and belief, many of the significant structural features and much of the technology embodied in the safety syringes now being offered for sale by OMI in the United States were in fact invented or designed by Retractable and by Retractable's Chinese manufacturer under a contract that vested ownership of such features and technology in Retractable.

RTI's Discovery of its Claims and OMI's Fraudulent Concealment

31. OMI recently asserted statute of limitations as an affirmative defense to RTI's claims for tortious interference, misappropriation of trade secrets, and conversion. To the extent necessary, RTI's claims are not barred by limitations because RTI could not have discovered them before 2007 and because OMI fraudulently concealed its wrongdoing.

32. Up through at least 2006, OMI made repeated representations, including representations in sworn affidavits in a related litigation between the parties in Australia, that it did not have any knowledge or reason to know of RTI's contract with Double Dove prior to entering into its own agreement with China Medical and that it did not have access to and had not received any of RTI's confidential information or trade secrets.

33. RTI relied on these representations. Between 2003-2006, RTI did not have any independent evidence or any way of discovering that OMI actually had knowledge of the RTI-Double Dove contract at the time it contracted with China Medical or that OMI had access to or was using RTI's confidential information and trade secrets. RTI used reasonably diligent efforts

to try to discover such evidence, including having its attorneys send letters to OMI in an attempt to obtain an explanation of OMI's relationship and dealings with China Medical and trying to obtain formal discovery in the Australian litigation. None of these efforts were successful.

34. RTI did not learn of OMI's knowledge of the RTI-Double Dove contract until RTI received certain documents appearing to be OMI's internal business records. These documents were received by OMI from an anonymous source in 2007. These documents also indicated that that OMI had improper access to and was using RTI's confidential information and trade secrets.

35. Based on these documents, RTI discovered that OMI's prior representations regarding its innocence were false and that OMI had lied about its conduct related to Double Dove/China Medical.

36. RTI also discovered in 2007 that OMI was using its confidential information and trade secrets when OMI began commercializing its own syringes evidencing use of RTI's information.

37. RTI filed these claims in April 2008, shortly after learning of facts to support jurisdiction over OMI. RTI was diligent in pursuing its claims once it discovered the information described herein and learned of OMI's fraudulent concealment.

38. RTI's claims are not barred by the applicable statute of limitations because the discovery of these claims was delayed and the limitations period was tolled by OMI's fraudulent concealment.

V. RETRACTABLE'S ASSERTED UNITED STATES PATENTS

39. Retractable is the owner of all right, title and interest in and to United States Patent No. 6,572,584 B1 ("the '584 patent"), titled Retractable Syringe With Reduced Retraction Force, issued June 3, 2003. All maintenance fees due for this patent have been paid. No right or license under this patent has previously been granted to OMI. A copy of the '584 patent is attached as Exhibit A to this First Amended Complaint.

40. Retractable is the exclusive licensee from Thomas J. Shaw, the sole inventor, of United States Patent No. 7,351,224 B1 ("the '224 patent"), titled Retractable Syringe Assembly Designed For One Use, issued April 1, 2008, and has the right to sue infringers in its own name. No right or license under this patent has previously been granted to OMI. The '584 and '224 patents have not been invalidated or found to be unenforceable in any prior litigation. A copy of the '224 patent is attached as Exhibit B to this First Amended Complaint.

41. The '224 patent is a continuing application claiming priority from United States Patent Nos. 5,578,011, 5,632,733, and 6,090,077, all of which are also exclusively licensed by Retractable. U.S. 5,578,011 (the '011 patent) and 6,090,077 (the '077 patent) have both previously been asserted by Retractable against another defendant and contain claims that have previously been construed pursuant to a Markman proceeding before this Court.

42. At all times relevant to this action, Retractable has marked the packages of its VanishPoint® retractable syringes with the number of the '584 patent as provided by 35 U.S.C. §287 and has complied with the notice provisions of 35 U.S.C. §287 with respect to the '224 patent.

VI. CAUSES OF ACTION

Count I – Patent Infringement

43. Retractable hereby realleges and incorporates by reference into this Count 1 the subject matter of the preceding paragraphs of this First Amended Complaint.

44. OMI is, without permission from Retractable or Thomas J. Shaw, making, having made and importing syringes that infringe at least one claim of each of the '584 and '224 patents ("infringing syringes") into the United States, and is offering for sale and/or selling the infringing syringes in the United States and in the State of Texas, and deriving revenue therefrom in contravention of Retractable's legal and equitable rights and in violation of the patent laws of the United States as set forth in Title 35 of the United States Code, including without limitation, 35 U.S.C. §§271.

45. On information and belief, the activities of OMI as set forth above are also inducing others to infringe the '584 and '224 patents by using the subject syringes, and/or contributing to the infringement of the '584 and '224 patents in the United States during the term of the patents.

46. The infringing activities of OMI have caused damage and irreparable injury to Retractable and, unless enjoined by this Court as provided by 35 U.S.C. § 283, will continue to cause damage to Retractable, for which damages Retractable is entitled to recovery pursuant to 35 U.S.C. §284.

47. On information and belief, at least as to the '584 patent, OMI's infringement of the '584 patent has been willful, intentional, and in deliberate disregard of Retractable's patent rights, and is totally without justification, thereby supporting the award of enhanced damages in an amount equal to three times the amount found or assessed pursuant to 35 U.S.C. §284, and

the finding of an exceptional case supporting the award of attorney fees to Retractable under 35 U.S.C. § 285.

Count II – Misappropriation of Trade Secrets and Confidential Information

48. The preceding paragraphs of this First Amended Complaint are incorporated herein by reference as if fully set forth.

49. Defendant OMI improperly solicited and obtained Retractable confidential information from Double Dove. Such information was used by Defendant OMI and Double Dove or its affiliates in the development and design of the OMI retractable syringe.

50. Until now, Retractable has not been able to establish personal jurisdiction over OMI in the State of Texas.

51. Defendant's use and disclosure of the confidential information and trade secrets belonging to Retractable constitutes misappropriation and theft of trade secrets, and Defendant has thereby violated the statutory and common law of the State of Texas. Accordingly, Defendant is liable to Retractable for all of Retractable's actual damages, which are in an amount far in excess of the minimum jurisdictional limits of this Court, resulting from this wrongful misappropriation and theft, together with additional damages as allowed under the law. Defendant's continued use of the improperly obtained Retractable confidential information and trade secrets will cause irreparable injury to Retractable and thus should be preliminarily and permanently enjoined.

Count III – Conversion

52. The preceding paragraphs of this First Amended Complaint are incorporated herein by reference as if fully set forth.

53. The confidential information regarding Retractable's VanishPoint® retractable syringes is the rightful property of Retractable. By wrongfully controlling, disclosing, and utilizing the confidential information of Retractable for its own benefit and the benefit of third parties, Defendant has unlawfully converted Retractable's property in violation of the statutory and common law of the State of Texas.

54. As a direct result of Defendant's conversion, Retractable has been damaged in an amount in excess of the minimum jurisdictional limits of this Court. Defendant's continued use of the converted Retractable confidential information and trade secrets will cause irreparable injury to Retractable and thus should be preliminarily and permanently enjoined.

Count IV – Intentional Interference with Contractual Relations

55. The preceding paragraphs of this First Amended Complaint are incorporated herein by reference as if fully set forth.

56. Defendant OMI knowingly interfered with Retractable's contractual relations with Double Dove by inducing Double Dove to breach its contract with Retractable by disclosing Retractable confidential information to one or more third parties, by using Retractable confidential information in developing the OMI retractable syringe, and by inducing Double Dove and its affiliates to breach Double Dove's contract with Retractable by manufacturing retractable syringes for another company, namely OMI, all in violation of the statutory and common laws of the State of Texas.

57. Defendant's actions have caused injury and economic loss to Retractable in an amount greatly in excess of the minimum jurisdictional limits of this Court.

Count V – Unfair Competition and False Advertising

58. The preceding paragraphs of this First Amended Complaint are incorporated herein by reference as if fully set forth.

59. The foregoing actions of OMI, done intentionally and with full knowledge of their falsity and in reckless disregard of the rights of Retractable, in promoting the sale of OMI's accused products in the United States, constitute unfair competition, wrongful disparagement and false advertising in violation of 15 U.S.C. 1125(a), and have caused damage and loss of sales and profits to Retractable and its shareholders.

VII. PRAYER

WHEREFORE, premises considered, Retractable seeks judgment and relief against Defendant, including:

(a) OMI be adjudged and decreed to have directly, indirectly, and/or contributorily infringed the '584 and '224 patents;

(b) OMI be adjudged and decreed to have willfully and deliberately infringed the '584 and '224 patents;

(c) OMI be ordered to pay actual damages to Retractable and Shaw, but not less than a reasonable royalty, by reason of OMI's infringement of the '584 and '224 patents together with prejudgment interest, costs and increased damages pursuant to 35 U.S.C. § 284;

(d) A permanent injunction be entered against OMI, and its officers, agents, servants and employees, and all entities and individuals acting in concert with them, to permanently restrain any further infringement of the '584 and '224 patents and from making false claims regarding the products of OMI or Retractable;

(e) This case be declared an "exceptional case" within the meaning of 35 U.S.C. §285 and reasonable attorneys' fees, costs and treble damages be awarded to Plaintiffs;

(f) Entry of judgment against the Defendants on the above claims;

(g) Damages in an amount otherwise sufficient to compensate Retractable for its loss;

(h) Entry of judgment that this is an exceptional case and awarding Retractable its costs, expenses, and reasonable attorney fees for prosecuting this action against Defendants;

(i) Entry of preliminary and permanent injunctions enjoining the Defendants from disclosing or using any confidential information or trade secrets of Retractable or from selling retractable syringes that incorporate any confidential information or trade secrets of Retractable;

(j) Entry of judgment for pre-judgment interest and post-judgment interest; and

(k) Such other and further relief to which Retractable may be justly entitled.

VIII. JURY DEMAND

Retractable demands a trial by jury as their right under the Seventh Amendment to the Constitution of the United States or as given by statute. Fed. R. Civ. P. 38.

Date: May 11, 2009

Respectfully submitted,

/s/ Roy W. Hardin

Roy W. Hardin
Texas Bar No. 08968300
George E. Bowles
Texas Bar No. 02743300
Stephen D. Wilson
Texas Bar No. 24003187
Mark R. Backofen
Texas Bar No. 24031838
LOCKE LORD BISSELL & LIDDELL LLP
2200 Ross Avenue, Suite 2200
Dallas, Texas 75201-6776
Telephone: (214) 740-8000
Facsimile: (214) 740-8800
Email: rwhardin@lockelord.com

ATTORNEYS FOR PLAINTIFF
RETRACTABLE TECHNOLOGIES, INC.

Of Counsel:

Otis Carroll
Texas Bar No. 03895700
Deborah Race
Texas Bar No. 16448700
Ireland, Carroll & Kelley, PC
6101 S. Broadway, Suite 500
Tyler, Texas 75703
Telephone: (903) 561-1600
Facsimile: (903) 581-1071
Email: fedserv@icklaw.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3).

/s/ Roy W. Hardin

EXHIBIT A

(12) **United States Patent**
Shaw et al.

(10) **Patent No.: US 6,572,584 B1**
(45) **Date of Patent: Jun. 3, 2003**

(54) **RETRACTABLE SYRINGE WITH REDUCED RETRACTION FORCE**

(75) Inventors: **Thomas J. Shaw**, Little Elm, TX (US); **Judy Zhu**, Plano, TX (US); **Diane Rutherford**, Corinth, TX (US)

(73) Assignee: **Retractable Technologies, Inc.**, Little Elm, TX (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/633,657**

(22) Filed: **Aug. 7, 2000**

(51) **Int. Cl.**[7] **A61M 5/00**
(52) **U.S. Cl.** **604/110**; 604/195
(58) **Field of Search** 604/110, 229, 604/230, 239, 240, 264, 187, 195, 218

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,306,290	A	2/1967	Weltman
4,747,831	A	5/1988	Kulli
4,838,863	A	6/1989	Allard et al.
4,838,869	A	6/1989	Allard
4,841,985	A	6/1989	Wanamaker
4,874,382	A	10/1989	Lindemann et al.
4,904,242	A	2/1990	Kulli
4,955,870	A	9/1990	Ridderheim et al.
4,994,034	A	2/1991	Botich et al.
5,019,044	A	5/1991	Tsao
5,046,508	A	9/1991	Weissler
5,049,133	A	9/1991	Villen Pascual
5,053,010	A	10/1991	McGary et al.
5,064,419	A	11/1991	Gaarde
5,084,018	A	1/1992	Tsao
5,084,029	A	1/1992	Tagliaferri et al.
5,090,962	A	2/1992	Landry, Jr. et al.
5,092,853	A	3/1992	Courvertier, II
5,112,316	A	5/1992	Venturini
5,114,410	A	5/1992	Caralt Batlle
5,120,310	A	6/1992	Shaw
5,163,918	A	11/1992	Righi et al.
5,180,369	A	1/1993	Dysarz
5,180,370	A	1/1993	Gillespie
5,188,599	A	2/1993	Botich et al.
5,201,710	A	4/1993	Caselli
5,211,629	A	5/1993	Pressly et al.
5,304,138	A	4/1994	Mercado
5,324,265	A	6/1994	Murray et al.

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

GB	2 197 792 A	6/1988
JP	146773	5/2000
WO	WO 95/08358	3/1995
WO	WO 96/35463	11/1996
WO	WO 98/48869	11/1998

OTHER PUBLICATIONS

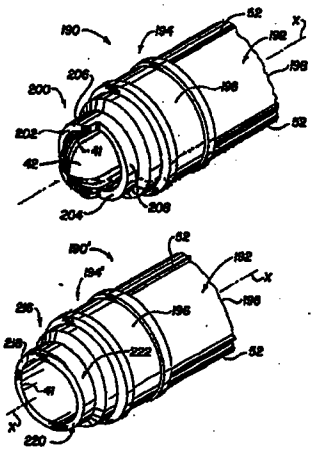
"Disappearing Needle", Designer News, p. 58, Mar. 22, 1993.

Primary Examiner—Kevin C. Sirmons
(74) *Attorney, Agent, or Firm*—Locke Liddell & Sapp LLP; Monty L. Ross

(57) **ABSTRACT**

A tamperproof retractable non-reusable syringe has a one piece hollow outer body with a barrel for a slidable plunger, a transition zone and a smaller diameter nose portion. An elongated needle holder and spring combination is installable from the rear of the outer body, guided into the nose portion and held by cooperating inwardly and outwardly facing surfaces oriented in the direction of retraction at the most constricted part of the transition zone where the nose begins. The plunger has an opening with a dislodgable stopper for receiving parts of the retraction mechanism. The stopper and the head of the needle holder are of significantly reduced diameter from the injection fluid chamber to resist blowing out prematurely. In one embodiment the head of the needle holder is surrounded by a separable retainer member which is slidingly removed by contact with the tip of the plunger after the stopper is mostly or fully removed to avoid cumulation of force required for retraction after the injection.

28 Claims, 13 Drawing Sheets



U.S. PATENT DOCUMENTS

5,346,480	A	9/1994	Hess et al.
5,370,620	A	12/1994	Shonfeld
5,376,080	A	12/1994	Petrussa
5,385,551	A	1/1995	Shaw
5,389,076	A	2/1995	Shaw
5,407,431	A	4/1995	Botich et al.
5,411,489	A	5/1995	Pagay et al.
5,423,758	A	6/1995	Shaw
5,505,703	A	4/1996	Bartlett et al.
5,527,286	A	6/1996	Lekhgolts et al.
5,578,011	A	11/1996	Shaw
5,613,952	A	3/1997	Pressley, Sr. et al.
5,632,733	A	5/1997	Shaw
5,800,403	A	9/1998	Pressly, Sr. et al.
5,810,775	A	9/1998	Shaw
5,997,512	A	12/1999	Shaw
6,015,438	A	1/2000	Shaw
6,090,077	A	7/2000	Shaw

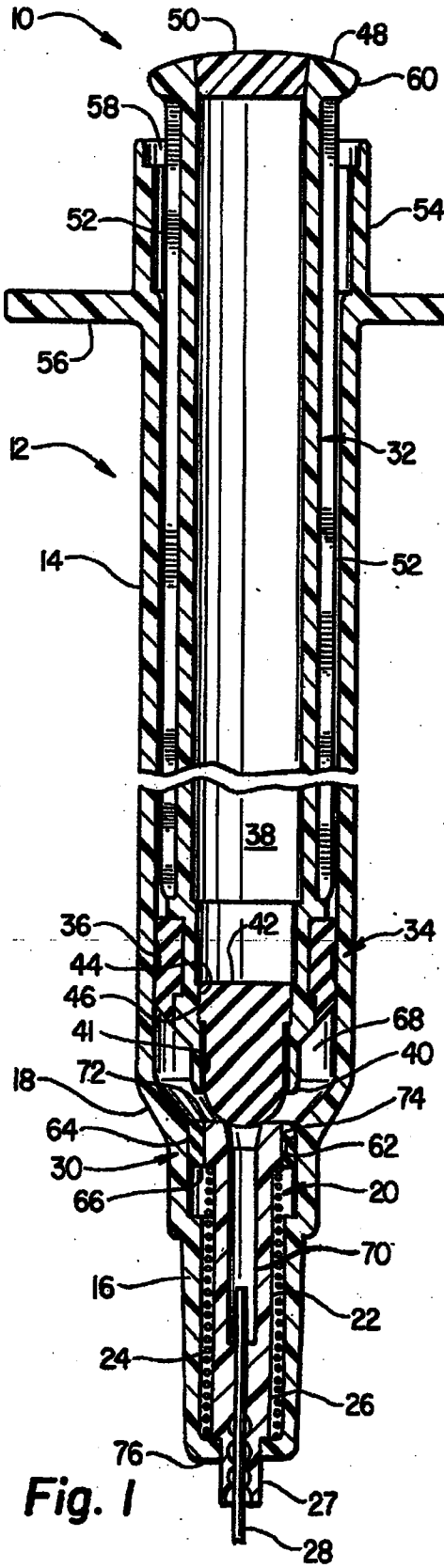

10
50
48
60
58
52
54
56
12
32
14
52
38
36
42
34
44
46
41
68
40
18
72
74
64
62
30
20
66
70
16
22
24
26
76
27
28

Fig. 1

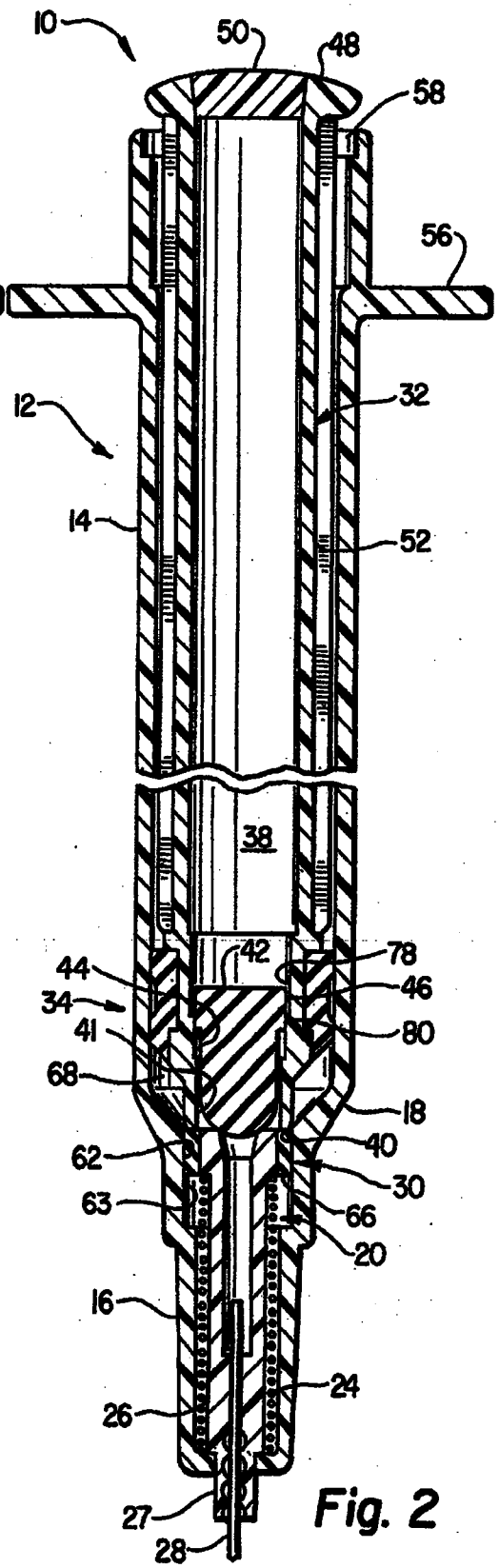

10
50
48
58
56
12
32
14
52
38
42
78
44
46
34
41
80
68
18
62
40
30
63
66
20
16
24
26
27
28

Fig. 2

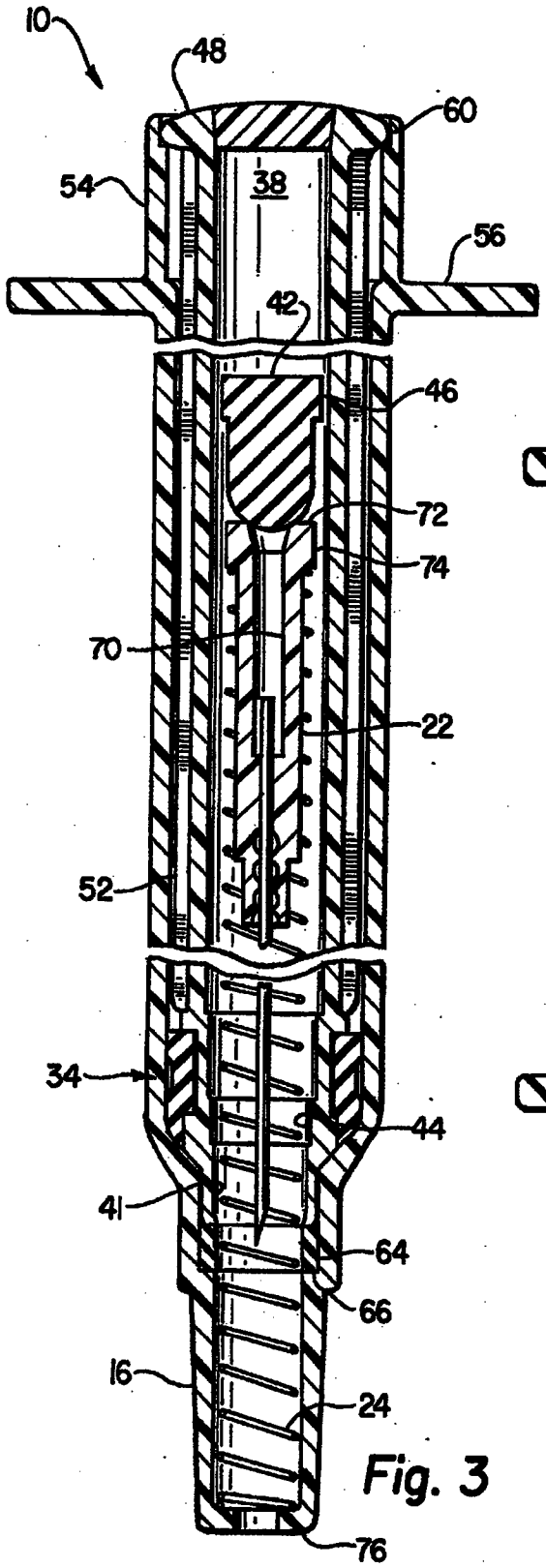


Fig. 3

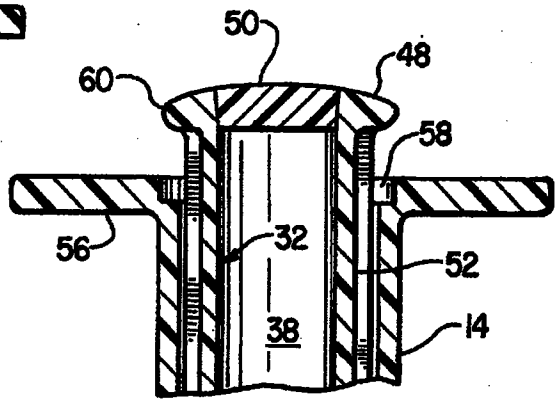


Fig. 4A

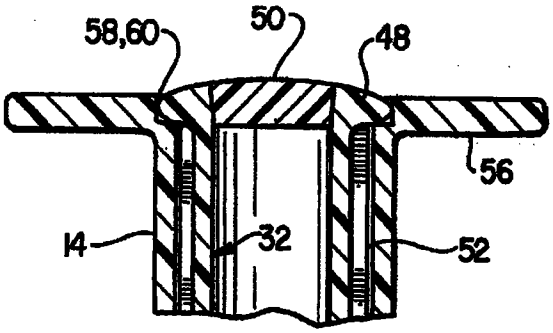


Fig. 4B

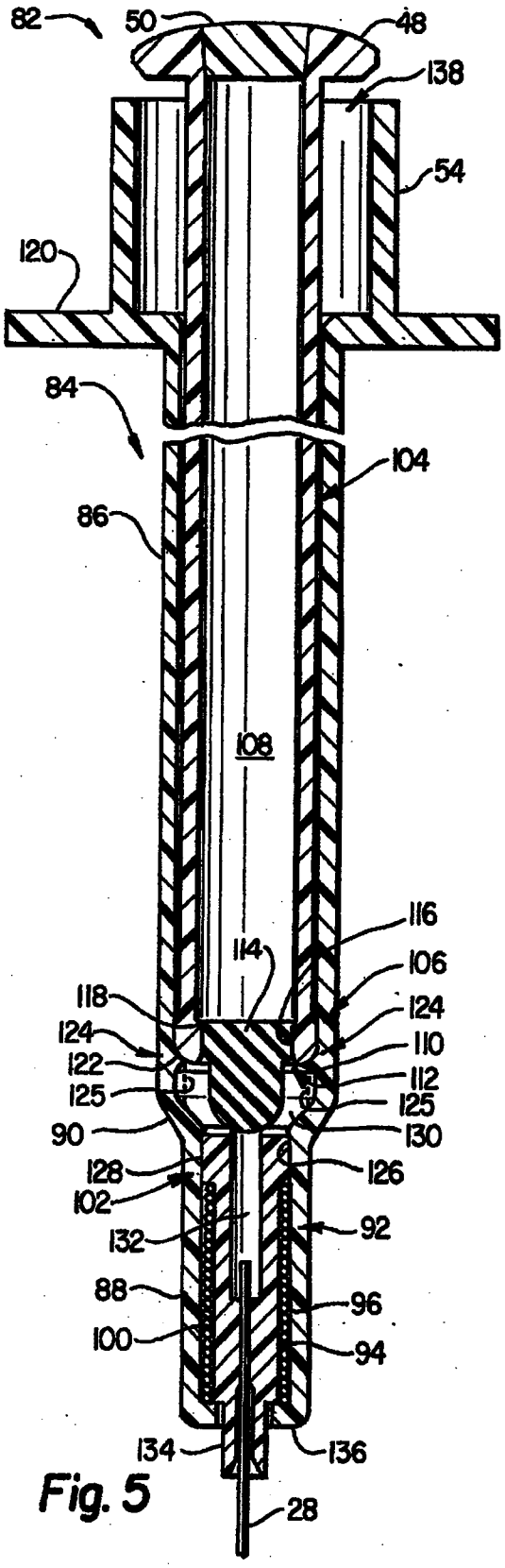

82
50
48
138
54
120
84
104
86
108
116
114
106
118
124
110
122
112
125
125
90
130
128
126
102
92
132
88
96
100
94
134
136
28

Fig. 5

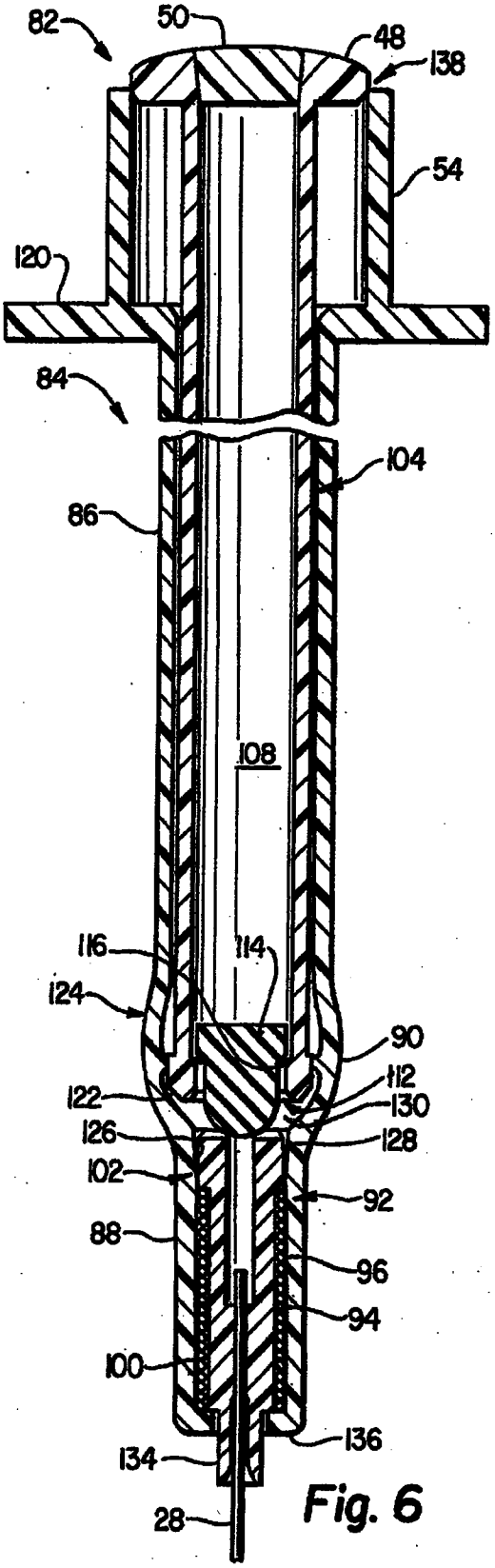

82
50
48
138
54
120
84
104
86
108
116
114
124
90
112
122
130
126
128
102
92
88
96
94
100
136
134
28

Fig. 6

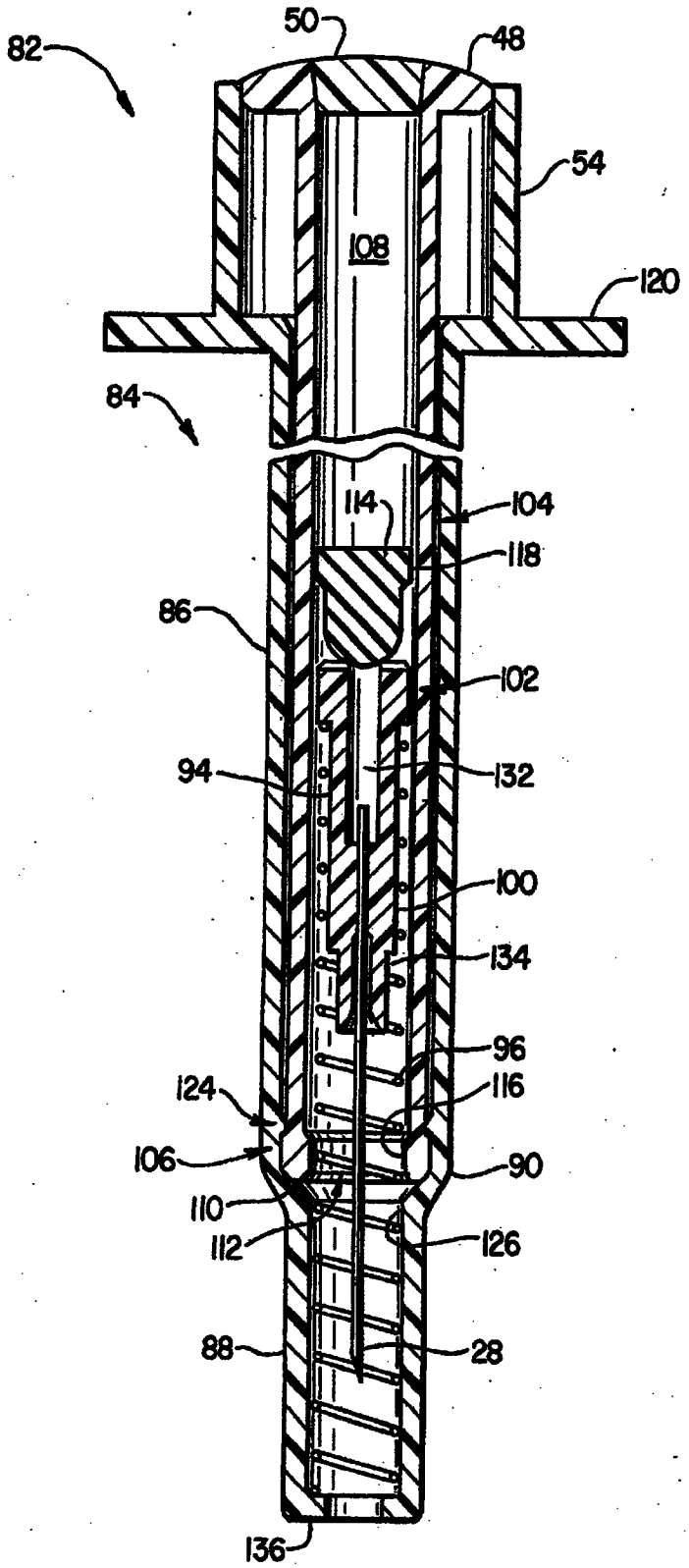

82
50
48
54
108
120
84
114
104
118
86
102
94
132
100
134
96
124
116
106
90
110
112
126
88
28
136

Fig. 7

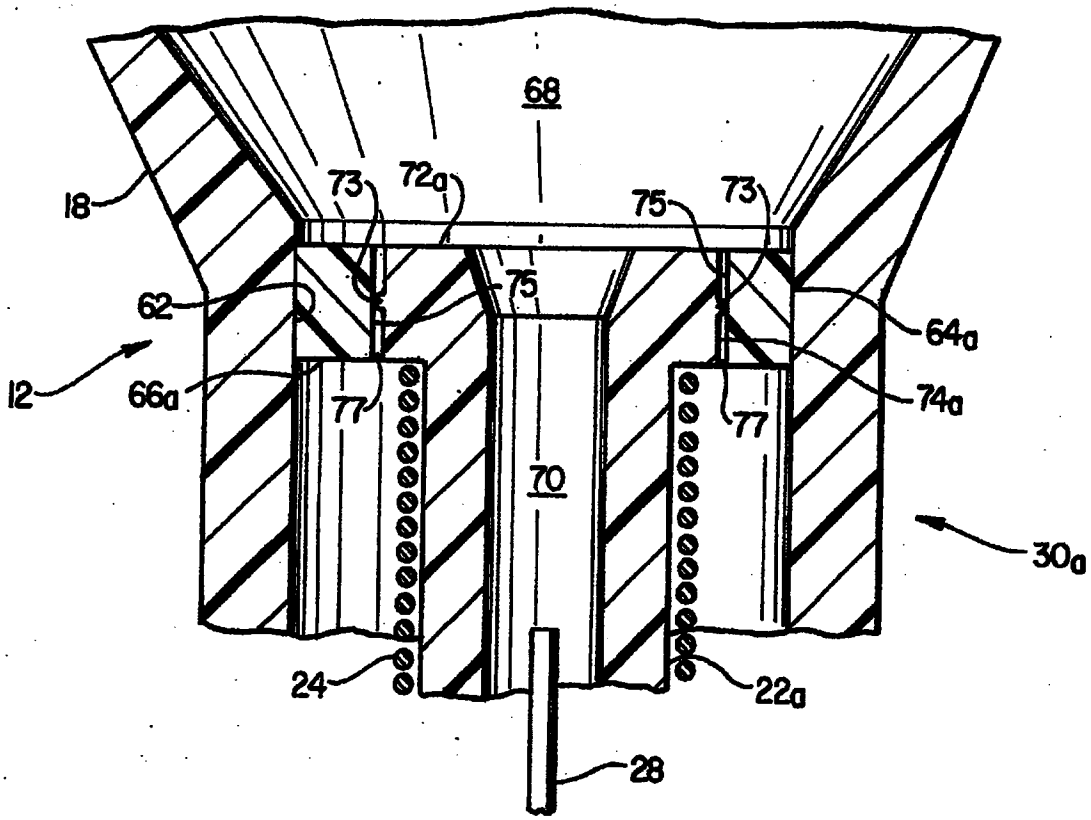


Fig. 8

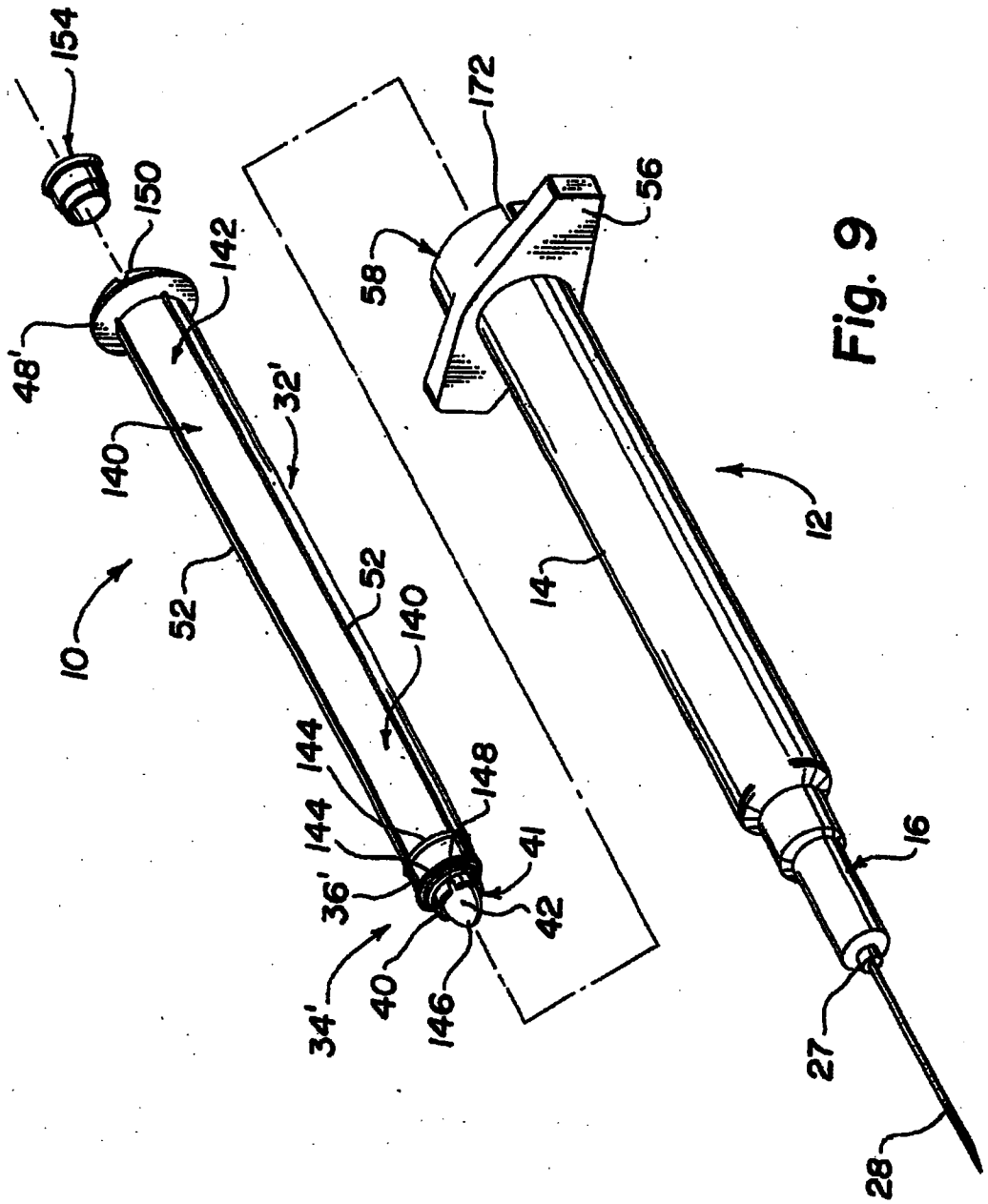

154
150
142
48'
32'
140
52
52
140
10
12
14
172
56
58
144
148
144
36'
41
42
34'
40
146
16
27
28

Fig. 9

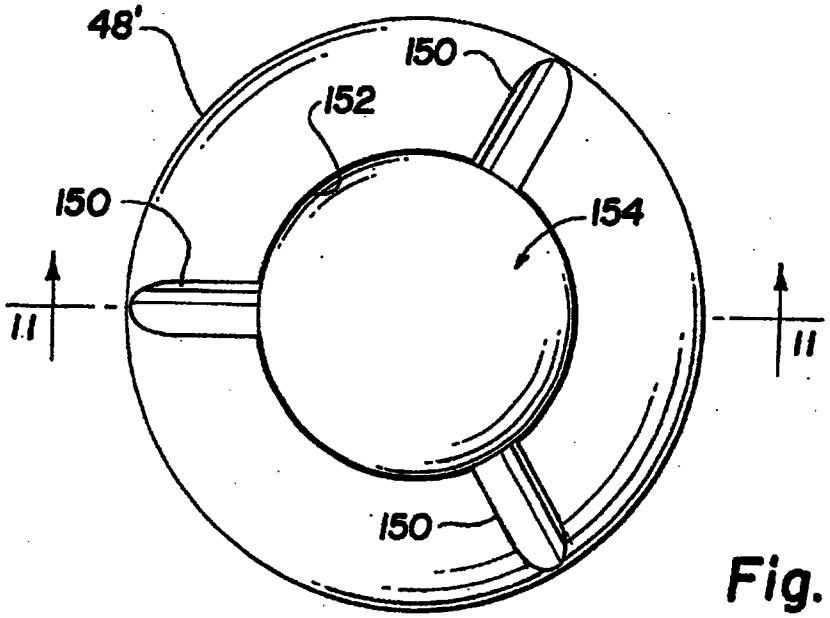

48'
150
152
150
154
11
11
150

Fig. 10

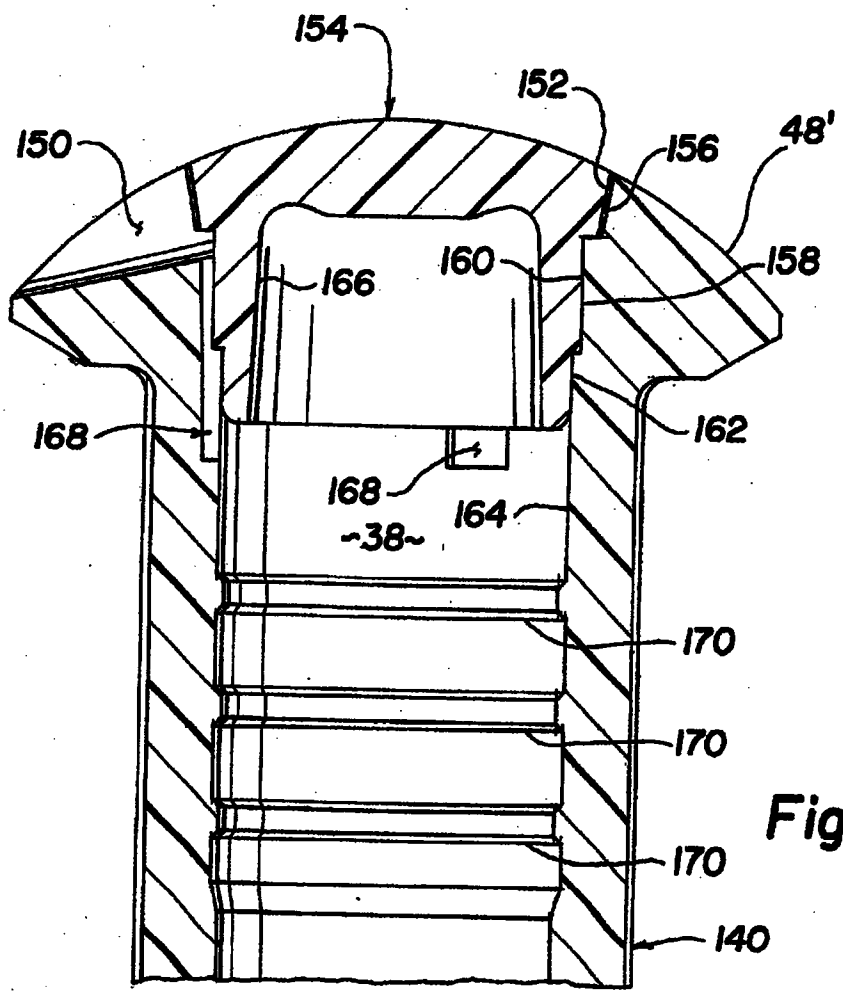

154
152
150
156
48'
166
160
158
168
162
168
164
~38~
170
170
170
140

Fig. 11

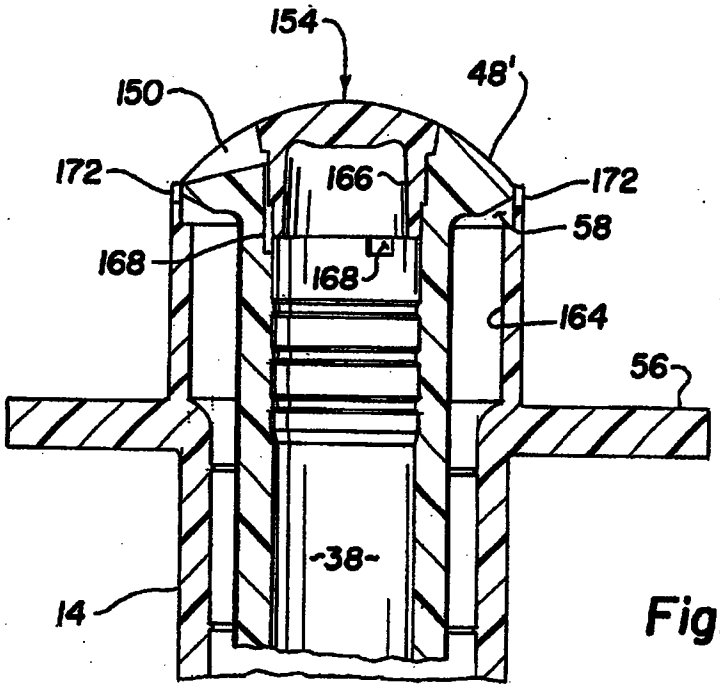


Fig. 12

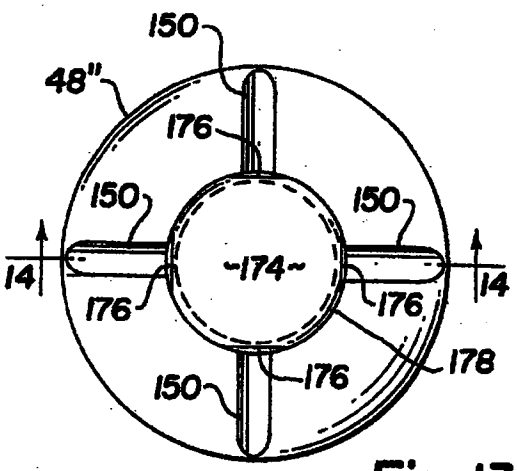


Fig. 13

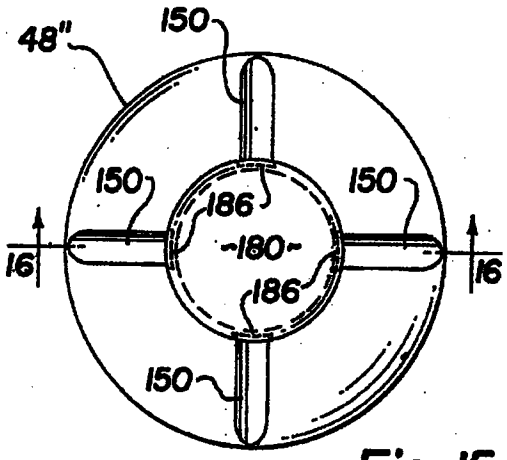


Fig. 15

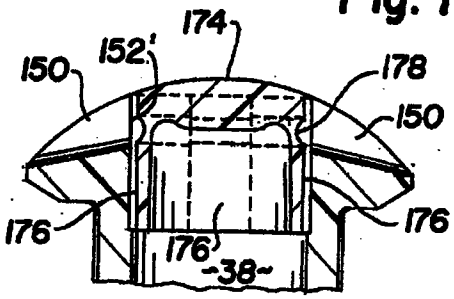


Fig. 14

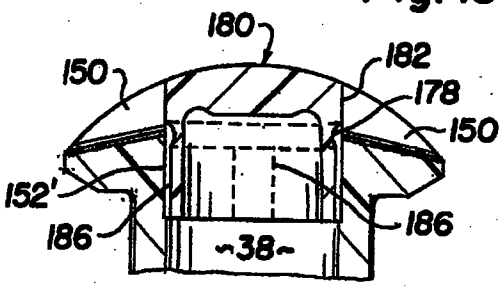


Fig. 16

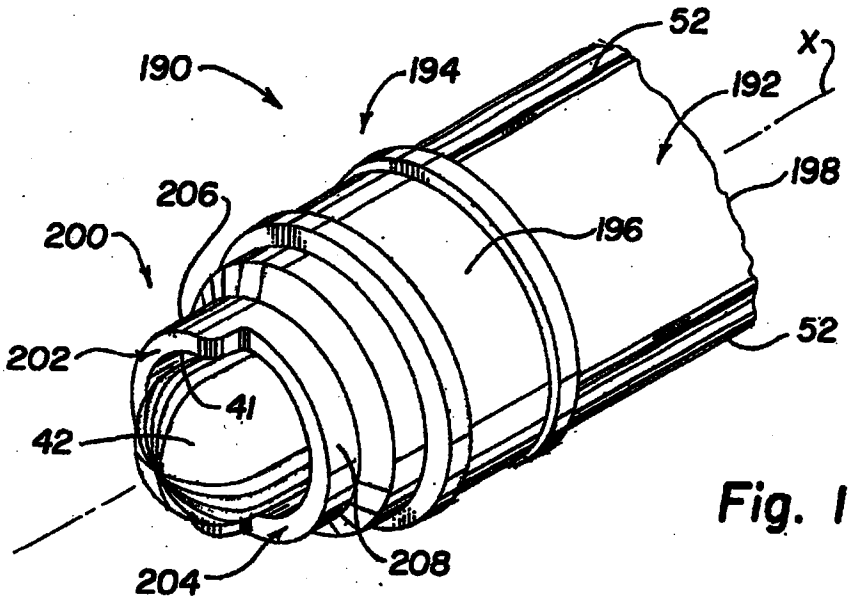


Fig. 17

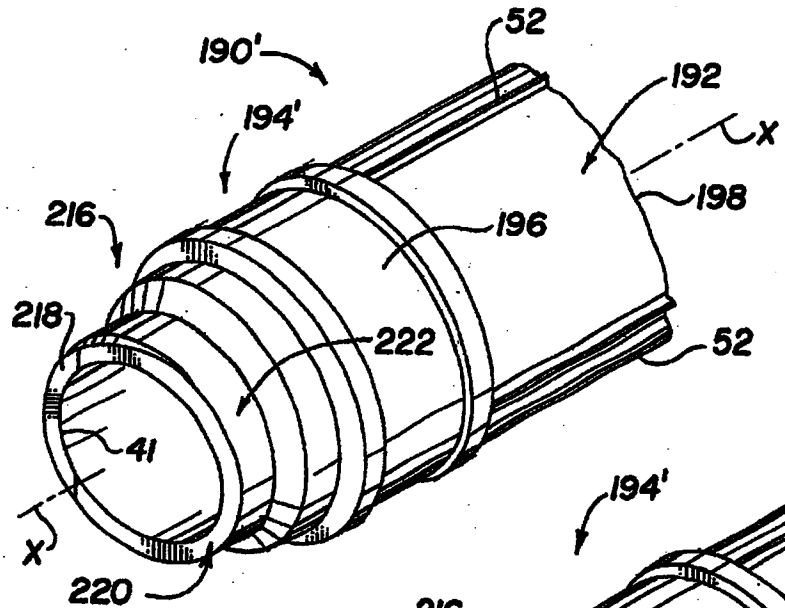


Fig. 18

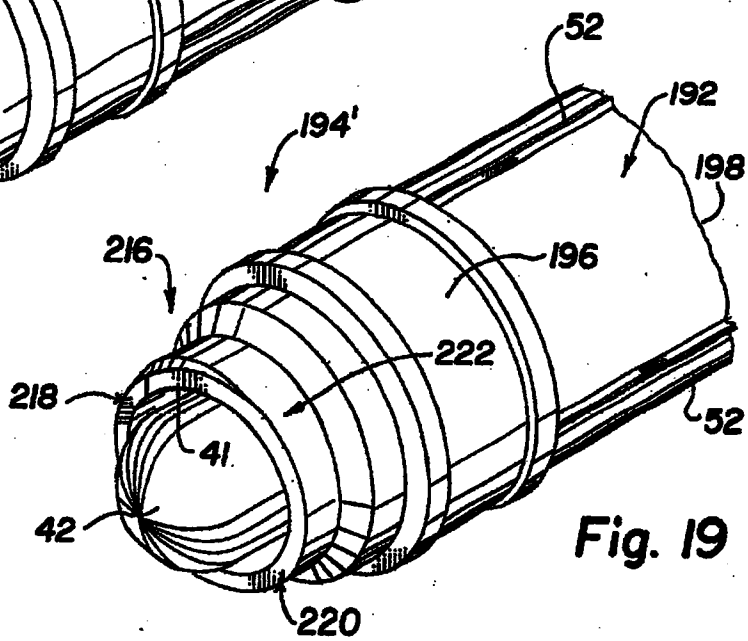


Fig. 19

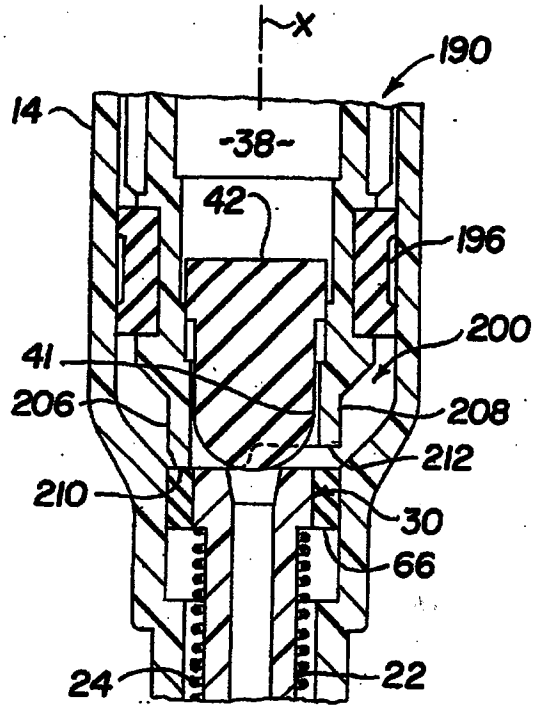


Fig. 20

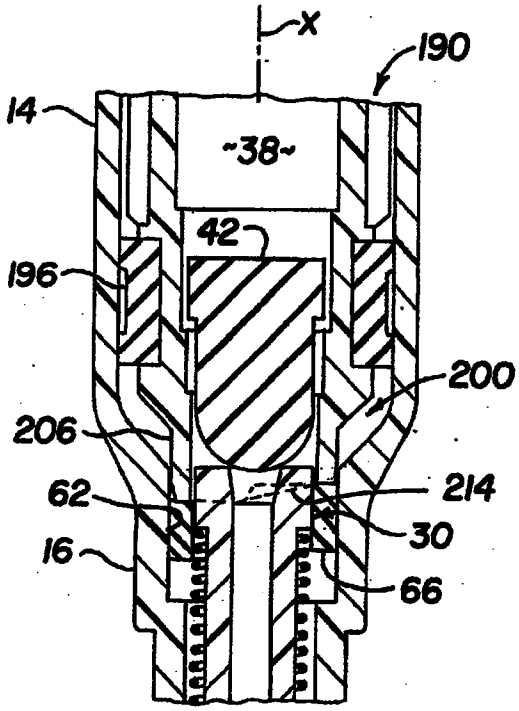


Fig. 21

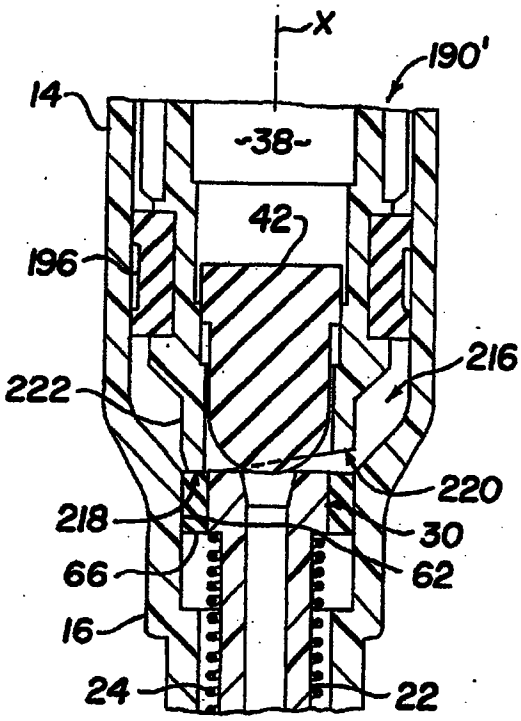


Fig. 22

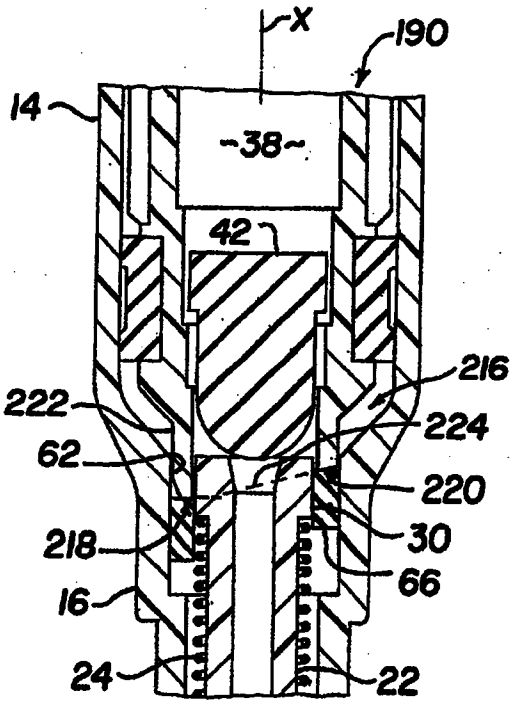


Fig. 23

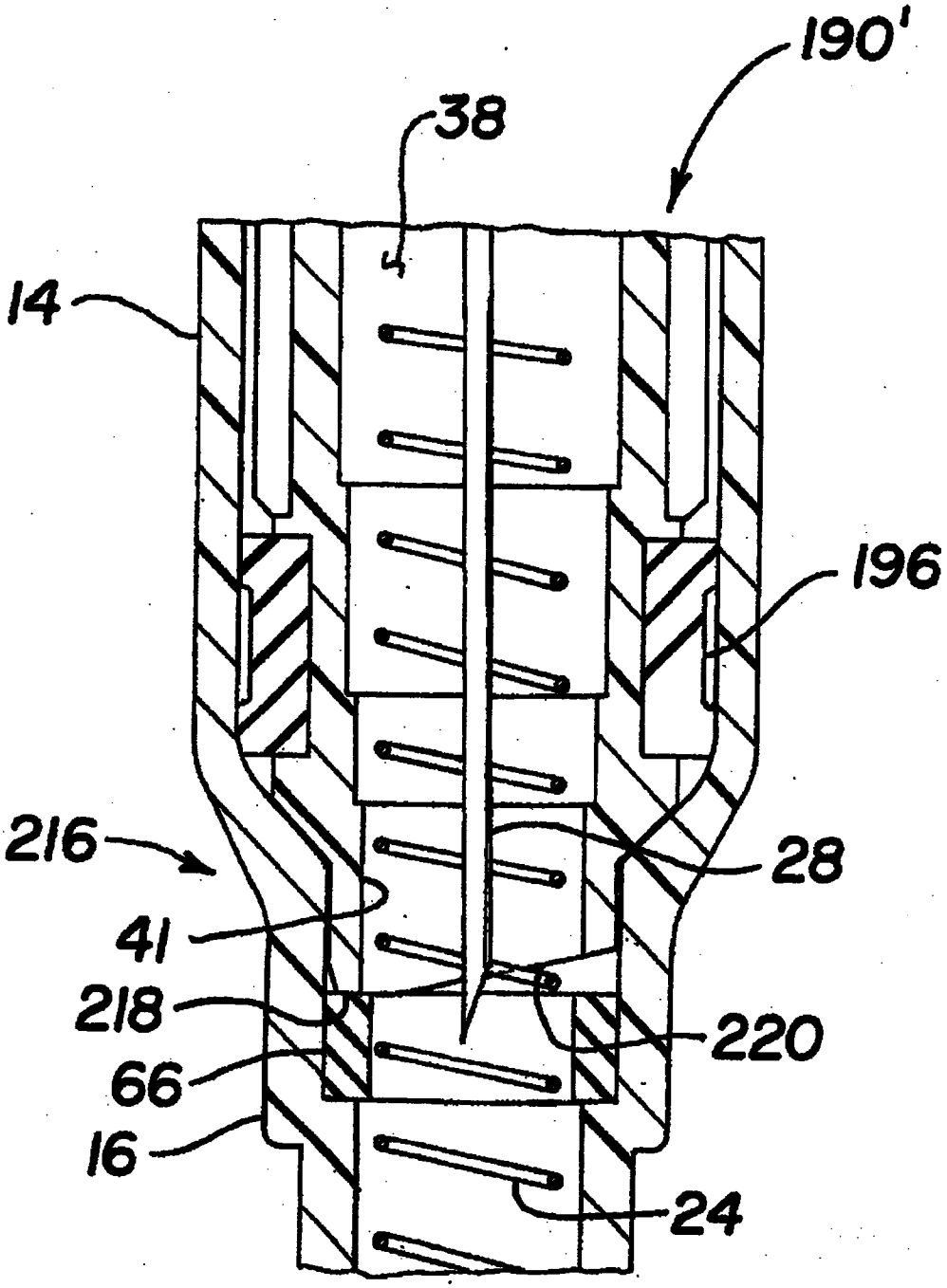


Fig. 24

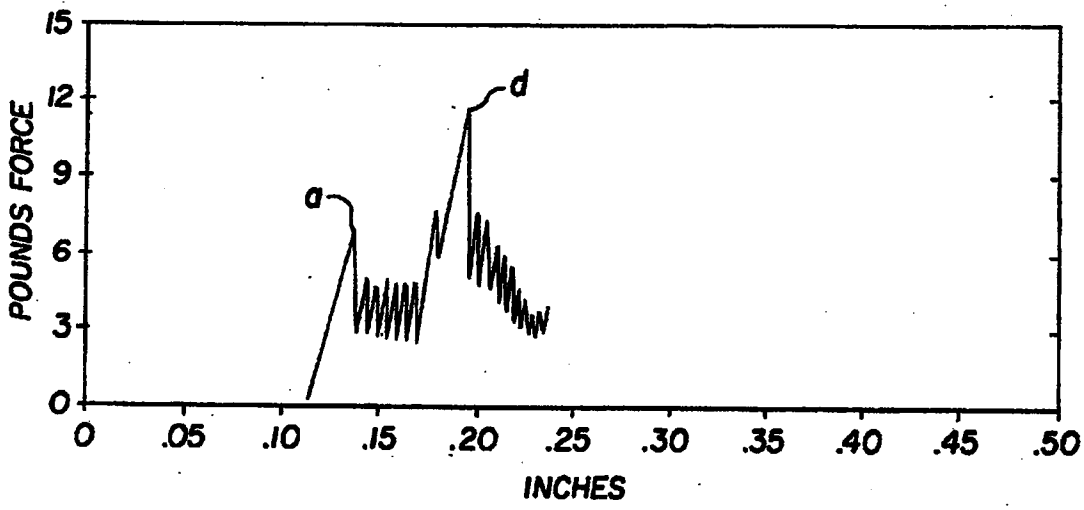

15
12
9
6
3
0
POUNDS FORCE
a
d
0
.05
.10
.15
.20
.25
.30
.35
.40
.45
.50
INCHES

Fig. 25

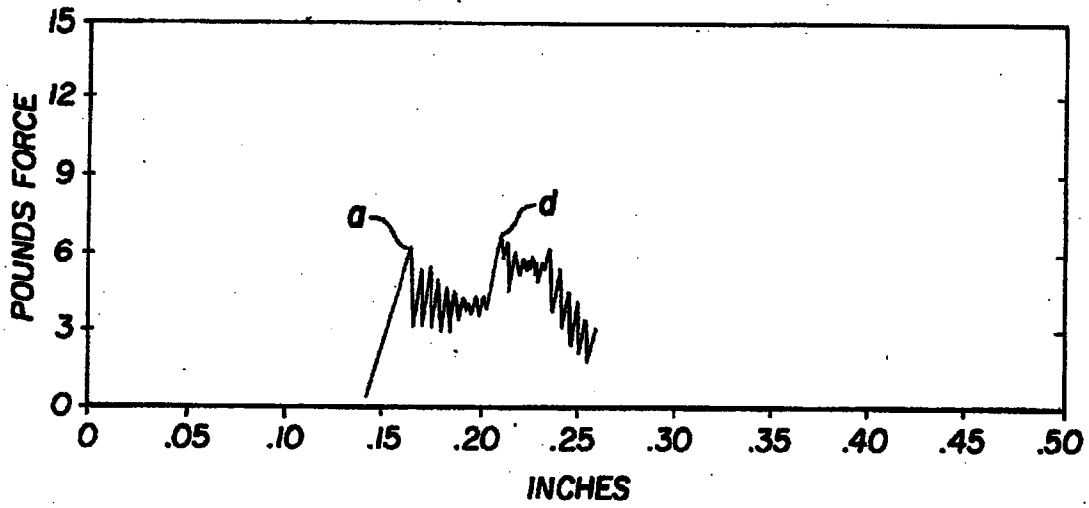

15
12
9
6
3
0
POUNDS FORCE
a
d
0
.05
.10
.15
.20
.25
.30
.35
.40
.45
.50
INCHES

Fig. 26

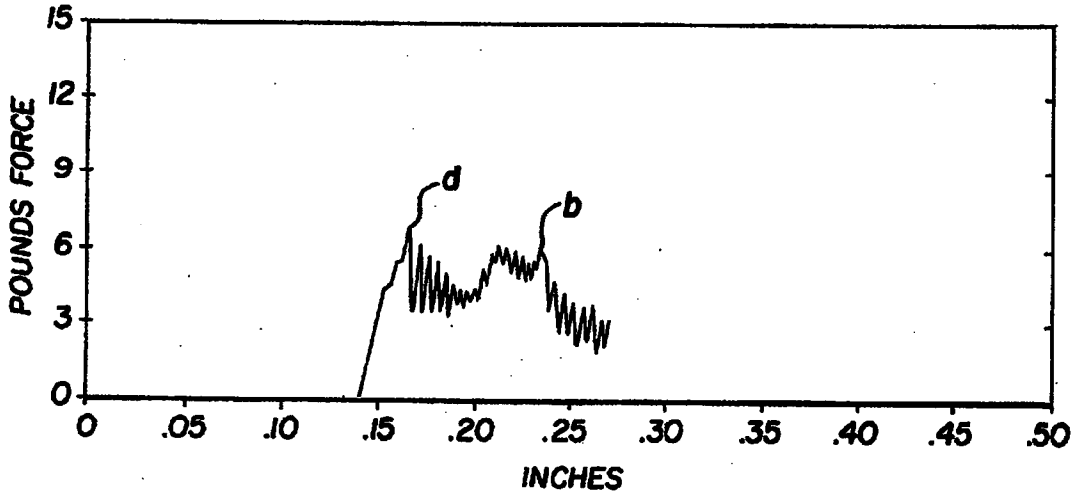

15
12
9
6
3
0
POUNDS FORCE
d
b
0
.05
.10
.15
.20
.25
.30
.35
.40
.45
.50
INCHES

Fig. 27

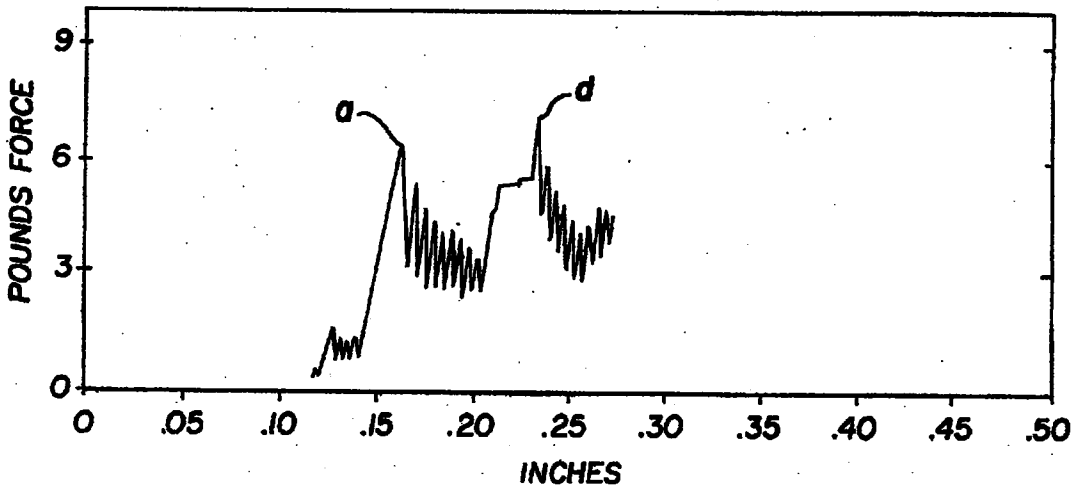

9
6
3
0
POUNDS FORCE
a
d
0
.05
.10
.15
.20
.25
.30
.35
.40
.45
.50
INCHES

Fig. 28

RETRACTABLE SYRINGE WITH REDUCED RETRACTION FORCE

FIELD OF THE INVENTION

This invention relates to a medical device, and more particularly to a retractable syringe and components suitable for mass production and assembly having a low triggering force and high blowout pressure which is nonreusable after one use.

BACKGROUND OF THE ART

A major cause to the spread of AIDS in the general population is the presence of IV drug users who share and reuse hypodermic syringes to inject drugs. Infection can be spread from AIDS patients in hospitals and medical facilities through accidental needle sticks from needles used on infected patients. Used syringes with extended needles present a risk to medical personnel and sanitation employees and others in the disposal chain.

The gravity of the threat posed by AIDS and the fact that the main vector of the spread of the dreaded disease is through reuse of syringes by IV drug users has resulted in intense activity to develop the most practical, most reliable, easily assemblable, mass-producible syringe.

There are a number of syringes of different designs which have needles which will retract at the end of the injection cycle. Most of these have never reached the market because of various deficiencies. Prime among the usual deficiencies of the prior art are problems of complexity, reliability, cost and ease of use. The most commonly used syringes are 1 cc and 3 cc syringes which must be mass-produced at the rate of millions per day. Cost is a significant factor both in manufacture of the parts and assembly of the device. High speed production requires molds with 64 cavities or more to reduce unit cycle time. Therefore, molded structures within the barrel that require collapsing core pins such as are shown in much of the art are unlikely to be producible at competitive costs.

One of the problems of the prior art of retractable syringes is the sheer number and complexity of parts which must be formed and assembled. Other problems with the prior art are dependence on flexing or breaking of internal parts by the plunger in order to release the retraction mechanism and use of a diaphragm at the end of the plunger which must be penetrated by a needle holding member and spring. These structures present serious quality control and assembly problems. Small broken off pieces can present a risk of hang-ups. Hooks are often used to releaseably secure retraction mechanisms. Hooks present difficult holding and control problems, may cause retention of air bubbles upon filling and may be undesirably temperature sensitive.

The prior art frequently has a two-piece barrel in order to be able to assemble a retraction device in the nose. This requires at least an additional part and assembly step. It is still necessary to pass the sharp injection needle through a small opening often while compressing a spring before the two parts can be assembled. The tiny needles are produced in the form of coil tubing and vary significantly from straightness after they are cut to length. This leads to difficult assembly problems if the needle must be passed through a small opening. The extremely sharp tip will catch the edge of a hole and jam the production line.

The rare prior art that employs a front mounted retraction mechanism in a one-piece barrel with a plugged hollow plunger, Tsao U.S. Pat. No. 5,084,018, among other things does not show reduced barrel area to prevent excessive blowout pressure, employs engaging flanges to secure all retraction parts, requires concurrent distortion of internal parts and flanges to effect release, cumulating in excessive force required to retract and requires ventilation holes because of a compartmented barrel.

The prior art has not produced a retractable nonreusable tamperproof syringe for mass production and assembly which is simple, reliable, cost effective, easy to use and retract, looks like a conventional syringe, has few parts which are easy to make and assemble, is not temperature sensitive and not subject to danger of premature retraction.

The prior art has not recognized a retraction mechanism with separable parts that relies entirely on clamping force or friction at a smooth walled reduced diameter transition zone in the barrel with mating lands which are slidably or separably released in response to relatively low thumb pressure while having resistance to premature retraction and high blowout pressure resulting from high pressure produced in the fluid chamber during an injection. The prior art has not recognized that such a structure can be molded as a one piece outer body over a core that can be pulled out from behind allowing the retraction mechanism to be easily pushed into place from behind, steered by the narrow nose portion. Neither does the prior art in such a combination realize the desirable non-cumulation of forces resisting retraction in order to minimize the thumb force required, having a most simple tamperproof feature and the fewest number of easily made parts.

The syringe plunger assembly has a combination of features not found in a prior art syringe. A head end which acts like a piston when installed in a syringe barrel has a reduced diameter front end having an opening and a dislodgeable stopper slidingly mounted in the opening projecting forwardly from the tip. Cooperating lands within the opening and on the head of the dislodgeable stopper seal the opening into the hollow interior of the plunger. The area of the stopper is relatively small when compared to the area exposed to the piston, which compresses fluid in a chamber below the piston. The ratio of the total area of the fluid chamber to the fluid exposed area of the stopper is at least two to one, more preferably three to one or more so that the stopper requires less holding force without blowing out back into the internal cavity. The cooperating lands have sufficient length so that the stopper can move back to the tip when the plunger moves forward at the end of an injection stroke without unsealing the plunger opening. A reduced holding force is sufficient to prevent blowout of the stopper after the stopper has been moved back to the tip because the stopper is exposed to a lower pressure generated force because of its relatively smaller area. The back of the plunger is vented so that entry of retractable parts which upon retraction finish dislodging the stopper and carry it back into the cavity, do not generate internal pressure that can blow out the nose of the syringe carrying any residual fluid with it. The thumb cap on the plunger is received and recessed into the opening at the back of the barrel when retraction occurs. The plunger cannot be grasped after this occurs to help prevent reuse.

These features and more are found in the inventive combination herein further disclosed which is especially suited for high speed production and assembly at low cost.

SUMMARY OF THE INVENTION

The invention is a reliable retractable tamperproof syringe having multiple tamperproof features which operates on a

principle which permits low cost parts which are few in number and well suited for high speed mass production and assembly. The syringe structure features a one piece hollow outer body having a longitudinally extending wall which is stepped. The wall comprises an elongated barrel and nose with a transition zone connecting the barrel and nose. The nose has a reduced diameter relative to the barrel. The outer body has an inwardly facing surface in the wall at the most constricted part of the transition zone where the nose begins. A plunger assembly is disposed partially within the elongated barrel with an end cap for depression of the plunger extending from an opening in the back of the barrel. The head of the plunger, which has a retraction cavity for receiving parts of a retraction mechanism, moves in slidable sealed contact with the interior of the barrel.

A retraction mechanism is lodged in the nose of the body. The retraction mechanism comprises an elongated needle holder and spring combination wherein the needle holder has an elongated body with a needle holding portion in front and a head in back. The head of the needle holder has a cooperating outwardly facing surface configured to cooperate with said inwardly facing surface along an interface oriented in the direction of retraction to produce a holding force on the needle holder when installed in the nose in the unretracted position. The needle holder and spring are easily installable from the rear of the barrel toward the nose and releaseably held by sliding engagement of said cooperating inwardly and outwardly facing surfaces while compressing the spring and thereby producing a holding force on the needle holder in opposition to the retraction force applied to the needle holder by the spring. The parts are circular in cross section.

The outwardly facing surface on the circular head of the needle holder is slightly greater in diameter than the circular inward facing surface in the wall at the most constricted portion where the nose begins. The needle holder is thus clamped in position by hoop stresses induced in the outer body and held in position by frictional holding force. The needle holder is released in response to depression of the plunger to a retraction position. Retraction occurs in response to thumb force on the plunger when a portion of the plunger passing into the transition zone separates at least a portion of the inwardly and outwardly facing cooperating surfaces thereby reducing the holding force on the needle holder to an amount less than a retraction force on the needle holder produced by the spring whereby the needle holder is retracted into the cavity a distance sufficient to withdraw an injection needle, attached to the needle holder, into the outer body.

In one embodiment, the head of the needle holder is a two part head comprising an inner head surrounded by a separable retainer member wherein the outer surface of the retainer member is the outwardly facing surface with cooperates with the inwardly facing surface in the wall to retain the needle holder in an unretracted position at the most constricted part of the transition zone where the nose begins. The retainer member is a ring member coupled to the inner head along a sliding interface oriented in the direction of retraction with a friction force which exceeds the retraction force provided by the spring. The front of the needle holder is grounded in the nose portion against forward movement. The plunger head is configured to pass through the most constricted area and push against the retainer member without also pushing against the head of the needle holder. An alternate construction of the two part head of the needle holder comprises the separable retainer member being tack welded to the inner head of the needle holder, preferably along a very small ridge or bridge between the mating surfaces which holds the two part head together until the bridge is ruptured by movement of the plunger after an injection has occurred.

The front of the plunger has an opening for a stopper slidingly fitted therein in an interference fit. The stopper is fitted in the opening in an interference fit along a sliding interface oriented in the direction of retraction. The stopper is mostly or fully dislodged by contact with the retraction mechanism at the end of an injection cycle by continued depression of the plunger from a first position at the end of the injection cycle to a second position with the tip of the plunger in contact with the retainer ring. This avoids cumulation of the force on the plunger required to dislodge the stopper from the opening and the force required to dislodge the retainer member from the head of the needle holder and outer body wall. Upon further depression of the plunger from the second position to the retraction position, the frictional holding force on the needle holder is reduced until the retraction force provided by the spring exceeds the remaining holding force and the needle holder and needle connected thereto are ejected into the cavity carrying the dislodged stopper along with them. The dislodging of the stopper and the retainer member alone make the syringe non-reusable. The plunger cannot be removed after retraction because the graspable end cap enters an opening at the back of the barrel when the plunger is depressed to the retraction position to prevent tampering after retraction.

The retraction cavity of the plunger is preferably vented to prevent a puff of air coming forward at the instant of retraction from blowing a tiny amount of retained fluid from the nose. This condition can occur if the plunger is fully depressed to release the needle holder and dislodge the stopper while the needle is physically restrained from retracting by the septum of a vial which has just been filled with fluid from the syringe. The thumb cap at the rear of the syringe is preferably provided with channels in fluid communication with the interior in cooperation with a closure removably installed in a centrally located opening in the thumb cap. One or more stepped portions of the opening and closure provide seating for the closure. Undercut portions at the side of the closure together with grooves in the interior surface of the plunger wall create passages for air to vent through channels on the thumb cap. This structure prevents air from being trapped by the user's thumb when the thumb cap is pressed to fire the syringe. One or more slots at the back of the barrel around the opening which receives the thumb cap prevent vented air from being trapped by the user's thumb when the plunger is fully depressed.

The syringe has a high blowout pressure and a low plunger thumb force required to cause retraction. Blowout pressure is the fluid pressure operating on the stopper and retainer ring during an actual injection. High blowout pressure resistance is obtained because the retainer ring is mounted in the most constricted portion of the barrel where the nose begins which significantly reduces the amount of area exposed to fluid pressure. The smaller retainer ring allows the use of a small needle holder such that the opening in the plunger and the stopper can be only a fraction of the cross sectional area of the fluid chamber below the plunger head. The ratio of the greatest cross sectional area of the variable chamber and that of the dislodgeable stopper or the ring member are selected so that the maximum expected thumb force on the plunger during an injection will produce a maximum pressure in the chamber which will generate a blowout force on the stopper and retainer member slightly less than the amount of dislodging force necessary to

dislodge the stopper and retainer member during retraction. This ratio should be at least two to one, or more preferably three to one or more, in order to ensure against premature blowout of the stopper or retainer ring.

In an alternate embodiment, the fewest number of easily made separate parts are used in a retractable syringe. The alternate embodiment has a similar stopper in the head of the plunger and a similar needle holder and spring combination with mating cooperating inwardly facing and outwardly facing interengaged surfaces at the most constricted part of a transition zone where the nose begins. In the alternate embodiment, there is no retainer ring around the head of the needle holder. Instead a tiny ramp is provided at the transition zone or adjacent the transition zone whereby the head of the plunger gently spreads the barrel outwardly while dislodging the stopper thereby reducing the clamping or friction force on the head of the needle holder provided by the wall of the outer body. The holding force is thereby reduced below the retraction force provided by the compressed spring and the needle holder is ejected into the cavity of the plunger carrying the dislodged stopper along with it.

A modification of the front tip of the syringe plunger has surprisingly been found to reduce the amount of plunger force required to initiate and complete retraction of the retraction mechanism shown in FIGS. 1–3. The modified front tip of the plunger is an irregular shape configured such that one portion of the tip is advanced beyond the remainder of the tip. When the plunger is moved forward after the end of an injection to initiate retraction, the advanced portion of the tip contacts one portion of the transversely positioned retainer before it contacts the remainder of the retainer thereby moving the one portion of the retainer relative to the wall surface of the barrel and tilting the retainer as the retainer member is being separated by the plunger from the needle holder of the retractable needle. In one modified form of the improved syringe plunger handle, the front tip end portion has a longitudinally varying front surface comprising a stepped front contact surface having a high step and a lower step with the high step being a forwardly extended portion of the tip. The high step first pushes against the retainer member and moves one portion of it forward when the plunger moves forward at the end of an injection. In an alternate preferred embodiment of the modified syringe plunger handle, the longitudinally varying front surface is generally angled with respect to the longitudinal axis of the syringe such that one part of the front surface of the tip first presses against part of the retainer member when the plunger moves forward at the end of an injection. In a variation of this structure, a portion of the front contact surface at the forwardmost extending part of the tip has a flat transversely oriented surface which is the part which first contacts the transversely positioned retainer and moves one part of the retainer before the remainder of the contact surface contacts the rest of the retainer to move the retainer ring and separate the retainer member from the needle and needle holder.

Manufacture and assembly is facilitated by the fact that the plunger and the outer body can be molded with a non-collapsible core tool that can be pulled out from behind. The parts are simply shaped and do not have hooks and parts with reentrant angles that require collapsible core pin technology. The outer body can be made in one piece and assembled from the rear. The narrowed nose portion provides no lateral space with will permit bunching of the spring and jamming when the retraction assembly is moved forward in the outer body. In fact, the nose serves as a guide to steer the parts into the proper position in one smooth stroke.

The needle does not have to be installed before the retraction mechanism is put in place because it is readily installed from the front after the needle holder is slidingly lodged in the nose. Significant variations in the holding force on the needle holder and the dislodging force on the stopper due to slight variances in the tolerance of the mating parts is avoided because the longitudinal wall of the outer body has some flexibility. The wall can spread outwardly slightly and the stopper and head of the needle holder can compress slightly radially and expand slightly in the longitudinal direction to avoid significant changes in the holding force caused by small changes in the actual diameters. Consistency in the amount of retraction force is thereby provided and economy is assured.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross section along the central axis of a first embodiment of the invention with the plunger positioned in a first position at the end of an injection cycle;

FIG. **2** is the syringe of FIG. **1** with the plunger depressed additionally to dislodge the stopper at a second position of the plunger wherein the tip of the plunger is ready to operate the retraction mechanism;

FIG. **3** is the syringe of FIG. **2** wherein the plunger has been further depressed to a retraction position, retraction has occurred and the cap at the back of the plunger is closely received in an opening at the back of the outer body;

FIG. **4A** is a partial cross section on the entral axis of an alternate tamperproof opening in the back of the outer body prior to retraction;

FIG. **4B** is the structure of FIG. **4A** with the plunger in the retracted position received in an opening at the back of the outer body;

FIG. **5** is a cross section along the central axis of a simplified alternate syringe structure without a retainer member around the needle holder, which is released by separation of the friction surfaces, shown in the plunger position which represents the end of an injection cycle;

FIG. **6** is the syringe structure of FIG. **5** wherein the plunger is further depressed to dislodge the stopper and begin to release the friction surfaces just prior to retraction;

FIG. **7** is the syringe structure of FIG. **6** with the plunger further depressed beyond the position of FIG. **6** to the retraction position where retraction has occurred and the cap is secure within an opening in the back of the hollow outer body.

FIG. **8** is a schematic longitudinal cutaway view in elevation through the center of the two part head showing how a tack weld can be applied to simultaneously seal and hold the retainer ring in place on the needle holder.

FIG. **9** is an exploded perspective view showing the barrel and retraction mechanism of FIG. **1** with a modified plunger assembly;

FIG. **10** is a plan view of the thumb cap of the plunger assembly shown in FIG. **9** with the preferred closure;

FIG. **11** is a cut away elevational view of the structure at the back end of the plunger and end cap of FIGS. **9** and **10** along line **11**—**11** showing the preferred closure;

FIG. **12** is a cut away elevational view of the plunger end cap and closure of FIG. **11** as the thumb cap is just being received into the barrel opening;

FIG. **13** is a plan view of a first alternative thumb cap and closure combination utilizing a flat sided closure and four channels in the thumb cap;

FIG. **14** is a cut away elevational view on the lines **14**—**14** of the thumb cap closure combination of FIG. **13**;

FIG. **15** is a plan view of a second alternate thumb cap and closure combination with four channels in the thumb cap and undercut portions to provide a vent passage;

FIG. **16** is a cut away elevational view on the lines **16**—**16** of the combination of FIG. **16**;

FIG. **17** is a cut away perspective view of a reduced force syringe plunger handle for the syringe of FIGS. **1–3** or **9** showing part of the plunger and the modified plunger head having a plunger seal and a stepped front end tip portion with a releasable plug member shown extending from the opening in the tip leading into the retraction cavity;

FIG. **18** is a cut away perspective view of an alternate form of the modified plunger head of FIG. **17** wherein the front tip portion of the plunger is generally cut at an angle with respect to the syringe axis such that one part of the front contact surface of the tip will press first against the retainer member when the plunger moves forward;

FIG. **19** illustrates the reduced force syringe plunger handle head and part of the plunger of FIG. **18** further including the releasable plug member positioned for use in the opening at the front of the syringe leading to the retraction cavity;

FIG. **20** is a cut away central elevation section through the modified head end of the syringe of FIG. **17** installed in the syringe body of FIGS. **1–3** or **9** showing the high part of the stepped front end in contact with a part of the transverse ring retainer holding the retractable needle;

FIG. **21** is a cut away central elevation section of the structure of FIG. **20** showing in exaggerated form how the transverse retainer is tilted because of the stepped front end of the plunger as the plunger is moved forward from the position of FIG. **20**;

FIG. **22** is a cut away central elevation section through the modified head of the plunger of FIG. **19** corresponding to the view shown in FIG. **20** wherein the high or longest part of the angled front edge at the tip of the plunger is just coming in contact with one part of the transverse retainer at the end of an injection;

FIG. **23** is a cut away central elevation section through the structure of FIG. **22** showing in greatly exaggerated form how the transverse retainer is tilted as the plunger moves forward from the position of FIG. **22** whereby one part of the retainer ring is moved before the rest of the retainer ring is moved;

FIG. **24** is a cut away central elevation section of the structure of FIGS. **22** and **23** after the reduced force plunger handle is pushed forward beyond the position of FIG. **23** causing retraction to occur;

FIG. **25** is a graph illustrating axial plunger forces during retraction of the unmodified standard syringe plunger shown in FIGS. **1–3** and **9** wherein the hollow front end of the plunger is transverse and perpendicular to the long axis of the syringe;

FIG. **26** is a graph similar to FIG. **25** showing the plunger retraction forces on the syringe shown in FIGS. **1–3** using the stepped front reduced force syringe plunger handle of FIG. **17**;

FIG. **27** is another example of a graph illustrating plunger retraction forces in the syringe of FIGS. **1–3** when using the stepped front reduced force syringe plunger handle of FIG. **17**,

FIG. **28** is an exemplary graph of the plunger forces during retraction of the syringe of FIGS. **1–3** utilizing the

angled front reduced force syringe plunger handle as illustrated in FIG. **19**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the description that follows, like parts will be referred to by the same reference numerals. Parts with a subscript letter are mean to illustrate a minor variation of a part with the same number. The drawings are enlarged significantly in order to show the details of the invention but generally reflect the true scale which is contemplated. The parts as shown are understood to be preferably circular and symmetrical as is conventional for syringes. The drawings reflect a syringe structure typically having a 1 cc to 3 cc injection fluid capacity.

FIG. **1** shows the structure of the first embodiment generally referred to by reference numeral **10**. Syringe **10** has a one piece hollow outer body **12**. Body **12** has a longitudinally extending wall comprising an elongated barrel **14** and a nose **16** with a transition zone **18** connecting the barrel and nose. A front mounted retraction mechanism lodged in the nose is generally referred to by the reference numeral **20**. It comprises the combination of an elongated needle holder **22** and spring **24**. The needle holder has an elongated body with a needle holding portion **26** in front for holding a needle **28** and a head **30** in back. Head **30** may consist of a two part head as in FIGS. **1–3** or a one part head as in FIGS. **5–7**. The needle holder is released by depression of a plunger that will be described.

A plunger generally designated by the reference numeral **32** is disposed for use partially within barrel **14**. The plunger has a head and seal generally referred to by reference numeral **34**, in slidable sealed contact with the interior of barrel **14** of outer body **12**. The plunger has a seal element **36** that is conventional and a retraction cavity **38** therein.

Head **34** has a tip portion **40** forming an opening **41** into retraction cavity **38**. A resilient dislodgable stopper **42** is sealingly positioned in opening **41** with a front portion thereof extending beyond tip **40**. Head portion **34** and the back part of stopper **42** have cooperating lands **44**, **46**, respectively, which seal opening **41**. Plunger **32** has an end cap **48** for depression of the plunger by the thumb. End cap **48** has a central opening for permanently receiving force fit plug **50** to close retraction cavity **38** at the back end.

A plurality of longitudinally extending flutes **52** slidingly support plunger **32** in barrel **14**. In the embodiment of FIG. **1**, outer body **12** has a collar **54** extending behind finger grips **56** having opening **58** which closely receives the outer periphery **60** of cap **48** when the plunger is depressed to the retracted position. An alternate arrangement is shown in FIGS. **4A** and **4B** in which barrel **14** is extended longitudinally, if necessary, so that end cap **48** fits closely within an opening at the back of the barrel where the finger grips are. FIG. **4B** shows the tamperproof position with the plunger in the retracted position. It should be noted that depending on the relationship of the inside diameter of the barrel and the diameter of the end cap, the end cap could instead be received right inside the opening at the back of the barrel. Regardless of how the end cap in back of the outer body and barrel are configured, the plunger can no longer be grasped after retraction has occurred because end cap **48** is depressed into an opening.

The wall of outer body **12** and head **30** of the needle holder have mating cooperating smooth surfaces which hold needle holder **22** in the position shown in FIG. **1** with spring **24** compressed. Nose **16** has a reduced diameter relative to

the barrel. The outer body has a most constricted part where head **30** of needle holder **22** is engaged and held. The outer body has an inwardly facing surface **62** at the most constricted part of the transition zone where nose **16** begins. Similarly, head **30** has an outwardly facing surface **64** configured to cooperate with inwardly facing surface **62** to produce a holding force on needle holder **22** when the retraction mechanism is installed in the nose from the rear. Mating surfaces **62, 64** constitute a sliding interface oriented in the direction of retraction, which seals nose **16**. Mating surfaces **62, 64** are preferably friction surfaces which have an interference sliding fit to apply a frictional holding force which holds needle holder **22** in position by friction between the mating parts. It is within contemplation of the invention that one or more of the cooperating interface surfaces could employ a coating or adhesive bond which is ruptured or released when the mating surfaces or lands are separated or moved relative to each other.

Head **30** provides a lower boundary for a variable fluid chamber **68** below head **34**. Needle holder **22** has a fluid path **70** in fluid communication with fluid chamber **68** and needle **28**. Needle holder **22** has a smaller diameter inner head **72** which is part of head **30**. Retainer member **66** is coupled to inner head **72** along sliding interface **74** oriented in the direction of retraction. Retainer member **66** is coupled to inner head **72** with a holding force which exceeds a retraction force applied to the underside of inner head **72** by means of the end of compressed spring **24**. A reduced diameter portion **27** of needle holder **22** protrudes through an opening in front **76** of nose **16**.

Importantly, retainer member **66** can be visualized as an annular ring surrounding circular inner head **72**. The location of retainer member **66** at the most constricted part of the transition zone where the nose begins and the relatively small area exposed to pressurized fluid in chamber **68** results in a high blowout pressure. Since the front portion **26** of the needle holder is grounded or bottomed inside front **76** of nose **16**, no amount of pressure will allow needle holder **22** or needle **28** to move forward. Blowout pressure may be defined as the pressure in chamber **68** acting on the exposed area of retainer member **66** to produce a force sufficient to overcome the holding force such that retainer **66** could "blowout" by moving forward and prematurely release needle holder **22**.

Some users have strong hands and might, at the outer limit in an emergency, be able to generate a force of as much as fifteen to eighteen pounds on the plunger during an injection. It is considered almost impossible, for anyone to exert a force of more than eighteen pounds. This may be regarded as the maximum expected force which must be taken into account so that ring member **66** will not blowout while an injection is being made. The greatest cross sectional area of variable chamber **68** and the area of retainer member **66** exposed to fluid pressure are selected so that the blowout pressure is higher than the maximum pressure in chamber **68** expected to result from the maximum expected thumb force applied to cap **48** during an injection. This ratio is preferably about two to one and more preferably about three to one or more so that the holding force holding the retraction mechanism in place can be kept at a comfortably low level while the blowout pressure remains high.

Dislodgeable stopper **42** has a similar blowout problem to recognize. The front and middle portion of stopper **42** are relieved slightly from opening **41** such that the fluid pressure in chamber **68** is directed against the cross sectional area at cooperating lands **44, 46** and could cause stopper **42** to blowout. A frictional holding force is generated at the lands **44, 46** which may be called a dislodging force which must be overcome to slide stopper **42** rearwardly before retraction. The ratio of the maximum cross sectional area across the interior of variable chamber **68** to the maximum cross sectional area of stopper **42** exposed to pressure in chamber **68** are selected so that the maximum expected thumb force on plunger **32** during an injection will produce a maximum force slightly less than the amount of dislodging force necessary to dislodge the stopper so that stopper **42** will not blowout during an injection. This ratio is preferably not less than about two to one, more preferably three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds, respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The stopper is dislodged after the injection by thumb force applied to the stopper by movement of the plunger.

The components used for retraction are arranged to avoid cumulation of force during the retraction sequence. In FIG. **1**, stopper **42** has a forward extension beyond tip **40** which allows full thumb pressure to be applied to the stopper before any other portion of the retraction mechanism is engaged. The amount of forward extension beyond tip **40** is related to the length of lands **44, 46** such that the forward extension of stopper **42** preferably represents about **80** percent of the engaged land length. When stopper **42** is moved back until the front is even with tip **40**, as seen in FIG. **2**, only about **20** percent of engaged land remains. In FIG. **2** it can be seen that thumb force on plunger cap **48** has been applied to partially dislodge stopper **42** such that a gap **78** is created and the remaining engaged land area is represented as area **80**.

Since I believe the amount of frictional holding force or dislodging force is roughly proportional to the amount of the length of the sliding interface between cooperating lands **44, 46**, it follows, ignoring dynamic effects, that the amount of force remaining decreases as the engaged sliding interface area is reduced. This is what happens as stopper **42** moves back into cavity **38** from the position of FIG. **1** to the position of FIG. **2**. It is believed appropriate to set the initial dislodging force to allow about five pounds at the position of FIG. **1** which is reduced to about one pound remaining when the stopper or plug member **42** reaches the position of FIG. **2**. It might be noted at this point in the description that the front portion of tip **40** preferably has some longitudinally extending slits or openings so that fluid is not trapped in the trapezoidal shaped area of chamber **68**, seen in FIG. **2**, because of contact between tip **40** and the upper surface of retainer ring **66**.

Needle holder **22** and spring **24** are combinably installable from the rear of the barrel before the plunger is assembled and releasably held at the most constricted part of the transition zone where the nose begins by sliding engagement of the cooperating inwardly and outwardly facing friction surfaces **62, 64** while compressing spring **24**. The length of the engaging land **64** and the amount of interference fit is preferably designed to provide a frictional holding force in opposition to the retraction force provided by the compressed spring **24** of somewhere around five pounds even though the spring may apply a retraction force in the retraction direction of somewhere around a half pound. In use the needle is pushed against a rubber seal in a vial so the needle holder must resist a resulting backward force without being dislodged during the filling operation. This requirement and blowout pressure limits the low end of the holding force on the needle holder.

Referring again to FIG. 2, it can be seen that further depression of the plunger beyond the second position of FIG. 2 dislodges retainer ring member 66 along the sliding interface 74 provided by the outer surface of inner head 72 and along the inwardly facing friction surface 62. As the amount of remaining engaged interface is reduced, the amount of force required to continue moving retainer member 66 off needle holder 22 is reduced and the small remaining engagement area 80 between lands 44, 46 of the plunger and stopper preferably cause stopper 42 to be dislodged before needle holder 22 is released. When the remaining residual friction force during continued depression of the plunger becomes less than the retraction force provided by compressed spring 24, the retraction position of FIG. 3 is reached whereby retraction occurs.

When retraction occurs needle holder 22 moves through opening 41 into cavity 38. The uncompressed length of spring 24 is selected to provide backward movement sufficient to withdraw an injection needle 28 fixed in front portion 26 entirely within outer body 12, carrying dislodged stopper 42 with it. At the same time, cap 48 enters opening 58 of the barrel with peripheral edge 60 closely confined, in order to prevent tampering after retraction. It is immaterial whether cap 48 moves into the opening at the instant of retraction or after retraction has already occurred because the movement is automatic due to the continued thumb force applied to trigger the retraction. Sufficient unengaged length of inwardly facing friction surface 62 is provided so that retainer member 66 can move downwardly a sufficient distance to reach the retraction position of FIG. 3. After retraction, retainer member 66 preferably remains stuck and prevents any possibility of any one being able to reengage it with the head of needle holder 22. The diameter of land 62 in the area designated 63 can be increased slightly to provide relief for retainer ring 66 as it is pushed down by tip 40.

It is also within the contemplation of the invention that separable retainer member 66 may be removably coupled to inner head 72 of needle holder 22 by means of a relatively small in area "tack" weld which is sufficient to resist the retraction force applied to needle holder by spring 24 but which can be ruptured or separated by depression of the plunger beyond the position shown in FIG. 2, to release the needle holder and allow retraction. This is schematically illustrated in FIG. 8 with respect to alternate head 30*a* with the parts of syringe body 12 and needle holder 22. cutaway to focus on the modification. The remainder of the syringe structure would be like FIGS. 1–3.

In FIG. 8, inner head 72*a* has an outwardly facing surface 74*a* and a very small raised portion or series of horizontally spaced apart raised portions 73 around the periphery in a continuous band or annular ring which extend relatively uniformly outwardly beyond peripheral surface 74*a* of head 72*a*. The raised portion could be on the inner surface 75 of retainer 66*a* instead of being on surface 74*a* of the needle holder. The head of the needle holder is preferably circular but could be conceivably another shape with the retainer member 66*a* correspondingly configured to conform to it.

The inwardly facing surface 75 of inner head 72*a* is in contact with raised portion 73 on the outer surface of inner head 72*a* and there may be a small gap 77 between them all around. The raised portion 73 couples retainer 66*a* to inner head 72*a* and may be referred to as a bridging portion which resists the blowout pressure referred to above and holds the needle holder in place against the retraction force imposed on the needle holder by spring 24 together with any small additional forces that may be applied when the needle is pushed against the rubber seal of a vial in preparation for use. The bridging portion may be formed by "tack" welding the raised portion 73 to the inner surface of the ring 66*a* or by providing any other form of frangible bridging portion that holds the separable ring member 66 and needle holder head 72*a* together. It is required that however done, the bridging portion must also serve as a seal between the facing surfaces of the ring member and inner head so that fluid under pressure cannot pass from chamber 68 through gap 77 to reach the nose portion of the device. All fluid must pass through fluid passage 70.

It can be seen that when the position of FIG. 2 is reached the front tip 40 of the plunger presses against retainer ring 66*a* after stopper 42 is almost dislodged and uncouples the retainer ring 66*a* from the inner head 72*a* of needle holder 22*a*. Any tack weld connecting the separable parts at the bridging portion is ruptured, fractured or otherwise separated so as to separate retainer ring 66 a from inner head 72*a* thus releasing needle holder 22*a* from further restraint. They and the force applied by spring 24 causes retraction to occur much as before described and shown in FIG. 3.

It is believed that the increased diameter of the raised portion 73 should be within the range of about 1 to 8 thousandths of an inch which may be dictated by the ability of the molding equipment available to produce a consistent bridging portion without defects. It is believed that it may be desirable to employ different polymeric materials for the retainer ring and needle holder to facilitate tack welding, such as a suitable polyvinyl chloride (PVC) for the retainer ring and a suitable polycarbonate plastic material for the needle holder. One way to couple these two parts may be to assemble them and expose them to a temperature of about 120° C. for twenty minutes or so to allow some diffusion or incipient melting to occur where they touch. The raised portion creates a high unit pressure where it comes into contact with the inwardly facing surface of retainer 66*a*. Sonic welding could also be employed. A coating or adhesive which couples the retainer ring to the needle holder and can be uncoupled by means of force applied to the retainer ring by the plunger is also within the contemplation of the invention.

An alternate syringe 82 is disclosed in FIGS. 5–7. In FIG. 5, Syringe 82 has a one piece hollow outer syringe body 84. Body 84 has a longitudinally extending wall comprising an elongated barrel 86 and a nose 88 with a transition zone 90 connecting the barrel and nose. A front mounted retraction mechanism lodged in nose 88 is generally referred to by the reference numeral 92. It comprises the combination of an elongated needle holder 94 and spring 96. The needle holder has an elongated stem body with a needle holding portion 100 in front for holding needle 28 and a head 102 in back. In this case, head 102 is a one part head integral with the rest of needle holder 94. Spring 96 delivers a retraction force in a retraction direction to the underside of head 102.

A plunger generally designated by reference numeral 104 is disposed for use partially within barrel 86. Plunger 104 has a head portion 106 which moves in slidable sealed contact with the interior of barrel 86 of outer body 84. Although a separate seal might be used on head 106, this embodiment is suitable for a smaller diameter, such as a 1 cc syringe, and can be used with head 106 also serving as the seal. A retraction cavity 108 is provided in the interior of hollow plunger 104. Head 106 has a tip portion 110 forming an opening 112 for a dislodgable stopper 114 having a front portion extending beyond tip 110. Head portion 106 has an inwardly facing land 116 and the back of stopper 114 has an outwardly facing land 118 comprising cooperating friction surfaces which seal opening 112. The back portion of outer

body **84** may have finger grips **120** and the same collar **54** and end cap **48** previously disclosed. The alternate arrangement of FIGS. **4A** and **4B** may also be employed.

The outer portion of tip **110** may be equipped with an angled surface **122** designed to cooperate with a small ramp surface **124** located in the vicinity of transition zone **90**. The wall of outer body **84** and head **102** of the needle holder have mating cooperating friction surfaces which frictionally hold needle holder **102** in the position shown in FIG. **5** with spring **96** compressed. Nose **88** has a reduced diameter relative to barrel **86**. The outer body has a most constricted part where the head **102** of needle holder **94** is frictionally engaged. The outer body has an inwardly facing surface or land **126** at the most constricted part of the transition zone where nose **88** begins. Similarly, head **102** has an outwardly facing friction surface **128** configured to cooperate with inwardly facing surface **126** to produce a frictional holding force on needle holder **94** when the retraction mechanism is installed in the nose from the rear.

Mating surfaces **126, 128** constitute a sliding interface oriented in the direction of retraction, which seal nose **88**. Mating surfaces **126, 128** are preferably smooth friction surfaces which have an interference sliding fit when needle holder **94** is installed from the rear whereby a frictional holding force holds needle holder **94** in position by friction between land **126** and head **102** of needle holder **94**. It is within contemplation of the invention that one or both of these surfaces could have a coating or adhesive bond which is ruptured when the mating surfaces are separated to release the needle holder.

Head **106** provides the upper boundary for a variable fluid chamber **130** below head **106**. Needle holder **94** has a fluid path **132** in fluid communication with chamber **130** and needle **28**. Needle holder **94** is releasably coupled at surfaces or lands **126, 128** with a holding force that exceed the retraction force applied to the underside of head **102** by the end of compressed spring **96**. A reduced diameter portion **134** of needle holder **94** protrudes through an opening in front **136** of nose **88**. Blowout pressure is not a factor with respect to the needle holder on the alternate embodiment. No amount of pressure will allow needle holder **94** or needle **28** to move forward since the front portion **100** of the needle holder is grounded or bottomed inside front **136** of nose **88**.

Blowout pressure is still a factor to be considered in connection with stopper **114**. Blowout pressure would be the pressure in chamber **130** produced by thumb force on cap **48** acting on the cross sectional area of stopper **114** which could overcome the holding force, causing stopper **114** to dislodge from opening **112** prematurely. The ratio of the maximum cross sectional area across the interior of variable chamber **130** to the maximum cross sectional area of stopper **142** exposed to pressure in chamber **130**, and the dislodging force necessary to dislodge stopper **144**, are selected so that the maximum expected thumb force on plunger **104** during an injection will not cause the stopper to blowout. Yet the stopper will still be dislodged by the dislodging force on the plunger once the front of stopper **114** contacts the retraction mechanism after the injection has ended. The ratio referred to is preferably not less than about two to one, or more preferably about three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The smaller diameter stopper allows two or three times the thumb force to be used during the injection cycle than required to actually dislodge the stopper by direct application of force.

By reference to FIGS. **5–7**, the operation and further features of the alternate embodiment are discussed. The syringe is used in the normal manner until the plunger is depressed to the first position of FIG. **5** which is the end of the injection cycle. Stopper **114** has a forwardly extending end which has come into contact with head **102** of needle holder **94** to block fluid path **132**. Further depression of plunger **104** toward the position of FIG. **6** mostly or fully dislodges stopper **114** and begins spreading barrel **84** at the transition zone by sliding contact between head portion **106** and ramp **124**. Ramp **124** is a very small inwardly extending annular thickening of the wan of barrel **86** which can take many shapes or forms. For example, ramp **124** may be a small step **125** in the wall which continues vertically downward as indicated by the dotted line, which is somewhat exaggerated in FIG. **5**.

The barrel is flexible and is spread outwardly a slight amount to the position of FIG. **6** just prior to retraction. Here the mating surfaces **126, 128** are separated an amount which reduces the clamping force on the needle holder **94**. The spreading shown in FIG. **6** is greatly exaggerated for illustration. It is estimated that an expansion of only about four thousandths of an inch is sufficient to release needle holder **94** from nose **88**. By slight further depression of the plunger from the position of FIG. **6** to the retracted position of FIG. **7**, retraction occurs when the retraction force applied by spring **96** exceeds the remaining holding force on needle holder **94**. Needle holder **94** then moves through opening **112** into cavity **108** along with a portion of spring **96**. The uncompressed length of spring **96** is designed to provide sufficient backward movement to withdraw an injection needle **28** fixed in front portion **94** and carry dislodged stopper **114** with it. At the same time, cap **42** enters opening **138** at the rear of a barrel extension **54** where the peripheral edge is closely confined in order to prevent tampering after retraction.

The location and configuration of ramp **124** is arranged to avoid cumulation of force required during the retraction sequence. Most of stopper **114** should be dislodged by thumb pressure on plunger **104** before significant resistance develops as angled surfaces **122** begin pushing outwardly on ramp **124**. The selection of the location of ramp **24** and the angle of the engaging surfaces make it possible to have a fairly smooth continuous force since the dislodging force continuously decreases as the sliding interface area **116, 118** between the plunger and the stopper is linearly decreased. Because ramp **124** is relatively very small, it is still possible to remove a stepped molding core from the rear of the outer body **84**. Alternately, ramp **124** can be the smaller diameter step **125** which avoids reentrant angles whereby resistance to removal of the molding core could occur. After retraction, the back of the plunger is unaccessible and there is no way to reach to stopper or the needle holder in order to reinstall them for re-use.

When used normally, syringe **10** may have a small amount of fluid remaining in the variable chamber in the second position shown in FIG. **2** which is, of course, greatly exaggerated in scale. This may amount to no more than a drop or a few drops of fluid in the remaining space above the retraction mechanism. When syringe **10** is fired by pushing down on end cap **48**, to the position of FIG. **3**, the expanding spring and rearwardly moving needle holder carry any remaining fluid up into retraction cavity **38**. Surface tension effects hold the tiny droplets in place along the walls of the plunger and no fluid escapes from nose **16**. The syringe is normally used to withdraw fluid from a vial. The fluid is injected into a patient followed by immediate retraction of

the needle holder and needle in one step. No leakage of fluid from the nose is observed when the syringe is used to inject fluid into a patient.

It has been discovered, however, that if the needle is forcibly prevented from retracting after syringe **10** is "fired" by pushing down until plunger **48** enters opening **58**, the small amount of retained fluid from variable chamber **68** can flow into the nose in the space between the needle holder and nose. If the seal around the head of the needle holder is removed while the needle holder is being restrained from retracting, remaining fluid has time to move down into the nose, but it does not leak out from the opening in the front of the nose. Then if the needle holder is suddenly released and allowed to retract normally, it has been found that leakage of fluid from the opening in the front of the nose could be observed. This undesirable scenario was found to occur under the following circumstances. If the syringe is used to draw blood from the patient, the blood filled syringe is removed from the patient and the needle passed through a rubber septum in a sterile vial. The plunger is then depressed to discharge the patient's blood into the vial. Users expect to depress the plunger fully after the fluid is discharged to retract the needle. When the plunger is depressed fully to cause retraction, the needle cannot retract normally due to the fact it is frictionally held by the rubber septum of the vial. When the empty syringe is then withdrawn from the vial by pulling the needle out of the septum, it immediately retracts. Droplets of fluid were observed on the vial as soon as retraction took place.

Surprisingly, it was found that a small "puff" of air is the source of this problem. If the needle or needle holder is temporarily restrained and prevented from retracting in the normal manner, a brief puff of forwardly directed air is generated when the needle holder is finally allowed to retract. This puff of air was found to emerge from the front of the syringe causing retained fluid trapped around the needle holder to be blown out of the opening left in the nose when the needle holder retracts. It was discovered that if the hollow interior of the plunger is vented, preferably in the area of thumb cap, this condition does not occur and the fluid is entirely retained within the syringe body.

FIGS. **9** through **16** illustrate the syringe generally designated as syringe **10** with a modification on the end cap or thumb cap on the plunger to provide for venting of the hollow interior of the plunger which is the retraction cavity. Insofar as possible the original numbering of FIGS. **1–4** is retained with primes used to indicate differences.

Head **34'** of plunger **32'** is preferably slightly modified from plunger head **34** of FIG. **2** in the following respects. The elongated plunger has a longitudinally extending generally tubular wall **140** defining a hollow interior along the length of the plunger. The plunger has a head end **34'** in front and a rear end portion **142** with a thumb cap **48'** behind. The outer side of wall **140** at head end **34'** is sealingly surrounded with a resilient plunger seal member **36'** which is like a band with a pair of separated raised rings **144**. Plunger seal **36'** fits in a depression in the outer surface of wall **140** where it is securely held in position and prevented from longitudinal movement. Seal member **36'** is adapted to slide in sealed contact with a tubular wall when the plunger is moved within syringe barrel **14**. It is within contemplation of the invention to have a raised piston molded as part of the plastic plunger to serve as a plunger seal in place of a separate rubber plunger seal **36'**, although the rubber seal member is preferred.

Wall **140** at head end **34'** of the plunger **32'** has a reduced diameter front portion extending forward from seal member **36'** terminating at tip **40** at the front of plunger **32'**. Tip **40** defines the opening **41** which leads into the hollow interior **38**. The internal structure is as shown in FIG. **1**. The wall **140** behind tip **40** has a stepped inner side surface comprising a land having an inwardly facing surface and a larger diameter portion extending behind the land into the hollow interior. A separate dislodgeable stopper **42** is slidingly held within the reduced diameter front portion of plunger head **34'** by a holding force in excess of the fluid injection pressure force to be expected during use of the plunger in syringe barrel **14**. Stopper **42** has a back end portion comprising a land **46** and a reduced diameter front end portion extending forwardly beyond tip **40** a fixed distance to its front **146**. The fixed distance is the distance between front **146** and tip **40**.

As is seen in FIG. **1**, the outwardly facing surface **46** of dislodgeable stopper **42** is in sliding sealed engagement with the inwardly facing surface of land **44** in the plunger wall. These lands cooperate to apply a holding force to the stopper and seal hollow interior **38** of plunger **32'** from the expected amount of fluid injection pressure force generated in the variable chamber **68** during an injection. The ratio of the effective area of variable chamber **68** to the area of stopper **42** exposed to fluid pressure is at least two to one and preferably three to one or more as previously indicated. This makes it possible to utilize lower holding forces without blowing out the stopper during an injection. The cooperating lands on the inside of the plunger head and the stopper have sufficient longitudinal length to allow dislodgeable stopper **42** to move the fixed distance between its initial extension at **146** and tip **40** in sliding response to forward movement of the plunger after front **146** of stopper **42** contacts a stop.

As indicated in FIGS. **1–3**, front **146** of the stopper **42** encounters head **72** of needle holder **22** which serves as a stop. The fluid opening in head **72** of needle holder **22** is preferably provided with some fine slots or grooves so that fluid can continually enter fluid path **70** as the plunger moves from the position of FIG. **1** to that of FIG. **2**. As the position of FIG. **2** is reached, the holding force on stopper **42** is reduced by substantial disengagement of the cooperating lands **44, 46** in preparation for dislodgement of the stopper, without unsealing the hollow interior/retraction chamber **38** within plunger **32'**. A notch **148** is preferably provided in the tip to prevent trapping fluid at the tip.

Thumb cap **48'** at the rear end portion **142** of plunger **32'** includes one or more channels **150** which receive vented air from hollow interior **38**. Thumb cap **48'** has an opening **152** for a closure **154** best seen in FIGS. **10** and **11**. Channels **150** are open at the top for ease of molding although closed channels could also be used.

FIG. **10** shows an enlarged top plan view illustrating the use of three channels **150** in combination with a preferred closure **154** installed in circular opening **152**. FIG. **11** best shows how the channels **150** receive vented air from hollow interior **38**. Closure **154** preferably has a stepped outer surface comprising a rear step **156** which rests in opening **152**, an intermediate step **158** which rests in an enlarged portion **160** of the inner side of wall **140** and a front step **162** which rests against inner surface **164** of wall **140**. In effect, these structures provide convenient seating for closure **154**. Steps **158** and **162** are conveniently provided in a downwardly depending skirt **166**.

Importantly, inner surface **164** everywhere there is a channel **150**, is provided with a longitudinally extending groove **168** in fluid communication with the hollow interior **38** and the channels **150**. Any convenient number may be chosen as the channels are easily molded into the end cap

when it is formed. The longitudinally extending grooves **168** do not extend through the entirety of the wall **140** although they could. They are designed for ease of molding since they can formed in the mold that makes the plunger without using separate pins to form an opening. This is an important cost consideration in a multiple out high speed molding process. This structure is designed for preventing the user's thumb from obstructing the vent opening leading from the interior of the plunger thereby assuring that venting will take place.

Referring now to FIGS. **9** and **12**, it will be noted that opening **58** in the back end of barrel **14** includes slots **172** in fluid communication with the hollow interior of the plunger through one or more channels **150** so that when thumb cap **48'** is received in opening **58**, no seal is created by the thumb being in contact with opening **58** which might otherwise prevent air from venting. The outer periphery of thumb cap **48'** is closely received in opening **58** as the syringe is fired, to prevent reuse. Thumb cap **48'** is preferably sized in relation to barrel **14** such that opening **58** is simply an extension in a linear direction of the wall of barrel **14** rather than enlarged as shown. Finally, the interior surface **164** preferably has several annular constrictions **170** designed to catch the head of stopper **42** during its rearward travel. Since stopper **42** is preferably installed from the rear of the plunger before closure **154** is put in place, the constrictions **170** must allow stopper **42** to be forced through to the front.

A first alternative thumb cap and closure arrangement is illustrated in FIGS. **13** and **14**. In this embodiment, four channels **150** are provided in thumb cap **48"**. Closure **174** has four flat side portions **176** spaced around the periphery at 90° intervals, each in fluid communication with a channel **150**. A gap is created at each flat side between the flat sides **176** and the opening **152'** which are in fluid communication with interior **38** to create a flow passage for air from interior **38** through the gap along the flat side then into channel **150**. Annular groove **178** in closure **174** may be used to fluidly connect each of the flat areas **176** at the level of channels **150**. In addition to equalizing air flow, the annular groove allows venting of air regardless of the angular orientation of closure **174** with respect to thumb cap **48"**.

A second alternate embodiment has the same thumb cap **48"** with a modified closure **180**. Closure **180** has a head **182** which snugly fits within opening **152'** which is at the back of the plunger. Opening **152'** is only slightly larger than the interior of the plunger to provide a seat for the closure. Four undercut portions **186** are each in joint fluid communication with the interior **38** and one of the channels **150** to create a flow passage from the interior **38**. Closure **180** effectively seals the opening **152'** so that no fluid particles can escape from the opening. As in the previous embodiment, an annular groove **178** bridges each undercut portion opening into a corresponding channel **150** thereby tying the undercut portions together in fluid communication regardless of the angular orientation of the parts.

In operation, there are many advantages to the improved combination disclosed herein. The diameter of the stopper in both embodiments and the slidable retaining ring member in the first embodiment, in relation to the diameter across the fluid chamber, makes it possible to produce a syringe which withstands high blowout pressure. By minimizing the effective surface area exposed to the pressurized fluid during an injection, the syringe will withstand injection thumb force of around fifteen to eighteen pounds during injection and at the same time retract in response to as little as five to six pounds of force on the plunger once the injection fluid has been injected. Once the fluid has been injected, cumulation of force required to concurrently operate the retraction mechanism is avoided. First the stopper is moved back and then the needle holder is released. By constricting the diameter of the syringe near a transition zone where the nose begins, a constriction enables the needle holder to be smaller which in turn allows it to fit in a smaller opening with a smaller stopper in the retraction cavity of the hollow plunger.

A vacuum must be pulled in order to fill the syringe. The ring member or the needle holder, as the case may be, must seal the front nose of the syringe body because otherwise vacuum could be lost and fluid could enter the spring area and leak out the front. The hollow outer body and syringe plunger are preferably made from conventional plastic material used for syringes, which has some flexibility. The tolerances on the diameter of mating facing surfaces between the head of the needle holder and the barrel and between the stopper and head of the plunger are not critical in order to maintain a consistent holding and dislodging force. This is believed to be because increasing interference fit increases the frictional holding force only up to a point and then the surrounding wall simply expands a small amount or the internal parts are compressed a small amount without a corresponding increase in the longitudinal force required to move the retainer member or plug member in the retraction direction. It is a desirable self correcting mechanism which is a cost and quality benefit in making the parts. It is believed that a plastic retainer member could be used and the same self limiting frictional holding force would be obtained.

A reduced force syringe plunger handle indicated generally by the reference numeral **190** for use in retracting a retractable syringe of the type shown in FIGS. **1–3** is illustrated in FIGS. **17, 20** and **21**. Reduced force syringe plunger handle **190** is suited for use in retracting a retractable syringe of the type having an elongated hollow syringe barrel **14** having a front end portion such as nose **16** containing a retraction mechanism **20** configured for operation by forward movement of the plunger wherein the retraction mechanism has a retractable rearwardly biased needle holder **22** held by a separable retainer member or retainer **66** lodged in the front end portion **16** of barrel **14**. The retainer or retainer ring **66** is a needle holding member positioned transversely at a right angle with respect to the longitudinal axis of syringe **10**. The reduced force syringe plunger handle has a tubular body **192** containing flutes **52**, which is reciprocatably mounted in barrel **14**. The reduced force plunger has a modified head **194** upon which is mounted a plunger seal **196** for sealingly sliding in the barrel **14**. Plunger seal **196** is slightly modified from the shape of seal element **36**, but serves the same purpose.

Tubular body **192** is a hollow body with a wall **198** which extends forward into a tip **200** at the front of plunger handle **190**. Tip **200** is configured for separating a transversely mounted retainer ring **66** from a retractable needle **28, 22** which is retracted by forward movement of the plunger at the end of an injection. It is understood that plunger **190** is completely interchangeable with plunger **32, 32** for the purpose of operating and retracting the retraction mechanism **20** of syringe **10**. The only substantive difference between the plunger **32** and plunger **190** is seen at the front tip **200** where tip **200** at the front of reduced retraction force plunger **190** has a longitudinally varying front contact surface **202** configured to press first against one portion of retainer member **66** before the rest of tip **200** presses against the rest of retainer member **66**. This action moves one portion of transverse retainer **66** with respect to the barrel wall and the retractable needle before the remainder of

retainer 66 begins moving as the plunger 190 is moved forward. This action is believed to result in a reduction in the retraction force required to initiate and complete retraction of the retraction mechanism 20.

The longitudinally varying surface can be considered a forwardly extended portion 202 and a recessed portion 204 whereby forwardly extended portion 202 first presses against and moves part of retainer member 66 when the plunger moves forward. This constitutes a stepped front surface comprising a high step 206 and a lower step 208 with the high step 206 being the forwardly extended portion 202. Like plunger 32, plunger 190 has a wall which forms the opening 41 for a removable seal member which comprises a stopper or plug member 42. The longitudinal center line of the plunger and the syringe itself is indicated by the dotted line "X". The internal configuration of head 194 is the same as head 34 of plunger 32 as previously described.

Referring now to FIG. 20, plunger 190 is seen reciprocatably fitted in barrel 14 of syringe body 12. Here an injection has been completed and the plunger has moved forward until the high step 206 of hollow tip portion 200 comes in contact with part of the upper surface of transversely mounted retainer 66. Contact surface 210 of high step 206 is first to push against the transversely positioned retainer member 66 before the contact surface 212 of lower step 208 has been moved forward enough to touch retainer member 66. The contact surfaces 210, 212 can be considered a stepped rim around opening 41 wherein the stepped rim has a high step and a lower step. The rim preferably comprises a circular shaped wall of uniform thickness which forms the steps. As mentioned before, the effect of this structure is to apply all of the plunger force to part of the retainer ring before the plunger force is applied to the rest of the retainer thereby reducing the overall force required to move the retainer (slide it) along the inner wall of the front portion of the barrel and begin separating the retainer from the head of the needle holder in the area where it begins moving.

What happens when syringe 190 is pushed forward beyond the position of FIG. 20 is illustrated in an exaggerated fashion in FIG. 21 to illustrate the effect. Plug member 42 is pushed further back as plunger 190 moves part of the retainer member 66 which begins to slide along wall 62 of nose 16. It can be seen that this action causes retainer member 66 to tilt with respect to the axis X of the syringe. The tilting surface of the retainer member 66 is indicated by the dotted line 214. It can be appreciated that this action allows the plunger to separate one part of the retainer member from the retractable needle and move the transverse retainer relative to the front end of the barrel before the rest of the transverse retainer is separated from the retractable needle. The configuration is such that one part of the retainer must begin moving while the rest of the retainer remains stationary at some position of the plunger 190 between the positions of FIGS. 20 and 21. There is believed to be some point during this process when one side of the retainer begins. coming free of the retractable needle while the other side is still partially holding the needle.

Another version of the reduced force syringe plunger handle for use with a syringe of the type shown in FIGS. 1–3 and 9 is illustrated as plunger 190'. Plunger 190' is like plunger 32 and plunger 190 except for the modified head portion 194'. This structure is used and functions in essentially the same manner as does plunger 190 having modified plunger head 194. Tubular body 192 of FIGS. 18 and 19 is a hollow body with a wall 198 which extends forward into a tip 216 at the front of plunger handle 190'. Tip 216 is configured for separating a transversely mounted retainer ring 66 from a retractable needle 22, 28 which is retracted by forward movement of the plunger at the end of an injection cycle. The only substantive difference between plunger 32 and plunger 190' is seen at front tip 216 where tip 216 has a longitudinally varying front surface configured to press first against one portion of transverse retainer member 66 before pressing against the rest of retainer member 66. The longitudinally varying surface can be considered a forwardly extending portion 218 which in this case is transverse surface lying in a plane perpendicular to the longitudinal axis X of the syringe. The remainder of the contact surface at the front of syringe 190' is an angled surface 220 which is formed in the rim 222 at the front tip 216 of syringe 190'. Angled surface 220 is angled from the longitudinal center line of the syringe and with respect to the flat surface 218. It is formed as if the transverse tip at the front end syringe plunger 32 were partially cut off at an angle to its long axis. Rim 222 is preferably a circular wall of uniform thickness. The rim 222 defines the opening 41 which is shown in FIG. 19 as containing the removable seal member comprising a stopper or plug member 42. The internal configuration of head 194' is the same as head 34 of plunger 32 as previously described. When used in a syringe of FIGS. 1–3, the flat portion 218 on tip 216 presses against and moves the transverse retainer member 66 first when the plunger moves forward to retract the syringe before the angled surface 220 begins pushing on the other side of the retainer ring 66 thereby moving it and separating it from the retractable needle.

Referring now to FIGS. 22 and 23, plunger 190' is seen fitted in barrel 14 of syringe body 12. In FIG. 22, an injection has been completed and the plunger is moved forward until the relatively flat portion 218 of rim 222 comes into contact with part of transverse retainer 66. FIG. 23 shows the position of retraction parts just as the plunger has been moved forward at the end of the injection. Flat portion 218 of tip 216 begins moving part of transverse retainer 66 with respect to the wall 62 of the front of barrel 14 before angled contact surface 220 comes in to forceful contact with the remainder of retainer 66.

FIG. 23 shows the position of the plunger and retractable parts in an exaggerated fashion as plunger 190 has been pushed forward from the position of FIG. 22. Plug member 42 is pushed further back as plunger 190' moves one part of transverse retainer 66 which begins to slide along the inner wall at the front of the barrel comprising nose 16 before the other part of retainer 66 is moved. It can be seen that this action causes retainer member 66 to tilt (exaggerated) with respect to the axis X of the syringe. The exaggeratedly tilted surface of retainer member 66 is illustrated by the dotted line 224. The action is similar to that of the tip structure of FIG. 17 in that the irregularly shaped front edge of the plunger 190' allows the plunger to begin to move and separate one part of transverse retainer 66 with respect to the surface of the barrel and the head of the retractable needle before the rest of the transverse retainer is moved by the angled surface 220. This condition would occur at some forward position of the plunger intermediate the position shown in FIGS. 22 and 23.

FIG. 24 shows the fully retracted position of the syringe 10 with the modified reduced force syringe plunger 190' after it has been fully depressed. The retainer member 66 is shown in a transverse position but it would not necessarily have to be in a transverse position after the retraction has been completed. It could be slightly tilted in the final retraction position of FIG. 24 without harming the retraction process.

We believe surprising results are demonstrated in a series of tests based upon samples of 30 prototype syringes in Table 1 below, which are designated "Control Group", "Stepped Plunger" and "Sloped Plunger". The control group is actually the production syringe which is essentially the same as the syringe disclosed, in FIGS. 1–3 and 9. Although the control group plungers have some small slots in the rim at the front edge of the tip to allow fluid to pass laterally, the front edge (rim) is square and at right angles to the main long axis of the syringe as shown in FIG. 1. The stepped plunger and the sloped plunger were tested in the same barrel design of the control group, which is the production barrel and retraction mechanism essentially the same as FIG. 1. The plungers were modified by altering only the tip into a step or a slope without changing anything else except for a slightly different outer plunger seal 196. The retraction mechanism in all three sets of tests remained exactly the same.

The syringes were tested in a United Tensile Tester Model SSTN-1 using a 100 pound load cell on the tester and a test speed of one inch per minute. The syringe was placed in a fixture with the needle downward and the block which is connected to the load cell was moved downward to rest upon the plunger handle thumb cap and moved forward to determine the functionality force. The functionality or functionality force is defined as the highest load force measured during the forward movement of the plunger until retraction occurred. It includes the force required to move the seal comprising the stopper or plug 42 in the central opening 41 of the plunger as well as the plunger force required to accomplish the retraction of the retractable needle by moving the retainer ring forward. Functionality is the highest peak in the force graphs in FIGS. 25–28 which will be discussed later. Table 1 includes the average plunger force, maximum plunger force, minimum plunger force, and standard deviation (Stdev) for each group of data. This data for the sloped plunger is based upon 29 samples due to one bad data point. Functionality is rounded to the nearest 1/10 pound.

TABLE 1

Control Group		Stepped Plunger		Sloped Plunger	
Sample #	Functionality	Sample #	Functionality	Sample #	Functionality (lbs)
1	10.5	1	6.7	1	8.7
2	9.1	2	7.2	2	7.4
3	9.1	3	6.2	3	6.8
4	13.7	4	7.4	4	7.4
5	11.9	5	10.4	5	8.1
6	11.5	6	6.4	6	8.4
7	7.6	7	6.3	7	7.6
8	12.7	8	6.9	8	7.2
9	10.8	9	6.6	9	8.8
10	11.8	10	6.7	10	8.2
11	8.9	11	6.7	11	7.4
12	10.4	12	6.5	12	7.1
13	11.1	13	6.4	13	7.6
14	9.1	14	6.3	14	8.8
15	10.5	15	7.7	15	7.3
16	10.7	16	7.4	16	9.3
17	8.8	17	6.6	17	7.1
18	9.3	18	6.7	18	7.7
19	9.7	19	5.6	19	8.3
20	9.8	20	7.0	20	7.7
21	12.4	21	7.4	21	8.2
22	10.9	22	6.4	22	7.6
23	10.5	23	6.9	23	7.2
24	9.1	24	7.3	24	7.6
25	10.3	25	7.3	25	9.2
26	12.9	26	6.7	26	7.2
27	14.9	27	7.2	27	Bad Data

TABLE 1-continued

Control Group		Stepped Plunger		Sloped Plunger	
Sample #	Functionality	Sample #	Functionality	Sample #	Functionality (lbs)
28	8.9	28	7.6	28	8.3
29	11.1	29	6.4	29	8.0
30	7.6	30	7.8	30	7.1
Min	7.6	Min	5.6	Min	6.8
Max	14.9	Max	10.4	Max	9.3
Average	10.5	Average	7.0	Average	7.8
Stdev	1.7	Stdev	0.8	Stdev	0.7
Range	7.3	Range	4.8	Range	2.5

A very substantial reduction in the average plunger retraction force functionality is indicated by the average of the 30 tests. The control group showed an average of 10.5 pounds plunger force as compared to only 7 pounds for the stepped plunger of FIG. 17. This is roughly a 30% reduction in the average plunger retraction force. Moreover, although there are a few anomalous test results, variation and range of the functionality force was also less with the stepped plunger of FIG. 17 and the sloped plunger of FIG. 19 than with the control group. Although the sloped plunger had a slightly higher average plunger functionality force, it was still very substantially lower than the control group.

FIGS. 25–28 are graphical representations of some examples taken out of Table 1. These graphs all follow the same pattern. They measure the functionality force on the plunger as the plunger moves from its end of injection position of FIG. 1 over a relatively short period of plunger forward displacement until retraction occurs. Because the seal member 42 extends slightly beyond the front tip of the plunger, it starts to slide rearwardly with respect to the plunger before the front edge of the plunger tip contacts retainer 66. This part of the curve is exemplified by the first peak which is identified as "a" in FIGS. 25, 26 and 28. The peak denominated "d" is automatically placed on the highest peak by the testing machine. This is irrespective whether it is a first or second peak.

In the control group of example 25, the peak "a" represents the initial force required to first move the plug member 42 and the second peak "d" represents the force required to initiate movement of the transverse retainer 66 with the standard plunger of FIGS. 1–3. Although there are some lower values in the group, some 18 of the 30 samples have a functionality force of 10 pounds or more. The plunger force first required to move the retainer ring with respect to the walls of the barrel and the retractable needle is substantially more than the force required to move the plug back into the plunger. In this example it is nearly twice as much.

FIGS. 26 and 27 represent two examples of the stepped plunger with a substantially lower peak force required to move the retainer member 66 denominated at point "d" in FIG. 26 and point "b" in FIG. 27. In fact, in FIG. 27 the plunger force is actually less than the initial force required to move the stopper 42 which the machine identified as the first peak "d". The reduction in plunger force associated with the second peak, i.e. movement of the transverse retainer, suggests that the plunger force required to move the ring member during retraction using the stepped plunger is now nearly the same as the lower force required to remove the sealing stopper 42. Based on the graphs of FIGS. 25–28, it appears the force required to remove the stopper never rises above about 7 pounds.

FIG. 28 which represents the slopped plunger is plotted on a larger force scale than the other graphs. FIG. 28 illustrates

a first peak "a" for removal of the stopper and the second peak "d" where the retainer is being moved. This graph is quite similar to the results using the stepped plunger tip, although average plunger force is slightly higher than the results obtained with the stepped plunger in FIGS. **26** and **27**. The identity of the graphs is given in the following table:

TABLE 2

FIG.	Test Group	Sample #	Functionality
25	Control Group	6	11.5
26	Stepped Plunger	9	6.6
27	Stepped Plunger	18	6.7
28	Sloped Plunger	12, 17 or 30	7.1

The significance of this improvement cannot be over estimated. In the superior syringe design of FIGS. **1–3** and **9**, the retaining ring member **66** frictionally holds the head of the needle holder in opposition to the biasing force applied by the spring. In addition, it is frictionally supported at the inner wall of the barrel and is subject to forces imposed on the needle by the act of puncturing rubber seals on vials on the retainer and by blow out pressure as mentioned in the specification. Therefore, it is difficult to achieve reliability and avoid premature retractions unless these frictional holding forces are high enough to withstand these imposed forces. There must be a certain amount of frictional force imposed on the retractable parts which must be overcome by the plunger force during retraction. This makes it difficult to reduced the amount of plunger force required to retract the syringe below a certain amount.

The beauty of the present invention is that a way has been found to reduce the force on the plunger required to retract the syringe without making any changes whatsoever to the retraction mechanism itself. All of the design features and characteristics that prevent the problem of premature retraction by forces imposed on the needle and retainer ring remain effective, but the plunger retraction force is desirably reduced to a lower level and made more uniform and reliable when the modified plunger tips are used.

In the best mode, it is believed that the stepped plunger tip is preferable to the sloped plunger although the exact shape and dimensions have not been optimized. It is clear that the basic principle of configuring the tip to apply all of the plunger force to one part of the retainer ring before the plunger force is applied to the rest of the retainer ring is a fundamental principle regardless of the specific shape of the tip. The high step on the stepped plunger preferably represents about half of the area of the rim at the tip. The samples in Table 1 of FIGS. **25–28** are based on a 3 cc syringe wherein the opening **41** has a diameter of about 0.18 inches. The length of the high step in the axial direction is about 0.030 inches more than the low step of the FIG. **17** embodiment although the actual dimensions may vary because the prototypes were prepared by hand.

It is believed that a step of about 10–30 thousandths of an inch is appropriate depending upon the diameter of the tip. It is believed that the step has to be higher for a syringe of a greater diameter and lower for a syringe with a smaller diameter tip. The sloped plunger is believed to have about a 5 degree angle on the angled portion **220** of the surface while the flat portion **218** represents an area of about 13% of the area of the rim **222**. If the step or the slope is too great as compared to the diameter of the tip, it would be possible to get a locking effect that could actually increase the friction to remove the retainer member and possibly result in an inconsistent retraction. Some experimentation would be required to find the best combination of dimensions.

These factors may also be affected by the resiliency of the retainer member, the height of the retainer relative to the retractable needle on which it is mounted, and other factors. Although two preferred embodiments of the tip shape have been disclosed, it should be understood that other variations in shape including more or less step or slope and more or less initial contact area between the tip and the retainer, are within the scope of the invention as long as the force applied by the plunger is not uniformly placed upon the retainer, and allows some tilting of the retainer to occur during forward motion of the plunger.

In the best mode the stopper and the ring member are preferably made from a thermoplastic rubber material designated number 181-55 available from Advanced Elastomer Systems, 540 Maryville Central Drive, St. Louis, Mo. and sold under the trade name Santoprene®. It is said to have a characteristic hardness around 55 on the Shore A durometer scale which allows for the right amount of resistance to compression, fluid resistance such that the material does not swell when in contact with most fluids, environmental stability allowing the friction and sealing properties to remain non-temperature sensitive, good property retention after aging and excellent property retention after sterilization by all accepted methods. The plunger seal around the head of the plunger is conventional.

The parts are few in number and easily mass produced. The alternate embodiment has the fewest number of separate parts of any tamperproof retractable syringe. The plunger has a one piece hollow outer body with a transition zone and a narrow nose portion. The internal diameter is stepped to greater diameters from front to back for molding around a non-collapsible core which can be extracted from the rear. The same is true for the plunger.

Assembly is greatly simplified and can be accomplished with high speed mechanized equipment. The needle holder and spring are installable from the rear of the barrel without the needle. In the first embodiment the retainer member is forced fit over the inner head of the needle holder and the assembly together with the uncompressed spring are pushed forward and held by sliding engagement of the cooperating inwardly and outwardly facing surfaces while compressing the spring. The front of the needle holder passes through an opening in the nose which makes it easy to install the needle from the front by conventional means. The alternate embodiment is installed the same way except that there is no separable retainer member around the head of the needle holder.

The narrow nose provides a particular advantage for mechanized assembly. The nose has a wall defining an elongated internal cavity which closely confines the spring and needle holder combination. During installation this cavity serves as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring. This solves an important assembly problem. If there is much lateral space in the nose around the spring, when the uncompressed spring is being compressed, it is a laterally unstable column which flexes sideways and bunches up causing a jam up. It might be added that rounded edges on the bottom of the slot directly below retainer **66** would further facilitate entry of the end of the spring.

The stopper is also installable from the rear of the plunger by pushing it forward until the cooperating lands are slidingly engaged. Then plug member **50** is force fit or otherwise fixed in the opening at the back of the plunger and the plunger is installed in the outer body. It is not necessary to try to pass the sharp needle through an elongated body with

constricted openings where slight misalignment could cause hangups. The head of the needle holder simultaneously acts as a seal as well as a holding device such that no seal is required at the tip of the nose and no ultrasonic welding of separate parts is required.

There is no necessity for using internal locking teeth of any kind. No locking teeth are needed to hold the retraction mechanism or to lock the plunger after retraction. Locking teeth present difficult molding and quality control problems, tend to be temperature sensitive and tend to require a larger diameter barrel which increases premature blowout problems. In addition to the non-reusability provided by separation of the retainer ring from the head of the needle holder and dislodgement of the stopper, the plunger is not accessible after retraction because it is depressed within an opening at the back of the outer body. This additional tamperproof feature is provided in a one piece body without the necessity for hooking anything or twisting any thing. The easily made and installed force fit plug at the back of the retraction cavity prevents access to the retracted components.

We claim:

1. A reduced force syringe plunger handle for use in retracting a retractable syringe of the type having an elongated hollow syringe barrel having a front end portion containing a retraction mechanism activated by forward movement of the plunger relative to the barrel, the retraction mechanism comprising a rearwardly biased needle holder held by a separable retainer member lodged in the front end portion of the barrel, the retainer member having first and second sides oppositely disposed relative to a longitudinal axis through the barrel, the syringe plunger handle having a tubular body reciprocatably mounted in the barrel, the tubular body having a head comprising a front tip configured to contact and separate the retainer member from the needle holder by forward movement of the plunger relative to the barrel thereby releasing the needle holder for retraction, wherein the improvement comprises:

the front tip of the plunger having a longitudinally varying front surface comprising a first forwardly extending side configured to contact and move the first side of the retainer member relative to the needle holder and the barrel, and a second forwardly extending side disposed rearwardly of the first forwardly extending side, the second forwardly extending side configured to thereafter contact and move the second side of the retainer member relative to the needle holder and the barrel when the plunger is moved forwardly relative to the barrel, thereby reducing the plunger force required to activate the retraction mechanism.

2. The reduced force syringe plunger handle of claim 1 wherein the longitudinal varying front surface is longitudinally stepped relative to the longitudinal axis through the barrel.

3. The reduced force syringe plunger handle of claim 1 wherein a substantial portion of the longitudinally varying front surface is angled relative to the longitudinal axis through the barrel.

4. The reduced force syringe plunger handle of claim 3 wherein the longitudinally varying front surface includes a relatively flat portion which contacts the first side of the retainer member when the plunger moves forward relative to the barrel to retract the syringe.

5. The reduced force syringe plunger handle of claim 1 wherein a releasable plug member is lodged in the front tip of the syringe plunger, the plug member being exposed more on one side than on the other side because of the longitudinally varying front surface.

6. The reduced force syringe plunger handle of claim 5 wherein the releasable plug member has a portion which extends forward beyond the front tip of the plunger.

7. The reduced force syringe plunger handle of claim 1 wherein the first forwardly extending side of the longitudinally varying front surface tilts the retainer member relative to the needle holder and barrel prior to being contacted and moved by the second forwardly extending side.

8. A reduced force syringe plunger handle for use in retracting a retractable syringe having a long axis and a transversely positioned retainer member in a retraction mechanism having a retractable needle, comprising:

an elongated tubular syringe plunger having an end cap for depression of the plunger at a back end and a head portion at a front end of the plunger, the head portion having a plunger seal for sealingly slidingly in a syringe barrel;

the syringe plunger having a tubular wall containing a retraction cavity within the syringe plunger, the tubular wall extending forwardly into the head portion;

the head portion having a forwardly extending hollow tip portion defining an opening through the tip portion leading into the retraction cavity;

the hollow tip portion having a contact surface at the front of the plunger which varies axially in forward extension at different angular locations with respect to said opening, wherein one portion of the contact surface is configured to push first against the transversely positioned retainer member before the rest of the contact surface engages the retainer member thereby tilting the retainer member during retraction of the retractable needle;

whereby the plunger force required for release of the retainer member from the retractable needle is reduced as compared to a plunger having a generally transverse contact surface and the same retainer member and retraction mechanism.

9. The reduced force plunger handle of claim 8, wherein said contact surface comprises a stepped rim around said opening, the stepped rim having a high step and a lower step wherein the high step is first to push against the transverse retainer member.

10. The reduced force plunger handle of claim 9, wherein the high step portion of the stepped rim is roughly half of the total stepped rim configuration.

11. The reduced force plunger handle of claim 9, wherein the high step portion of the stepped rim extends for more than about one quarter of the total stepped rim configuration.

12. The reduced force plunger handle of claim 9, whereas the hollow tip portion defining said opening is of a reduced diameter as compared to the tubular syringe plunger.

13. The reduced force plunger handle of claim 8, wherein the opening through the tip portion leading into the retraction cavity has a removable seal.

14. The reduced force plunger handle of claim 13, wherein the opening through the tip portion leading into the retraction cavity is sealed with a releasable plug member that is lodged in the tip portion of the syringe plunger wherein a portion of the plug member extends forwardly beyond the high step portion of the stepped rim.

15. The reduced force plunger handle of claim 8, wherein a releasable plug member is lodged in the tip of the syringe plunger, the plug member being exposed more on one side where the lower step is located and exposed less where the higher step is located.

16. The reduced force plunger handle of claim 8, wherein the contact surface at the front of the plunger is substantially

an angled surface with respect to the long axis of the syringe such that one portion of the angled contact surface presses against the retainer member when the plunger moves forward before the remainder of the angled surface presses against the retainer member.

17. The reduced force plunger handle of claim **8**, wherein the contact surface at the front of the plunger has a relatively flat transverse portion and an angled portion with respect to said long axis, said relatively flat transverse portion being the part of said contact surface which presses first against the retainer member when the plunger moves forward.

18. A method of reducing plunger retraction force in a retractable syringe of the type having a barrel, a syringe plunger which reciprocates axially in the barrel and a front mounted retraction mechanism in the barrel having a retractable needle being held in position in the barrel by means of a transverse retainer which is separated from the retractable needle by contact between the front tip portion of the plunger and the transverse retainer when the plunger is moved forward after an injection to push the retainer off the retractable needle and allow retraction, comprising the step of:

providing a plunger having a front edge on the front tip portion configured to push on one portion of the retainer before pushing on the rest of the retainer when the plunger is pushed forward at the end of an injection;

pushing the plunger forward to bring the front edge of the tip portion in contact with the transverse retainer member; and

tilting the transverse retainer with respect to the retractable needle while it is being separated from the retractable needle by forward movement of the plunger.

19. The method of claim **18** wherein the step of tilting the transverse retainer member with respect to the retractable needle while it is being separated from the retractable needle by forward movement of the plunger includes the step of separating one part of the transverse retainer member from the retractable needle before the rest of the transverse retainer is separated from the retractable needle.

20. The method of claim **18** wherein the plunger is configured with a front edge comprising an opening and a stepped rim around said opening having a high step and a lower step wherein the step of pushing the plunger forward comprises the step of bringing the high step into first contact with the transverse retainer before the lower step contacts the transverse retainer.

21. The method of claim **20** wherein the step of providing a plunger includes a releasable plug lodged in said opening and wherein the step of pushing the plunger forward to bring the front edge of the front tip portion in contact with the transverse retainer member is preceded by the step of moving said plug member.

22. The method of claim **18** wherein the plunger is configured with a hollow front tip portion having an angled opening leading into a hollow portion of the syringe plunger and the step of pushing the plunger forward comprises the step of bringing the forwardmost part of the front edge into first contact with the transverse retainer thereby tilting the transverse retainer with respect to the retractable needle while it is being separated from the retractable needle by forward movement of the plunger.

23. The method of claim **22** wherein the step of providing a plunger includes a releasable plug lodged in said opening and wherein the step of pushing the plunger forward to bring the forwardmost part of the front tip portion in contact with the transverse retainer member is preceded by the step of moving said plug member.

24. A method of reducing plunger retraction force in a retractable syringe of the type having a barrel, a syringe plunger which reciprocates axially in the barrel, and a front mounted retraction mechanism in the barrel having a retractable needle being held in position by means of a transverse retainer with an outside edge in contact with the inside surface of the front of the barrel wherein the transverse retainer is separable from the retractable needle upon forward movement of the plunger after an injection is made whereby a front tip portion of the plunger pushing against the retainer moves the retainer forward in the front of the barrel thereby freeing the retractable needle, comprising the steps of:

providing a plunger having a front edge on the front tip portion configured to slide one portion of the outer edge of the transverse retainer with respect to the front of the barrel before beginning to move the rest of the retainer with respect to the front of the barrel when the plunger is pushed forward at the end of an injection; and

pushing the plunger forward to bring the front edge of the tip portion in contact with the transverse retainer member; and

moving one portion of the transverse retainer with respect to the front of the barrel before moving the rest of the transverse retainer during forward movement of the plunger while the retractable needle is being separated from the transverse retainer.

25. The method of claim **24** wherein the steps of providing a plunger, bringing the front edge of the tip portion in contact with the transverse retainer member and moving one part of the transverse retainer member with respect to the front of the barrel before the remainder of the transverse retainer begins moving include the step of contacting the transverse retainer with the front edge of the plunger comprising an opening and a stepped rim around said opening having a high step and an lower step wherein the step of pushing the plunger forward comprises the step of bringing the high step into first contact with the transverse retainer before the lower step comes into contact with the transverse retainer.

26. The method of claim **24** wherein the step of providing a plunger includes providing a plunger having and opening in the tip portion and a releasable plug member lodged in said opening of the syringe plunger and the step of pushing the plunger forward to bring the front edge of the tip portion in contact with the transverse retainer member is preceded by the step of moving said plug member.

27. The method of claim **24** wherein the plunger is configured with a front edge comprising substantially an angled surface with respect to the long axis of the syringe such that one portion of the angled contact surface pushes first against one part of the transverse retainer member when the plunger is pushed forward and thereby begins separating the transverse retainer from the retractable needle by sliding one part of the transverse retainer with respect to the front of the barrel before the remainder of the transverse retainer begins sliding with respect to the barrel.

28. The method of claim **27** wherein the step of providing a plunger includes the step of providing an angled contact surface which includes a relatively flat transverse portion and an angled portion with respect to the long axis of the syringe wherein the relatively flat transverse portion is the portion which first contacts the transverse retainer and first moves a part of the transverse retainer with respect to the front of the barrel before the rest of the transverse retainer is moved.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,572,584 B1
DATED : June 3, 2003
INVENTOR(S) : Thomas J. Shaw, Judy Zhu and Diane Rutherford

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3,
Line 53, replace "with" with -- which --.

Column 9,
Line 48, replace "impossible," with -- impossible --.

Column 12,
Line 17, replace "66 a" with -- 66a --.

Column 13,
Line 34, replace "exceed" with -- exceeds --.

Column 18,
Line 57, replace "32, 32" with -- 32, 32' --.

Column 19,
Line 57, replace "begins," with -- begins --.

Column 20,
Line 42, replace "190" with -- 190' --.

Column 25,
Line 18, replace "any thing" with -- anything --.

Column 26,
Line 16, replace "sealingly slidingly" with -- sealingly sliding --.

Signed and Sealed this

Seventh Day of October, 2003

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

EXHIBIT B

US007351224B1

(12) United States Patent
Shaw

(10) Patent No.: US 7,351,224 B1
(45) Date of Patent: *Apr. 1, 2008

(54) **RETRACTABLE SYRINGE ASSEMBLY DESIGNED FOR ONE USE**

(76) Inventor: **Thomas J. Shaw**, 1510 Hillcrest, Little Elm, TX (US) 75068

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 458 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/617,868**

(22) Filed: **Jul. 17, 2000**

Related U.S. Application Data

(63) Continuation of application No. 08/843,050, filed on Apr. 25, 1997, now Pat. No. 6,090,077, which is a continuation-in-part of application No. 08/537,242, filed on Sep. 29, 1995, now Pat. No. 5,632,733, which is a continuation-in-part of application No. 08/438,954, filed on May 11, 1995, now Pat. No. 5,578,011.

(51) **Int. Cl.**
A61M 5/00 (2006.01)
A61M 5/32 (2006.01)

(52) **U.S. Cl.** **604/110**; 604/192

(58) **Field of Classification Search** 604/110, 604/195, 187, 192–198, 218
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,876,770 A	3/1959	White
3,306,290 A	2/1967	Weltman
3,463,152 A	8/1969	Sorenson
3,890,971 A	6/1975	Leeson
4,026,287 A	5/1977	Haller
4,333,457 A	6/1982	Margulies
4,378,015 A	3/1983	Wardlaw
4,392,859 A	7/1983	Dent
4,425,120 A	1/1984	Sampson
4,507,117 A	3/1985	Vining
4,507,118 A	3/1985	Dent
4,542,749 A	9/1985	Caselgrandi
4,573,976 A	3/1986	Sampson

(Continued)

FOREIGN PATENT DOCUMENTS

CH 669910 A5 4/1989

(Continued)

OTHER PUBLICATIONS

"Disappearing Needle", Designer News, p. 58, Mar. 22, 1993.

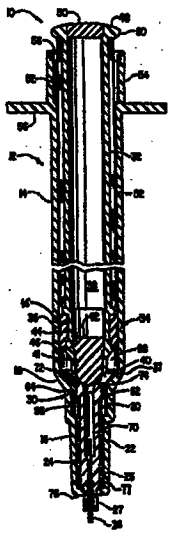
(Continued)

Primary Examiner—Kevin C. Sirmons
Assistant Examiner—Elizabeth MacNeill

(57) **ABSTRACT**

A syringe assembly having a retractable needle, the syringe assembly being rendered unusable after a single injection and having a hollow syringe body, a retraction mechanism with a spring disposed in the front portion of the syringe and an inner head, a continuous retainer member surrounding the inner head, and a bridging portion disposed between the continuous retainer member and the inner head, wherein the bridging portion couples the continuous retainer member and the inner head to form a fluid seal between a fluid passageway and the barrel prior to retraction, and a plunger reciprocally disposed inside the barrel and forming a variable chamber between the plunger and the needle holder prior to and during retraction, wherein the continuous retainer member is releasable from the inner head of the needle holder when the plunger is further depressed inside the barrel following injection.

62 Claims, 8 Drawing Sheets



U.S. PATENT DOCUMENTS

4,592,744	A		6/1986	Jagger
4,631,057	A		12/1986	Mitchell
4,664,654	A		5/1987	Strauss
4,675,005	A		6/1987	DeLuccia
4,692,156	A		9/1987	Haller
4,710,170	A		12/1987	Haber
4,723,943	A		2/1988	Spencer
4,725,267	A		2/1988	Vaillancourt
4,737,144	A		4/1988	Choksi
4,747,831	A		5/1988	Kulli
4,767,413	A		8/1988	Haber et al.
4,770,655	A		9/1988	Haber
4,813,426	A		3/1989	Haber et al.
4,828,548	A		5/1989	Walter
4,838,863	A		6/1989	Allard et al.
4,838,869	A		6/1989	Allard
4,841,985	A		6/1989	Wanamaker
4,850,968	A		7/1989	Romano
4,863,435	A		9/1989	Sturman
4,874,382	A		10/1989	Lindemann et al.
4,887,998	A		12/1989	Martin
4,894,055	A		1/1990	Sudnak
4,898,589	A		2/1990	Dolgin
4,900,307	A		2/1990	Kulli
4,904,242	A		2/1990	Kulli
4,906,236	A		3/1990	Alberts
4,911,693	A		3/1990	Paris
4,917,673	A		4/1990	Coplin
4,919,652	A		4/1990	Alter et al.
4,921,486	A		5/1990	DeChellis et al.
4,927,414	A		5/1990	Kulli
4,927,416	A		5/1990	Tomkiel
4,929,237	A		5/1990	Medway
4,932,947	A		6/1990	Cardwell
4,946,446	A		8/1990	Vadher
4,955,868	A		9/1990	Klein
4,955,869	A		9/1990	Bin
4,955,870	A		9/1990	Ridderheim et al.
4,966,593	A		10/1990	Lennox
4,973,316	A		11/1990	Dysarz
4,988,339	A		1/1991	Vadher
4,994,034	A	*	2/1991	Botich et al. 604/110
5,017,187	A		5/1991	Sullivan 604/110
5,019,044	A		5/1991	Tsao
5,046,508	A		9/1991	Weissler
5,049,133	A		9/1991	Villen Pascual
5,053,010	A		10/1991	McGary et al.
5,064,419	A		11/1991	Gaarde
5,084,018	A	*	1/1992	Tsao 604/110
5,084,029	A		1/1992	Tagliaferri et al.
5,090,962	A		2/1992	Landry, Jr. et al.
5,092,853	A		3/1992	Courvertier, II
5,112,316	A		5/1992	Venturini
5,114,410	A		5/1992	Caralt Batlle
5,116,320	A		5/1992	Lo Duca
5,120,310	A		6/1992	Shaw
5,125,898	A		6/1992	Kaufhold, Jr. et al.
5,129,884	A		7/1992	Dysarz
5,163,918	A		11/1992	Righi et al.
5,180,369	A	*	1/1993	Dysarz 604/110
5,180,370	A		1/1993	Gillespie
5,188,599	A		2/1993	Botich et al.
5,188,613	A		2/1993	Shaw
5,190,526	A		3/1993	Murray et al.
5,201,710	A		4/1993	Caselli
5,211,628	A		5/1993	Marshall
5,211,629	A	*	5/1993	Pressly et al. 604/110
5,295,975	A		3/1994	Lockwood, Jr.
5,304,138	A	*	4/1994	Mercado 604/110
5,324,265	A		6/1994	Murray et al.
5,346,480	A		9/1994	Hess et al.
5,370,620	A		12/1994	Shonfeld
5,376,075	A		12/1994	Haughton et al.
5,376,080	A		12/1994	Petrussa
5,385,551	A	*	1/1995	Shaw 604/110
5,389,076	A		2/1995	Shaw
5,407,431	A		4/1995	Botich et al.
5,407,436	A		4/1995	Toft et al.
5,411,489	A		5/1995	Pagay et al.
5,423,758	A		6/1995	Shaw
5,458,576	A		10/1995	Haber et al.
5,505,703	A		4/1996	Bartlett et al.
5,527,286	A		6/1996	Lekhgolts et al.
5,578,011	A		11/1996	Shaw
5,613,952	A		3/1997	Pressley, Sr. et al.
5,632,733	A		5/1997	Shaw
5,800,403	A		9/1998	Pressly, Sr. et al.
5,810,775	A		9/1998	Shaw
5,997,512	A		12/1999	Shaw
6,015,438	A		1/2000	Shaw
6,074,370	A		6/2000	Pressly, Sr. et al. 604/195
6,090,077	A		7/2000	Shaw

FOREIGN PATENT DOCUMENTS

GB	2 197 792 A	6/1988
JP	H02-504114	11/1990
JP	146773	12/1990
JP	H06-508768	10/1994
JP	H07-47123	2/1995
WO	WO 92/18187	10/1992
WO	WO 93/12830	7/1993
WO	WO 95/08358	3/1995
WO	WO 95/11713	5/1995
WO	WO 96/32981	10/1996
WO	WO 96/35463	11/1996
WO	WO 98/48869	11/1998

OTHER PUBLICATIONS

Memorandum Opinion dated Mar. 2, 2004, *Retractable Technologies, Inc. et al.* v. *New Medical Technology, Inc. et al.*, cont. No. 4:02-CV-34, U.S. District Court Eastern District, Sherman Division.

Plaintiff Retractable Technologies, Inc. and Third-Party Defendant Thomas J. Shaw's Markman Brief dated Feb. 28, 2003, cont. *Retractable Technologies, Inc. et al.* v. *New Medical Technology, Inc. et al.*, No. 4:02-CV-34, U.S. District Court Eastern District, Sherman Division.

Defendants' Markman Brief dated Mar. 28, 2003, *Retractable Technologies, Inc. et al.* v. *New Medical Technology, Inc. et al.*, No. 4:02-CV-34, U.S. District Court, cont. Eastern District, Sherman Division.

Plaintiffs' Markman Reply Brief dated Apr. 14, 2003, *Retractable Technologies, Inc. et al.* v. *New Medical Technology, Inc. et al.*, No. 4:02-CV-34, U.S. District Court, cont. Eastern District, Sherman Division.

Defendants' Final Invalidity Contentions dated Apr. 21, 2004, *Retractable Technologies, Inc. et al.* v. *New Medical Technology, Inc. et al.*, No. 4:02-CV-34, cont. U.S. District Court Eastern District, Sherman Division.

Preliminary Invalidity Contentions in Civil Action No. 2:07-cv-00250-DF.

* cited by examiner

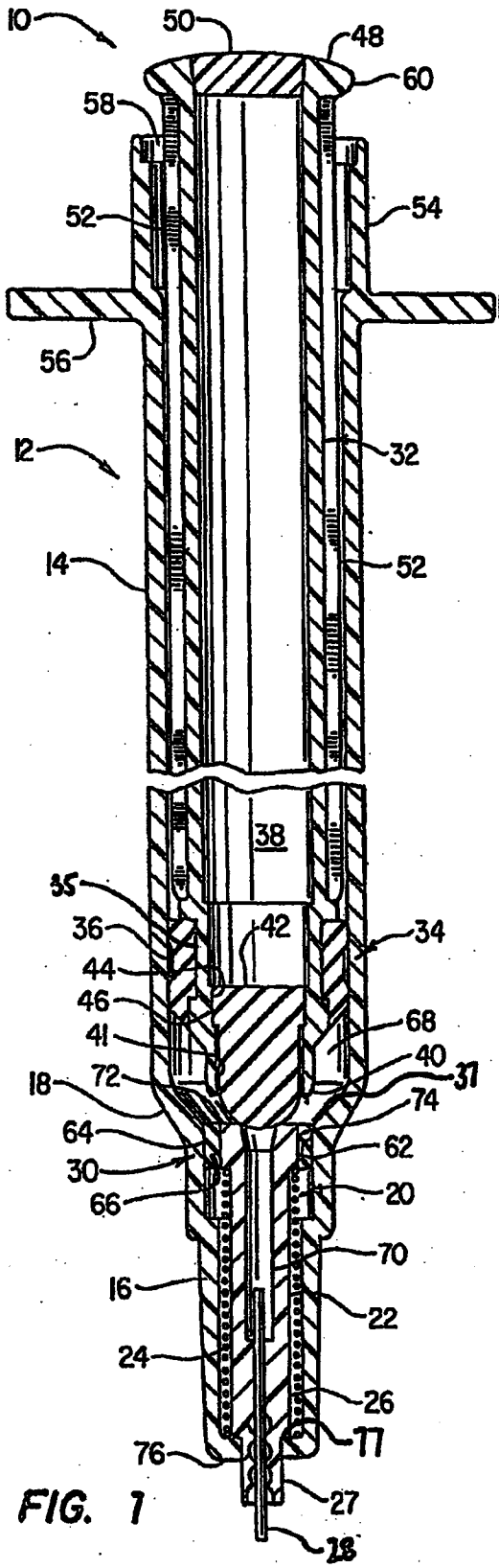

10
50
48
60
58
52
54
56
12
32
14
52
38
35
36
42
34
44
46
68
41
40
37
18
72
74
64
62
30
20
66
70
16
22
24
26
76
77
27
28

FIG. 1

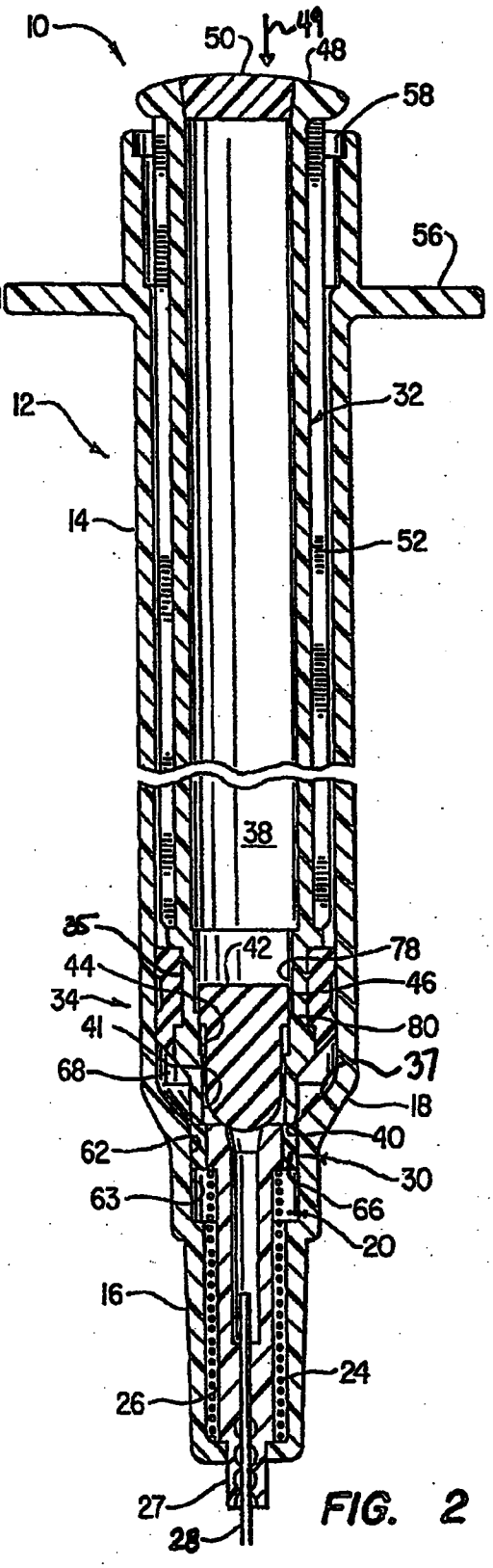

10
50
49
48
58
56
12
32
14
52
38
35
42
78
44
46
34
41
80
68
37
18
40
62
30
63
66
20
16
24
26
27
28

FIG. 2

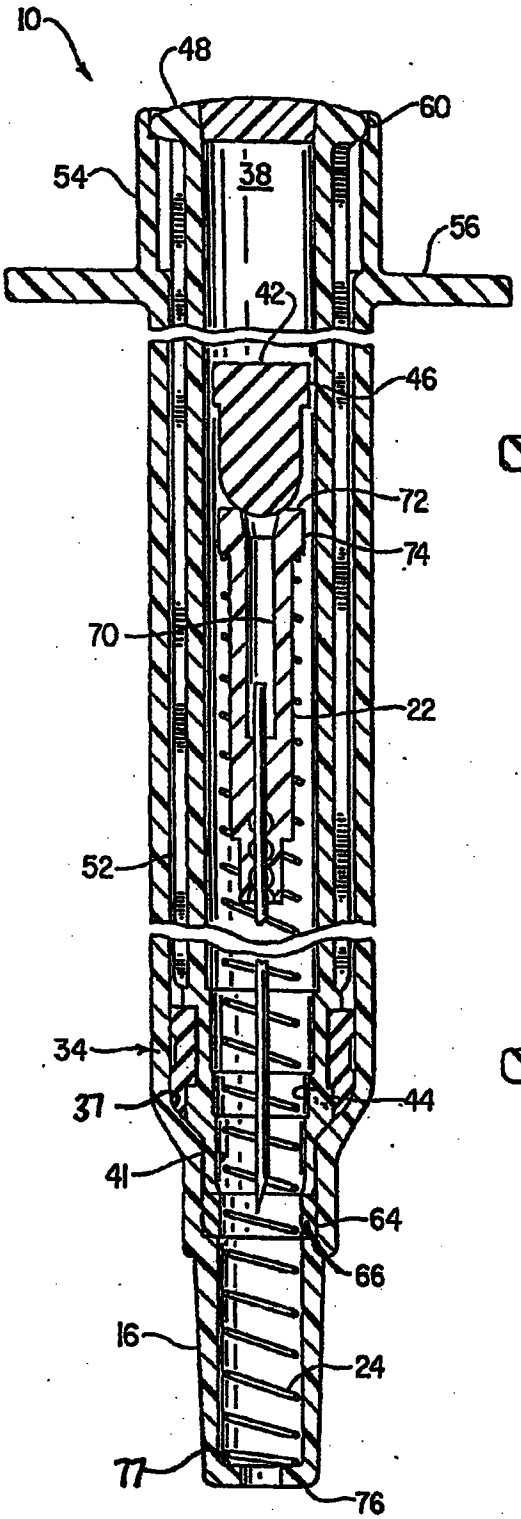


FIG. 3

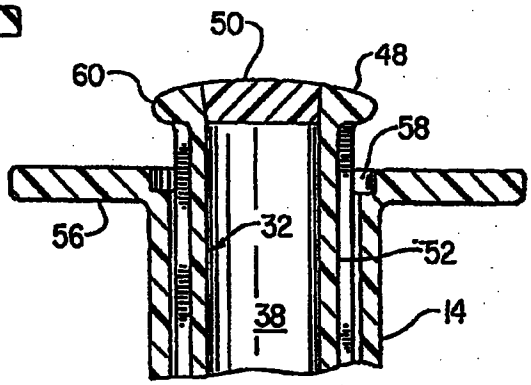


FIG. 4A

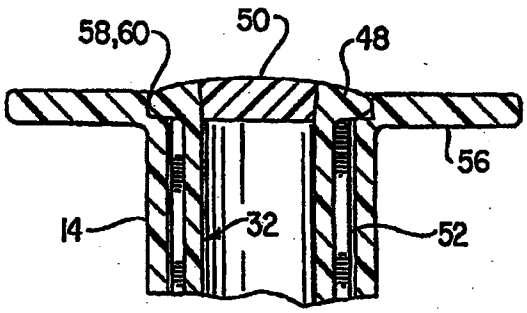


FIG. 4B

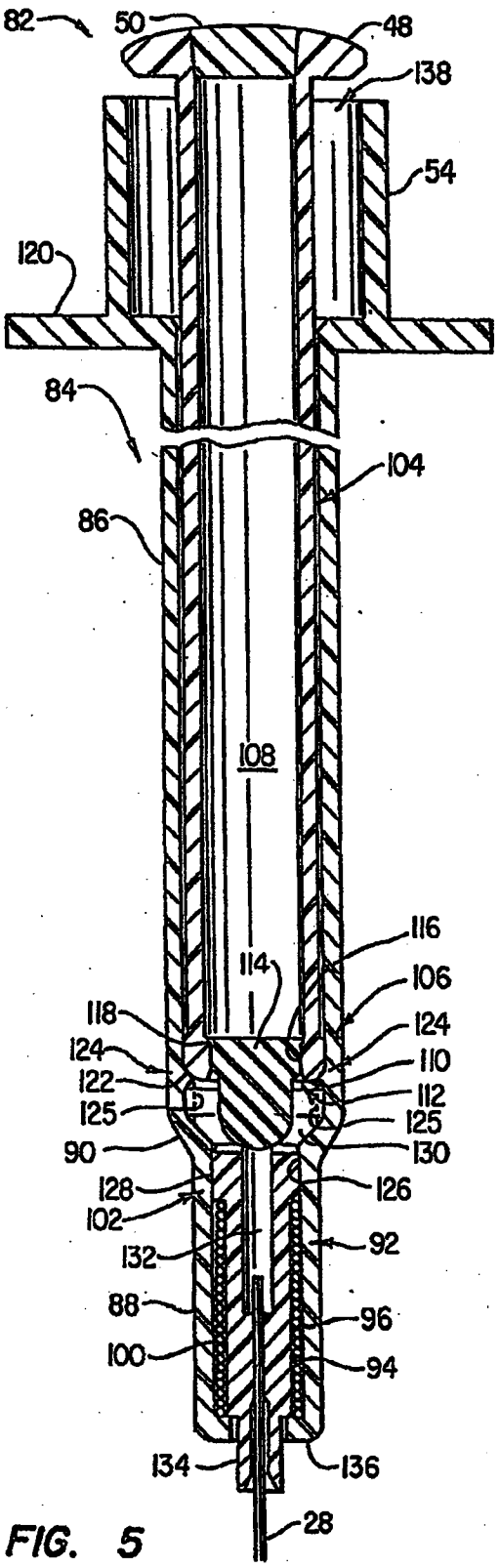

82
50
48
138
54
120
84
104
86
108
116
114
106
118
124
124
110
122
112
125
125
90
130
128
126
102
92
132
88
96
100
94
134
136
28

FIG. 5

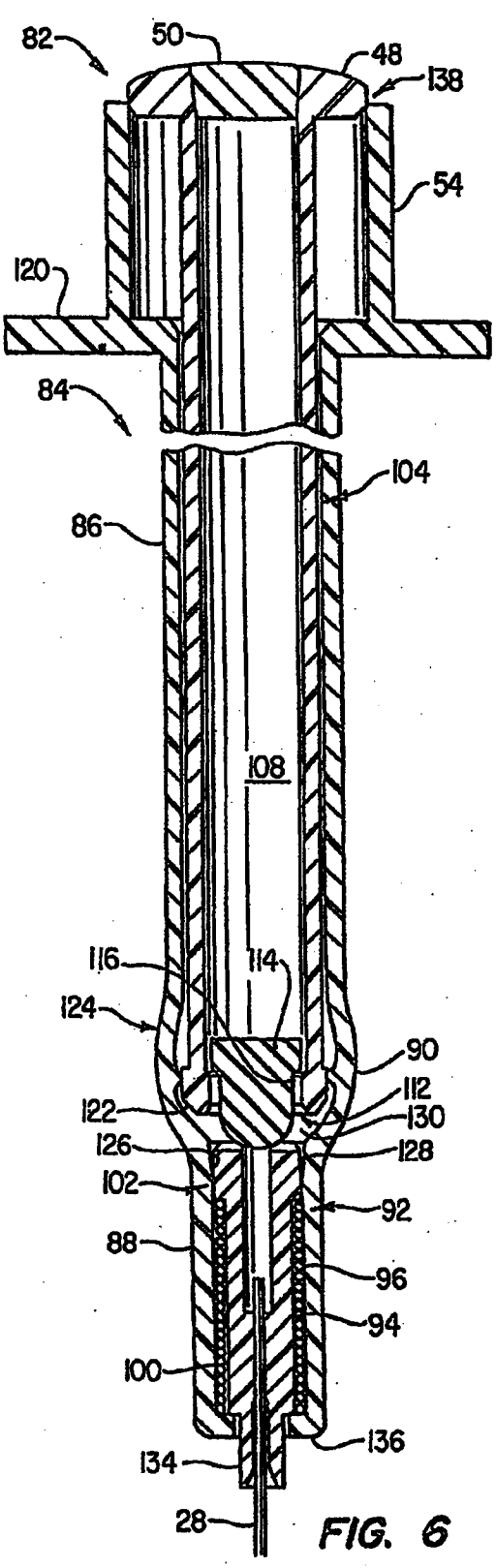

82
50
48
138
54
120
84
104
86
108
116
114
124
90
112
122
130
126
128
102
92
88
96
94
100
136
134
28

FIG. 6

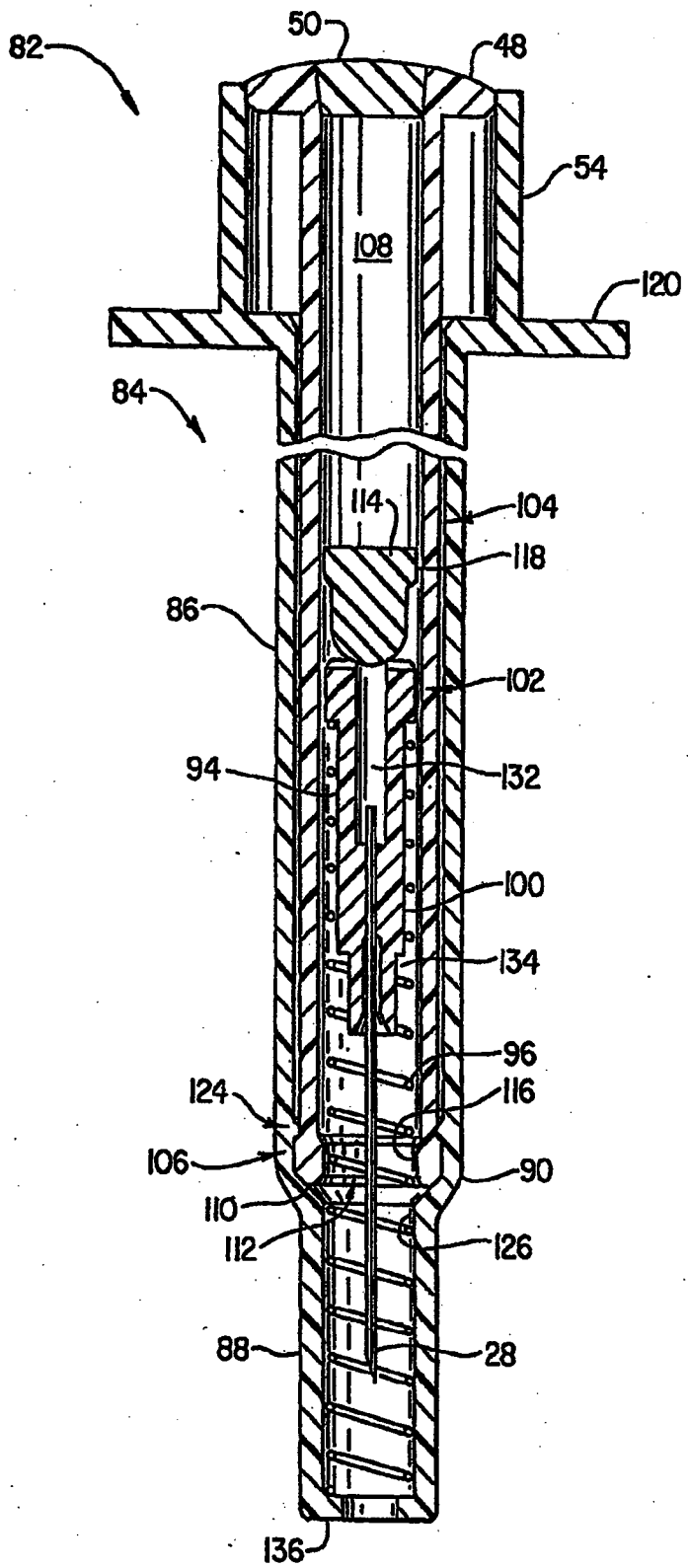

82
50
48
54
108
120
84
114
104
118
86
102
94
132
100
134
96
124
116
106
90
110
112
126
88
28
136

FIG. 7

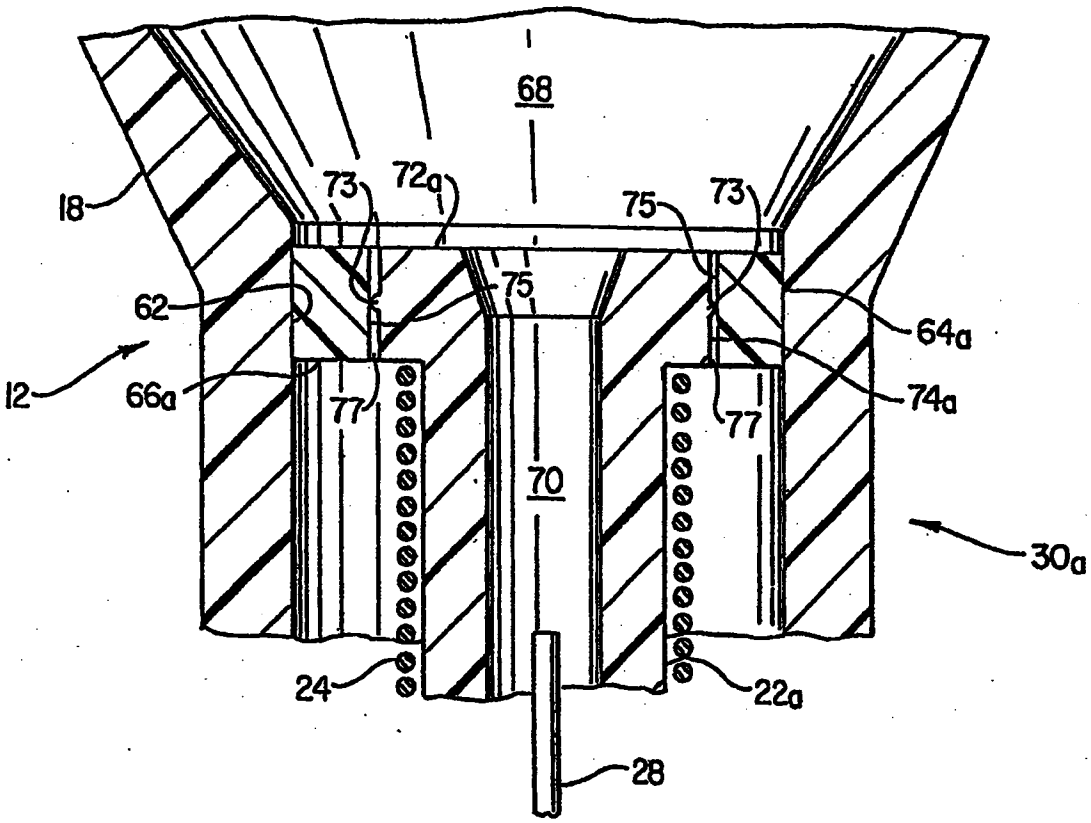


FIG. 8

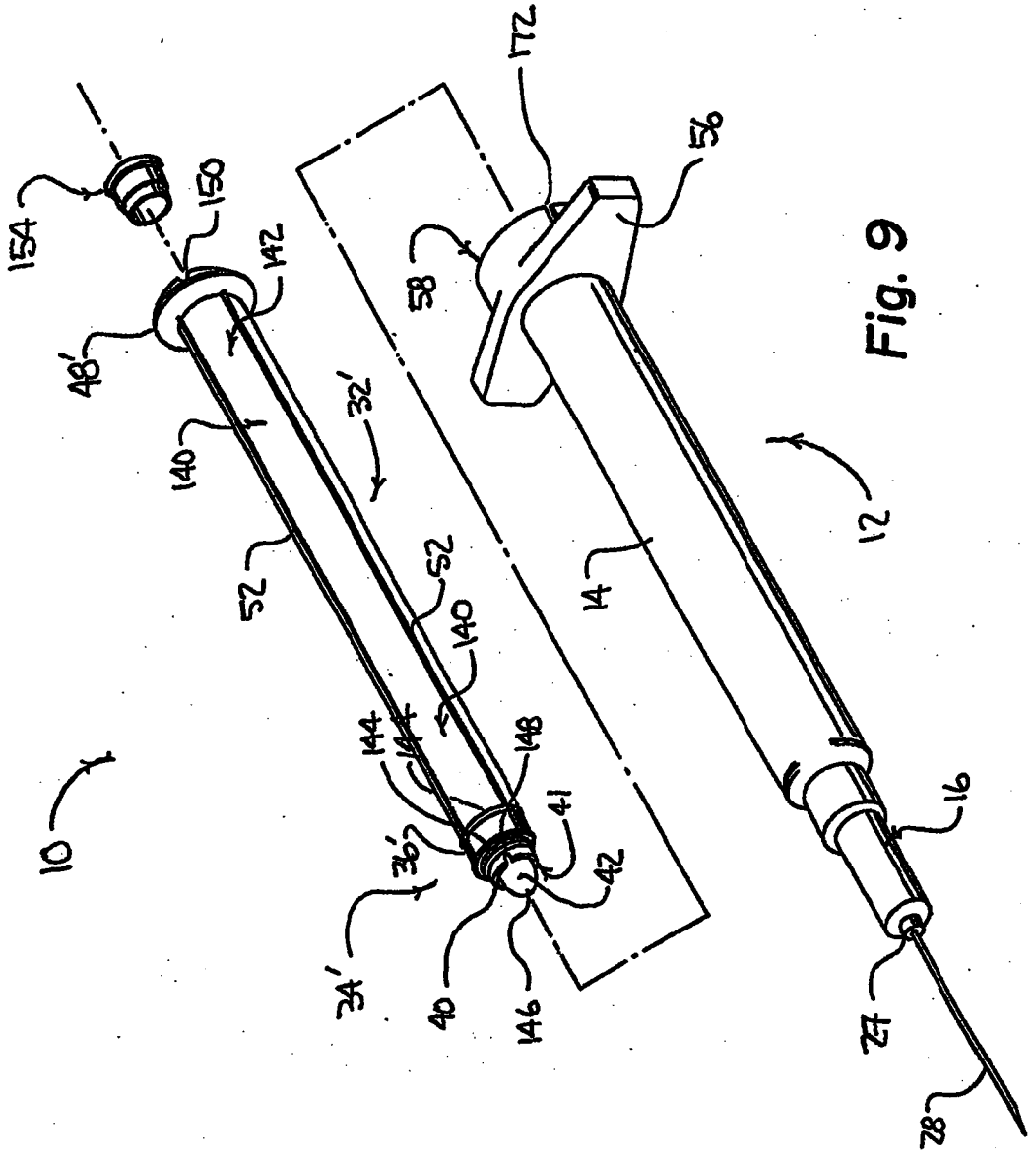

172
56
154
150
142
58
48'
32'
140
52
52
140
14
12
144
148
10
41
36'
42
34'
40
146
16
27
28

Fig. 9

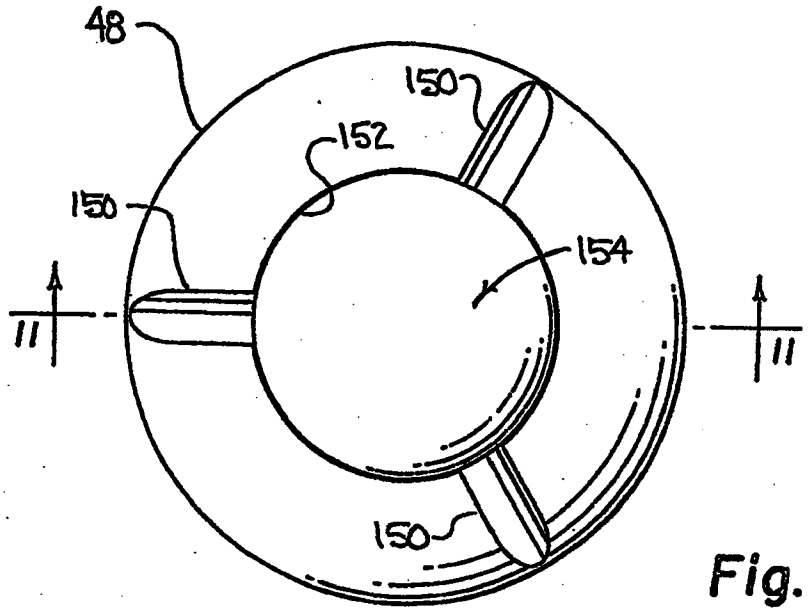

48
150
152
150
154
II
II
150

Fig. 10

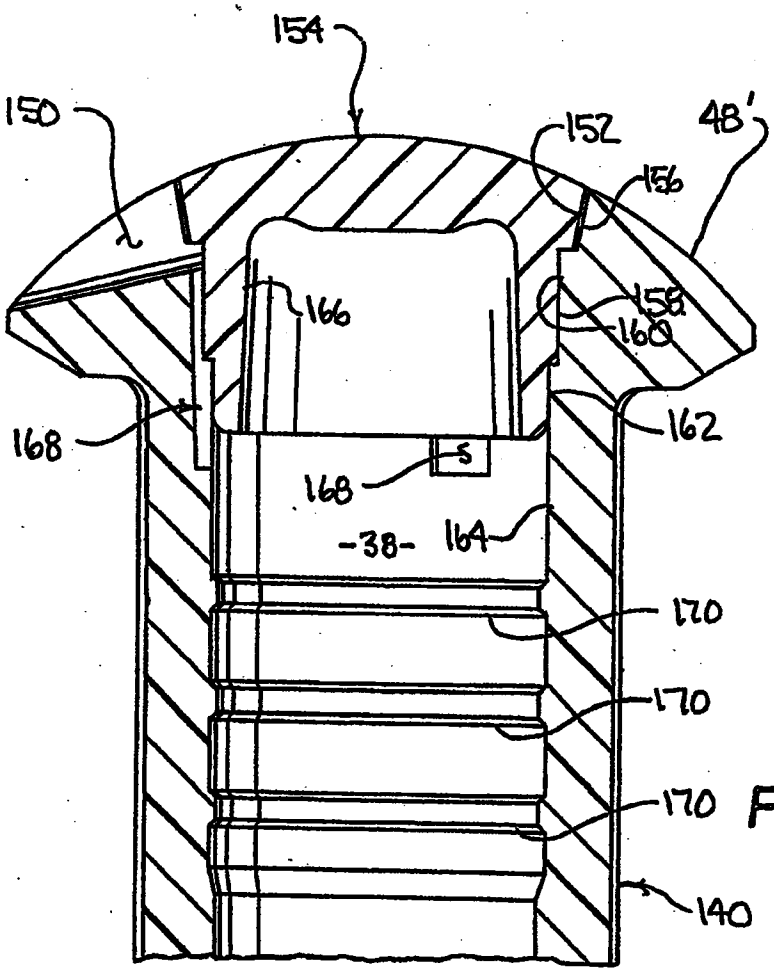

154
150
152
48'
156
166
158
160
168
162
S
168
-38-
164
170
170
170
140

Fig. 11

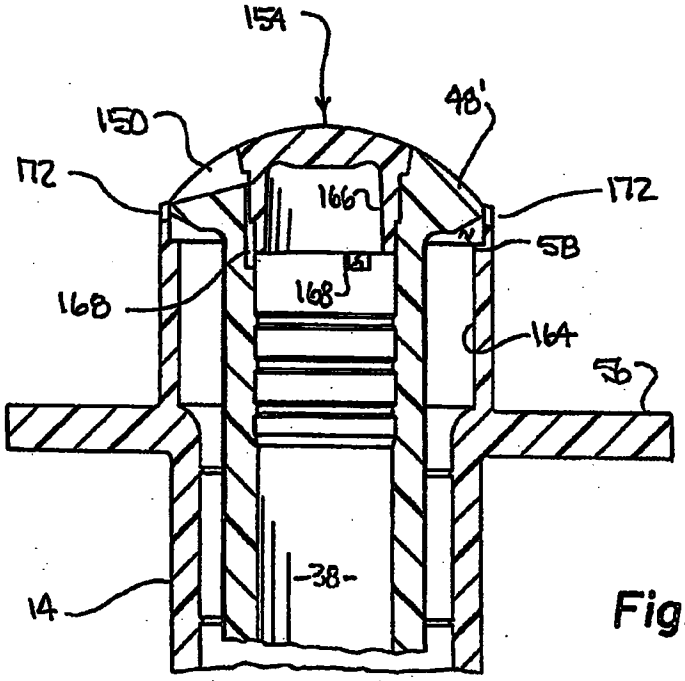


Fig. 12

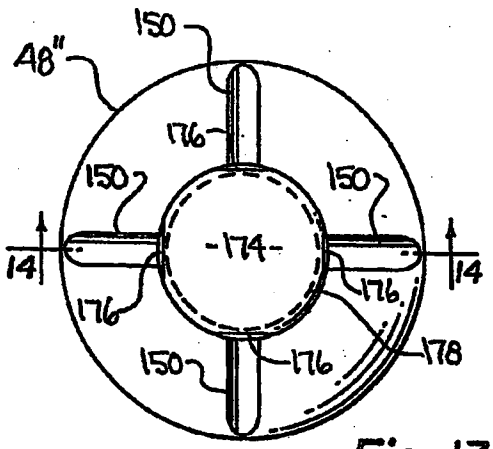


Fig. 13

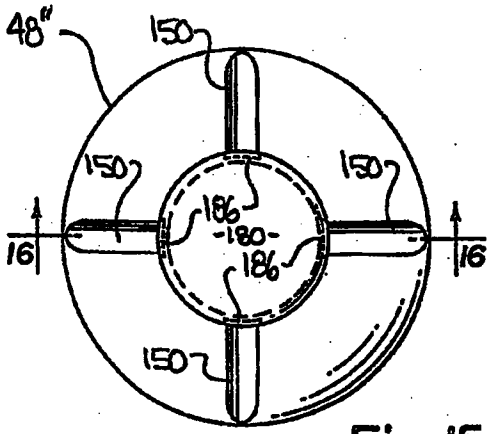


Fig. 15

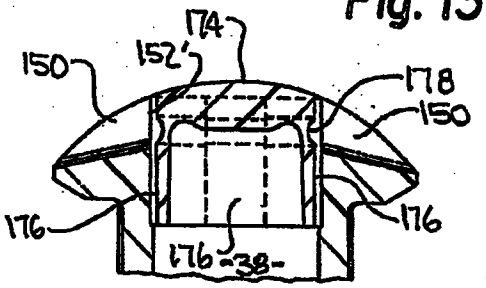


Fig. 14

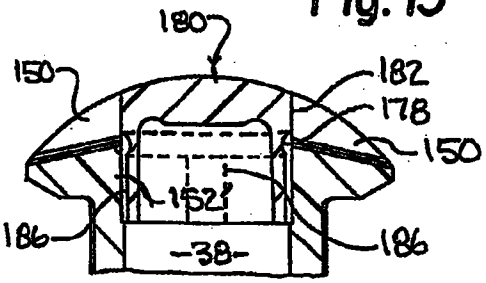


Fig. 16

RETRACTABLE SYRINGE ASSEMBLY DESIGNED FOR ONE USE

CROSS REFERENCE TO RELATED APPLICATION

This is a continuation of patent application Ser. No. 08/843,050 filed Apr. 25, 1997 entitled "Syringe Plunger Handle Assembly and Barrel, now U.S. Pat. No. 6,090,077, which was a continuation-in-part of patent application Ser. No. 08/537,242 filed Sep. 29, 1995 entitled "Tamperproof Retractable Syringe", now U.S. Pat. No. 5,632,733, which in turn was a continuation-in-part of patent application Ser. No. 08/438,954 filed May 11, 1995, now U.S. Pat. No. 5,578,011, all by the same inventors, for which benefit of 35 U.S.C. § 120 is claimed.

FIELD OF THE INVENTION

This invention relates to a medical device, and more particularly to a retractable syringe and components suitable for mass production and assembly having a low triggering force and high blowout pressure which is nonreusable after one use.

BACKGROUND OF THE ART

A major cause to the spread of AIDS in the general population is the presence of IV drug users who share and reuse hypodermic syringes to inject drugs. Infection can be spread from AIDS patients in hospitals and medical facilities through accidental needle sticks from needles used on infected patients. Used syringes with extended needles present a risk to medical personnel and sanitation employees and others in the disposal chain.

The gravity of the threat posed by AIDS and the fact that the main vector of the spread of the dreaded disease is through reuse of syringes by IV drug users has resulted in intense activity to develop the most practical, most reliable, easily assemblable, mass-producible syringe.

There are a number of syringes of different designs which have needles which will retract at the end of the injection cycle. Most of these have never reached the market because of various deficiencies. Prime among the usual deficiencies of the prior art are problems of complexity, reliability, cost and ease of use. The most commonly used syringes are 1 cc and 3 cc syringes which must be mass-produced at the rate of millions per day. Cost is a significant factor both in manufacture of the parts and assembly of the device. High speed production requires molds with 64 cavities or more to reduce unit cycle time. Therefore, molded structures within the barrel that require collapsing core pins such as are shown in much of the art are unlikely to be producible at competitive costs.

One of the problems of the prior art of retractable syringes is the sheer number and complexity of parts which must be formed and assembled. Other problems with the prior art are dependence on flexing or breaking of internal parts by the plunger in order to release the retraction mechanism and use of a diaphragm at the end of the plunger which must be penetrated by a needle holding member and spring. These structures present serious quality control and assembly problems. Small broken off pieces can present a risk of hang-ups. Hooks are often used to releaseably secure retraction mechanisms. Hooks present difficult holding and control problems, may cause retention of air bubbles upon filling and may be undesirably temperature sensitive.

The prior art frequently has a two-piece barrel in order to be able to assemble a retraction device in the nose. This requires at least an additional part and assembly step. It is still necessary to pass the sharp injection needle through a small opening often while compressing a spring before the two parts can be assembled. The tiny needles are produced in the form of coil tubing and vary significantly from straightness after they are cut to length. This leads to difficult assembly problems if the needle must be passed through a small opening. The extremely sharp tip will catch the edge of a hole and jam the production line.

The rare prior art that employs a front mounted retraction mechanism in a one-piece barrel with a plugged hollow plunger, Tsao U.S. Pat. No. 5,084,018, among other things does not show reduced barrel area to prevent excessive blowout pressure, employs engaging flanges to secure all retraction parts, requires concurrent distortion of internal parts and flanges to effect release, cumulating in excessive force required to retract and requires ventilation holes because of a compartmented barrel.

The prior art has not produced a retractable nonreusable tamperproof syringe for mass production and assembly which is simple, reliable, cost effective, easy to use and retract, looks like a conventional syringe, has few parts which are easy to make and assemble, is not temperature sensitive and not subject to danger of premature retraction.

The prior art has not recognized a retraction mechanism with separable parts that relies entirely on clamping force or friction at a smooth walled reduced diameter transition zone in the barrel with mating lands which are slidably or separably released in response to relatively low thumb pressure while having resistance to premature retraction and high blowout pressure resulting from high pressure produced in the fluid chamber during an injection. The prior art has not recognized that such a structure can be molded as a one piece outer body over a core that can be pulled out from behind allowing the retraction mechanism to be easily pushed into place from behind, steered by the narrow nose portion. Neither does the prior art in such a combination realize the desirable non-cumulation of forces resisting retraction in order to minimize the thumb force required, having a most simple tamperproof feature and the fewest number of easily made parts.

The syringe plunger assembly has a combination of features not found in a prior art syringe. A head end which acts like a piston when installed in a syringe barrel has a reduced diameter front end having an opening and a dislodgeable stopper slidingly mounted in the opening projecting forwardly from the tip. Cooperating lands within the opening and on the head of the dislodgeable stopper seal the opening into the hollow interior of the plunger. The area of the stopper is relatively small when compared to the area exposed to the piston, which compresses fluid in a chamber below the piston. The ratio of the total area of the fluid chamber to the fluid exposed area of the stopper is at least two to one, more preferably three to one or more so that the stopper requires less holding force without blowing out back into the internal cavity. The cooperating lands have sufficient length so that the stopper can move back to the tip when the plunger moves forward at the end of an injection stroke without unsealing the plunger opening. A reduced holding force is sufficient to prevent blowout of the stopper after the stopper has been moved back to the tip because the stopper is exposed to a lower pressure generated force because of its relatively smaller area. The back of the plunger is vented so that entry of retractable parts which upon retraction finish dislodging the stopper and carry it back into the cavity, do

not generate internal pressure that can blow out the nose of the syringe carrying any residual fluid with it. The thumb cap on the plunger is received and recessed into the opening at the back of the barrel when retraction occurs. The plunger cannot be grasped after this occurs to help prevent reuse.

These features and more are found in the inventive combination herein further disclosed which is especially suited for high speed production and assembly at low cost.

SUMMARY OF THE INVENTION

The invention is a reliable retractable tamperproof syringe having multiple tamperproof features which operates on a principle which permits low cost parts which are few in number and well suited for high speed mass production and assembly. The syringe structure features a one piece hollow outer body having a longitudinally extending wall which is stepped. The wall comprises an elongated barrel and nose with a transition zone connecting the barrel and nose. The nose has a reduced diameter relative to the barrel. The outer body has an inwardly facing surface in the wall at the most constricted part of the transition zone where the nose begins. A plunger assembly is disposed partially within the elongated barrel with an end cap for depression of the plunger extending from an opening in the back of the barrel. The head of the plunger, which has a retraction cavity for receiving parts of a retraction mechanism, moves in slidable sealed contact with the interior of the barrel.

A retraction mechanism is lodged in the nose of the body. The retraction mechanism comprises an elongated needle holder and spring combination wherein the needle holder has an elongated body with a needle holding portion in front and a head in back. The head of the needle holder has a cooperating outwardly facing surface configured to cooperate with said inwardly facing surface along an interface oriented in the direction of retraction to produce a holding force on the needle holder when installed in the nose in the unretracted position. The needle holder and spring are easily installable from the rear of the barrel toward the nose and releaseably held by sliding engagement of said cooperating inwardly and outwardly facing surfaces while compressing the spring and thereby producing a holding force on the needle holder in opposition to the retraction force applied to the needle holder by the spring. The parts are circular in cross section.

The outwardly facing surface on the circular head of the needle holder is slightly greater in diameter than the circular inward facing surface in the wall at the most constricted portion where the nose begins. The needle holder is thus clamped in position by hoop stresses induced in the outer body and held in position by frictional holding force. The needle holder is released in response to depression of the plunger to a retraction position. Retraction occurs in response to thumb force on the plunger when a portion of the plunger passing into the transition zone separates at least a portion of the inwardly and outwardly facing cooperating surfaces thereby reducing the holding force on the needle holder to an amount less than a retraction force on the needle holder produced by the spring whereby the needle holder is retracted into the cavity a distance sufficient to withdraw an injection needle, attached to the needle holder, into the outer body.

In one embodiment, the head of the needle holder is a two part head comprising an inner head surrounded by a separable retainer member wherein the outer surface of the retainer member is the outwardly facing surface with cooperates with the inwardly facing surface in the wall to retain

the needle holder in an unretracted position at the most constricted part of the transition zone where the nose begins. The retainer member is a ring member coupled to the inner head along a sliding interface oriented in the direction of retraction with a friction force which exceeds the retraction force provided by the spring. The front of the needle holder is grounded in the nose portion against forward movement. The plunger head is configured to pass through the most constricted area and push against the retainer member without also pushing against the head of the needle holder. An alternate construction of the two part head of the needle holder comprises the separable retainer member being tack welded to the inner head of the needle holder, preferably along a very small ridge or bridge between the mating surfaces which holds the two part head together until the bridge is ruptured by movement of the plunger after an injection has occurred.

The front of the plunger has an opening for a stopper slidingly fitted therein in an interference fit. The stopper is fitted in the opening in an interference fit along a sliding interface oriented in the direction of retraction. The stopper is mostly or fully dislodged by contact with the retraction mechanism at the end of an injection cycle by continued depression of the plunger from a first position at the end of the injection cycle to a second position with the tip of the plunger in contact with the retainer ring. This avoids cumulation of the force on the plunger required to dislodge the stopper from the opening and the force required to dislodge the retainer member from the head of the needle holder and outer body wall. Upon further depression of the plunger from the second position to the retraction position, the frictional holding force on the needle holder is reduced until the retraction force provided by the spring exceeds the remaining holding force and the needle holder and needle connected thereto are ejected into the cavity carrying the dislodged stopper along with them. The dislodging of the stopper and the retainer member alone make the syringe non-reusable. The plunger cannot be removed after retraction because the graspable end cap enters an opening at the back of the barrel when the plunger is depressed to the retraction position to prevent tampering after retraction.

The retraction cavity of the plunger is preferably vented to prevent a puff of air coming forward at the instant of retraction from blowing a tiny amount of retained fluid from the nose. This condition can occur if the plunger is fully depressed to release the needle holder and dislodge the stopper while the needle is physically restrained from retracting by the septum of a vial which has just been filled with fluid from the syringe. The thumb cap at the rear of the syringe is preferably provided with channels in fluid communication with the interior in cooperation with a closure removably installed in a centrally located opening in the thumb cap. One or more stepped portions of the opening and closure provide seating for the closure. Undercut portions at the side of the closure together with grooves in the interior surface of the plunger wall create passages for air to vent through channels on the thumb cap. This structure prevents air from being trapped by the user's thumb when the thumb cap is pressed to fire the syringe. One or more slots at the back of the barrel around the opening which receives the thumb cap prevent vented air from being trapped by the user's thumb when the plunger is fully depressed.

The syringe has a high blowout pressure and a low plunger thumb force required to cause retraction. Blowout pressure is the fluid pressure operating on the stopper and retainer ring during an actual injection. High blowout pressure resistance is obtained because the retainer ring is

mounted in the most constricted portion of the barrel where the nose begins which significantly reduces the amount of area exposed to fluid pressure. The smaller retainer ring allows the use of a small needle holder such that the opening in the plunger and the stopper can be only a fraction of the cross sectional area of the fluid chamber below the plunger head. The ratio of the greatest cross sectional area of the variable chamber and that of the dislodgeable stopper or the ring member are selected so that the maximum expected thumb force on the plunger during an injection will produce a maximum pressure in the chamber which will generate a blowout force on the stopper and retainer member slightly less than the amount of dislodging force necessary to dislodge the stopper and retainer member during retraction. This ratio should be at least two to one, or more preferably three to one or more, in order to ensure against premature blowout of the stopper or retainer ring.

In an alternate embodiment, the fewest number of easily made separate parts are used in a retractable syringe. The alternate embodiment has a similar stopper in the head of the plunger and a similar needle holder and spring combination with mating cooperating inwardly facing and outwardly facing interengaged surfaces at the most constricted part of a transition zone where the nose begins. In the alternate embodiment, there is no retainer ring around the head of the needle holder. Instead a tiny ramp is provided at the transition zone or adjacent the transition zone whereby the head of the plunger gently spreads the barrel outwardly while dislodging the stopper thereby reducing the clamping or friction force on the head of the needle holder provided by the wall of the outer body. The holding force is thereby reduced below the retraction force provided by the compressed spring and the needle holder is ejected into the cavity of the plunger carrying the dislodged stopper along with it.

Manufacture and assembly is facilitated by the fact that the plunger and the outer body can be molded with a non-collapsible core tool that can be pulled out from behind. The parts are simply shaped and do not have hooks and parts with reentrant angles that require collapsible core pin technology. The outer body can be made in one piece and assembled from the rear. The narrowed nose portion provides no lateral space that will permit bunching of the spring and jamming when the retraction assembly is moved forward in the outer body. In fact, the nose serves as a guide to steer the parts into the proper position in one smooth stroke.

The needle does not have to be installed before the retraction mechanism is put in place because it is readily installed from the front after the needle holder is slidingly lodged in the nose. Significant variations in the holding force on the needle holder and the dislodging force on the stopper due to slight variances in the tolerance of the mating parts is avoided because the longitudinal wall of the outer body has some flexibility. The wall can spread outwardly slightly and the stopper and head of the needle holder can compress slightly radially and expand slightly in the longitudinal direction to avoid significant changes in the holding force caused by small changes in the actual diameters. Consistency in the amount of retraction force is thereby provided and economy is assured.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross section along the central axis of a first embodiment of the invention with the plunger positioned in a first position at the end of an injection cycle;

FIG. **2** is the syringe of FIG. **1** with the plunger depressed additionally to dislodge the stopper at a second position of the plunger wherein the tip of the plunger is ready to operate the retraction mechanism;

FIG. **3** is the syringe of FIG. **2** wherein the plunger has been further depressed to a retraction position, retraction has occurred and the cap at the back of the plunger is closely received in an opening at the back of the outer body;

FIG. **4A** is a partial cross section on the central axis of an alternate tamperproof opening in the back of the outer body prior to retraction;

FIG. **4B** is the structure of FIG. **4A** with the plunger in the retracted position received in an opening at the back of the outer body;

FIG. **5** is a cross section along the central axis of a simplified alternate syringe structure without a retainer member around the needle holder, which is released by separation of the friction surfaces, shown in the plunger position which represents the end of an injection cycle;

FIG. **6** is the syringe structure of FIG. **5** wherein the plunger is further depressed to dislodge the stopper and begin to release the friction surfaces just prior to retraction;

FIG. **7** is the syringe structure of FIG. **6** with the plunger further depressed beyond the position of FIG. **6** to the retraction position where retraction has occurred and the cap is secure within an opening in the back of the hollow outer body.

FIG. **8** is a schematic longitudinal cutaway view in elevation through the center of the two part head showing how a tack weld can be applied to simultaneously seal and hold the retainer ring in place on the needle holder.

FIG. **9** is an exploded perspective view showing the barrel and retraction mechanism of FIG. **1** with a modified plunger assembly;

FIG. **10** is a plan view of the thumb cap of the plunger assembly shown in FIG. **9** with the preferred closure;

FIG. **11** is a cut away elevational view of the structure at the back end of the plunger and end cap of FIGS. **9** and **10** along line **11-11** showing the preferred closure;

FIG. **12** is a cut away elevational view of the plunger end cap and closure of FIG. **11** as the thumb cap is just being received into the barrel opening;

FIG. **13** is a plan view of a first alternative thumb cap and closure combination utilizing a flat sided closure and four channels in the thumb cap;

FIG. **14** is a cut away elevational view on the lines **14-14** of the thumb cap closure combination of FIG. **13**;

FIG. **15** is a plan view of a second alternate thumb cap and closure combination with four channels in the thumb cap and undercut portions to provide a vent passage;

FIG. **16** is a cut away elevational view on the lines **16-16** of the combination of FIG. **16**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the description that follows, like parts will be referred to by the same reference numerals. Parts with a subscript letter are mean to illustrate a minor variation of a part with the same number. The drawings are enlarged significantly in order to show the details of the invention but generally reflect the true scale which is contemplated. The parts as shown are understood to be preferably circular and symmetrical as is conventional for syringes. The drawings reflect a syringe structure typically having a 1 cc to 3 cc injection fluid capacity.

FIG. 1 shows the structure of the first embodiment generally referred to by reference numeral 10. Syringe 10 has a one piece hollow outer body 12. Body 12 has a longitudinally extending wall comprising an elongated barrel 14 and a nose 16 with a transition zone 18 connecting the barrel and nose. A front mounted retraction mechanism lodged in the nose is generally referred to by the reference numeral 20. It comprises the combination of an elongated needle holder 22 and spring 24. The needle holder has an elongated body with a needle holding portion 26 in front for holding a needle 28 and a head 30 in back. Head 30 may consist of a two part head as in FIGS. 1-3 or a one part head as in FIGS. 5-7. The needle holder is released by depression of a plunger that will be described.

A plunger generally designated by the reference numeral 32 is disposed for use partially within barrel 14. The plunger has a head and seal generally referred to by reference numeral 34, in slidable sealed contact with the interior of barrel 14 of outer body 12. The plunger has a seal element 36 that is conventional and a retraction cavity 38 therein. Plunger seal element 36 fits in supporting surface 35 of the outer surface of head 34. Supporting surface 35 securely holds plunger seal element 36 in position and prevents plunger seal element 36 from longitudinal movement. The inside wall of the transition zone 18 forms a rigid plunger seal element stop surface 37, which acts as a plunger seal element stop upon forward movement of plunger 32.

Head 34 has a tip portion 40 forming an opening 41 into retraction cavity 38. A resilient dislodgable stopper 42 is sealingly positioned in opening 41 with a front portion thereof extending beyond tip 40. Head portion 34 and the back part of stopper 42 have cooperating lands 44, 46, respectively, which seal opening 41. Plunger 32 has an end cap 48 for depression of the plunger by the thumb. End cap 48 has a central opening for permanently receiving force fit plug 50 to close retraction cavity 38 at the back end.

A plurality of longitudinally extending flutes 52 slidingly support plunger 32 in barrel 14. In the embodiment of FIG. 1, outer body 12 has a collar 54 extending behind finger grips 56 having opening 58 which closely receives the outer periphery 60 of cap 48 when the plunger is depressed to the retracted position. An alternate arrangement is shown in FIGS. 4A and 4B in which barrel 14 is extended longitudinally, if necessary, so that end cap 48 fits closely within an opening at the back of the barrel where the finger grips are. FIG. 4B shows the tamperproof position with the plunger in the retracted position. It should be noted that depending on the relationship of the inside diameter of the barrel and the diameter of the end cap, the end cap could instead be received right inside the opening at the back of the barrel. Regardless of how the end cap in back of the outer body and barrel are configured, the plunger can no longer be grasped after retraction has occurred because end cap 48 is depressed into an opening.

The wall of outer body 12 and head 30 of the needle holder have mating cooperating smooth surfaces which hold needle holder 22 in the position shown in FIG. 1 with spring 24 compressed. Nose 16 has a reduced diameter relative to the barrel. The outer body has a most constricted part where head 30 of needle holder 22 is engaged and held. The outer body has an inwardly facing surface 62 at the most constricted part of the transition zone where nose 16 begins. Similarly, head 30 has an outwardly facing surface 64 configured to cooperate with inwardly facing surface 62 to produce a holding force on needle holder 22 when the retraction mechanism is installed in the nose from the rear. Mating surfaces 62, 64 constitute a sliding interface oriented in the direction of retraction, which seals nose 16. Mating surfaces 62, 64 are preferably friction surfaces which have an interference sliding fit to apply a frictional holding force which holds needle holder 22 in position by friction between the mating parts. It is within contemplation of the invention that one or more of the cooperating interface surfaces could employ a coating or adhesive bond which is ruptured or released when the mating surfaces or lands are separated or moved relative to each other.

Head 30 provides a lower boundary for a variable fluid chamber 68 below head 34. Needle holder 22 has a fluid path 70 in fluid communication with fluid chamber 68 and needle 28. Needle holder 22 has a smaller diameter inner head 72 which is part of head 30. Retainer member 66 is coupled to inner head 72 along sliding interface 74 oriented in the direction of retraction. Retainer member 66 is coupled to inner head 72 with a holding force which exceeds a retraction force applied to the underside of inner head 72 by means of the end of compressed spring 24. A reduced diameter portion 27 of needle holder 22 protrudes through an opening in front 76 of nose 16.

Importantly, retainer member 66 can be visualized as a continuous, annular ring surrounding circular inner head 72. The location of retainer member 66 at the most constricted part of the transition zone where the nose begins and the relatively small area exposed to pressurized fluid in chamber 68 results in a high blowout pressure. Since the front portion 26 of the needle holder is grounded or bottomed inside front 76 of nose 16 at annular shoulder 77, no amount of pressure will allow needle holder 22 or needle 28 to move forward. Blowout pressure may be defined as the pressure in chamber 68 acting on the exposed area of retainer member 66 to produce a force sufficient to overcome the holding force such that retainer 66 could "blowout" by moving forward and prematurely release needle holder 22.

Some users have strong hands and might, at the outer limit in an emergency, be able to generate a force of as much as fifteen to eighteen pounds on the plunger during an injection. It is considered almost impossible for anyone to exert a force of more than eighteen pounds. This may be regarded as the maximum expected force which must be taken into account so that ring member 66 will not blowout while an injection is being made. The greatest cross sectional area of variable chamber 68 and the area of retainer member 66 exposed to fluid pressure are selected so that the blowout pressure is higher than the maximum pressure in chamber 68 expected to result from the maximum expected thumb force (as shown by arrow 49) applied to cap 48 during an injection. This ratio is preferably about two to one and more preferably about three to one or more so that the holding force holding the retraction mechanism in place can be kept at a comfortably low level while the blowout pressure remains high.

Dislodgeable stopper 42 has a similar blowout problem to recognize. The front and middle portion of stopper 42 are relieved slightly from opening 41 such that the fluid pressure in chamber 68 is directed against the cross sectional area at cooperating lands 44, 46 and could cause stopper 42 to blowout. A frictional holding force is generated at the lands 44, 46 which may be called a dislodging force which must be overcome to slide stopper 42 rearwardly before retraction. The ratio of the maximum cross sectional area across the interior of variable chamber 68 to the maximum cross sectional area of stopper 42 exposed to pressure in chamber 68 are selected so that the maximum expected thumb force on plunger 32 during an injection will produce a maximum force slightly less than the amount of dislodging force necessary to dislodge the stopper so that stopper 42 will not

blowout during an injection. This ratio is preferably not less than about two to one, more preferably three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds, respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The stopper is dislodged after the injection by thumb force applied to the stopper by movement of the plunger.

The components used for retraction are arranged to avoid cumulation of force during the retraction sequence. In FIG. 1, stopper 42 has a forward extension beyond tip 40 which allows full thumb pressure to be applied to the stopper before any other portion of the retraction mechanism is engaged. The amount of forward extension beyond tip 40 is related to the length of lands 44, 46 such that the forward extension of stopper 42 preferably represents about 80 percent of the engaged land length. When stopper 42 is moved back until the front is even with tip 40, as seen in FIG. 2, only about 20 percent of engaged land remains. In FIG. 2 it can be seen that thumb force on plunger cap 48 has been applied to partially dislodge stopper 42 such that a gap 78 is created and the remaining engaged land area is represented as area 80.

Since I believe the amount of frictional holding force or dislodging force is roughly proportional to the amount of the length of the sliding interface between cooperating lands 44, 46, it follows, ignoring dynamic effects, that the amount of force remaining decreases as the engaged sliding interface area is reduced. This is what happens as stopper 42 moves back into cavity 38 from the position of FIG. 1 to the position of FIG. 2. It is believed appropriate to set the initial dislodging force to allow about five pounds at the position of FIG. 1 which is reduced to about one pound remaining when the stopper or plug member 42 reaches the position of FIG. 2. It might be noted at this point in the description that the front portion of tip 40 preferably has some longitudinally extending slits or openings so that fluid is not trapped in the trapezoidal shaped area of chamber 68, seen in FIG. 2, because of contact between tip 40 and the upper surface of retainer ring 66.

Needle holder 22 and spring 24 are combinably installable from the rear of the barrel before the plunger is assembled and releasably held at the most constricted part of the transition zone where the nose begins by sliding engagement of the cooperating inwardly and outwardly facing friction surfaces 62, 64 while compressing spring 24. The length of the engaging land 64 and the amount of interference fit is preferably designed to provide a frictional holding force in opposition to the retraction force provided by the compressed spring 24 of somewhere around five pounds even though the spring may apply a retraction force in the retraction direction of somewhere around a half pound. In use the needle is pushed against a rubber seal in a vial so the needle holder must resist a resulting backward force without being dislodged during the filling operation. This requirement and blowout pressure limits the low end of the holding force on the needle holder.

Referring again to FIG. 2, it can be seen that further depression of the plunger beyond the second position of FIG. 2 dislodges retainer ring member 66 along the sliding interface 74 provided by the outer surface of inner head 72 and along the inwardly facing friction surface 62. As the amount of remaining engaged interface is reduced, the amount of force required to continue moving retainer member 66 off needle holder 22 is reduced and the small remaining engagement area 80 between lands 44, 46 of the plunger and stopper preferably cause stopper 42 to be dislodged before needle holder 22 is released. When the remaining residual friction force during continued depression of the plunger becomes less than the retraction force provided by compressed spring 24, the retraction position of FIG. 3 is reached whereby retraction occurs.

When retraction occurs needle holder 22 moves through opening 41 into cavity 38. The uncompressed length of spring 24 is selected to provide backward movement sufficient to withdraw an injection needle 28 fixed in front portion 26 entirely within outer body 12, carrying dislodged stopper 42 with it. At the same time, cap 48 enters opening 58 of the barrel with peripheral edge 60 closely confined, in order to prevent tampering after retraction. It is immaterial whether cap 48 moves into the opening at the instant of retraction or after retraction has already occurred because the movement is automatic due to the continued thumb force applied to trigger the retraction. Sufficient unengaged length of inwardly facing friction surface 62 is provided so that retainer member 66 can move downwardly a sufficient distance to reach the retraction position of FIG. 3. After retraction, retainer member 66 preferably remains stuck and prevents any possibility of any one being able to reengage it with the head of needle holder 22. The diameter of land 62 in the area designated 63 can be increased slightly to provide relief for retainer ring 66 as it is pushed down by tip 40.

It is also within the contemplation of the invention that separable retainer member 66 may be removably coupled to inner head 72 of needle holder 22 by means of a relatively small in area "tack" weld which is sufficient to resist the retraction force applied to needle holder by spring 24 but which can be ruptured or separated by depression of the plunger beyond the position shown in FIG. 2, to release the needle holder and allow retraction. This is schematically illustrated in FIG. 8 with respect to alternate head 30*a* with the parts of syringe body 12 and needle holder 22 cutaway to focus on the modification. The remainder of the syringe structure would be like FIGS. 1-3.

In FIG. 8, inner head 72*a* has an outwardly facing surface 74*a* and a very small raised portion or series of horizontally spaced apart raised portions 73 around the periphery in a continuous band or annular ring which extend relatively uniformly outwardly beyond peripheral surface 74*a* of head 72*a*. The raised portion could be on the inner surface 75 of retainer 66*a* instead of being on surface 74*a* of the needle holder. The head of the needle holder is preferably circular but could be conceivably another shape with the retainer member 66*a* correspondingly configured to conform to it.

The inwardly facing surface 75 of inner head 72*a* is in contact with raised portion 73 on the outer surface of inner head 72*a* and there may be a small gap 77 between them all around. The raised portion 73 couples retainer 66*a* to inner head 72*a* and may be referred to as a bridging portion which resists the blowout pressure referred to above and holds the needle holder in place against the retraction force imposed on the needle holder by spring 24 together with any small additional forces that may be applied when the needle is pushed against the rubber seal of a vial in preparation for use. The bridging portion may be formed by "tack" welding the raised portion 73 to the inner surface of the ring 66*a* or by providing any other form of frangible bridging portion that holds the separable ring member 66 and needle holder head 72*a* together. It is required that however done, the bridging portion must also serve as a seal between the facing surfaces of the ring member and inner head so that fluid

under pressure cannot pass from chamber **68** through gap **77** to reach the nose portion of the device. All fluid must pass through fluid passage **70**.

It can be seen that when the position of FIG. **2** is reached the front tip **40** of the plunger presses against retainer ring **66***a* after stopper **42** is almost dislodged and uncouples the retainer ring **66***a* from the inner head **72***a* of needle holder **22***a*. Any tack weld connecting the separable parts at the bridging portion is ruptured, fractured or otherwise separated so as to separate retainer ring **66** a from inner head **72***a* thus releasing needle holder **22***a* from further restraint. They and the force applied by spring **24** causes retraction to occur much as before described and shown in FIG. **3**.

It is believed that the increased diameter of the raised portion **73** should be within the range of about 1 to 8 thousandths of an inch which may be dictated by the ability of the molding equipment available to produce a consistent bridging portion without defects. It is believed that it may be desirable to employ different polymeric materials for the retainer ring and needle holder to facilitate tack welding, such as a suitable polyvinyl chloride (PVC) for the retainer ring and a suitable polycarbonate plastic material for the needle holder. One way to couple these two parts may be to assemble them and expose them to a temperature of about 120° C. for twenty minutes or so to allow some diffusion or incipient melting to occur where they touch. The raised portion creates a high unit pressure where it comes into contact with the inwardly facing surface of retainer **66***a*. Sonic welding could also be employed. A coating or adhesive which couples the retainer ring to the needle holder and can be uncoupled by means of force applied to the retainer ring by the plunger is also within the contemplation of the invention.

An alternate syringe **82** is disclosed in FIGS. **5-7**. In FIG. **5**, Syringe **82** has a one piece hollow outer syringe body **84**. Body **84** has a longitudinally extending wall comprising an elongated barrel **86** and a nose **88** with a transition zone **90** connecting the barrel and nose. A front mounted retraction mechanism lodged in nose **88** is generally referred to by the reference numeral **92**. It comprises the combination of an elongated needle holder **94** and spring **96**. The needle holder has an elongated stem body with a needle holding portion **100** in front for holding needle **28** and a head **102** in back. In this case, head **102** is a one part head integral with the rest of needle holder **94**. Spring **96** delivers a retraction force in a retraction direction to the underside of head **102**.

A plunger generally designated by reference numeral **104** is disposed for use partially within barrel **86**. Plunger **104** has a head portion **106** which moves in slidable sealed contact with the interior of barrel **86** of outer body **84**. Although a separate seal might be used on head **106**, this embodiment is suitable for a smaller diameter, such as a 1 cc syringe, and can be used with head **106** also serving as the seal. A retraction cavity **108** is provided in the interior of hollow plunger **104**. Head **106** has a tip portion **110** forming an opening **112** for a dislodgable stopper **114** having a front portion extending beyond tip **110**. Head portion **106** has an inwardly facing land **116** and the back of stopper **114** has an outwardly facing land **118** comprising cooperating friction surfaces which seal opening **112**. The back portion of outer body **84** may have finger grips **120** and the same collar **54** and end cap **48** previously disclosed. The alternate arrangement of FIGS. **4A** and **4B** may also be employed.

The outer portion of tip **110** may be equipped with an angled surface **122** designed to cooperate with a small ramp surface **124** located in the vicinity of transition zone **90**. The wall of outer body **84** and head **102** of the needle holder have mating cooperating friction surfaces which frictionally hold needle holder **102** in the position shown in FIG. **5** with spring **96** compressed. Nose **88** has a reduced diameter relative to barrel **86**. The outer body has a most constricted part where the head **102** of needle holder **94** is frictionally engaged. The outer body has an inwardly facing surface or land **126** at the most constricted part of the transition zone where nose **88** begins. Similarly, head **102** has an outwardly facing friction surface **128** configured to cooperate with inwardly facing surface **126** to produce a frictional holding force on needle holder **94** when the retraction mechanism is installed in the nose from the rear.

Mating surfaces **126, 128** constitute a sliding interface oriented in the direction of retraction, which seal nose **88**. Mating surfaces **126, 128** are preferably smooth friction surfaces which have an interference sliding fit when needle holder **94** is installed from the rear whereby a frictional holding force holds needle holder **94** in position by friction between land **126** and head **102** of needle holder **94**. It is within contemplation of the invention that one or both of these surfaces could have a coating or adhesive bond which is ruptured when the mating surfaces are separated to release the needle holder.

Head **106** provides the upper boundary for a variable fluid chamber **130** below head **106**. Needle holder **94** has a fluid path **132** in fluid communication with chamber **130** and needle **28**. Needle holder **94** is releasably coupled at surfaces or lands **126, 128** with a holding force that exceed the retraction force applied to the underside of head **102** by the end of compressed spring **96**. A reduced diameter portion **134** of needle holder **94** protrudes through an opening in front **136** of nose **88**. Blowout pressure is not a factor with respect to the needle holder on the alternate embodiment. No amount of pressure will allow needle holder **94** or needle **28** to move forward since the front portion **100** of the needle holder is grounded or bottomed inside front **136** of nose **88**.

Blowout pressure is still a factor to be considered in connection with stopper **114**. Blowout pressure would be the pressure in chamber **130** produced by thumb force on cap **48** acting on the cross sectional area of stopper **114** which could overcome the holding force, causing stopper **114** to dislodge from opening **112** prematurely. The ratio of the maximum cross sectional area across the interior of variable chamber **130** to the maximum cross sectional area of stopper **142** exposed to pressure in chamber **130**, and the dislodging force necessary to dislodge stopper **144**, are selected so that the maximum expected thumb force on plunger **104** during an injection will not cause the stopper to blowout. Yet the stopper will still be dislodged by the dislodging force on the plunger once the front of stopper **114** contacts the retraction mechanism after the injection has ended. The ratio referred to is preferably not less than about two to one, or more preferably about three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The smaller diameter stopper allows two or three times the thumb force to be used during the injection cycle than required to actually dislodge the stopper by direct application of force.

By reference to FIGS. **5-7**, the operation and further features of the alternate embodiment are discussed. The syringe is used in the normal manner until the plunger is depressed to the first position of FIG. **5** which is the end of the injection cycle. Stopper **114** has a forwardly extending

end which has come into contact with head **102** of needle holder **94** to block fluid path **132**. Further depression of plunger **104** toward the position of FIG. **6** mostly or fully dislodges stopper **114** and begins spreading barrel **84** at the transition zone by sliding contact between head portion **106** and ramp **124**. Ramp **124** is a very small inwardly extending annular thickening of the wall of barrel **86** which can take many shapes or forms. For example, ramp **124** may be a small step **125** in the wall which continues vertically downward as indicated by the dotted line, which is somewhat exaggerated in FIG. **5**.

The barrel is flexible and is spread outwardly a slight amount to the position of FIG. **6** just prior to retraction. Here the mating surfaces **126, 128** are separated an amount which reduces the clamping force on the needle holder **94**. The spreading shown in FIG. **6** is greatly exaggerated for illustration. It is estimated that an expansion of only about four thousandths of an inch is sufficient to release needle holder **94** from nose **88**. By slight further depression of the plunger from the position of FIG. **6** to the retracted position of FIG. **7**, retraction occurs when the retraction force applied by spring **96** exceeds the remaining holding force on needle holder **94**. Needle holder **94** then moves through opening **112** into cavity **108** along with a portion of spring **96**. The uncompressed length of spring **96** is designed to provide sufficient backward movement to withdraw an injection needle **28** fixed in the front portion of needle holder **94** and carry dislodged stopper **114** with it. At the same time, cap **48** enters opening **138** at the rear of a barrel extension **54** where the peripheral edge is closely confined in order to prevent tampering after retraction.

The location and configuration of ramp **124** is arranged to avoid cumulation of force required during the retraction sequence. Most of stopper **114** should be dislodged by thumb pressure on plunger **104** before significant resistance develops as angled surfaces **122** begin pushing outwardly on ramp **124**. The selection of the location of ramp **24** and the angle of the engaging surfaces make it possible to have a fairly smooth continuous force since the dislodging force continuously decreases as the sliding interface area **116, 118** between the plunger and the stopper is linearly decreased. Because ramp **124** is relatively very small, it is still possible to remove a stepped molding core from the rear of the outer body **84**. Alternately, ramp **124** can be the smaller diameter step **125** which avoids reentrant angles whereby resistance to removal of the molding core could occur. After retraction, the back of the plunger is unaccessible and there is no way to reach to stopper or the needle holder in order to reinstall them for re-use.

When used normally, syringe **10** may have a small amount of fluid remaining in the variable chamber in the second position shown in FIG. **2** which is, of course, greatly exaggerated in scale. This may amount to no more than a drop or a few drops of fluid in the remaining space above the retraction mechanism. When syringe **10** is fired by pushing down on end cap **48**, to the position of FIG. **3**, the expanding spring and rearwardly moving needle holder carry any remaining fluid up into retraction cavity **38**. Surface tension effects hold the tiny droplets in place along the walls of the plunger and no fluid escapes from nose **16**. The syringe is normally used to withdraw fluid from a vial. The fluid is injected into a patient followed by immediate retraction of the needle holder and needle in one step. No leakage of fluid from the nose is observed when the syringe is used to inject fluid into a patient.

It has been discovered, however, that if the needle is forcibly prevented from retracting after syringe **10** is "fired" by pushing down until plunger **48** enters opening **58**, the small amount of retained fluid from variable chamber **68** can flow into the nose in the space between the needle holder and nose. If the seal around the head of the needle holder is removed while the needle holder is being restrained from retracting, remaining fluid has time to move down into the nose, but it does not leak out from the opening in the front of the nose. Then if the needle holder is suddenly released and allowed to retract normally, it has been found that leakage of fluid from the opening in the front of the nose could be observed. This undesirable scenario was found to occur under the following circumstances. If the syringe is used to draw blood from the patient, the blood filled syringe is removed from the patient and the needle passed through a rubber septum in a sterile vial. The plunger is then depressed to discharge the patient's blood into the vial. Users expect to depress the plunger fully after the fluid is discharged to retract the needle. When the plunger is depressed fully to cause retraction, the needle cannot retract normally due to the fact it is frictionally held by the rubber septum of the vial. When the empty syringe is then withdrawn from the vial by pulling the needle out of the septum, it immediately retracts. Droplets of fluid were observed on the vial as soon as retraction took place.

Surprisingly, it was found that a small "puff" of air is the source of this problem. If the needle or needle holder is temporarily restrained and prevented from retracting in the normal manner, a brief puff of forwardly directed air is generated when the needle holder is finally allowed to retract. This puff of air was found to emerge from the front of the syringe causing retained fluid trapped around the needle holder to be blown out of the opening left in the nose when the needle holder retracts. It was discovered that if the hollow interior of the plunger is vented, preferably in the area of thumb cap, this condition does not occur and the fluid is entirely retained within the syringe body.

FIGS. **9** through **16** illustrate the syringe generally designated as syringe **10** with a modification on the end cap or thumb cap on the plunger to provide for venting of the hollow interior of the plunger which is the retraction cavity. Insofar as possible the original numbering of FIGS. **1-4** is retained with primes used to indicate differences.

Head **34'** of plunger **32'** is preferably slightly modified from plunger head **34** of FIG. **2** in the following respects. The elongated plunger has a longitudinally extending generally tubular wall **140** defining a hollow interior along the length of the plunger. The plunger has a head end **34'** in front and a rear end portion **142** with a thumb cap **48'** behind. The outer side of wall **140** at head end **34'** is sealingly surrounded with a resilient plunger seal member **36'** which is like a band with a pair of separated raised rings **144**. Plunger seal **36'** fits in a depression in the outer surface of wall **140** where it is securely held in position and prevented from longitudinal movement. Seal member **36'** is adapted to slide in sealed contact with a tubular wall when the plunger is moved within syringe barrel **14**. It is within contemplation of the invention to have a raised piston molded as part of the plastic plunger to serve as a plunger seal in place of a separate rubber plunger seal **36'**, although the rubber seal member is preferred.

Wall **140** at head end **34'** of the plunger **32'** has a reduced diameter front portion extending forward from seal member **36'** terminating at tip **40** at the front of plunger **32'**. Tip **40** defines the opening **41** which leads into the hollow interior **38**. The internal structure is as shown in FIG. **1**. The wall **140** behind tip **40** has a stepped inner side surface comprising a land having an inwardly facing surface and a larger diameter

portion extending behind the land into the hollow interior. A separate dislodgeable stopper **42** is slidingly held within the reduced diameter front portion of plunger head **34'** by a holding force in excess of the fluid injection pressure force to be expected during use of the plunger in syringe barrel **14**. Stopper **42** has a back end portion comprising a land **46** and a reduced diameter front end portion extending forwardly beyond tip **40** a fixed distance to its front **146**. The fixed distance is the distance between front **146** and tip **40**.

As is seen in FIG. **1**, the outwardly facing surface **46** of dislodgeable stopper **42** is in sliding sealed engagement with the inwardly facing surface of land **44** in the plunger wall. These lands cooperate to apply a holding force to the stopper and seal hollow interior **38** of plunger **32'** from the expected amount of fluid injection pressure force generated in the variable chamber **68** during an injection. The ratio of the effective area of variable chamber **68** to the area of stopper **42** exposed to fluid pressure is at least two to one and preferably three to one or more as previously indicated. This makes it possible to utilize lower holding forces without blowing out the stopper during an injection. The cooperating lands on the inside of the plunger head and the stopper have sufficient longitudinal length to allow dislodgeable stopper **42** to move the fixed distance between its initial extension at **146** and tip **40** in sliding response to forward movement of the plunger after front **146** of stopper **42** contacts a stop.

As indicated in FIGS. **1-3**, front **146** of the stopper **42** encounters head **72** of needle holder **22** which serves as a stop. The fluid opening in head **72** of needle holder **22** is preferably provided with some fine slots or grooves so that fluid can continually enter fluid path **70** as the plunger moves from the position of FIG. **1** to that of FIG. **2**. As the position of FIG. **2** is reached, the holding force on stopper **42** is reduced by substantial disengagement of the cooperating lands **44, 46** in preparation for dislodgement of the stopper, without unsealing the hollow interior/retraction chamber **38** within plunger **32'**. A notch **148** is preferably provided in the tip to prevent trapping fluid at the tip.

Thumb cap **48'** at the rear end portion **142** of plunger **32'** includes one or more channels **150** which receive vented air from hollow interior **38**. Thumb cap **48'** has an opening **152** for a closure **154** best seen in FIGS. **10** and **11**. Channels **150** are open at the top for ease of molding although closed channels could also be used.

FIG. **10** shows an enlarged top plan view illustrating the use of three channels **150** in combination with a preferred closure **154** installed in circular opening **152**. FIG. **11** best shows how the channels **150** receive vented air from hollow interior **38**. Closure **154** preferably has a stepped outer surface comprising a rear step **156** which rests in opening **152**, an intermediate step **158** which rests in an enlarged portion **160** of the inner side of wall **140** and a front step **162** which rests against inner surface **164** of wall **140**. In effect, these structures provide convenient seating for closure **154**. Steps **158** and **162** are conveniently provided in a downwardly depending skirt **166**.

Importantly, inner surface **164** everywhere there is a channel **150**, is provided with a longitudinally extending groove **168** in fluid communication with the hollow interior **38** and the channels **150**. Any convenient number may be chosen as the channels are easily molded into the end cap when it is formed. The longitudinally extending grooves **168** do not extend through the entirety of the wall **140** although they could. They are designed for ease of molding since they can formed in the mold that makes the plunger without using separate pins to form an opening. This is an important cost consideration in a multiple out high speed molding process. This structure is designed for preventing the user's thumb from obstructing the vent opening leading from the interior of the plunger thereby assuring that venting will take place.

Referring now to FIGS. **9** and **12**, it will be noted that opening **58** in the back end of barrel **14** includes slots **172** in fluid communication with the hollow interior of the plunger through one or more channels **150** so that when thumb cap **48'** is received in opening **58**, no seal is created by the thumb being in contact with opening **58** which might otherwise prevent air from venting. The outer periphery of thumb cap **48'** is closely received in opening **58** as the syringe is fired, to prevent reuse. Thumb cap **48'** is preferably sized in relation to barrel **14** such that opening **58** is simply an extension in a linear direction of the wall of barrel **14** rather than enlarged as shown. Finally, the interior surface **164** preferably has several annular constrictions **170** designed to catch the head of stopper **42** during its rearward travel. Since stopper **42** is preferably installed from the rear of the plunger before closure **154** is put in place, the constrictions **170** must allow stopper **42** to be forced through to the front.

A first alternative thumb cap and closure arrangement is illustrated in FIGS. **13** and **14**. In this embodiment, four channels **150** are provided in thumb cap **48"**. Closure **174** has four flat side portions **176** spaced around the periphery at 90° intervals, each in fluid communication with a channel **150**. A gap is created at each flat side between the flat sides **176** and the opening **152'** which are in fluid communication with interior **38** to create a flow passage for air from interior **38** through the gap along the flat side then into channel **150**. Annular groove **178** in closure **174** may be used to fluidly connect each of the flat areas **176** at the level of channels **150**. In addition to equalizing air flow, the annular groove allows venting of air regardless of the angular orientation of closure **174** with respect to thumb cap **48"**.

A second alternate embodiment has the same thumb cap **48"** with a modified closure **180**. Closure **180** has a head **182** which snugly fits within opening **152'** which is at the back of the plunger. Opening **152'** is only slightly larger than the interior of the plunger to provide a seat for the closure. Four undercut portions **186** are each in joint fluid communication with the interior **38** and one of the channels **150** to create a flow passage from the interior **38**. Closure **180** effectively seals the opening **152'** so that no fluid particles can escape from the opening. As in the previous embodiment, an annular groove **178** bridges each undercut portion opening into a corresponding channel **150** thereby tying the undercut portions together in fluid communication regardless of the angular orientation of the parts.

In operation, there are many advantages to the improved combination disclosed herein. The diameter of the stopper in both embodiments and the slidable retaining ring member in the first embodiment, in relation to the diameter across the fluid chamber, makes it possible to produce a syringe which withstands high blowout pressure. By minimizing the effective surface area exposed to the pressurized fluid during an injection, the syringe will withstand injection thumb force of around fifteen to eighteen pounds during injection and at the same time retract in response to as little as five to six pounds of force on the plunger once the injection fluid has been injected. Once the fluid has been injected, cumulation of force required to concurrently operate the retraction mechanism is avoided. First the stopper is moved back and then the needle holder is released. By constricting the diameter of the syringe near a transition zone where the nose begins, a constriction enables the needle holder to be smaller which in

turn allows it to fit in a smaller opening with a smaller stopper in the retraction cavity of the hollow plunger.

A vacuum must be pulled in order to fill the syringe. The ring member or the needle holder, as the case may be, must seal the front nose of the syringe body because otherwise vacuum could be lost and fluid could enter the spring area and leak out the front. The hollow outer body and syringe plunger are preferably made from conventional plastic material used for syringes, which has some flexibility. The tolerances on the diameter of mating facing surfaces between the head of the needle holder and the barrel and between the stopper and head of the plunger are not critical in order to maintain a consistent holding and dislodging force. This is believed to be because increasing interference fit increases the frictional holding force only up to a point and then the surrounding wall simply expands a small amount or the internal parts are compressed a small amount without a corresponding increase in the longitudinal force required to move the retainer member or plug member in the retraction direction. It is a desirable self correcting mechanism which is a cost and quality benefit in making the parts. It is believed that a plastic retainer member could be used and the same self limiting frictional holding force would be obtained.

In the best mode the stopper and the ring member are preferably made from a thermoplastic rubber material designated number 181-55 available from Advanced Elastomer Systems, 540 Maryville Centra Drive, St. Louis, Mo. and sold under the trade name Santoprene®. It is said to have a characteristic hardness around 55 on the Shore A durometer scale which allows for the right amount of resistance to compression, fluid resistance such that the material does not swell when in contact with most fluids, environmental stability allowing the friction and sealing properties to remain non-temperature sensitive, good property retention after aging and excellent property retention after sterilization by all accepted methods. The plunger seal around the head of the plunger is conventional.

The parts are few in number and easily mass produced. The alternate embodiment has the fewest number of separate parts of any tamperproof retractable syringe. The plunger has a one piece hollow outer body with a transition zone and a narrow nose portion. The internal diameter is stepped to greater diameters from front to back for molding around a non-collapsible core which can be extracted from the rear. The same is true for the plunger.

Assembly is greatly simplified and can be accomplished with high speed mechanized equipment. The needle holder and spring are installable from the rear of the barrel without the needle. In the first embodiment the retainer member is forced fit over the inner head of the needle holder and the assembly together with the uncompressed spring are pushed forward and held by sliding engagement of the cooperating inwardly and outwardly facing surfaces while compressing the spring. The front of the needle holder passes through an opening in the nose which makes it easy to install the needle from the front by conventional means. The alternate embodiment is installed the same way except that there is no separable retainer member around the head of the needle holder.

The narrow nose provides a particular advantage for mechanized assembly. The nose has a wall defining an elongated internal cavity which closely confines the spring and needle holder combination. During installation this cavity serves as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring. This solves an important assembly problem. If there is much lateral space in the nose around the spring, when the uncompressed spring is being compressed, it is a laterally unstable column which flexes sideways and bunches up causing a jam up. It might be added that rounded edges on the bottom of the slot directly below retainer **66** would further facilitate entry of the end of the spring.

The stopper is also installable from the rear of the plunger by pushing it forward until the cooperating lands are slidingly engaged. Then plug member **50** is force fit or otherwise fixed in the opening at the back of the plunger and the plunger is installed in the outer body. It is not necessary to try to pass the sharp needle through an elongated body with constricted openings where slight misalignment could cause hangups. The head of the needle holder simultaneously acts as a seal as well as a holding device such that no seal is required at the tip of the nose and no ultrasonic welding of separate parts is required.

There is no necessity for using internal locking teeth of any kind. No locking teeth are needed to hold the retraction mechanism or to lock the plunger after retraction. Locking teeth present difficult molding and quality control problems, tend to be temperature sensitive and tend to require a larger diameter barrel which increases premature blowout problems. In addition to the non-reusability provided by separation of the retainer ring from the head of the needle holder and dislodgement of the stopper, the plunger is not accessible after retraction because it is depressed within an opening at the back of the outer body. This additional tamperproof feature is provided in a one piece body without the necessity for hooking anything or twisting anything. The easily made and installed force fit plug at the back of the retraction cavity prevents access to the retracted components. The Federal government has rights in the invention under 35 U.S.C. §203. The Federal government has a nonexclusive, nontransferable irrevocable, paid up license to the invention as set forth in the priority documents.

I claim:

1. A syringe comprising a hollow body with first and second open ends and an inside wall of varying inside diameter extending between the first and second open ends, a needle retraction mechanism insertable into the body through the second open end, a plunger having a forwardly extending plunger head insertable into the body through the second open end behind the needle retraction mechanism, and a needle extending forwardly of the first open end, wherein:

the body comprises a nose adjacent to the first open end, a barrel adjacent to the second open end, and a transition zone connecting the barrel and nose;

the needle retraction mechanism comprises an elongated needle holder, a compressed retraction spring, and a retainer member;

the elongated needle holder further comprises a needle holding portion secured in fixed relation to the needle, a reduced diameter portion at one end of the needle holding portion, the reduced diameter portion extending forwardly through the first open end; a head at another end of the needle holding portion opposite the reduced diameter portion; a fluid path extending longitudinally through the needle holder in fluid communication with the needle and with a variable fluid chamber inside the body between the needle holder and the plunger;

the needle holding portion is grounded inside the nose adjacent to the first open end by a barrier limiting forward motion of the elongated needle holder inside a front portion of the nose prior to or during retraction;

the compressed retraction spring is positioned prior to retraction in an annulus disposed between the needle holding portion and the inside wall of the hollow body;

the plunger head is aligned to separate the retainer member from the head of the needle holding portion and release the compressed retraction spring during retraction; and

the plunger comprises a retraction cavity into which part of the retraction mechanism is received during retraction so that the needle no longer extends forwardly of the first open end.

2. The syringe of claim 1 wherein the inside diameter of the barrel is larger than the inside diameter of the nose, and the inside diameter of the transition zone tapers inwardly between the barrel and the nose.

3. The syringe of claim 1 wherein the inside wall of the body comprises an annular shoulder proximal to the first open end that is the barrier limiting forward motion of the elongated needle holder inside a front portion of the nose.

4. The syringe of claim 1 wherein the plunger head further comprises a tip forming an opening into the retraction cavity.

5. The syringe of claim 4 wherein a resilient dislodgeable stopper is positioned in the opening into the retraction cavity.

6. The syringe of claim 5 wherein a front portion of the dislodgeable stopper extends forwardly of the tip.

7. The syringe of claim 1 wherein the plunger head further comprises a seal slidably engaging the inside wall of the barrel.

8. The syringe of claim 7 wherein the seal is mounted in a fixed axial position on the plunger.

9. The syringe of claim 1 wherein the plunger further comprises a rear end portion opposite the plunger head, and a thumb cap at the rear end portion.

10. The syringe of claim 9 wherein the thumb cap has an opening.

11. The syringe of claim 10 wherein a closure is installed in the opening and the retraction cavity is vented.

12. The syringe of claim 9 wherein the barrel comprises a collar adjacent to the second open end, and the thumb cap fits in close proximity to the collar when the plunger is depressed during retraction.

13. The syringe of claim 12 wherein the plunger end cap is lodged in the barrel collar by pressing the plunger to cause retraction.

14. The syringe of claim 1 comprising a one-piece barrel.

15. The syringe of claim 1 wherein the retainer member is positioned at the most constricted portion of the transition zone prior to retraction.

16. The syringe of claim 1 wherein the retainer member is coupled to the needle holder head with a holding force which exceeds a retraction force applied to the needle holder head by the compressed retraction spring.

17. The syringe of claim 1 wherein the nose comprises an annular space between the inside wall and the retraction spring into which the retainer member is forced by the plunger head during retraction.

18. The syringe of claim 1 wherein the needle is inserted into the reduced diameter portion of the elongated needle holder extending forwardly of the body and is attached to the elongated needle holder.

19. The syringe of claim 1 wherein the inside wall of the body forwardly of the transition zone cooperates with the needle holder as a spring guide during compression of the retraction spring.

20. The syringe of claim 1 wherein the retainer member has an outside mating surface making a seal with the inside wall.

21. The retraction mechanism of claim 4 wherein the retraction mechanism is releasable by forward movement of the plunger to disengage the retainer member from the needle holder head without contact between the plunger seal element and the retainer member.

22. The syringe of claim 1 wherein the retainer member acts as a fluid seal for the variable fluid chamber prior to retraction.

23. The syringe of claim 1 wherein the plunger is vented.

24. The syringe of claim 23 wherein the retraction cavity of the plunger is vented.

25. A syringe comprising a hollow body with first and second open ends and an inside wall of varying inside diameter extending between the first and second open ends, a needle retraction mechanism, a plunger having a forwardly extending plunger head insertable into the body through the second open end, and a needle extending forwardly of the first open end, wherein:

the body further comprises a nose adjacent to the first open end, a substantially cylindrical barrel adjacent to the second open end, and a transition zone connecting the barrel and nose;

the needle retraction mechanism comprises an elongated needle holder, a compressed retraction spring, and a retainer member holding the retraction spring in compression prior to retraction;

the elongated needle holder further comprises a needle holding portion secured in fixed relation to the needle and a head opposite the needle holding portion, the needle holding portion extending forwardly through the first open end; a fluid path extending longitudinally through the needle holder in fluid communication with the needle and with a variable fluid chamber inside the body between the needle holder and the plunger;

wherein the needle retraction mechanism is grounded inside the nose by a barrier limiting forward motion of the elongated needle holder inside a front portion of the nose prior to or during retraction;

the compressed retraction spring is positioned prior to retraction in an annulus disposed between the needle holder and the inside wall of the hollow body;

the plunger head comprises a seal mounted in fixed axial relation to the plunger, the seal slidably engaging the inside wall of the body;

the plunger head advances beyond a portion of the needle holder following injection to release the compressed retraction spring during retraction;

the plunger comprises a retraction cavity into which part of the retraction mechanism is received during retraction so that the needle no longer extends forwardly of the first open end; and

the plunger comprises an end cap having an outer periphery, the outer periphery being disposed in close proximity to the second open end of the body during retraction to prevent reuse of the syringe.

26. The syringe of claim 25 wherein the inside diameter of the barrel is larger than the inside diameter of the nose, and the inside diameter of the transition zone tapers inwardly between the barrel and the nose.

27. The syringe of claim 25 wherein the barrel comprises at least one radially extending member having a front side and a back side, the front side providing finger grips for the syringe body, and a collar comprising an open back end, the collar extending rearwardly behind the back side of the at

least one radially extending member and longitudinally separating the back side of the at least one radially extending member from the open back end, and wherein the end cap has an outer periphery that fits closely inside the collar when the plunger is depressed during retraction.

28. The syringe of claim **25** wherein the retainer member is positioned at the most constricted portion of the transition zone prior to retraction.

29. The syringe of claim **25** wherein the retainer member is coupled to the needle holder head with a holding force which exceeds a retraction force applied to the needle holder head by the compressed retraction spring.

30. The syringe of claim **25** wherein the needle is inserted into the needle holder through a portion of the needle holder extending forwardly of the body and attached to the needle holder.

31. The syringe of claim **25** comprising a one-piece body.

32. The syringe of claim **25** wherein the inside wall of the body forwardly of the transition zone cooperates with the needle holder as a spring guide during compression of the retraction spring.

33. The syringe of claim **25** wherein the retainer member has an outside mating surface making a seal with the inside wall.

34. The syringe of claim **25** wherein at least a portion of the retraction mechanism is received into the retraction cavity during retraction.

35. The syringe of claim **25** wherein the retainer member acts as a fluid seal for the variable fluid chamber prior to retraction.

36. The syringe of claim **27** wherein the outer periphery of the plunger end cap is lodged in the barrel collar by pressing the plunger to cause retraction, thereby preventing subsequent withdrawal of the plunger from the barrel.

37. The syringe of claim **25** wherein the plunger comprises a tip that extends forwardly of the plunger seal to initiate retraction.

38. The syringe of claim **25** wherein the needle retraction mechanism is insertable into the body through the second open end.

39. A syringe assembly having a hollow body with an inside wall, a retractable needle, a needle retraction assembly seated inside the body and a plunger slidably engaging a portion of the inside wall,

the retraction assembly comprising a compressible retraction spring, a needle holder and a retainer member continuously surrounding the needle holder to hold the retraction spring in compression prior to retraction, the inside wall and needle holder cooperating as a spring guide during compression of the retraction spring,

the plunger comprising a handle with a longitudinally extending retraction cavity having a first inside diameter and a forwardly extending tip having a second inside diameter less than the first inside diameter, the tip defining an opening through which the needle holder is receivable into the retraction cavity during retraction; a seal disposed in fixed longitudinal relation to the plunger handle and in sliding engagement with the inside wall of the body, and having a forwardly facing surface,

the body further comprising a rigid stop surface that is contacted directly by the forward facing surface of the plunger seal and stops forward movement of the plunger inside the body following release of the retractable needle.

40. A syringe assembly having a retractable needle and designed for one-time use, comprising:

a hollow syringe body having a barrel further comprising a front end portion supporting a needle retraction mechanism comprising a needle holder and a compression spring having a forward end, the front end portion having a small diameter open end disposed forwardly of any larger diameter section of the barrel, wherein any forward movement of the needle holder relative to the barrel is limited by an annular shoulder disposed adjacent to and defining the small diameter open end at a narrowest part of the barrel, the annular shoulder being adjacent to the forward end of the spring wherein a portion of the needle holder extends forwardly of any portion of the barrel.

41. The syringe assembly of claim **40** wherein the needle holder abuts the annular shoulder.

42. The syringe assembly of claim **40**, the hollow syringe body further comprising a back end portion having at least one radially extending member having a front side and a back side, the front side providing finger grips for the syringe body, and a collar comprising an open back end, the collar extending rearwardly of the back side of the at least one radially extending member and longitudinally separating the back side of the at least one radially extending member from the open back end; and

a plunger having a front end portion insertable into the barrel and slidably engageable with the inside diameter of the barrel in front of the at least one radially extending member, the plunger further comprising a retraction cavity adapted to receive a portion of the needle retraction mechanism following retraction of the needle and a plunger end cap disposed rearwardly of the retraction cavity, the plunger end cap being receivable into close proximity with the collar following retraction.

43. A syringe assembly having a retractable needle that is rendered unusable after a single injection of fluid into a patient, the assembly comprising:

a hollow syringe body comprising a barrel and having a front end portion and a back end portion, the back end portion further comprising at least one radially extending member providing finger grips for the syringe body;

a retraction mechanism disposed in the front end portion, the retraction mechanism further comprising a needle holder having a head portion, an elongated needle holding portion, and a longitudinally extending fluid passageway through the head portion and the elongated needle holding portion, the head portion further comprising an inner head, a continuous retainer member surrounding the inner head, and a bridging portion disposed between the continuous retainer member and the inner head, wherein said bridging portion couples the continuous retainer member and the inner head to form a fluid seal between the fluid passageway and the barrel prior to retraction, and a compressed retraction spring surrounding at least part of the elongated needle holding portion and biasing the inner head toward the back end portion prior to retraction;

a retractable needle extending into the front end portion of the body through an opening in the front end portion of the body, the retractable needle being held in fixed relation to the elongated needle holding portion of the needle holder and in fluid communication with the longitudinally extending fluid passageway through the head portion and the needle holding portion;

a plunger reciprocally disposed inside the barrel and forming a variable chamber between the plunger and the needle holder prior to and during injection, the

plunger being receivable into the barrel through the back end portion of the body and comprising an outer wall, a retraction cavity disposed inwardly of the outer wall, a plunger seal element providing sliding, sealed engagement between the plunger and the barrel and preventing fluid leakage between the plunger and the barrel, the plunger seal element being restrained from sliding longitudinally along the outer wall of the plunger, and a back end with an end cap having an outer periphery; and

a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction;

wherein the continuous retainer member is releasable from the inner head of the needle holder when the plunger is further depressed inside the barrel following injection.

44. The syringe assembly of claim **43** wherein the retraction mechanism is receivable through the back end portion of the barrel.

45. The syringe assembly of claim **43** wherein the plunger carries a tip that protrudes forwardly of the plunger seal element to contact the needle holder and release the retractable needle when the plunger is further depressed inside the barrel following injection.

46. The syringe assembly of claim **45** wherein the continuous retainer member is released from the inner head of the needle holder by means of a force applied by the tip to the needle holder.

47. The syringe assembly of claim **43** wherein the body further comprises a collar having an open back end, the collar extending rearwardly behind the at least one radially extending member and longitudinally separating the at least one radially extending member from the open back end, and wherein the outer periphery of the end cap is in close proximity to the back end of the collar following injection and during retraction.

48. The syringe assembly of claim **47** wherein the end cap is lodged in close confinement with the back end of the collar after retraction.

49. The syringe assembly of claim **43** wherein the barrel is not distorted during retraction.

50. The syringe assembly of claim **43** wherein the barrier is an annular shoulder disposed in the front portion of the barrel.

51. The syringe assembly of claim **50** wherein the annular shoulder is disposed adjacent to the opening in the front end portion of the body.

52. The syringe assembly of claim **50** wherein the needle holding portion is grounded on the annular shoulder.

53. The syringe assembly of claim **43** wherein the body has a rigid stop surface that is contacted directly by the plunger seal and stops forward movement of the plunger inside the body when the plunger is further depressed inside the body following injection.

54. The syringe assembly of claim **43** wherein the end cap has an opening and a closure is installed in the opening.

55. The syringe assembly of claim **43** wherein the retraction cavity is vented behind the plunger seal element.

56. The syringe assembly of claim **55** wherein the retraction cavity is vented between the plunger seal element and the end cap.

57. The syringe assembly of claim **43** wherein the body comprises a one-piece barrel.

58. The syringe assembly of claim **43** wherein the continuous retainer member is coupled to the inner head with a holding force that exceeds a biasing force exerted on the inner head by the compressed retraction spring.

59. The syringe assembly of claim **43** wherein a portion of the elongated needle holding portion extends forwardly of the body.

60. The syringe assembly claim **43** wherein the continuous retaining member has an outside mating surface making a fluid seal with the barrel.

61. The syringe assembly of claim **43** wherein the body and the elongated needle holder cooperate as a spring guide during compression of the retraction spring.

62. The syringe assembly of claim **43** wherein the bridging portion is frangible.

* * * * *

EXHIBIT C

OMI Safety Syringe

OMI's innovative Safety Syringe design is protected by worldwide patents

OMI Safety Syringe

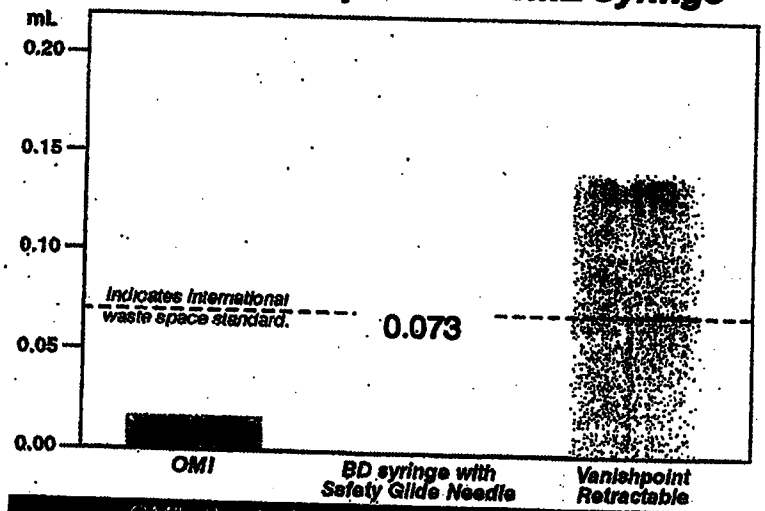
KEY BENEFITS

The OMI Safety Syringe has the lowest amount of waste space when compared to any other safety retractable syringe available on the market*. By increasing the number of doses per multidose vial, the OMI Safety Syringe offers significant financial savings to your healthcare facility.

1. Available in a wide array of syringe and needle sizes to meet all your clinical needs.
2. Having a lower waste space syringe maximises savings in medications costs.
3. Optically clear, precision marked barrels ensure patients receive an accurate dose of medication.
4. Auto safety mechanism significantly reduces the risk of occupational injury prior to disposal.
5. OMI's retractable safety syringe technology requires a simple one-handed activation.
6. Needle manufactured to international standards to ensure sharpness and increase patient comfort.

The result is a safe, non-reusable product designed to reduce potential needle stick injuries.

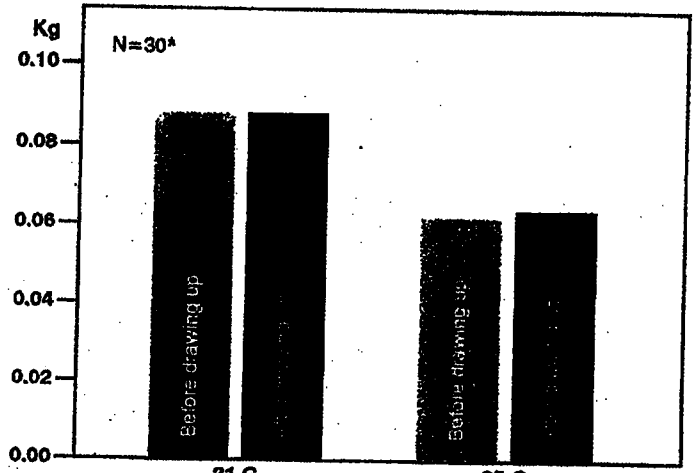
Waste Space Comparison - 3mL Syringe



OMI's Safety Syringe waste space volume is less than comparative safety syringes.

Source: University test results. December 2006 document #0791.

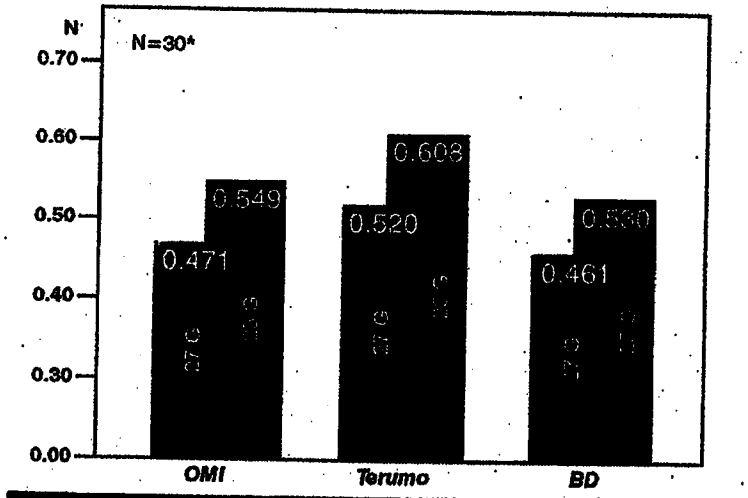
Sharpness before and after Drawing Up



University study proves OMI needle can be used for drawing up and injection with bottles of medication.

Source: University test results. December 2006 document #0790. Sharpness is measured as force (in kgs) to pierce an artificial skin membrane.

Sharpness Comparison - 25G & 27G Needles



OMI needle sharpness testing confirms that they are as sharp as the market leaders.

Source: University test results. December 2006 document #0789. 27G & 25G needles tested.

NEW FEA