IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Hologic, Inc., a Delaware corporation; Cytyc Surgical Products, LLC, a Massachusetts limited liability company Plaintiffs, v. Minerva Surgical, Inc., a Delaware corporation Defendant.	Civil Action No. 15-1031-SLR **JURY TRIAL DEMANDED**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

For its Second Amended Complaint against Minerva Surgical, Inc. ("Defendant"), Plaintiffs Hologic, Inc. ("Hologic") and Cytyc Surgical Products, LLC ("Cytyc") (collectively "Plaintiffs") by its attorneys, allege as follows:

NATURE OF THE ACTION

1. In this action, Plaintiffs Hologic and Cytyc allege that Defendant infringes U.S. Patent Nos. 6,872,183 ("the '183 Patent"), 8,998,898 ("the '898 Patent"), 9,095,348 ("the '348 Patent"), and 9,247,989 ("the '989 Patent") (collectively "the Patents-in-Suit").

PARTIES

2. Plaintiff Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Hologic is a leader in women's health care including diagnostics, screening, and imaging, as well as medical intervention and treatment.

3. Plaintiff Cytyc is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive,

Marlborough, Massachusetts, 01752. Cytyc is a leader in designing, developing, and selling medical devices for the treatment of excessive or abnormal endometrial bleeding. Cytyc is a wholly-owned subsidiary of Hologic.

4. Prior to January 15, 2016 (and prior to the filing of the original Complaint in the instant case), Cytyc was the owner by assignment of the '183, '898, and '348 Patents. On January 15, 2016, Cytyc, at Hologic's direction, assigned the '183, '898, and '348 Patents. Prior to the assignment and currently, Cytyc has been and continues to be wholly-owned and controlled by Hologic. At the time of the filing of the original Complaint and continuing without interruption to the present day, Hologic has controlled Cytyc's business decisions including its patent licensing and enforcement policies. Hologic also controlled Cytyc's decision to divest itself of the '183, '898, and '348 Patents and assign them to Hologic. Cytyc, as a member-controlled LLC, has not had decision-making authority independent of Hologic and has not acted contrary to Hologic's control. As such, Hologic has enjoyed exclusive rights to practice the '183, '898, and '348 Patents as well as control over the assignment and enforcement thereof. Cytyc is the assignee and lawful owner of all right, title, and interest in and to the '989 Patent.

5. On information and belief, Defendant Minerva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States, Title 35 of the United States Code. This action also includes claims for unfair competition arising under the Lanham Act, 15 U.S.C. § 1051 *et seq.*, and the laws of the State of Delaware.

7. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338, and 15 U.S.C. §§ 1121(a) and 1125(a). This Court has jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. § 1367, as the state law claims arise from the same common nucleus of operative facts as the federal claims.

8. This Court has personal jurisdiction over the Defendant based on its incorporation in Delaware as well as its contacts with the State and this District. On information and belief, Defendant has had systematic and continuous contacts with this District, regularly transacts business within this District, and regularly avails themselves of the benefits of this District. On information and belief, Defendant, directly or through intermediaries (including sales agents and others), uses, offers for sale, sells, imports and/or distributes to others for such purposes, endometrial ablation products for the treatment of abnormal uterine bleeding, in the United States and this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) as, among other reasons, Defendant is subject to personal jurisdiction in this District and a substantial part of the events giving rise to the claims occurred in this District.

BACKGROUND

10. Plaintiffs Hologic and Cytyc are leading developers, manufacturers, and suppliers of medical devices dedicated to helping medical care professionals deliver superior healthcare to their patients. One such medical product that Cytyc makes and distributes is the NovaSure® endometrial ablation system, a system designed to, among other things, remove the endometrial lining of the uterus and control abnormal uterine bleeding. The NovaSure® system has been used to treat more than two million women since it was approved for use by the FDA in 2001. The novel design (*e.g.*, using radiofrequency impedance-based technology allowing for fast

treatment time with no hormonal pretreatment required) of the NovaSure® system allows medical care professionals to quickly, efficiently, and comfortably control abnormal uterine bleeding.

11. Plaintiffs have made significant investments into the research, development, and testing of safe tissue ablation, including the technology embodied by the NovaSure® endometrial ablation system.

12. Plaintiffs have made significant investments into bringing the product to market.

13. To protect these investments, Cytyc applied for and obtained a number of patents, including the '183, '898, '348, and '989 Patents.

14. On information and belief, Defendant has been directly competing with Plaintiffs since at least August, 2015, by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use the Minerva Endometrial Ablation Device. A true and correct copy of the Minerva Endometrial Ablation System Operator's manual which can be obtained from the FDA website (http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140013d.pdf) or from Defendant's website (http://www.minervasurgical.com/health-care-professionals/clinical-study-data/#downloadifu) is attached as Exhibit A.

15. Plaintiffs have made significant investments to cultivate and establish long-standing relationships with physicians and hospital staff. Plaintiffs have trained these physicians and hospital staff to use the NovaSure® system, and many have been long-term customers. Also, Plaintiffs have made significant investments in the NovaSure® brand and clinical data, including clinical trials, studies, and programs that provide evidence for patients on NovaSure®'s safety and efficacy.

16. Defendant has engaged in a concerted marketing campaign targeting Plaintiffs' existing customers. Defendant's executives and sales representatives visit with physicians and purchasing agents, prepare correspondence, and host dinners, among other things, to market the Minerva Endometrial Ablation System to physicians and hospital staff that are Plaintiffs' existing customers. During its interactions with these physicians and hospital personnel, Defendant has negatively impacted Plaintiffs' goodwill with existing physician and hospital customers.

17. Defendant has hired former members of Plaintiffs' NovaSure® sales team and has used these former NovaSure® sales representatives to market the Minerva Endometrial Ablation System to Plaintiffs' existing customers. The former NovaSure® sales representatives, now Minerva sales representatives, assert to existing physician customers of Plaintiffs that they work for the makers of NovaSure® and that they are selling the new NovaSure®. For example, in and around early December 2015, a Minerva sales representative for the Minerva Endometrial Ablation System told existing customers of Plaintiffs in the Southeast Texas and Southwest Louisiana regions that he works for the makers of NovaSure® and that he can provide the new NovaSure®, suggesting a partnership between Minerva and Plaintiffs. Defendant has created and continues to create the false impression that the Minerva Endometrial Ablation System is the new NovaSure®. On information and belief, Defendant's actions have caused physicians to use the Minerva system due to the mistaken belief that physicians can rely on the NovaSure® brand and its clinical data, including clinical trials, studies, and programs that provide evidence for patients on NovaSure®'s safety and efficacy. Existing customers of Plaintiffs, specifically physicians, have asked Plaintiffs' sales team whether the system that Minerva's sales representatives are marketing is the new, updated version of the NovaSure® branded system.

18. On information and belief, Defendant's sales representatives have been marketing Defendant as the makers of NovaSure®. On information and belief, Defendant's sales representatives have been describing the Minerva Endometrial Ablation System as the new NovaSure® and as a technical update to the NovaSure® system. Specific instances of this and similar false statements are described in Plaintiffs' opening brief and the declarations in support of Plaintiffs' Motion for a Preliminary Injunction, which are incorporated by reference herein in their entirety. Defendant's sales representatives create the impression that there is an affiliation, connection, or association between Defendant and Plaintiffs, and physician customers have specifically asked the Plaintiffs' sales team about the alleged partnership between Plaintiffs and Defendant.

19. Defendant's description of the Minerva Endometrial Ablation System as an updated version of the NovaSure® technology increases physicians' interest in the Minerva Endometrial Ablation System based on the physicians' familiarity with the NovaSure® system.

20. On information and belief, Defendant's sales representatives assert that, because the team that developed the Minerva Endometrial Ablation System developed the NovaSure® system, Defendant's development team knows the alleged shortcomings of the prior NovaSure® systems and has sought to make a better, updated version. For example, on September 19, 2015, one of Defendant's executives participated in a talk radio show asserting that he and his team developed the NovaSure® system and that he and his team now have an updated design. The executive also asserted that he and his team were aware of supposed detriments and weaknesses of the prior NovaSure® systems. The talk radio show aired on radio station KCMO, 710 AM and 103.7 FM, in the Kansas City area and now is available as a podcast.

21. On information and belief, Defendant's sales representatives correspond with physicians and provide an internet link to the executive's podcast. For example, on September 21, 2015, one of Defendant's sales representatives emailed a potential costumer and provided the Internet link to the podcast, asserting that the potential customer would find the podcast very compelling.

22. On August 20, 2015, one of Defendant's sales representatives emailed a potential customer asserting that the same exact group developed both the Minerva Endometrial Ablation System and the NovaSure® system and that the Minerva Endometrial Ablation System is an improved version of the NovaSure® system using newer technology.

23. On information and belief, Defendant's Minerva Endometrial Ablation System has been used in approximately seventy-five hospitals and Defendant has sold approximately two hundred units. On information and belief, Defendant's sales and customer usage are a result of Defendant's false designation of origin and misleading description of facts in connection with its marketing and/or sale of the Minerva Endometrial Ablation System. On information and belief, Defendant's Minerva Endometrial Ablation System is sold and used throughout the United States.

24. On information and belief, Defendant, in light of the similarities between the Minerva Endometrial Ablation System and the NovaSure® system, intentionally engaged in false, misleading, and deceptive conduct while targeting Plaintiffs' existing customers using former NovaSure® sales representatives.

25. Defendant provides a 44-page detailed Operator's Manual for the Endometrial Ablation System to its physician customers. At the beginning of the Operator's Manual, Minerva instructs its physician customers to "READ ALL INSTRUCTIONS, CAUTIONS AND

WARNINGS PRIOR TO USE. FAILURE TO FOLLOW ANY INSTRUCTIONS OR TO HEED ANY WARNINGS OR PRECAUTIONS COULD RESULT IN SERIOUS PATIENT INJURY." On information and belief, Minerva prepared this Operator's Manual after conducting its own testing and trials using the Minerva Endometrial Ablation System in the United States on patients. In addition, on information and belief, Minerva hired licensed physicians as Minerva's agents to test and trial the Minerva Endometrial Ablation System, where Minerva would direct, control, and instruct the physician on the precise way to test and use Minerva Endometrial Ablation System to avoid patient injury, consistent with its Operator's Manual for the system.

COUNT I

(Defendant's Infringement of the '183 Patent)

26. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

27. On March 29, 2005, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '183 Patent, entitled "System and Method for Detecting Perforations in a Body Cavity," to Russel M. Sampson, Mike O'Hara, Csaba Truckai, and Dean T. Miller as inventors. A true and correct copy of the '183 Patent is attached as Exhibit B.

28. Prior to January 15, 2016 and prior to the filing of the original Complaint in the instant case, Cytyc was the assignee and lawful owner of all right, title, and interest in and to the '183 Patent. At the time of the filing of the original Complaint and continuing without interruption to the present day, Cytyc has been owned by Hologic and under Hologic's control, and Hologic thus has enjoyed the unfettered rights to practice, enforce, and assign the '183

patent. As of January 15, 2016, Cytyc assigned the '183 Patent to Hologic pursuant to Hologic's direction.

29. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with respect to products that they manufacture and sell under the '183 Patent.

30. Defendant has had knowledge of the '183 Patent since at least the filing of the original Complaint of the instant case and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Minerva Endometrial Ablation System would infringe one or more claims of the '183 Patent. On information and belief, Defendant has had knowledge of the '183 Patent before the filing of the original Complaint for at least the reason that Defendant's founder Mr. Csaba Truckai is a named inventor of the '183 Patent.

31. On information and belief, Defendant was aware that Plaintiffs' NovaSure® system embodied the claimed invention of the '183 Patent and knew or should have known that Defendant's products, including the Minerva Endometrial Ablation System, infringed one or more claims of the '183 Patent due to their substantially similar designs. Defendant has represented to potential customers that Defendant's personnel formerly worked on the NovaSure® system.

32. On information and belief, Defendant has infringed and continues to infringe, literally and/or through the doctrine of equivalents, the '183 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products, services, methods, or processes that are covered by at least claims 1-7, 9, 11, and 13-15 of the '183 Patent. On information and belief, such devices include, but are not limited to, the Minerva Endometrial Ablation System. At Exhibit E, Plaintiffs attach a claim chart, which is excerpted from the Declaration of William Lucas

Churchill in support of Plaintiffs' Motion for a Preliminary Injunction (D.I. 27) (redacted version of Sealed Declaration, D.I. 15), showing the infringement of the '183 Patent by the Minerva Endometrial Ablation System. On information and belief, Defendant has and continues to directly infringe the claims of the '183 Patent by using in the United States the Minerva Endometrial Ablation System during its own testing and trials of the system. For example, Minerva's testing and use of the Minerva Endometrial Ablation System is demonstrated by the system's Operator's Manual that warns physician customers to follow Minerva's precise instructions of use. Further, on information and belief, Defendant tests and trials the Minerva Endometrial Ablation System, including with physicians employed by or consulting with Minerva to treat patients by ablating the uterine walls and by detecting for a perforation in a uterus to perform the steps claimed in the '183 Patent.

33. On information and belief, Defendant has indirectly infringed and continues to indirectly infringe the '183 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendant's customers, namely physicians and staff conducting the ablation procedure on patients, directly infringe at least claims 1-7, 9, 11, and 13-15 of the '183 Patent by practicing the claimed method. On information and belief, Defendant has knowingly induced infringement and has had a specific intent to induce infringement of the '183 Patent by their activities relating to the marketing, sales, support, and distribution of the Minerva Endometrial Ablation System, including, for example without limitation, providing through Defendant's website video and print instructions to use the Minerva Endometrial Ablation System in a manner that infringes one or more claims of the '183 Patent. Further, Defendant has knowingly induced infringement and has had a specific intent to induce infringement of the '183 Patent by their organization of trial usage of the Minerva Endometrial Ablation System. Defendant's representatives have organized

trials with potential customers, namely physicians and hospital staff, whereby Defendant's representatives instruct physicians and staff to use the Minerva Endometrial Ablation System as claimed in the '183 Patent. Minerva representatives participate in the trials with the physicians in the ordinary course of marketing the Minerva Endometrial Ablation System to new customers. At these trials, a Minerva representative works with the physician to treat actual patients, whereby the use of the Minerva Endometrial Ablation System will ablate the uterine walls and detect for a perforation in the patient's uterus, as claimed by the '183 Patent. On information and belief, Defendant has contributed to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Minerva Endometrial Ablation System knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '183 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use. With knowledge of the '183 Patent, Defendant especially made or especially adapted for use its Minerva Endometrial Ablation System to ablate the endometrial lining of the uterus and to detect for a perforation in the uterus, as claimed in the '183 Patent, while Defendant knowing that this system would not have any substantial non-infringing uses.

34. On information and belief, Defendant's infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

35. As a result of Defendant's infringement of the '183 Patent, Plaintiffs have suffered and continues to suffer damages.

36. Defendant's infringement of the '183 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

COUNT II

(Defendant's Infringement of the '898 Patent)

37. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

38. On April 7, 2015, the USPTO duly and legally issued the '898 Patent, entitled "Moisture Transport System for Contact Electrocoagulation" to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, Estela Hilario, and David C. Auth as inventors. A true and correct copy of the '898 Patent is attached as Exhibit C.

39. Prior to January 15, 2016 and prior to the filing of the original Complaint in the instant case, Cytyc was the assignee and lawful owner of all right, title, and interest in and to the '898 Patent. At the time of the filing of the original Complaint and continuing without interruption to the present day, Cytyc has been owned by Hologic and under Hologic's control, and Hologic thus has enjoyed the unfettered rights to practice, enforce, and assign the '898 patent. As of January 15, 2016, Cytyc assigned the '898 Patent to Hologic pursuant to Hologic's direction.

40. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with respect to products that it manufactures and sells under the '898 Patent.

41. Defendant has had knowledge of the '898 Patent since at least the filing of the original Complaint of the instant case and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Minerva Endometrial Ablation System would infringe one or more claims of the '898 Patent. On information and belief, Defendant has had knowledge of the '898 Patent before the filing of the original Complaint for at least the reason

that Defendant's founder Mr. Csaba Truckai is a named inventor of the '898 Patent and another named inventor Mr. David C. Auth is on the Board of Directors of Defendant.

42. On information and belief, Defendant was aware that Plaintiffs' NovaSure® system embodied the claimed invention of the '898 Patent and knew or should have known that Defendant's products, including the Minerva Endometrial Ablation System, infringed one or more claims of the '898 Patent due to their substantially similar designs. Defendant has represented to potential customers that Defendant's personnel formerly worked on the NovaSure® system.

43. On information and belief, Defendant has infringed and continues to infringe, literally and/or through the doctrine of equivalents, the '898 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products, services, methods, or processes that are covered by at least claims 1-6, 8, and 14-16 of the '898 Patent. On information and belief, such devices include, but are not limited to, the Minerva Endometrial Ablation System. At Exhibit F, Plaintiffs attach a claim chart, which is excerpted from the Declaration of William Lucas Churchill in support of Plaintiffs' Motion for a Preliminary Injunction (D.I. 27) (redacted version of Sealed Declaration, D.I. 15), showing the infringement of the '898 Patent by the Minerva Endometrial Ablation System. On information and belief, Defendant has and continues to directly infringe the claims of the '898 Patent by using in the United States the Minerva Endometrial Ablation System during its own tests and trials of the system. For example, Minerva's testing and use of the Minerva Endometrial Ablation System is demonstrated by the system's Operator's Manual that warns physician customers to follow Minerva's precise instructions of use. Further, on information and belief, Defendant tests and trials the Minerva

Endometrial Ablation System, including with physicians employed by or consulting with Minerva to treat patients by ablating the uterine walls to perform the steps claimed in the '898 Patent.

44. On information and belief, Defendant has indirectly infringed and continues to indirectly infringe the '898 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendant's customers, namely physicians and staff conducting the ablation procedure on patients, directly infringe at least claims 1-6, 8, and 14-16 of the '898 Patent by practicing the claimed method. On information and belief, Defendant has knowingly induced infringement and have had a specific intent to induce infringement of the '898 Patent by their activities relating to the marketing, sales, support, and distribution of the Minerva Endometrial Ablation System, including, for example without limitation, providing video and print instructions to use the Minerva Endometrial Ablation System in a manner that infringes one or more claims of the '898 Patent. Further, Defendant has knowingly induced infringement and has had a specific intent to induce infringement of the '898 Patent by their organization of trial usage of the Minerva Endometrial Ablation System. Defendant's representatives have organized trials with potential and existing customers, namely physicians and hospital staff, whereby Defendant's representatives instruct physicians and staff to use the Minerva Endometrial Ablation System as claimed in the '898 Patent. Minerva representatives participate in the trials with the physicians in the ordinary course of marketing the Minerva Endometrial Ablation System to new customers. At these trials, a Minerva representative works with the physician to treat actual patients, whereby the use of the Minerva Endometrial Ablation System will ablate the uterine walls, as claimed by the '898 Patent. On information and belief, Defendant has contributed to infringement by selling and/or offering to sell within the United States, or importing into the

United States, the Minerva Endometrial Ablation System knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '898 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use. With knowledge of the '898 Patent, Defendant especially made or especially adapted for use its Minerva Endometrial Ablation System to ablate the endometrial lining of the uterus, as claimed in the '898 Patent, while Defendant knowing that this system would not have any substantial non-infringing uses.

45. On information and belief, Defendant's infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

46. As a result of Defendant's infringement of the '898 Patent, Plaintiffs have suffered and continues to suffer damages.

47. Defendant's infringement of the '898 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

COUNT III

(Defendant's Infringement of the '348 Patent)

48. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

49. On August 4, 2015, the USPTO duly and legally issued the '348 Patent, entitled "Moisture Transport System for Contact Electrocoagulation" to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, and Estela Hilario as inventors. A true and correct copy of the '348 Patent is attached as Exhibit D.

50. Prior to January 15, 2016 and prior to the filing of the original Complaint in the instant case, Cytyc was the assignee and lawful owner of all right, title, and interest in and to the '348 Patent. At the time of the filing of the original Complaint and continuing without interruption to the present day, Cytyc was owned by Hologic and under Hologic's control, and Hologic thus has enjoyed the unfettered rights to practice, enforce, and assign the '348 patent. As of January 15, 2016, Cytyc assigned the '348 Patent to Hologic pursuant to Hologic's direction.

51. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with respect to products that it manufactures and sells under the '348 Patent.

52. Defendant has had knowledge of the '348 Patent since at least the filing of the original Complaint in the instant case and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Minerva Endometrial Ablation System would infringe one or more claims of the '348 Patent. On information and belief, Defendant has had knowledge of the '348 Patent before the filing of the original Complaint because, for example, Defendant's founder Mr. Csaba Truckai is a named inventor of the '348 Patent.

53. On information and belief, Defendant was aware that Plaintiffs' NovaSure® system embodied the claimed invention of the '348 Patent and knew or should have known that Defendant's products, including the Minerva Endometrial Ablation System, infringed one or more claims of the '348 Patent due to their substantially similar designs. Defendant has represented to potential customers that Defendant's personnel formerly worked on the NovaSure® system.

54. On information and belief, Defendant has infringed and continues to infringe, literally and/or through the doctrine of equivalents, the '348 Patent in violation of 35 U.S.C.

§ 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products that are covered by at least claims 1, 3, and 8-10 of the '348 Patent. On information and belief, such devices include, but are not limited to, the Minerva Endometrial Ablation System. At Exhibit G, Plaintiffs attach a claim chart, which is excerpted from the Declaration of William Lucas Churchill in support of Plaintiffs' Motion for a Preliminary Injunction (D.I. 27) (redacted version of Sealed Declaration, D.I. 15), showing the infringement of the '348 Patent by the Minerva Endometrial Ablation System.

55. On information and belief, Defendant has indirectly infringed and continues to indirectly infringe the '348 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendant's customers, namely physicians and staff conducting the ablation procedure on patients, directly infringe at least claims 1, 3, and 8-10 of the '348 Patent by using the claimed apparatus. On information and belief, Defendant has knowingly induced infringement and have had a specific intent to induce infringement of the '348 Patent by their activities relating to the marketing, sales, support, and distribution of the Minerva Endometrial Ablation System, including, for example without limitation, providing video and print instructions to use the Minerva Endometrial Ablation System in a manner that infringes one or more claims of the '348 Patent. Further, Defendant has knowingly induced infringement and has had a specific intent to induce infringement of the '348 Patent by their organization of trial usage of the Minerva Endometrial Ablation System. Defendant's representatives have organized trials with potential and existing customers, namely physicians and hospital staff, whereby Defendant's representatives instruct physicians and staff to use the Minerva Endometrial Ablation System as claimed in the '348 Patent. Minerva representatives participate in the trials with the physicians in the ordinary course of marketing the Minerva Endometrial Ablation System to new customers.

At these trials, a Minerva representative works with the physician to treat actual patients, whereby Minerva Endometrial Ablation System will treat the uterine walls, as claimed by the '348 Patent. On information and belief, Defendant has contributed to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Minerva Endometrial Ablation System knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '348 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use. With knowledge of the '348 Patent, Defendant especially made or especially adapted for use its Minerva Endometrial Ablation System to treat the endometrial lining of the uterus, as claimed in the '348 Patent, while Defendant knowing that this system would not have any substantial non-infringing uses.

56. On information and belief, Defendant's infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

57. As a result of Defendant's infringement of the '348 Patent, Plaintiffs have suffered and continues to suffer damages.

58. Defendant's infringement of the '348 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

COUNT IV

(Unfair Competition Under 15 U.S.C. § 1125(a))

59. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

60. Defendant has used and continues to use a false designation of origin and false or misleading description of facts in connection with its marketing and/or sale of the Minerva Endometrial Ablation System, including without limitation, by and through its false and misleading description of the Minerva Endometrial Ablation System as the new NovaSure® and as being made by the makers of NovaSure®.

61. Defendant markets and/or sells its Endometrial Ablation System throughout the United States and travels in interstate commerce.

62. Defendant's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing Hologic customers as to the origin, sponsorship, or approval of the Minerva Endometrial Ablation System by Plaintiffs.

63. Defendant's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing Hologic customers as to the affiliation, connection, or association of Defendant with Plaintiffs.

64. Defendant's conduct constitutes unfair competition in violation of 15 U.S.C. § 1125(a).

65. As a result of Defendant's false designation of origin and false or misleading description of facts, Plaintiffs have suffered and continue to suffer damages, including without limitation, by a loss of sales.

66. On information and belief, Defendant's false designation of origin and false or misleading description of facts has been and continues to be willful, making this an exceptional case and entitling Plaintiffs to recover Defendant's profits on sales of the Minerva Endometrial Ablation System, actual and enhanced damages, and costs Plaintiffs incurred in prosecuting its claims, pursuant to 15 U.S.C. § 1117(a).

67. Defendant's false designation of origin and false or misleading description of facts has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins Defendant's false and misleading statements pursuant to 15 U.S.C. § 1116(a).

COUNT V

(Deceptive Trade Practice Under 6 Del. C. § 2532)

68. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

69. Defendant, in the course of its business, has caused and continues to cause likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the Minerva Endometrial Ablation System, including without limitation, by and through its false and misleading description of the Minerva Endometrial Ablation System as the new NovaSure® and as being made by the makers of NovaSure®.

70. Defendant, in the course of its business, has caused and continues to cause likelihood of confusion or of misunderstanding as to affiliation, connection, or association with Plaintiffs, including without limitation, by and through its false and misleading description of the Minerva Endometrial Ablation System as the new NovaSure® and as being made by the makers of NovaSure®.

71. On information and belief, Defendant, in the course of its business, has engaged in and continues to engage in conduct that disparages the prior NovaSure® systems, including without limitation, by and through its false and misleading representation that the Minerva Endometrial Ablation System is a new or updated NovaSure® system that addresses prior weaknesses or detriments.

72. On information and belief, Defendant, in the course of its business, has engaged in and continues to engage in conduct that causes likelihood of confusion or of misunderstanding, including without limitation, by and through its false and misleading description of the Minerva Endometrial Ablation System as the new NovaSure® and as being made by the makers of NovaSure®.

73. On information and belief, in the course of its business, Defendant, by and through its false and misleading representations of fact and conduct, has engaged in and continues to engage in deceptive trade practices in violation of 6 Del. C. § 2532, including without limitation by its activities in Delaware offering for sale the Minerva Endometrial Ablation System.

74. As a result of Defendant's conduct, Plaintiffs have suffered and continue to suffer damages including without limitation by a loss of sales.

75. The principles of equity favor this Court enjoining Defendant's conduct pursuant to 6 Del. C. § 2533(a).

76. On information and belief, Defendant's conduct has been and continues to be willful, making this an exceptional case under 6 Del. C. § 2533(b) and entitling Plaintiffs to attorneys' fees and costs incurred in prosecuting its claims.

77. Plaintiffs are entitled to damages under the Delaware common law thereby entitling Plaintiffs to treble damages under 6 Del. C. § 2533(c).

COUNT VI

(Unfair Competition -- Delaware Common Law)

78. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

79. Plaintiffs had a reasonable expectancy of entering and continuing its valid business relationships with its existing and prospective customers.

80. On information and belief, Defendant wrongfully interfered with those business relationships by targeting Plaintiffs' existing customers and (i) using a false designation of origin and false or misleading description of facts in connection with its marketing and/or sale of the Minerva Endometrial Ablation System; (ii) causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the Minerva Endometrial Ablation System; (iii) causing likelihood of confusion or of misunderstanding as to affiliation, connection, or association with Plaintiffs; (iv) disparaging the prior NovaSure® systems; and (v) engaging in conduct that causes likelihood of confusion or of misunderstanding, including without limitation, by and through its false and misleading description of the Minerva Endometrial Ablation System as the new NovaSure® and as being made by the makers of NovaSure®.

81. Defendant has used and continues to use a false designation of origin and false or misleading description of facts in connection with its marketing and/or sale of the Minerva Endometrial Ablation System by and through its false and misleading description of the Minerva Endometrial Ablation System as the new NovaSure® and as being made by the makers of NovaSure®.

82. Defendant's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing Hologic customers as to the origin, sponsorship, or approval of the Minerva Endometrial Ablation System by Plaintiffs.

83. Defendant's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing Hologic customers as to the affiliation, connection, or association of Defendant with Plaintiffs.

84. Defendant's conduct has been and continues to be willful and has been and continues to be undertaken with the purpose of deceiving customers and appropriating Plaintiffs' goodwill.

85. On information and belief, Defendant's conduct constitutes unfair competition under the common law, including without limitation by its activities in Delaware offering for sale the Minerva Endometrial Ablation System.

86. As a result of Defendant's misconduct, Plaintiffs have suffered and continue to suffer economic harm, including without limitation by a loss of sales. As a result of Defendant's misconduct, Defendant has caused and will continue to cause customer confusion or misunderstanding and has caused and will continue to cause damage to Plaintiffs' goodwill with customers.

87. Defendant's misconduct has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such unfair conduct.

COUNT VII

(Tortious Interference With A Business Relationship -- Delaware Common Law)

88. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

89. Plaintiffs had a reasonable expectancy of entering and continuing its valid business relationships with its existing and prospective customers.

90. On information and belief, Defendant had knowledge of Plaintiffs' business relationships with its existing customers by, among other things, employing Plaintiffs' former NovaSure® sales representatives and former executives of Plaintiffs.

91. On information and belief, Defendant intentionally interfered with those business relationships by targeting Plaintiffs' existing customers and (i) using a false designation of origin and false or misleading description of facts in connection with its marketing and sale of the Minerva Endometrial Ablation System; (ii) causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the Minerva Endometrial Ablation System; (iii) causing likelihood of confusion or of misunderstanding as to affiliation, connection, or association with Plaintiffs; (iv) disparaging the prior NovaSure® systems; and (v) engaging in conduct that causes likelihood of confusion or of misunderstanding, including without limitation, by and through its false and misleading description of the Minerva Endometrial Ablation System as the new NovaSure® and as being made by the makers of NovaSure®.

92. Defendant, by and through its false and misleading description of facts and conduct, has engaged in and continues to engage in wrongful conduct in violation of the Lanham Act, 15 U.S.C. § 1125(a), and the Delaware Deceptive Trade Practices Act, 6 Del. C. § 2532.

93. As a result of Defendant's misconduct, Defendant has caused and will continue to cause customer confusion or misunderstanding and has caused and will continue to cause damage to Plaintiffs' goodwill with customers.

94. On information and belief, Defendant's conduct constitutes tortious interference with a business relationship under the common law, including without limitation by its activities in Delaware offering for sale the Minerva Endometrial Ablation System.

95. As a result of Defendant's intentional interference, Plaintiffs have suffered and continue to suffer economic harm, including without limitation by a loss of sales.

96. Defendant's actions have been and continue to be willful and have been and continue to be undertaken with the purpose of deceiving customers.

97. Defendant's intentional interference has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such conduct.

COUNT VIII

(Defendant's Infringement of the '989 Patent)

98. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

99. On February 2, 2016, the USPTO duly and legally issued the '989 Patent, entitled "Moisture Transport System for Contact Electrocoagulation" to Csaba Truckai as inventor. A true and correct copy of the '989 Patent is attached as Exhibit H.

100. Cytyc is the assignee and lawful owner of all right, title, and interest in and to the '989 Patent.

101. Defendant has had knowledge of the '989 Patent since at least the filing of this Second Amended Complaint in the instant case and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Minerva Endometrial Ablation System would infringe one or more claims of the '989 Patent.

102. On information and belief, Defendant is aware that Plaintiffs' NovaSure® system embodies the claimed invention of the '989 Patent and is aware that Defendant's products,

including the Minerva Endometrial Ablation System, infringes one or more claims of the '989 Patent due to their substantially similar designs.

103. On information and belief, Defendant infringes, literally and/or through the doctrine of equivalents, the '989 Patent in violation of 35 U.S.C. § 271 by making, selling, offering to sell, and/or importing into the United States for subsequent sale or use products, services, methods, or processes that are covered by at least claims 1-11, and 13 of the '989 Patent. On information and belief, such devices include, but are not limited to, the Minerva Endometrial Ablation System. On information and belief, Defendant indirectly infringes the '989 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendant's customers, namely physicians and staff conducting the ablation procedure on patients, directly infringe at least claims 1-11, and 13 of the '989 Patent by practicing the claimed method. On information and belief, Defendant knowingly induces infringement and has specific intent to induce infringement of the '989 Patent by their activities relating to the marketing, sales, support, and distribution of the Minerva Endometrial Ablation System, including, for example without limitation, providing video and print instructions to use the Minerva Endometrial Ablation System in a manner that infringes one or more claims of the '989 Patent. Further, Defendant knowingly induces infringement and has specific intent to induce infringement of the '989 Patent by their organization of trial usage of the Minerva Endometrial Ablation System. Defendant's representatives organize trials with potential and existing customers, namely physicians and hospital staff, whereby Defendant's representatives instruct physicians and staff to use the Minerva Endometrial Ablation System as claimed in the '989 Patent. Minerva representatives participate in the trials with the physicians in the ordinary course of marketing the Minerva Endometrial Ablation System to new customers. At these trials, a Minerva representative works

with the physician to treat actual patients, whereby the use of the Minerva Endometrial Ablation System will perform endometrial ablation, as claimed by the '989 Patent. On information and belief, Defendant contributes to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Minerva Endometrial Ablation System knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '989 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use. With knowledge of the '989 Patent, Defendant especially makes or especially adapts for use its Minerva Endometrial Ablation System to perform endometrial ablation, as claimed in the '989 Patent, while Defendant knowing that this system would not have any substantial non-infringing uses.

104. On information and belief, Defendant's infringement is willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

105. As a result of Defendant's infringement of the '989 Patent, Plaintiffs continue to suffer damages.

106. Defendant's infringement of the '989 Patent continues to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

1. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant has and continues to directly infringe and indirectly infringe (by inducement and contributory infringement) one or more claims of the '183 Patent;

2. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant's infringement of the '183 Patent has been and continues to be willful;

3. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant has and continues to directly infringe and indirectly infringe (by inducement and contributory infringement) one or more claims of the '898 Patent;

4. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant's infringement of the '898 Patent has been and continues to be willful;

5. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant has and continues to directly infringe and indirectly infringe (by inducement and contributory infringement) one or more claims of the '348 Patent;

6. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant's infringement of the '348 Patent has been and continues to be willful;

7. A preliminary and permanent injunction against Defendant Minerva Surgical, Inc. for infringement of the Patents-in-Suit;

8. Judgment awarding Plaintiffs Hologic and Cytyc damages adequate to compensate for Defendant Minerva Surgical, Inc.'s infringement of the Patents-in-Suit in an amount to be proven at trial, together with pre-judgment and post-judgment interest and costs, as fixed by the Court;

9. Judgment enhancing the damages due to Defendant Minerva Surgical, Inc.'s willful infringement, pursuant to 35 U.S.C. § 284;

10. Judgment declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Hologic and Cytyc their attorneys' fees and costs incurred in prosecuting its claims;

11. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant has and continues to engage in unfair competition under 15 U.S.C. § 1125(a);

12. A preliminary and permanent injunction against Defendant Minerva Surgical, Inc. restraining Defendant from making any false designation of origin in connection with its sales of the Minerva Endometrial Ablation System, pursuant to 15 U.S.C. § 1116(a);

13. Under 15 U.S.C. § 1117(a), awarding Plaintiffs Hologic and Cytyc: (i) Defendant's profits on sales of the Minerva Endometrial Ablation System; (ii) damages adequate to compensate for Defendant Minerva Surgical, Inc.'s unfair competition in an amount to be proven at trial, together with pre-judgment and post-judgment interest and costs, as fixed by the Court; and (iii) enhanced damages and Plaintiffs' attorneys' fees and costs incurred in prosecuting their claims;

14. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant has and continues to engage in deceptive trade practices under Delaware statutory law, and common law unfair competition and/or common law tortious interference with a business relationship under Delaware law;

15. A preliminary and permanent injunction against Defendant Minerva Surgical, Inc. restraining Defendant from engaging in deceptive trade practices and unfair competition and from interfering with Plaintiffs' business relationships;

16. Judgment awarding Plaintiffs Hologic and Cytyc damages adequate to compensate for Defendant Minerva Surgical, Inc.'s unfair competition and tortious interference with a

business relationship in an amount to be proven at trial, together with pre-judgment and post-judgment interest and costs, as fixed by the Court;

17. Judgment declaring this an exceptional case under 6 Del. C. § 2533(b) and awarding Plaintiffs Hologic and Cytyc its attorneys' fees and costs incurred in prosecuting its claims;

18. Judgment enhancing the damages due to Defendant Minerva Surgical, Inc. engaging in unfair competition and interfering with Plaintiffs' business relationships in addition to engaging in deceptive trade practices, pursuant to 6 Del. C. § 2533(c), and/or due to Defendant's willful conduct

19. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant indirectly infringes (by inducement and contributory infringement) one or more claims of the '989 Patent;

20. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant's infringement of the '989 Patent is willful; and

21. Such other relief as this Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury in this action on all issues so triable.

DATED: February 4, 2016

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EXHIBIT A

minerva SURGICAL

Endometrial Ablation System

Operator's Manual

Operator's Manual

Table of Contents

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN TRAINED IN THE USE OF THE MINERVA SYSTEM.

READ ALL INSTRUCTIONS, CAUTIONS AND WARNINGS PRIOR TO USE.

FAILURE TO FOLLOW ANY INSTRUCTIONS OR TO HEED ANY WARNINGS OR PRECAUTIONS COULD RESULT IN SERIOUS PATIENT INJURY.

THE MINERVA DISPOSABLE HANDPIECE MUST BE USED ONLY IN CONJUNCTION WITH THE MINERVA RF CONTROLLER AND THE MINERVA RF CONTROLLER MUST BE USED ONLY IN CONJUNCTION WITH THE MINERVA DISPOSABLE HANDPIECE.

THE MINERVA DISPOSABLE HANDPIECE IS NOT MADE FROM NATURAL RUBBER LATEX.

1.0 PHYSICIAN CHECKLIST

The Physician must:

- Have sufficient and adequate experience in performing procedures in the uterine cavity, such as IUD insertion or dilation and curettage (D&C) and hysteroscopy.
- Review and be familiar with the Instructions for Use (IFU).
- Be aware of the appropriate sequence of actions detailed in this Operator's Manual and the troubleshooting section in the event the system detects a high CO_2 flow rate during the Uterine Integrity Test, which may be indicative of a uterine perforation.
- Review the patient selection criteria for the Minerva clinical trials to determine which patients are appropriate for the Minerva procedure.

Adjunct personnel must be familiar with this Operator's Manual and other educational materials prior to using the Minerva Endometrial Ablation System.

2.0 SYSTEM DESCRIPTION

The Minerva Endometrial Ablation System is designed to treat abnormal uterine bleeding due to benign causes in pre-menopausal women for whom childbearing is complete. The System features a Minerva Disposable Handpiece which is positioned trans-cervically in the uterine cavity and connected to the Minerva RF Controller to deliver RF energy to ablate the endometrial lining of the uterus.

The Minerva Endometrial Ablation System is to be used by gynecologists with experience in performing blind intra-uterine manipulations and procedures.

The Minerva Endometrial Ablation System is a bipolar RF system that uses high voltage radio frequency (RF) electrical current at a frequency of 480 kHz to ionize argon gas that is fully contained and circulated within a sealed silicone membrane of the Plasma Formation Array (PFA). This stretchable silicone membrane is deployed in the uterine cavity. When the system is energized, the argon gas is ionized, turning it into plasma. It is this argon plasma that heats the interior surface of the silicone membrane. This energy, in the form of heat, is conducted through the silicone membrane to the tissue in contact with the membrane.

The combination of the heat conducted through the membrane wall from the plasma to the adjacent endometrial tissue, retained heated intra-cavitary moisture that fills gaps outside the array and a small amount of bipolar RF current travelling through the target tissue (and resultant heat), results in the ablation of endometrial tissue.

The Minerva Endometrial Ablation System consists of the Minerva Disposable Handpiece (with Desiccant), the Minerva RF Controller (with Footswitch and Power Cord), an argon (Ar) canister and

a carbon dioxide (CO_2) canister. **Figure 1** shows the Minerva Disposable Handpiece and Minerva RF Controller.

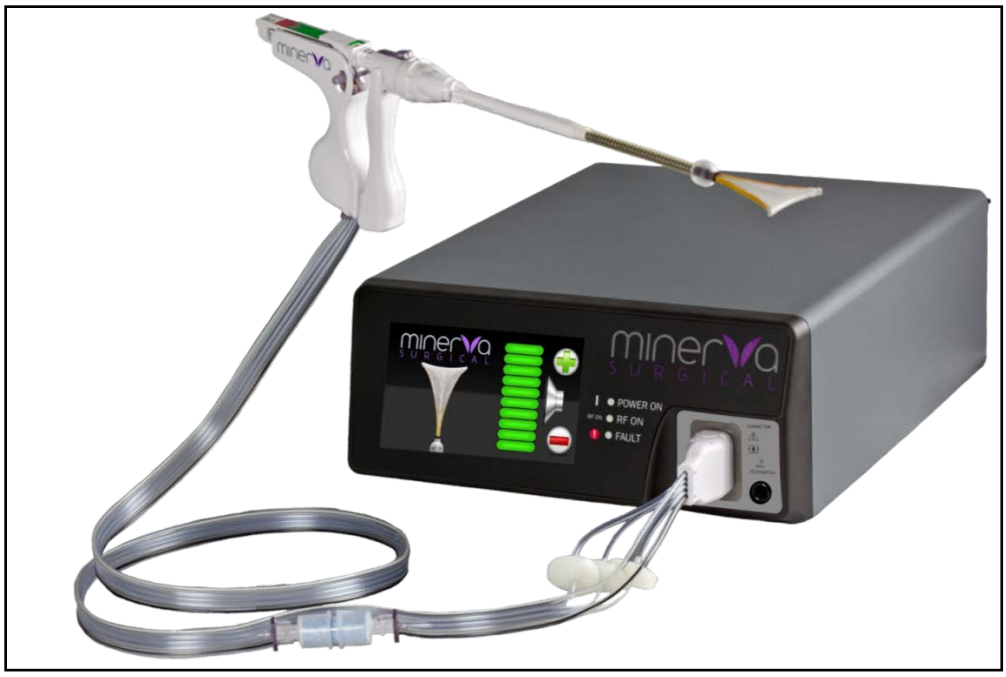


Figure 1: Minerva Disposable Handpiece and RF Controller

2.1 **Minerva Disposable Handpiece**

The Minerva Disposable Handpiece (**Figure 2**) is a single-patient, single-use component of the Minerva Endometrial Ablation System.

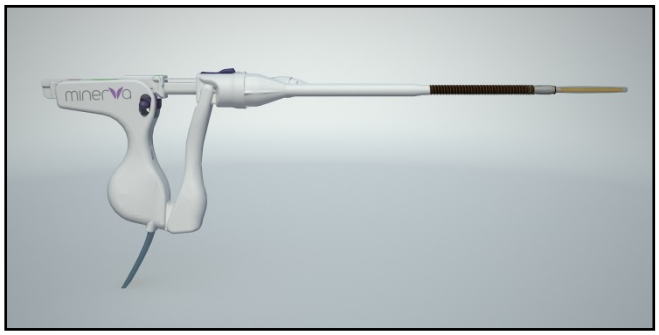


Figure 2: Minerva Disposable Handpiece

The Minerva Disposable Handpiece consists of the following:

- Plasma Formation Array (PFA): The PFA consists of an expandable metal frame, covered by a stretchable silicone membrane. The PFA is opened by a deployment mechanism using the handle, and the expanded frame acts as the internal electrode inside the membrane. A single tissue contacting electrode resides on the outer surface of the membrane. The final expanded triangular shaped PFA is intended to conform to the patient's uterine cavity (**Figure 3**). Argon gas inside the membrane is ionized by the RF energy delivered by the internal electrode. The RF current path extends through the internal electrode and is capacitively coupled through the

membrane and uterine tissue to the single external electrode on the membrane surface. The heat generated from the ionized argon plasma allows for the controlled transfer of energy to the uterus for the purpose of endometrial tissue ablation. Intra-cavitary moisture is not removed during the energy delivery process. Argon gas is fully contained within the Minerva Disposable Handpiece silicone membrane and is not released into the uterine cavity during the ablation procedure.

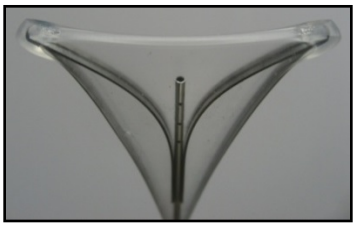


Figure 3: Plasma Formation Array (PFA)

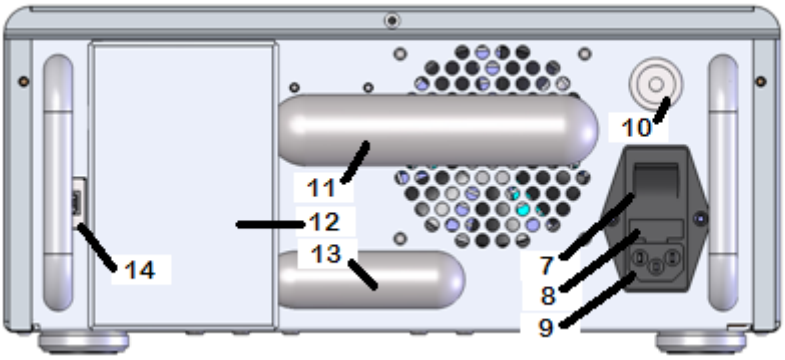
- Cervical Sheath: The Cervical Sheath contains the argon and CO_2 gas inflow/outflow circuits, electrical connections, insulation and mechanical connection between the PFA and the handle.
- Cervical Sealing Balloon: The Cervical Sealing Balloon is mounted on the outside of the Cervical Sheath and moves with the sheath when setting the PFA length sheath lock. When the sheath is locked to the calculated PFA length, the Cervical Sealing Balloon is positioned at the internal os to seal the uterine cavity for the Uterine Integrity Test (UIT) and to insulate the endocervical canal from possible thermal damage during the ablation cycle.
- Array Opening Indicator: This Red/Green Indicator is a mechanism which displays the progression of the PFA deployment/opening and does not indicate a dimension of the uterus.
- Handle: The handle assembly enables the deployment of the PFA. Additionally, the handle serves to electrically and pneumatically connect power and gas from the RF Controller to the PFA.
- Connecting Cord: The connecting cord consists of lumens for gas transfer and electrical power from the Minerva RF Controller to the Minerva Disposable Handpiece, as well as a proprietary connector. It also includes gas filters and a desiccant to prevent moisture from entering the RF Controller.

2.2 Minerva RF Controller

The Minerva RF Controller (**Figure 4** and **Figure 5**) is a controlled radio frequency (RF) power generator. The power provided to the Minerva Disposable Handpiece by the Minerva RF Controller is varied according to electro-physical changes in impedance characteristics of the uterine cavity during the ablation process. The system emits a maximum effective RF power of 40W at 480 kHz to perform its intended function. The Minerva RF Controller also controls the delivery of argon gas to the Minerva Disposable Handpiece. In addition, the Minerva RF Controller has a uterine integrity test (UIT) feature designed to assess possible defects of the uterus or the PFA using the introduction of CO_2 gas. The Minerva RF Controller includes a touch screen display and a footswitch. The Minerva RF Controller incorporates connections for the argon and CO_2 gas canisters on the back of the unit. The USB connection on the back of the unit is for use only by Minerva Surgical personnel. Handles located on the back of the unit facilitate transportation of the Minerva RF Controller.

1. Power On LED
2. RF On LED
3. FAULT LED
4. Footswitch Receptacle
5. Touch Screen Display
6. Disposable Handpiece Receptacle

Figure 4: Minerva RF Controller Front Panel



7. ON/OFF Switch
8. Fuse Drawer
9. Power Receptacle
10. Equipotential Ground Lug
11. Argon Canister
12. Argon and CO_2 Regulators
13. CO_2 Canister
14. USB Connector

Figure 5: Minerva RF Controller Back Panel

2.3 Desiccant

The Minerva desiccant is a non-sterile, single-patient use component that the user attaches in-line with the argon return line, prior to connecting the Minerva Disposable Handpiece to the Minerva RF Controller.

2.4 **CO_2 Canister**

The Minerva CO_2 canister is a 24-gram, CO_2 canister. It is attached to the regulator located on the back panel of the Minerva RF Controller.

2.5 **Argon (Ar) Canister**

The Minerva argon canister is a 25-gram, argon canister. It is attached to the regulator located on the back panel of the Minerva RF Controller prior to applying line voltage to the Minerva RF Controller (turning on the On/Off switch).

2.6 **Footswitch**

The Minerva Footswitch is a pneumatic switch that connects to the Minerva RF Controller front panel. It is used to activate the Minerva RF Controller and does not contain any electrical components.

2.7 **Power Cord**

The Minerva AC power cord, a medical grade cord, connects the Minerva RF Controller to the appropriate line voltage/power outlet. The receptacle for the power cord, the power input module, is located on the back panel of the Minerva RF Controller.

3.0 PRINCIPLES OF OPERATION

The Minerva Endometrial Ablation System is a bipolar RF system that uses high voltage radio frequency (RF) electrical current at a frequency of 480 kHz to ionize argon gas that is fully contained and circulated within a sealed silicone membrane. This stretchable silicone membrane of the Plasma Forming Array (PFA) is deployed in the uterine cavity. When the system is energized, the argon gas is ionized, forming plasma. It is this argon plasma that heats the interior surface of the silicone membrane. This energy, in the form of heat, is conducted through the silicone membrane and to the tissue in contact with the membrane. The combination of the heat conducted through the membrane wall from the plasma to the adjacent endometrial tissue, the retained heated intra-cavitary moisture that fills gaps around the surface of the array, and a small amount of bipolar RF current travelling through the target tissue (and resultant heat), results in the ablation of endometrial tissue.

The Minerva Disposable Handpiece is connected to the Minerva RF Controller, then inserted and positioned at the fundus of the uterine cavity. The handle of the Minerva Disposable Handpiece is actuated to expand the PFA. The Cervical Sealing Balloon is inflated to facilitate sealing of the endocervical canal. The UIT is performed to help assess the uterine cavity for possible uterine and Array defects. Upon successful completion of the UIT, the ablation cycle is initiated and plasma energy is delivered. After the ablation cycle is complete, the handle is unlocked to close the PFA, and the Cervical Sealing Balloon is deflated prior to removing the Minerva Disposable Handpiece from the uterus.

The Minerva RF Controller should be placed in proximity to the user and away from the sterile field. The Minerva RF Controller should be placed on a cart, to the left or right side of the user (the operator actuating the Minerva RF Controller is expected to be approximately within 1 meter of the Minerva RF Controller touch screen display). The Minerva RF Controller front panel should be facing the user, such that there is an unobstructed view of the touch screen. The footswitch should be connected to the connector on the Minerva RF Controller front panel and placed on the floor within easy reach of the user.

4.0 INDICATIONS FOR USE

The Minerva Endometrial Ablation System is intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

5.0 CONTRAINDICATIONS

The Minerva Endometrial Ablation System is contraindicated for use in:

- a patient who is pregnant or who wants to become pregnant in the future.
  PREGNANCIES FOLLOWING ABLATION CAN BE DANGEROUS FOR BOTH MOTHER AND FETUS.
- a patient with known or suspected uterine cancer or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- a patient with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy, including hysteroscopic and/or laparoscopic myomectomy performed immediately prior to the Minerva procedure) or pathologic condition (e.g., requiring long-term medical therapy) that could lead to weakening of the myometrium.
- a patient with a history of endometrial ablation and/or resection (including endometrial ablation/resection performed immediately prior to Minerva procedure) regardless of the modality by which it was performed.
  REPEAT ABLATION MAY RESULT IN SERIOUS PATIENT INJURY.
- a patient with active genital or urinary tract infection at the time of the procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis or cystitis).
- a patient with an intrauterine device (IUD) currently in place and which is not removed prior to the Minerva procedure.
- a patient with a uterine cavity length less than 4 cm. The minimum length of PFA is 4 cm. Treatment of a uterine cavity with a length less than 4 cm may result in thermal injury to the endocervical canal.
- a patient with a narrow uterine cavity.
- a patient where the Array Opening Indicator is in the Red Zone following deployment of the Minerva Disposable Handpiece.
- a patient with active pelvic inflammatory disease.
- a patient with undiagnosed vaginal bleeding.

6.0 WARNINGS

READ ALL INSTRUCTIONS CAREFULLY. FAILURE TO PROPERLY FOLLOW THE INSTRUCTIONS, WARNINGS, AND PRECAUTIONS MAY LEAD TO PATIENT INJURY.

THE MINERVA PROCEDURE IS INTENDED TO BE PERFORMED ONLY ONCE DURING A SINGLE OPERATIVE VISIT. THERMAL OR OTHER INJURIES TO THE BOWEL MAY OCCUR WHEN/IF MULTIPLE THERAPY CYCLES ARE PERFORMED DURING THE SAME OPERATIVE VISIT.

6.1 Uterine Perforation

- Use caution not to perforate the uterine wall when sounding, dilating or inserting the Minerva Disposable Handpiece.
- Activation of the Minerva Disposable Handpiece in the setting of a uterine perforation is likely to result in serious patient injury.
- The risk of uterine perforation is increased in patients with abnormal or obstructed uterine cavities including obstruction by fibroids that distort the uterine cavity.
- It has been reported in the literature that patients with a severely anteverted, retroflexed or laterally displaced uterus are at greater risk of uterine wall perforation during any intrauterine manipulation.
- If the Minerva Disposable Handpiece is difficult to insert into the cervical canal, use clinical judgment to determine whether or not further dilation is required. Forcibly advancing the Minerva Disposable Handpiece against resistance is likely to increase the risk of perforation or creation of a false passage. Sufficient dilation is required for safe insertion.
- To prevent injury to the endocervical canal, ensure the Plasma Formation Array is unlocked before removing the Minerva Disposable Handpiece from the uterus.
- Excessive force applied during placement of the Minerva Disposable Handpiece may result in tissue injury including perforation.

- Use caution during placement of the Minerva Disposable Handpiece in severe uterine angulations to prevent perforation.
- The Minerva System performs an integrity test to evaluate the integrity of the Minerva Disposable Handpiece and indirectly assess the integrity of the uterine cavity (Uterine Integrity Test) and sounds an alarm warning prior to treatment if the test fails. (See advisory note after Step 13.13).
- IF THE UTERINE INTEGRITY TEST FAILS AFTER REASONABLE ATTEMPTS TO IMPLEMENT THE TROUBLESHOOTING PROCEDURES (14.1.2-14.1.4), ABORT THE PROCEDURE.
- ALTHOUGH DESIGNED TO DETECT A PERFORATION OF THE UTERINE WALL, THIS TEST IS AN INDICATOR ONLY AND IT MIGHT NOT DETECT ALL PERFORATIONS. CLINICAL JUDGMENT MUST ALWAYS BE USED.
- IF A UTERINE PERFORATION IS SUSPECTED AND/OR CONFIRMED, THE PROCEDURE SHOULD BE TERMINATED IMMEDIATELY.
- For patients in whom the procedure was aborted due to a suspected uterine wall perforation, a work-up for perforation should be considered prior to discharge.
- **Post-treatment, any patient-reported signs/symptoms that could indicate a serious complication, e.g., bowel injury, should be thoroughly evaluated without delay.**

6.2 **General Warnings**

- Endometrial ablation using the Minerva System is not a sterilization procedure. Therefore, the patient should be advised of appropriate birth control methods.
- Endometrial ablation is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following the procedure. Pregnancy following ablation may be dangerous for both mother and fetus.
- Endometrial ablation does not eliminate the potential for endometrial hyperplasia or cancer of the endometrium and may mask the physician’s ability to detect or make a diagnosis of such pathology.
- Patients who undergo endometrial ablation procedures who have previously undergone tubal ligation are at increased risk of developing post ablation tubal sterilization syndrome which can require hysterectomy. This can occur as late as 10 years post procedure.
- The Minerva procedure should not be performed concomitantly with placement of the Essure device.
- The safety and effectiveness of the Minerva System has not been evaluated in patients with the Essure device.

6.3 **Technical Warnings**

- The Minerva Disposable Handpiece is supplied sterile. Do not use the sterile single-patient use Minerva Disposable Handpiece if the packaging appears to be damaged or there is evidence of tampering.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the Minerva Disposable Handpiece and/or lead to failure of the Minerva Disposable Handpiece which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the handpiece and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the handpiece may lead to injury, illness or death of the patient.
- The used Minerva Disposable Handpiece must be treated as biohazardous waste and disposed of in accordance with hospital or clinic standard practice where the treatment is performed.

- If any hysteroscopy procedure is performed with hypotonic solution immediately prior to Minerva procedure, then the uterine cavity must be flushed with normal saline prior to treatment with the Minerva System. The presence of hypotonic fluid may reduce the efficiency of the Minerva System.
- Plugging the Minerva Disposable Handpiece into the Minerva RF Controller starts the pre-insertion handpiece integrity check. CO_2 is delivered to the handpiece to verify patency. THIS TEST TAKES APPROXIMATELY 10 SECONDS TO COMPLETE AND MUST BE PERFORMED WITH THE MINERVA DISPOSABLE HANDPIECE EXTERNAL TO THE PATIENT TO ELIMINATE THE RISK OF AIR OR GAS EMBOLISM AS WELL AS ANY FALSE READINGS. The Minerva RF Controller screen will display the progress of the test (Step 12.3.9). After the test image disappears, it is safe to insert the Minerva Disposable Handpiece.
- The Minerva Endometrial Ablation System may interfere with normal functions of some types of implanted pacemakers or implanted cardioverters/defibrillators. The Minerva System should not be used with patients who have pacemakers or other electrical implants. Check if the patient has pacemaker or implanted cardioverter/defibrillator prior to use. Consult the cardio-rhythm device manufacturer for information about the effects of RF energy on these devices.
- Care should be taken to ensure the patient does not contact metal parts which are earthed or which have an appreciable capacitance to earth, such as direct contact with the metal on tables.
- DANGER: EXPLOSION HAZARD. Do not use in the presence of a flammable anesthetic mixture. Do not use in the presence of flammable gases or liquids.
- Failure of the Minerva RF Controller could result in an unintended increase in output power.
- Do not use the Minerva System near or in a magnetic resonance (MR) environment.

6.4 **Cautions**

- A false passage can occur during any procedure in which the uterus is instrumented, especially in cases of a severe anteverted retroflexed or a laterally displaced uterus. Use caution to ensure that the Minerva Disposable Handpiece is properly positioned in the uterine cavity.
- Patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have a progestin included in their medication regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- The safety and effectiveness of the Minerva System has not been fully evaluated in patients with:
    - with a uterine sound measurement greater than 10 cm;
    - with submucosal fibroids that distort the uterine cavity;
    - with bicornuate, septate or sub-septate uteri;
    - with medical (e.g., GnRH agonist) or surgical pretreatment; or
    - who have undergone a previous endometrial ablation including the Minerva endometrial ablation procedure.
- The Minerva System consists of the following components:
    - Single-patient use Minerva Disposable Handpiece with connecting cord and desiccant
    - Minerva RF Controller with footswitch and power cord
    - Minerva CO_2 canister
    - Minerva argon canister
- To ensure proper operation, never use other components with the Minerva System. Inspect the components regularly for damage, and do not use them if damage is apparent. The use of any cables or accessories other than those specified in these instructions may result in increased emissions or decreased immunity of the Minerva RF Controller.

- The Minerva Disposable Handpiece should only be used by physicians trained in the use of the Minerva Disposable Handpiece.
- The Minerva Disposable Handpiece must be used only in conjunction with the Minerva RF Controller. No other handpieces can be used with the Minerva RF Controller.
- Patients must be informed of the risks and possible adverse events associated with the endometrial ablation procedure and use of the Minerva Endometrial Ablation System.
- The user should inspect the Minerva Disposable Handpiece for damage prior to use.
- The Minerva Desiccant is non-sterile, and the packaging should not be placed in the sterile field.
- Do not use the Minerva Desiccant if desiccant material is pink in color.
- The Minerva Disposable Handpiece must be external to (outside of) the patient before plugging the connecting cord into the appropriate port on the front panel of the Minerva RF Controller (Step 12.3.9).
- Do not use the Minerva Endometrial Ablation System in presence of volatile solvents or flammable anesthetics.
- In the event of a Minerva RF Controller failure, disconnect the Minerva Disposable Handpiece, use the ON/OFF Switch, or unplug the power cord to stop Argon and CO_2 flow, and RF energy delivery.
- Do not operate unit in a moist environment, as a shock hazard may exist. If liquids have entered the unit, the Minerva RF Controller must be returned to the manufacturer for testing prior to use.
- Interference produced by the operation of high-frequency equipment, such as the Minerva RF Controller, may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems. If electromagnetic interference with other equipment is suspected, reorient the Minerva Disposable Handpiece or remove possible sources of interference (e.g., cellular phones, radios, etc.) from the room.
- It is recommended that any monitoring equipment or leads be placed as far as possible from the Plasma Formation Array when high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient. Needle monitoring electrodes are not recommended. Monitoring systems incorporating high frequency current-limiting devices are recommended for use.
- Do not use the Minerva Disposable Handpiece if wires are exposed as this increases the risk of an electrical shock or fire.
- Failure of the Minerva Endometrial Ablation System equipment could result in an unintended increase of output power.
- Use of accessories and cables, other than those specified for the Minerva Endometrial Ablation System, may result in increased emissions or decreased immunity of the system.
- Use only the hospital grade power cord and Minerva Footswitch supplied with the Minerva RF Controller.
- Removing screws and opening of the Minerva RF Controller will invalidate the warranty.
- The Minerva RF Controller contains no user serviceable parts. Return to manufacturer for repairs.
- Do not restrict the openings on the Minerva RF Controller enclosure, as they provide the required airflow for cooling.
- The patient should not come into contact with earthed metal parts or parts with appreciable capacitance to earth. The use of antistatic sheeting is recommended.
- Position the Minerva Disposable Handpiece connecting cord such that contact with patient or other electrical leads is avoided.
- Position the Minerva RF Controller on a flat surface for clinical use.

- Care should be taken not to damage the silicone membrane of the Plasma Formation Array during preparation and use.
- Careful measuring of the uterus is important for safe and proper Minerva Disposable length setting to prevent thermal injury to the endocervical canal.
- If during the ablation cycle the cervical balloon does not adequately seal the cervical canal, unintended thermal damage to the endocervical canal may occur as a result of hot fluid leaking from the uterine cavity into the canal. Use clinical judgment to continue with the ablation procedure if such a leak is suspected.
- During the ablation cycle, ensure the connection tubing is not kinked or twisted which could reduce the flow of argon gas and reduce the effect of ablation.
- During ablation, do not unlock the Minerva Disposable Handpiece handle or retract or remove the Minerva Disposable Handpiece.
- The Minerva RF Controller is for use without a neutral electrode.
- Use non-flammable agents for cleaning and disinfecting wherever possible.
- Flammable agents used for cleaning, disinfecting, or as solvents of adhesives should be allowed to evaporate before application of RF energy.
- Flammable solutions can pool under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Fluids pooled in the body depressions and cavities should be evacuated before the Minerva RF Controller is used.
- Endogenous gases (e.g., cotton and gauze saturated with oxygen) may be ignited by sparks produced during normal use of the Minerva RF Controller.
- Do not position the Minerva RF Controller such that it is difficult to connect/disconnect the Minerva Disposable Handpiece connector.
- To avoid risk of electric shock, the Minerva RF Controller must only be connected to a mains supply with protective earth.
- Do not modify the Minerva RF Controller without authorization from Minerva Surgical.
- The Minerva RF Controller needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in section 21.0.
- The use of Portable and Mobile RF Communications Equipment can affect the Minerva RF Controller.
- The Minerva RF Controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Minerva RF Controller should be observed to verify normal operation in the configuration in which it will be used.
- The power cord connection to the Minerva RF Controller provides a means of isolation. The Minerva RF Controller should be positioned so as to provide easy access to the power cord connection in the event that the unit must be quickly unplugged.

7.0 MINERVA CLINICAL DATA

The Minerva Endometrial Ablation System was evaluated in two clinical studies, the Minerva Single-Arm Study and the Minerva Randomized Clinical Trial (RCT).

The Minerva Single-Arm Study was a prospective, multi-center, single-arm, international clinical study of 110 patients with menorrhagia. Adverse events were reported from the time of procedure through the 12-month follow-up study period. Two- and three-year safety and effectiveness outcomes are being collected for this study. Device labeling will be updated when these data become available.

Additional adverse event information is available from an ongoing RCT evaluating the Minerva Endometrial Ablation System. The RCT is a prospective, controlled, randomized, multicenter, safety and effectiveness clinical study of 153 subjects (102 Minerva and 51 Rollerball) with menorrhagia. One month follow-up data are currently available. One-, two- and three-year safety and effectiveness

outcomes are being collected for this study. Device labeling will be updated when these data become available.

Table 1 shows the number and percent of patients in each study who reported specific endometrial ablation-related adverse events and symptoms (one or more times) up to 12 months post-procedure (up to 30 Days post-procedure in the RCT).

Table 1: Number and Percent of Patients with One or More Related* Adverse Events and Symptoms by Time of Occurrence

Adverse Event/Symptom	Minerva Single-Arm Study	Minerva Randomized Study	
	Minerva (n=110)	Minerva (n=102)	Rollerball (n=51)
Intra-operative Adverse Events			
Skin Rash and/or Itching or Burning Sensation	0 (0.0%)**	1 (1.0%)	0 (0.0%)
Post-operative Adverse Events (< 24 hours) * **			
Pelvic Cramping	64 (58.2%)	51 (50.0%)	23 (45.1%)
Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation	15 (13.6%)	32 (31.4%)	16 (31.4%)
Bleeding or Spotting	8 (7.3%)	39 (38.2%)	15 (29.4%)
Nausea and/or Vomiting	17 (15.5%)	17 (16.7%)	7 (13.7%)
Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness	6 (5.5%)	5 (4.9%)	1 (2.0%)
Abdominal Pain and/or Bloating	10 (9.1%)	0 (0.0%)	0 (0.0%)
Circulatory Symptoms	4 (3.6%)	5 (4.9%)	3 (5.9%)
Headache	4 (3.6%)	0 (0.0%)	2 (3.9%)
Backache	3 (2.7%)	1 (1.0%)	0 (0.0%)
Fever	0 (0.0%)	1 (1.0%)	0 (0.0%)
Agitation	0 (0.0%)	1 (1.0%)	2 (3.9%)
Vulvar Pruritus	0 (0.0%)	1 (1.0%)	0 (0.0%)
Urinary Disturbance	0 (0.0%)	1 (1.0%)	1 (2.0%)
Post-operative Adverse Events (≥ 24 hours – 2 Weeks) * **			
Pelvic Cramping	12 (10.9%)	0 (0.0%)	0 (0.0%)
Abdominal Pain and/or Bloating	1 (0.9%)	3 (2.9%)	1 (2.0%)
Nausea and/or Vomiting	1 (0.9%)	0 (0.0%)	1 (2.0%)
Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation	0 (0.0%)	1 (1.0%)	0 (0.0%)
Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness	0 (0.0%)	1 (1.0%)	1 (2.0%)
Circulatory Symptoms	1 (0.9%)	0 (0.0%)	0 (0.0%)
Constipation	1 (0.9%)	0 (0.0%)	1 (2.0%)
Pelvic Inflammatory Disease	1 (0.9%)	0 (0.0%)	0 (0.0%)
Fever	1 (0.9%)	0 (0.0%)	0 (0.0%)
Endometritis or Endomyometritis	0 (0.0%)	1 (1.0%)	2 (3.9%)
Skin Rash and/or Itching or Burning Sensation	0 (0.0%)	1 (1.0%)	1 (2.0%)
Post-operative Adverse Events	**>2 Weeks – 1 Year**	**>2 Weeks – 4 Weeks†**	
Abdominal Pain and/or Bloating	0 (0.0%)	0 (0.0%)	1 (2.0%)

* Possibly, probably, or highly probably related to Device or Procedure

** Percent of patients who reported specific endometrial ablation-related adverse events and symptoms*** Ten patients in the Single-Arm Study and two patients in the RCT reported the same AE at the < 24 hours and the 24 hours – 2 Weeks visits
† SAE (PID) occurred in one Minerva subject at 34 days

Table 2 shows the frequency (number of occurrences) of endometrial ablation-related adverse events and symptoms reported during the 12-month follow-up period (up to 30 Days post-procedure in the RCT). As an example, if the same patient reported two episodes of cramping, the table would reflect two occurrences.

Table 2: Number of Occurrences of Related* Adverse Events and Symptoms

Adverse Event/Symptom	Minerva Single-Arm Study	Minerva Randomized Study	
	Minerva (n=110)	Minerva (n=102)	Rollerball (n=51)
Intra-operative Adverse Events			
Skin Rash and/or Itching or Burning Sensation	0	1	0
Post-operative Adverse Events (< 24 hours)			
Pelvic Cramping	64	51	23
Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation	16	32	16
Bleeding or Spotting	8	39	16
Nausea and/or Vomiting	21	19	8
Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness	7	6	2
Abdominal Pain and/or Bloating	10	0	0
Circulatory Symptoms	4	5	3
Backache	3	2	0
Headache	4	0	2
Fever	0	1	0
Agitation	0	1	2
Vulvar Pruritus	0	1	0
Urinary Disturbance	0	1	1
Post-operative Adverse Events (≥ 24 hours – 2 Weeks)			
Pelvic Cramping	12	0	0
Abdominal Pain and/or Bloating	1	3	1
Nausea and/or Vomiting	1	0	1
Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation	0	1	0
Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness	0	1	1
Circulatory Symptoms	1	0	0
Constipation	1	0	1
Pelvic Inflammatory Disease	1	0	0
Fever	1	0	0
Endometritis or Endomyometritis	0	1	2
Skin Rash and/or Itching or Burning Sensation	0	1	1
Post-operative Adverse Events	**>2 Weeks – 1 Year**	**>2 Weeks – 4 Weeks†**	
Abdominal Pain and/or Bloating	0	0	1

* Possibly, probably, or highly probably related to Device or Procedure

† SAE (PID) occurred in one Minerva subject at 34 days

7.1 Anticipated Post-Procedural Symptoms

For any endometrial ablation procedure, commonly reported postoperative events include the following:

- Postoperative cramping can range from mild to severe. This cramping will typically last a few hours and rarely continues beyond the first day following the procedure.
- When present, nausea and vomiting typically occur immediately following the procedure, are associated with anesthesia and can be managed with medication.
- Vaginal discharge
- Vaginal bleeding/spotting

7.2 Other Adverse Events

As with all endometrial ablation procedures, serious injury or death can occur.
The following adverse events could occur or have been reported in association with the use of other endometrial ablation systems and may occur when the Minerva system is used:

- Post-ablation tubal sterilization syndrome
- Pregnancy-related complications
  NOTE: Pregnancy following endometrial ablation is very dangerous for both the mother and the fetus.
- Thermal injury to adjacent tissue, including bowl, bladder, cervix, vagina, vulva and/or perineum
- Perforation of the uterine wall
- Hemorrhage
- Hematometra
- Difficulty with defecation or micturition
- Uterine necrosis
- Air or gas embolism
- Infection or sepsis
- Complications leading to serious injury or death

8.0 MINERVA CLINICAL STUDIES SUMMARY

The Minerva Endometrial Ablation System was evaluated in two clinical studies, the Minerva Single-Arm Study and the Minerva RCT.

8.1 Minerva Single-Arm Clinical Study

The Minerva Single-Arm Study was a prospective, multi-center, single-arm, international clinical study of 110 patients with menorrhagia. Adverse events were reported from the time of procedure through the 12-month follow-up study period. Two- and three-year safety and effectiveness outcomes are being collected for this study. Device labeling will be updated when these data become available.

8.1.1 Purpose

The safety and effectiveness of the Minerva Endometrial Ablation System was evaluated in premenopausal women who had completed childbearing and were suffering from menorrhagia secondary to benign causes.

8.1.2 Study Endpoints

The primary effectiveness measure was a validated menstrual diary scoring system developed by Higham (Higham JM, O'Brien PMS, Shaw RW *Br J Obstet Gynaecol*

1990; 97:734-9). Assessment of menstrual blood loss was performed using a pictorial blood loss assessment chart (PBLAC). Patient success was defined as a reduction in menstrual diary score from ≥150 pre-treatment to ≤ 75 at 12 months post-procedure.

Study success was based on a comparison between the Minerva Endometrial Ablation System and an Objective Performance Criterion (OPC). The OPC is 66% based on the lower bound of the 95% confidence interval of the average success rate for the five approved global endometrial ablation (GEA) devices.

The primary safety measure was based on the adverse events reported during the study.

Secondary endpoints included amenorrhea, anesthesia regimen, length of procedure (Minerva Disposable Handpiece insertion to Minerva Disposable Handpiece removal) and responses from a patient satisfaction questionnaire.

8.1.3 Methods

A prospective, multi-center, single-arm, international clinical study was conducted at seven clinical sites and included 110 patients diagnosed with menorrhagia. Menstrual diary scores were collected pre-operatively and monthly for 12 months post-procedure. Patients were treated at any time in their menstrual cycle. Patients received no endometrial pretreatment (e.g., hormone, dilation and curettage, or cycle timing).

Study subjects were required to meet the following key patient selection criteria:

Inclusion Criteria:

- Refractory menorrhagia with no definable organic cause
- Female subject from age 25 to 50 years
- Uterine sound measurement of 6.0cm to 10.0cm (external os to internal fundus)
- One of the following criteria:
  - Documented history of menorrhagia secondary to dysfunctional uterine bleeding (DUB).
  - If a pictorial blood loss assessment chart (PBLAC) scoring systems is used, a minimum PBLAC score of ≥150 for 1 month prior to study enrollment.
- Premenopausal at enrollment as determined by FSH measurement ≤ 40 mIU/ml
- Not pregnant and no desire to be pregnant in the future
- Patient agrees not to use hormonal contraception or any other medical intervention for bleeding during the study
- Able to provide written informed consent using a form that has been approved by the reviewing IRB/EC
- Subject agrees to follow-up exams and data collection, including ability to accurately use menstrual diaries for PBLAC analysis
- Subject demonstrates an understanding on how to use menstrual diaries.

Exclusion Criteria:

- Pregnancy or subject with a desire to conceive
- Endometrial hyperplasia as confirmed by histology
- Presence of active endometritis
- Active pelvic inflammatory disease
- Active sexually transmitted disease (STD), at the time of ablation
  Note: Treatment of STD documented in the chart serves as sufficient evidence of infection resolution. Patient may be considered for study enrollment.

- Presence of bacteremia, sepsis, or other active systemic infection
- Active infection of the genitals, vagina, cervix, uterus or urinary tract at the time of the procedure
- Known/suspected gynecological malignancy within the past 5 years
- Known clotting defects or bleeding disorders
- Untreated/unevaluated cervical dysplasia (except CIN I)
- Known/suspected abdominal/pelvic cancer
- Prior uterine surgery (except low segment cesarean section) that interrupts the integrity of the uterine wall (e.g., myomectomy or classical cesarean section)
- Previous endometrial ablation procedure
- Currently on medications that could thin the myometrial muscle, such as long-term steroid use (except inhaler or nasal therapy for asthma)
- Currently on anticoagulants
- Abnormal or obstructed cavity as confirmed by hysteroscopy or saline infusion sonohysterography (SIS), specifically:
  - Septate or bicornuate uterus or other congenital malformation of the uterine cavity
  - Pedunculated or submucosal myomas distorting the uterine cavity
  - Polyps likely to be the cause of the subject's menorrhagia
  - Intramural or subserosal myomas that distort the uterine cavity
- Presence of an intrauterine device (IUD) which the patient is unwilling to have removed at the time of the operative visit
- Presence of an implantable contraceptive device (e.g., Essure® or Adiana®).
- Subject currently on hormonal birth control therapy or unwilling to use a non-hormonal birth control post-ablation (including a Mirena® device).
- Subject who is within 6-weeks post-partum.
- Any general health condition which, in the opinion of the Investigator, could represent an increased risk for the subject
- Any subject who is currently participating or considers future participation in any other research of an investigational drug or device.

8.1.4 Patient Population

A total of 110 patients were enrolled in this study. Patients were between the ages of 25 to 50, with 35.5% under or at the age of 40, and 64.5% 41 years of age or older. There were no statistical differences in demographic or gynecological history parameters between the age groupings or among the seven investigational sites. **Table 3** describes the accountability of subjects throughout the study period.

Table 3: Patient Accountability

	TOTAL
Intent to Treat Population	110
Enrolled but not Treated • Failed Inclusion/Exclusion Screening	5
Aborted Treatment	1
Complete Treatments	**104**
Population with 12-Month Data Available	**104**

Demographics and Gynecologic History

Table 4 presents the baseline demographic and gynecologic history parameters for the Intent-to-Treat Population (all enrolled subjects).

Table 4: Baseline Demographics and Gynecological History

Subject Characteristic	Total Subjects (N=110)
Age (yrs)	
Mean ± SD (Median)	42.0 ± 5.3 (43.2)
Range (min, max)	(29.3, 49.7)
Race/Ethnicity	
Hispanic**	23.6% (26)
Asian	0.9% (1)
Caucasian	75.5% (83)
African American	0% (0)
Body Mass Index (BMI) (Kg/m^2)	
Mean ± SD (Median)	28.2 ± 5.8 (27.3)
Range (min, max)	(18.0, 57.3)
Reproductive History	
Gravida	
Mean ± SD (Median)	2.8 ± 1.4 (3.0)
Range (min, max)	(0, 6)
Para	
Mean ± SD (Median)	2.3 ± 1.0 (2.0)
Range (min, max)	(0, 5)
Menstrual History	
Regular Cycle Pattern	86.4% (95)
Dysmenorrhea	59.1% (65)
PMS	72.7% (80)
PBLAC Score at baseline	
Mean ±SD (Median)	469.4 ± 337.2 (381.4)
Range (min, max)	(151.1, 2048.0)
Laboratory Testing	
FSH (IU/L)	
Mean ±SD (Median)	8.0 ± 7.2 (6.0)
Range (min, max)	(0.4, 38.0)

** Note: Hispanic is not a race; however, it is listed as such in the database to provide information on ethnicity of this subject population.

8.1.5 Results

Primary Effectiveness Endpoint: Bleeding Score

Patient success at 12 months post-procedure is defined as a reduction in the PBLAC diary score from ≥150 pre-operatively to ≤75 post-procedure. Amenorrhea is defined as a score of 0. Data presented in **Table 5** represent the clinical results based on the total number of 110 patients enrolled (Intent-to-Treat group (ITT)) in the study. The worst-case scenario is presented whereby each of the discontinued patients (five screening failures and one aborted procedure described in **Table 3** for patient accountability) are counted as a "failures" for calculating the values listed in the table.

Table 5: Effectiveness: Success and Amenorrhea Rates (Intent-To-Treat Patients)

	12-Mo Follow-Up (N=110)	
	n	**%**
Success (PBLAC ≤ 75)	101/110	91.8
Amenorrhea (PBLAC = 0)	73/110	66.4

The purpose of the primary effectiveness analysis was to determine if the true Minerva success rate is greater than the OPC of 66%. The null hypothesis was that the Minerva success rate was equal to or less than the OPC of 66%. Based on the success rate of 91.8% observed in the Minerva ITT population, the null hypothesis was rejected at the significance level of 5%, and the 12-month follow-up success rate observed with the Minerva Endometrial Ablation System was demonstrated to be statistically significantly greater than the OPC of 66% (p-value <0.0001).

Safety Endpoint
Adverse event information is described above in the "Adverse Events" section of this manual (Section 7.0, Table 1 and Table 2).

Secondary Effectiveness Endpoint: Patient Satisfaction
Patient satisfaction with the Minerva procedure was assessed and at 12 months of follow-up, out of those subjects who have responded to the survey, 97.6% (81/83) of patients were satisfied or very satisfied with the Minerva procedure. In addition, during the same follow-up interval 98.8% (82/83) of patients stated that they would recommend the procedure to a friend or a relative with the remaining 1.2% (1/83) reporting "Not Sure."

Pre-menstrual symptoms and dysmenorrhea were evaluated at baseline and following the Minerva procedure. At the 12 months follow-up interval, reduction in pre-menstrual symptoms was reported by 80.8% (84/104) of subjects and 54.8% (57/104) of study subjects who were treated reported reduction in dysmenorrhea.

Secondary Endpoint: Procedure Time
Procedure time was determined for each patient by recording the time from insertion of the Minerva Disposable Handpiece to the time of removal. The mean procedure time was determined to be 3.9 ± 1.5 minutes.

Secondary Endpoint: Anesthesia Regimen
Anesthesia regimen was not dictated by the clinical protocol and was left to the discretion of each patient, clinical investigator, and attending anesthesiologist. Anesthesia regimen was also largely driven by the currently adopted guidelines specific to each medical facility/site. Anesthesia regimens used in the study are summarized in **Table 6**.

Table 6: Anesthesia Regimen (N=110)

Anesthesia Type	Total Subjects (N=110) % (N)
General	9.1% (10)

IV Sedation	11.8% (13)
Paracervical Block	9.1% (10)
IV Sedation/Paracervical Block	57.3% (63)
IV Sedation/Paracervical Block/ Other	12.7% (14)

8.1.6 Clinical Observations

Hysterectomy

During the 12-month follow-up period, there were no reported hysterectomies and/or any other medical/surgical interventions to control bleeding.

8.2 Minerva Randomized Clinical Trial (RCT) Summary

The Minerva Endometrial Ablation System is being evaluated in a prospective, controlled, randomized, multicenter, safety and effectiveness clinical study of 153 enrolled subjects with abnormal uterine bleeding (102 Minerva and 51 Rollerball) with menorrhagia. One month follow-up data are currently available. One-, two- and three-year safety and effectiveness outcomes are being collected for this study. Device labeling will be updated when these data become available.

The eligibility criteria (i.e., inclusion and exclusion criteria) for the Minerva RCT are similar to those for the Minerva Single-Arm study with a few exceptions (e.g., bleeding is assessed using the alkaline hematin method instead of PBLAC scores).

8.2.1 Study Objectives

The primary objective was to evaluate the safety and effectiveness of the Minerva Endometrial Ablation System compared to rollerball ablation in reducing menstrual blood loss at 12 months post-treatment. An additional objective was to identify complications or adverse events that may occur in the subjects treated in this study. Subjects were randomized 2:1 to the Minerva Endometrial Ablation Device or the rollerball ablation control arm, respectively. The two treatments were compared in a group of pre-menopausal women with menorrhagia (excessive uterine bleeding) from benign causes who no longer wished to retain fertility.

8.2.2 Study Design

The study was designed as a prospective, randomized (2:1), controlled, international, multicenter (13 sites) clinical investigation. The safety and effectiveness population consists of 153 enrolled subjects.

The primary effectiveness measure was a validated alkaline hematin method of measuring blood loss, assessing collected validated sanitary products (G.F. Ray, P. Burnett, D. Dadgar. Rapid quantitation of menstrual blood loss from feminine hygiene products. *Fertility and Sterility*, Volume 96, Issue 3, Supplement, Pages S281–S282, September 2011). Success was defined as a reduction in menstrual bleeding at 12 months to an alkaline hematin value of ≤80ml per cycle. Secondary endpoints included comparison of procedure time, patient satisfaction (as recorded by patient self-report), and amenorrhea rates between the two groups. Safety evaluation was based on the adverse events reported during the study, including device-related complications.

8.2.3 Demographics and Gynecologic History

Table 7 presents the baseline demographic and gynecologic history parameters for the ITT population.

Table 7: Patient Demographics and Gynecologic History

Subject Characteristic	Minerva (n=102)	Rollerball (n=51)	p-value
Age (Years)			
Mean ± SD (Median)	42.6 ± 4.2 (42.9)	42.5 ± 4.7 (43.1)	0.97
Range (Min - Max)	31.6 – 50.1	32.3 - 49.3	
Race			
American Indian or Alaskan Native	1 (1.0 %)	0 (0.0 %)	1.00
Black or African American	3 (2.9 %)	2 (3.9 %)	
White	98 (96.1 %)	49 (96.1 %)	
Ethnicity			
Hispanic or Latino	30 (29.4 %)	15 (29.4 %)	1.00
Not Hispanic or Latino	72 (70.6 %)	36 (70.6 %)	
Body Mass Index (BMI) (kg/m^2)			
Mean ± SD (Median)	30.0 ± 7.1 (29.7)	28.8 ± 5.3 (28.6)	0.28
Range (Min - Max)	16.6 – 52.1	19.8 - 40.6	
Reproductive History			
Gravida			
Mean ± SD (Median)	3.1 ± 1.7 (3)	3.3 ± 1.5 (3)	0.65
Range (Min - Max)	0.0 – 10.0	0.0 - 7.0	
Para			
Mean ± SD (Median)	2.6 ± 1.3 (3)	2.5 ± 1.2 (2)	0.65
Range (Min - Max)	0.0 - 9.0	0.0 - 6.0	
Menstrual History			
Regular Cycle Pattern	97 (95.1 %)	48 (94.1 %)	1.00
Dysmenorrhea	57 (55.9 %)	32 (62.7 %)	0.49
PMS	66 (64.7 %)	35 (68.6 %)	0.72
Alkaline Hematin Score at Baseline			
Mean ± SD (Median)	310.2 ± 169.0 (247.5)	301.8 ± 176.1 (249.0)	0.78
Range (Min - Max)	161.5 – 1120.0	160.0 – 1026.1	
Laboratory Results - FSH (IU/L)			
Mean ± SD (Median)	7.5 ± 5.5 (6.0)	8.0 ± 6.3 (6.0)	0.60
Range (Min - Max)	1.0 – 30.0	2.0 – 35.3	

8.2.4 Interim Safety Results: Adverse Events

The related adverse events (AEs) reported in both the Single-Arm study and the RCT to date are shown in Tables 1 and 2 above in Section 7.0.

8.2.5 Secondary Endpoint: Procedure Time

Procedure time was determined for each subject by recording the time of device insertion and the time of device removal. The mean procedure time for the Minerva procedure (3.1 $\pm$ 0.5 minutes) was statistically significantly less than the procedure time for the rollerball ablation procedure (17.2 $\pm$ 6.7 minutes).

8.2.6 Secondary Endpoint: Anesthesia

The anesthesia regimen was not dictated by the clinical protocol and was left to the discretion of each patient, clinical investigator and attending anesthesiologist. The type of anesthesia used in the Minerva procedure was nearly identical to the anesthesia regimen in the rollerball ablation procedure.

8.2.7 Secondary Endpoint: Cervical Dilation

The mean cervical dilation for the Minerva procedure (6.8 ± 1.1mm) was statistically significantly less than the cervical dilation used for the rollerball ablation procedure (9.3 ± 1.5 mm).

9.0 PATIENT SELECTION

Menorrhagia can be caused by a variety of underlying problems, including, but not limited to; endometrial cancer, myomas, polyps, drugs and dysfunctional uterine bleeding (anovulatory bleeding). Patients always should be screened and evaluated to determine the cause of excessive uterine bleeding before any treatment option is initiated. Consult medical literature relative to various endometrial ablation techniques, indications, contraindications, complications and hazards prior to the performance of any endometrial ablation procedure.

Patients with abnormal or obstructed uterine cavities were excluded from the clinical studies of the Minerva System. The risk of uterine perforation and serious complications (e.g., bowel injury) during endometrial ablation is likely increased in such patients.

10.0 PATIENT COUNSELING

As with any procedure, the physician needs to discuss risks, benefits and alternatives with the patient prior to performing endometrial ablation. Patient's expectations should be set in a way that the patient understands that the aim of the treatment is the reduction in bleeding to normal levels.

The Minerva Endometrial Ablation System is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following the procedure. Patients of childbearing capacity should be cautioned of potential complications, which may ensue if they should become pregnant. This counseling should include the need for post-procedure contraception where indicated. This procedure is not a sterilization procedure and subsequent pregnancies may be dangerous for the mother and fetus.

Vaginal discharge is typically experienced during the first few weeks following ablation and may last as long as a month. Generally, the discharge is described as bloody during the first few days; serosanguineous by approximately one week; then profuse and watery thereafter. Any unusual or foul-smelling discharge should be reported to the physician immediately. Other common post-procedural complications include cramping/pelvic pain, nausea and vomiting.

Uterine perforation should be considered in the differential diagnosis of any post-operative patient complaining of acute abdominal pain, fever, shortness of breath, dizziness, hypotension or any other symptom that may be associated with uterine perforation with or without damage to the adjacent organs of the abdominal cavity. Patients should be counseled that any such symptoms should be immediately reported to their physician.

11.0 PRETREATMENT PREPARATION OF PATIENT

The Minerva Endometrial Ablation System successfully treats a uterine cavity over a range of endometrium thickness. The lining of the uterus does not have to be thinned prior to the procedure, and the procedure may be performed during either the proliferative or the secretory phase of the cycle. The safety and effectiveness of the Minerva Endometrial Ablation System has not been fully and specifically evaluated in patients with medical or surgical pretreatment.

Active bleeding was not found to be a limiting factor when using the Minerva Endometrial Ablation System. It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least

one hour prior to treatment and continued postoperatively to reduce intra-operative and post-operative uterine cramping.

12.0 SET-UP

12.1 Required items

The following items are required when using the Minerva Endometrial Ablation System:

- One sterile Minerva Disposable Handpiece (with Desiccant)
- One Minerva RF Controller (with Footswitch and Power Cord)
- One Argon Canister
- One CO_2 Canister

12.2 Patient Preparation

12.2.1 Prepare the patient for the anesthesia.
12.2.2 Place patient in dorsal lithotomy position.
12.2.3 Induce anesthesia according to standard practice.
12.2.4 Perform bimanual examination. Evaluate for severe ante-version or retro-version of the uterus.
12.2.5 Prepare and drape patient similar to prep for D&C.
12.2.6 Insert a speculum into the vagina.
12.2.7 Grasp the cervix with a tenaculum.
12.2.8 Take a sound measurement of the uterus to measure the length from fundus to external cervical os.

WARNING: The efficacy of the Minerva Endometrial Ablation System has not been evaluated in patients with a uterine sound measurement greater than 10 cm.

12.2.9 Determine the length of the cervical canal and dilate cervical canal to 7.0 mm.

Optional diagnostic hysteroscopy using normal saline or Ringers Lactate for distention media can be performed at this time.

12.2.10 Using the uterine sound and cervical canal measurements, consult the cavity length table (**Table 8**) to obtain the appropriate PFA length setting. Numbers marked with an asterisk represent adjusted dimensions that should reflect the Minerva Disposable Handpiece PFA length setting and while not observed in the clinical study, may be associated with a higher rate of failure to pass the uterine integrity test. Correct determination of the cavity length is important for safe and effective treatment. Overestimating the cavity length may result in thermal injury to the endocervical canal.

WARNING: Use caution not to perforate the uterine wall when sounding, dilating or inserting the Minerva Disposable Handpiece.

Table 8: Cavity Length Table

Cervical Canal Length (cm)	Uterine Sound Length (cm)										
	10	**9.5**	**9**	**8.5**	**8**	**7.5**	**7**	**6.5**	**6**	**5.5**	**5**
1	**Do Not Treat**			6.5*	6.5*	6.5	6	5.5	5	4.5	4
1.5			6.5*	6.5*	6.5	6	5.5	5	4.5	4	
2		6.5*	6.5*	6.5	6	5.5	5	4.5	4		
2.5	6.5*	6.5*	6.5	6	5.5	5	4.5	4			
3	6.5*	6.5	6	5.5	5	4.5	4				
3.5	6.5	6	5.5	5	4.5	4					
4	6	5.5	5	4.5	4						
4.5	5.5	5	4.5	4			**Do Not Treat**				
5	5	4.5	4								
5.5	4.5	4									
6	4										

* The value of 6.5 where indicated with an asterisk is not intended to reflect the numerical difference between the sound length and the length of the cervical canal. The value 6.5* is entered because it represents the maximum length to which the Minerva Disposable Handpiece Array can be extended.

CONTRAINDICATION: Do not treat a patient with a uterine cavity length that is less than 4 cm, as cervical canal damage may occur.

12.3 **Minerva Disposable Handpiece and Minerva RF Controller Preparation Procedure**

12.3.1 Open the sterile Minerva Disposable Handpiece package. Place the Minerva Disposable Handpiece, with the connecting cord and the syringe into the sterile field while being careful to keep the non-sterile suction line desiccant box out of the sterile field.

WARNING: Do not use the sterile single-patient use Minerva Disposable Handpiece if the packaging appears to be damaged or there is evidence of tampering.

CAUTION: Minerva Disposable Handpiece must be external to (outside of) the patient while performing all steps in section 12.3 and steps 13.1 through 13.5 in section 13.

12.3.2 Open the non-sterile suction line desiccant box and pouch. Remove the two end caps.

CAUTION: The argon return line desiccant contents are non-sterile and its packaging should not be placed in the sterile field.

CAUTION: If the argon return line desiccant is pink, replace it prior to initiating the ablation procedure.

12.3.3 Connect the desiccant to the two ports on the tubing of Minerva Disposable Handpiece (**Figure 6**). When properly connected you will feel or hear a click.

Figure 6: Desiccant Connection

12.3.4 Using the toggle switch on the back of the unit, turn on the Minerva RF Controller. **Figure 7** will appear on the touch screen display for 5 seconds.

Figure 7: Initial Screen

12.3.5 Adjust volume according to your preference.

12.3.6 Confirm your adequate familiarity with the Minerva Endometrial Ablation System Operator's Manual / Instructions for Use by pressing the green check mark on the touch screen display (**Figure 8**).

Figure 8: Confirmation Request Screen

12.3.7 Upon confirmation, screen image will change to display the status of argon (Ar) and CO_2 canisters (**Figures 9-12**) to indicate if there is sufficient gas to complete the procedure. If either one or both canister icons appear red, remove and replace with a new canister(s) until both canister icons are green.

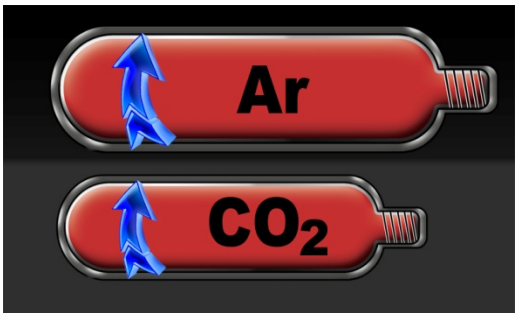


Figure 9: Replace Ar and CO_2

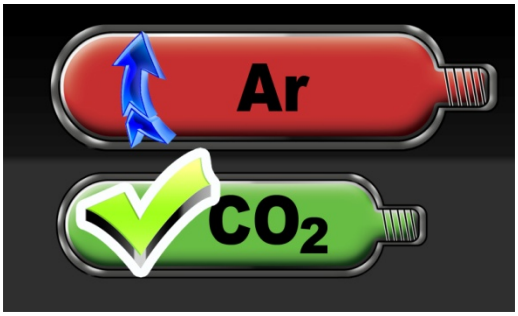


Figure 10: Replace Ar

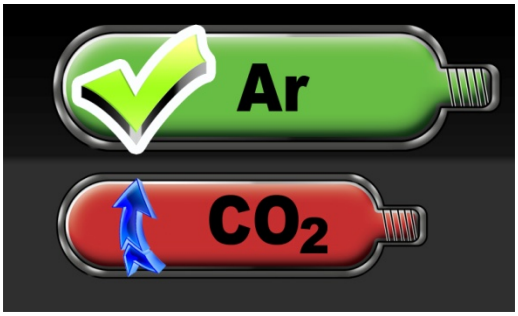


Figure11: Replace CO_2

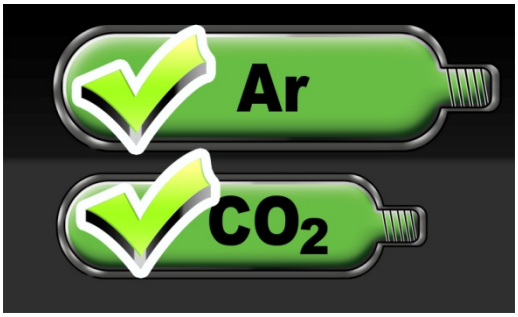


Figure 12: Sufficient Ar and CO_2

12.3.8 After both canister icons turn green, the screen will display the green canister status for 5 seconds after which the next screen (**Figure 13**) indicating that the Minerva Disposable Handpiece and Footswitch should be connected will appear.

Figure 13: Connect Minerva Disposable Handpiece and Footswitch

12.3.9 Connect the Minerva Disposable Handpiece connecting cord and foot-switch cord to the appropriate port on the front panel of the Minerva RF Controller. When connecting the Minerva Disposable Handpiece assure a snug fit such that the purple surface of the connector is not visible. When connecting the footswitch advance the black tubing over the nipple receptacle. At this time, the Minerva Disposable Handpiece test animation (**Figure 14**) will appear on the Minerva RF Controller touch screen display.

WARNING: Plugging the Minerva Disposable Handpiece into the Minerva RF Controller automatically starts a system test which takes approximately 7 seconds and must be performed with the Minerva Disposable Handpiece EXTERNAL to the patient.

CAUTION: Do not manipulate the Minerva Disposable Handpiece during the system test or test failure may result.

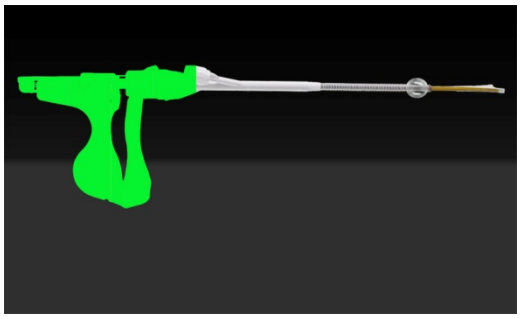


Figure 14: Minerva Disposable Handpiece Test

12.3.10 Successful completion of the tests will be reflected on the touch screen display (**Figure 15**).

Figure 15: Minerva Disposable Handpiece Test Successful

13.0 PROCEDURE

CAUTION: CO_2 continuously flows from the time that the Minerva Disposable Handpiece is plugged into the Minerva RF Controller until the Uterine Integrity Test portion of the procedure is complete.

WARNING: Use caution not to perforate the uterine wall when sounding, dilating or inserting the Minerva Disposable Handpiece.

13.1 **Using the uterine sound measurement and cervical canal measurements, consult the cavity length table as described in Step 12.2.10 above, to obtain the appropriate Plasma Formation Array length setting.**

CONTRAINDICATION: Do not treat a patient with a uterine cavity length that is less than 4 cm, as cervical canal damage may occur.

13.2 Adjust and lock the cavity length setting feature on the Minerva Disposable Handpiece (**Figure 16**) to the value obtained above (See step 12.2.10).

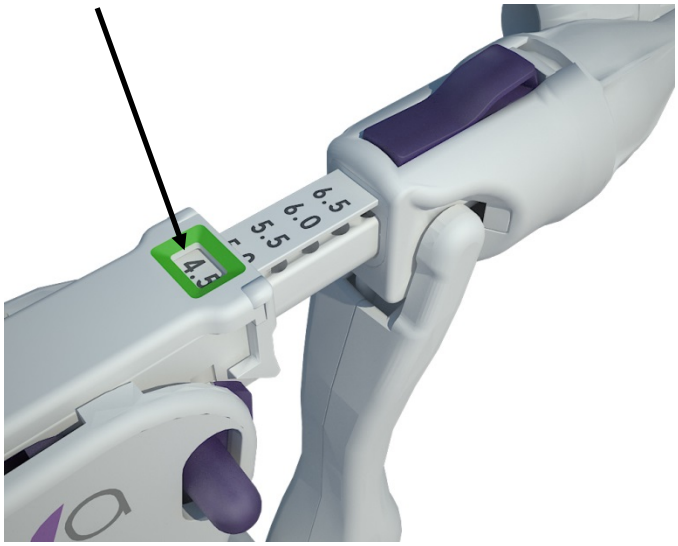


Figure 16: Minerva Disposable Handpiece PFA Length Setting Feature

13.3 Confirm that the cervix is dilated to at least 7.0 mm.
13.4 Maintain a slight traction on the tenaculum to minimize the angle of the uterus.
13.5 Press and hold the Green Button on the touch screen display (**Figure 17**) to draw vacuum on the PFA, thus minimizing the Minerva Disposable Handpiece tip insertion profile. The sheath of the Minerva Disposable Handpiece will not cover the PFA. Attempts to “sheath” the PFA will result in Minerva Disposable Handpiece damage.

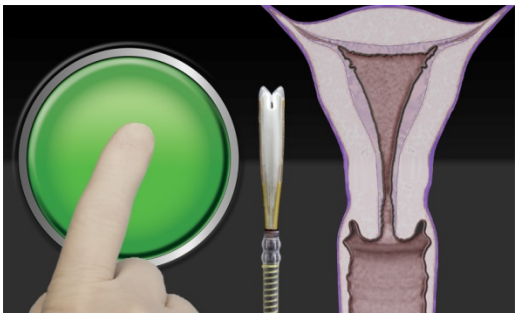


Figure 17: PFA Vacuum Button

13.6 Angle the Minerva Disposable Handpiece in-line with the axis of the uterus as the Minerva Disposable Handpiece is inserted transcervically into the uterine cavity and advance the Minerva Disposable Handpiece until the distal tip of the PFA touches the fundus. Release the Green button on touch screen display of the Minerva RF Controller.

WARNING: If the Minerva Disposable Handpiece is difficult to insert into the cervical canal, use clinical judgment to determine whether or not further dilation is required. Forcibly advancing the Minerva Disposable Handpiece against resistance is likely to increase the risk of perforation or creation of a false passage. Sufficient dilation is required for safe insertion.

13.7 The touch screen display will change to the Minerva Disposable Handpiece deployment screen (**Figure 18**) upon release of the Green Button, to reflect steps 13.7 – 13.10 described below.

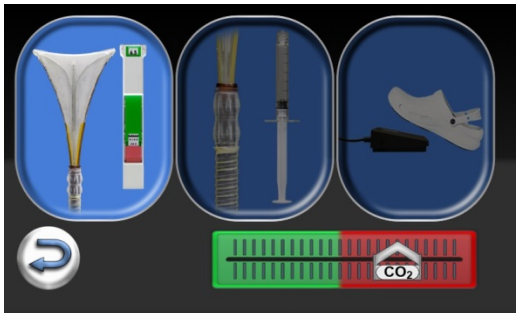


Figure 18: Minerva Disposable Handpiece Deployment

13.8 Maintain the distal tip of the PFA at the fundus. Slowly squeeze the Minerva Disposable Handpiece handle together while gently moving the Minerva Disposable Handpiece approximately 0.5 cm to and from the fundus until the Minerva Disposable Handpiece handle locks. DO NOT pull the deployed PFA back and away from the fundus. The Array Opening Indicator on the Minerva Disposable Handpiece should be in the Green zone (**Figure 19**).

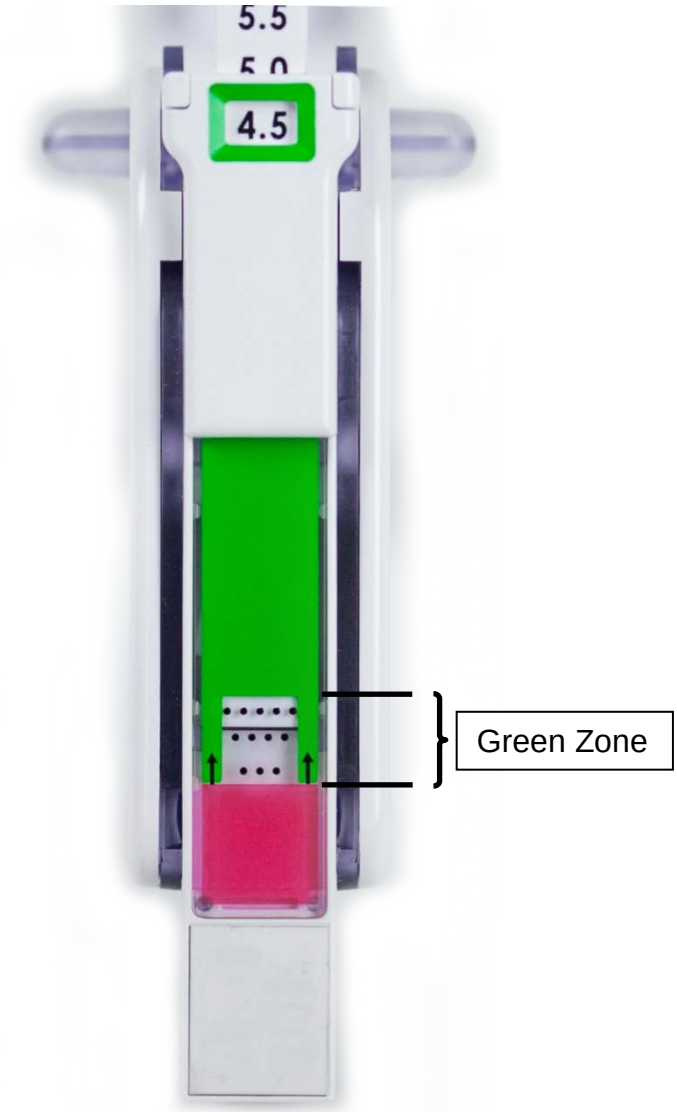


Figure 19: Array Opening Indicator Green Zone

NOTE: Once the Minerva Disposable Handpiece handle is locked, the uterus should move in conjunction with the Minerva Disposable Handpiece.

13.9 Gently move the Minerva Disposable Handpiece using anterior, posterior and lateral movements.

13.10 To complete placement, slightly pull back the Minerva Disposable Handpiece and then gently advance the Minerva Disposable Handpiece to the fundus. The Array Opening Black Indicator line on the Minerva Disposable Handpiece should now be in the Green Zone.

NOTE: The Black Indicator Line on the Array Opening Indicator displays the progression of the PFA deployment/opening and does not indicate a dimension of the uterus.

CONTRAINDICATION: Do not treat a patient if Array Opening Indicator is in the Red Zone following deployment of the Minerva Disposable Handpiece.

13.11 After connecting the sterile syringe (provided) to the inflation port on the sheath (**Figure 20**), fully inflate the Cervical Sealing Balloon to seal the uterine cavity. Exercise caution not to damage the Cervical Sealing Balloon by over inflating and/or causing mechanical damage by use of other instruments. The position of the CO_2 arrow icon along the red-green scale near the bottom of the touch screen display indicates the likelihood of passing or failing the subsequent Uterine Integrity Test (UIT). If the CO_2 arrow icon is in the green zone, the CO_2 flow rate is sufficiently low that initiation of the UIT test is appropriate. If the CO_2 arrow icon is in the red zone, however, the CO_2 flow rate remains sufficiently high that the UIT test will not likely pass if initiated.

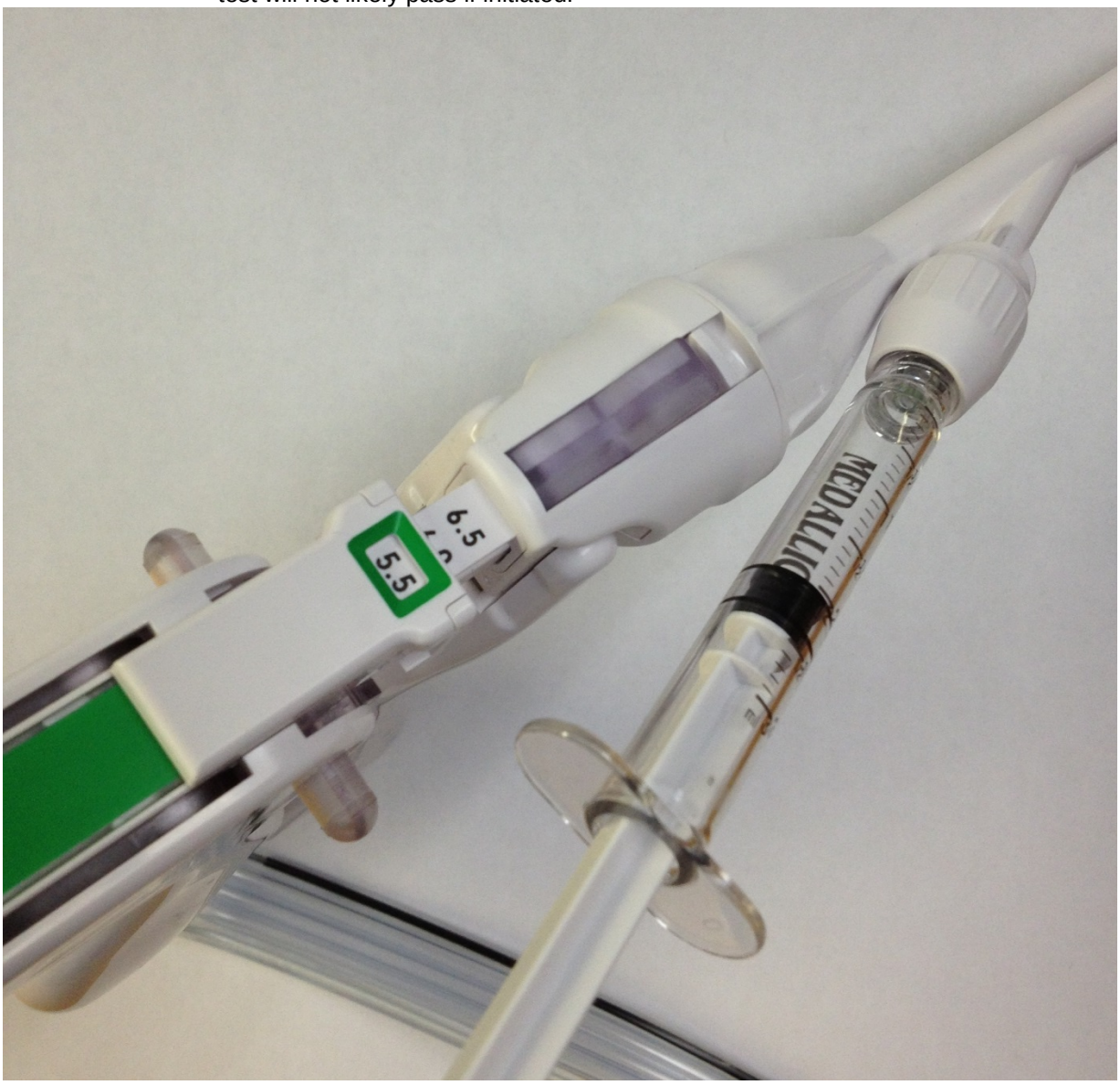


Figure 20: Syringe Connected to Inflation Port

13.12 Begin the uterine integrity test (UIT) procedure by stepping on and releasing the foot switch once. An animation indicating the progress of the UIT will appear on the touch screen display. See animation frame in (**Figure 21**)

Figure 21: Uterine Integrity Test Initiation

13.13 Upon successful completion of the UIT, the screen will switch (**Figure 22**) and the ablation procedure will start automatically.

Figure 22: Successful Uterine Integrity Test

NOTE: Power will not be applied to the Minerva Disposable Handpiece until the UIT passes. If the UIT fails, then the display on the Minerva RF Controller will indicate UIT Failure (Figure 23), and a rapid audible tone will sound. Consult the Troubleshooting section for more information.

Figure 23: Failed Uterine Integrity Test

13.14 Upon successful completion of the UIT, the screen will switch (**Figure 22**) and the ablation procedure will start automatically. The remaining ablation time will be displayed on the screen (**Figure 24**).

NOTE: Maintaining correct placement of the Minerva Disposable Handpiece PFA against the fundus is important for safe and effective treatment.

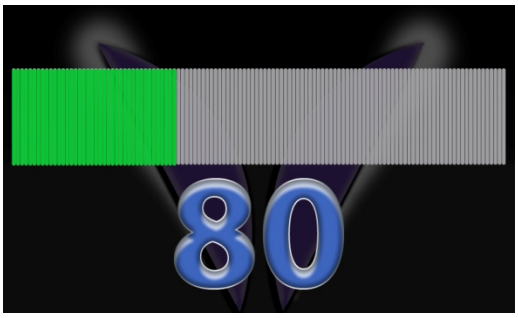


Figure 24: Remaining Ablation Time

13.15 During the ablation cycle, the blue “RF ON” LED on the front panel of the Minerva RF Controller will be ON. At the completion of the ablation cycle, this blue RF power delivery (RF ON LED) will switch off with the cessation of RF energy delivery.

NOTE: RF power delivery can be stopped at any time by pressing the foot switch. If Footswitch is accidently pressed, the cycle can be re-initiated by pressing the footswitch again.

13.16 Upon successful completion of the 2 minute ablation cycle, 2 images (**Figure 24** and **Figure 25**) will appear sequentially on the touch screen display.

Figure 24: Ablation Complete

Figure 25: Do Not Re-treat Warning

13.17 Using the supplied syringe deflate the Cervical Sealing Balloon.
13.18 Unlock and withdraw the Minerva Disposable Handpiece from the patient.

CAUTION: To avoid damaging the Minerva Disposable Handpiece, employ a gentle technique when retracting the Minerva Disposable Handpiece.

13.19 Using the toggle-switch, turn OFF the Minerva RF Controller.

13.20 Perform postoperative patient care according to standard procedures. The used Minerva Disposable Handpiece must be treated as biohazardous waste and disposed of in accordance with the standard practice of the clinic or hospital, where the treatment is performed.

13.21 Discharge the patient from the hospital or office as indicated by the managing physician.

WARNING: The Minerva procedure is indicated AS A SINGLE PROCEDURE ONLY. A repeat ablation either during the same operative visit or at a subsequent visit in the distant future is an absolute contraindication.

14.0 TROUBLESHOOTING

14.1 UIT Failure

14.1.1 If the UIT fails, a brief tone will sound and **Figure 26** will appear on the touch screen display.

WARNING: If a perforation is suspected, the procedure should be terminated immediately.

14.1.2 Return to the Minerva Disposable Handpiece deployment screen by pressing the "return" button in the lower left hand corner of the image on the touch screen display (**Figure 26**).

Figure 26: Uterine Integrity Test Failure and "Return" Button

14.1.3 Re-check for leaks between the cervix and Cervical Sealing Balloon by monitoring the CO_2 flow rate indicator image on bottom edge of the touch screen display (**Figure 27**).

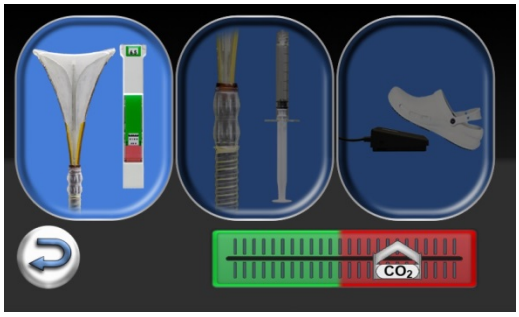


Figure 27: CO_2 Flow Rate Indicator

14.1.4 Remove the Minerva Disposable Handpiece from uterus and verify Cervical Sealing Balloon integrity by inflating the Cervical Sealing Balloon and checking for leaks. If the Cervical Sealing Balloon does not remain inflated, replace Minerva Disposable Handpiece. If the leak appears to be at the cervix and cannot be resolved by using the Cervical Sealing Balloon, use another tenaculum to grasp and tighten the cervix around the sheath. Repeat the UIT by stepping on and releasing the foot switch once the CO_2 indicator is in the green zone.

NOTE: CO_2 leakage may occur at the external cervical os due to the presence of an over-dilated cervix. Visible bubbles or the "hissing" sound of escaping gas may accompany CO_2 leakage under either of these conditions.

14.1.5 Apply good clinical judgment and consider stopping the procedure, if the UIT continues to fail after a reasonable number of attempts to implement the troubleshooting procedures (Steps 14.1.2 through 14.1.4 above)

NOTE: Removing the Minerva Disposable Handpiece from the uterine cavity after completing the UIT will require an additional UIT to be performed upon Minerva Disposable Handpiece re-insertion (whether or not the UIT previously passed) prior to initiating an ablation.

14.2 **Missing Desiccant**

14.2.1 If the desiccant is missing, **Figure 28** will appear on the touch screen display shortly after the Minerva Disposable Handpiece is connected the Minerva RF Controller.

Figure 28: Missing Desiccant

14.2.2 Attach both ends of the desiccant to the Minerva Disposable Handpiece cord.

14.3 **Minerva Disposable Handpiece Integrity Failure**

14.3.1 If the Minerva Disposable Handpiece fails the integrity test, **Figure 29** will appear on the touch screen display.

Figure 29: Minerva Disposable Handpiece Integrity Test Failure

14.3.2 This failure is an indication that something is obstructing the free flow of CO_2 through the Minerva Disposable Handpiece. Check for kinks in the Connector Cord tubing and/or inadvertent placement of a stool foot on the Minerva Disposable Handpiece cord. Disconnect and re-connect the Minerva Disposable Handpiece to re-start the test. If test fails for the second time, replace the Minerva Disposable Handpiece.

14.4 **Array Opening Indicator in Red Zone**

14.4.1 If the Array Opening Indicator is in the Red Zone after performing the seating procedure, close and remove the Minerva Disposable Handpiece from the uterine cavity. Inspect the Minerva Disposable Handpiece by opening in the air (outside of the patient's body). If the Array Opening Indicator is in the Red Zone when the Minerva Disposable Handpiece is deployed and locked in the air, replace the Minerva Disposable Handpiece. If the indicator is in the Green Zone, close the Minerva Disposable Handpiece and continue the procedure. If after performing the seating procedure the indicator is still in the Red Zone, rule out the possibility of uterine perforation or false passage.

14.4.2 Do not perform the procedure if the Array Opening Indicator is in the Red Zone.

14.5 **Footswitch Not Operational**

14.5.1 If the footswitch is not operational when pressing (initiating the procedure), make sure it is properly connected to the appropriate port on the front of the Minerva RF Controller, then re-attempt treatment initiation. If problem persists, contact Minerva Surgical Customer Service at 1-855-646-7874.

14.6 **Suspected Uterine Perforation**

14.6.1 *Prior to Application of Energy*:

14.6.1.1 Terminate the procedure
14.6.1.2 Assure patient stability
14.6.1.3 Consider patient work-up for perforation
14.6.1.4 Reschedule procedure, if appropriate

14.6.2 *During or after Application of Energy:*

14.6.2.1 Terminate the procedure
14.6.2.2 Assure patient stability
14.6.2.3 Rule out visceral injury
14.6.2.4 Reschedule procedure, if appropriate

14.7 **PFA Does Not Fully Deploy and Lock**

14.7.1 If the Minerva Disposable Handpiece does not lock, remove it from the uterus.
14.7.2 Inspect the Minerva Disposable Handpiece for damage;
14.7.3 Attempt to open and lock the Minerva Disposable Handpiece outside the patient; and
14.7.4 If damaged, then replace Minerva Disposable Handpiece.
14.7.5 If the Minerva Disposable Handpiece is not damaged, reinsert it into the patient's uterine cavity and attempt deployment; and
14.7.6 If unable to deploy the Minerva Disposable Handpiece to a width being in the GREEN ZONE, terminate the procedure.
14.7.7 Consider uterine perforation as a possible cause for not being able to deploy.

14.8 **Difficulty unlocking the Minerva Disposable Handpiece post-ablation**

14.8.1 If upon completion of the ablation cycle the Minerva Disposable Handpiece does not unlock using a single unlock lever, press on both levers simultaneously to unlock.

14.8.2 If the Disposable Handpiece does still not unlock, gradually withdraw the Minerva Disposable Handpiece from the patient.

15.0 ERROR MESSAGES

15.1 The user may encounter the error messages listed in **Table 9**.

Table 9: Error Messages

Error	Description	Required Action
001	Impedance too low	replace Disposable Handpiece
002	Membrane Defect Detected	replace Disposable Handpiece
003	Argon Return Valve too high	replace Disposable Handpiece
004	Argon Return Valve too low	replace Disposable Handpiece
005	Handpiece Connection Test Failed	replace Disposable Handpiece
006	No plasma detected	replace Disposable Handpiece
007	Argon Flow High	replace Disposable Handpiece
008	Argon Flow Low	replace Disposable Handpiece
009	Argon Return Flow High	replace Disposable Handpiece
010	Argon Pressure High (SALS)	replace Disposable Handpiece
011	Voltage/Phase Angle too low	replace Disposable Handpiece
012	Argon Flow/Return Flow Differential too high	replace Disposable Handpiece
013	CO_2 Canister Empty	replace CO_2 canister
014	Argon Canister Empty	replace Argon canister
015	Pause Expired	remove and re-insert Disposable Handpiece
016	Corrected Argon Differential flow too high	replace Disposable Handpiece

15.2 The user may encounter the system error messages listed in **Table 10**. The required action in all instances is to stop treatment and cycle the Minerva RF Controller power off and back on again. If the error is not cleared, contact Minerva Surgical customer service at 1-855-646-7874.

Table 10: System Error Messages

Error	Description
101	Operational CPU Failure
102	CO_2 1st stage regulated Pressure Too High
103	CO_2 Flow Too High
104	Argon 1st stage regulated Pressure Too High
105	Argon Flow Too High
106	Argon Return Flow Too High
107	RF Circuit Breaker Tripped
108	Watchdog Expired
109	RF Current Too High
110	RF Voltage Too High
111	RF Power Too High
112	Temperature Check
114	RF Delivery Time Too Long
115	DAC/ADC Validation Error
116	HALS (Hardware Argon Limit Switch)
117	HCLS (Hardware CO_2 Limit Switch)
118	Software loop timer exceeds limit
201	RF Over Current during POST
202	Display Test Failure
203	Processor Communication Test Failure
204	Stuck Button Validation Error
205	RF Power Self Test Failure
206	RF Power Validation Error
207	RF Impedance Validation Error
208	CO_2 Shutoff Test Failure
209	Argon Shutoff Test Failure
210	Argon Return Shutoff Test Failure
211	Watchdog Validation Failure
212	Converter Validation Failure
213	Timer Validation Failure
214	Residual Pressure/Vacuum Failure
215	Redundant Power Check
301	Reference Voltage Out of Range
302	+1.8 Volt Supply Out Of Range
303	+3.3 Volt Supply Out Of Range
304	+5 Volt Supply Out Of Range
305	+12 Volt Supply Out Of Range
306	-12 Volt Supply Out Of Range
307	+48 Volt Supply Out Of Range
308	Fan Error
401	POST RAM Validation Failure
402	POST FLASH Validation Failure
403	POST EEPROM Validation Failure

16.0 REPLACEMENT INSTRUCTIONS

The Minerva RF Controller uses a pair of fuses located in a fuse drawer in the power input module. The fuses are Type T5AL, 250 V, 5 x 20mm each. The drawer can be accessed by using a flat-head screwdriver to pull it open. Disconnect the power cord prior to accessing the fuse drawer. If required, the fuse drawer may then be removed and the fuses changed. Assembly is the reverse of these steps.

Any potentially defective Minerva Surgical product must be returned to Minerva Surgical for evaluation. Follow the instructions in the Service Returns section (Section 23.0), for obtaining a returned goods authorization number (RGA #).

17.0 HOW SUPPLIED

- The Minerva Disposable Handpiece is supplied sterile.
- The Minerva Disposable Handpiece is intended for single-patient and single-use only. Do not re-sterilize the Minerva Disposable Handpiece.
- The Minerva RF Controller is supplied in a semi-ready-to-use state. The shipping box contains the Minerva RF Controller, Footswitch, and a detached power cord.
- Minerva argon and CO_2 canisters are supplied separately.

18.0 STORAGE, HANDLING AND DISPOSAL

- Store the Minerva Disposable Handpiece at room temperature in a clean and dry environment. Keep dry.
- Store the Minerva RF Controller at room temperature in a clean and dry environment. Keep dry.
- Handle both the Minerva RF Controller and Minerva Disposable Handpiece with care.
- Use the handles on the back of the RF Controller to facilitate moving or transport.
- Inspect the Minerva Disposable Handpiece and packaging to verify that no damage has occurred as a result of shipping. Do not use the Minerva Disposable Handpiece if damage has occurred or if the sterilization barrier has been damaged or broken.
- Dispose of used Minerva Disposable Handpieces in accordance with applicable regulations for the disposal of biohazardous material. There are no other limitations regarding the disposal of the Minerva components or accessories.
- Return the Minerva RF Controller to Minerva Surgical, Inc. for disposal.

19.0 STERILITY

- The Minerva Disposable Handpiece is sterilized using gamma irradiation. Do not use if the package is damaged or open.
- The Minerva RF Controller is supplied non-sterile and is not intended to be sterilized by the user. The Minerva RF Controller should be cleaned with a hospital grade disinfectant after each use.

20.0 TECHNICAL SPECIFICATIONS

Specifications

Mode of Operation: ..... Intermittent 120 seconds on 10 minutes shut off
Input: 100-240VAC, 50-60Hz, 300VA
Dimensions: ..... 14”(W) x 7”(H) x 22”(D) (35 x 17 x 55 cm)
Weight: ..... 25 lbs (11kg)
Output:..... 40W (80Wmax), 480 kHz, 250V max
Fuses:.....5x20mm Type “T” 5A/250V slow blow (Qty. 2; Schurter or equivalent), Type “L” - 50 A breaking capacity

Weight and dimensions indicated are approximate. Specifications are subject to change without notice.

Protection
Class 1, Type BF applied part, intermittent operation; Enclosure IPX0

Operating Conditions
Temperature: ..... 59°F to 95°F (15°C to 35°C)
Relative Humidity: ..... 25% to 75% relative, non-condensing
Atmospheric Pressure: ..... 706 to 1082 cmH_2O (69 to 106 kPa)

Transport and Storage Requirements
Temperature: .....0°F to 140°F (-18°C to 60°C)
Relative Humidity: .....15% to 90% relative, non-condensing
Atmospheric Pressure: ..... 510 to 1082 cmH_2O (50 to 106 kPa)

Output Power
Minerva Disposable Handpiece and RF Controller are for use exclusively with each other, and since the main component of system impedance is predominantly unrelated to the patient, no power curve is required or provided.

21.0 GUIDANCE AND MANUFACTURER'S DECLARATION

Emissions
The Minerva RF Controller (MIN180S) and Minerva Disposable Handpiece (MIN9770) are intended for use in the electromagnetic environment specified in **Table 11**. The user should ensure that both are used in such an environment.

Table 11: Emissions

Emissions Test	Compliance	Electromagnetic Environment— Guidance
RF CISPR11	Group 1	The RF Controller (MIN180S) with Minerva Disposable Handpiece (MIN9770) must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected when RF is energized. As per IEC 60601-2-2, test was performed in a mode with EUT switched on and in an idle state with the HF output not energized. CISPR 11 Group 1 limits were followed as per clause 202.6.1.1.1
RF CISPR11	Class A	The RF Controller (MIN180S) with Handpiece (MIN9770) is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics EN 61000-3-2	Class A	
Flicker EN 61000-3-3	Complies	

Immunity
The Minerva RF Controller (MIN180S) and Minerva Disposable Handpiece (MIN9770) are intended for use in the electromagnetic environment specified in **Table 12**. The user should ensure that both are used in such an environment.

Table 12: Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%
Electrical Fast Transient (EFT) IEC 61000-4-4	± 2 kV Mains ± 2 kV I/Os	± 2 kV Mains ± 2 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	± 1 kV Differential ± 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips / Drop Outs IEC 61000-4-11	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5s	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Minerva RF Controller (MIN180S) and Minerva Disposable Handpiece (MIN9770) requires continued operation during power mains interruptions, it is recommended that the Minerva RF Controller and the Minerva Disposable Handpiece be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 **Radiated RF IEC 61000-4-3**	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile communications equipment should be separated from the Minerva RF Controller (MIN180S) and Minerva Disposable Handpiece (MIN9770) by no less than the distances calculated/listed below: $D=1.2\sqrt{P}$ 150kHz to 80MHz $D=1.2\sqrt{P}$ 80 to 800 MHz $D = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the max power in watts of the transmitter and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels. Interference may occur in the vicinity of equipment containing a transmitter.

Separation Distances
The Minerva RF Controller (MIN180S) and Minerva Disposable Handpiece (MIN9770) are intended for use in the electromagnetic environment in which radiated disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum

distance between portable and mobile RF Communications Equipment and the Minerva RF Controller and Minerva Disposable Handpiece as recommended in **Table 13**, according to the maximum output power of the communications equipment.

Table 13: Separation Distances

Rated Max Output Power of transmitter (watts)	Separation distance according to frequency of transmitter (meters)		
	150 kHz to 80 MHz $D=1.2\sqrt{P}$	80 MHz to 800 MHz $D=1.2\sqrt{P}$	800 MHz to 2.5 GHz $D=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

22.0 PARTS

Ordering information and related parts and accessories are found in **Table 14**.

Table 14: Parts List

Part Number	**Description**
MINCO2C	CO_2 Canister (5-pack)
MINARGC	Argon Canister (5-pack)
MINRFFS	Replacement Minerva RF Controller Footswitch
MINCRD1	Replacement Minerva RF Controller Power Cord (110 Volts, North America)
MINRGKT	RGA Biohazard Kit
MIN9770	Minerva Disposable Handpiece (single)
MIN3PAK	Minerva Disposable Handpieces (3-pack)
MIN180S	Minerva RF Controller

23.0 SERVICE RETURNS

Read these instructions prior to returning any used/unused potentially defective product to Minerva Surgical.

Contact Minerva Surgical Technical Support if the Minerva Disposable Handpiece or Minerva RF Controller fail to operate as intended. If product is to be returned to Minerva Surgical for any reason, Technical Support will issue a Returned Goods Authorization number (RGA #) and biohazard kit if applicable. Return the product according to the instructions provided with the Minerva Surgical-supplied biohazard kit.

Return the Minerva RF Controller according to the instructions provided by Minerva Surgical Technical Support. Be sure to clean the Minerva RF Controller before returning it and include all accessories in the box with the returned unit.

24.0 SYMBOLS

The symbols used on the Minerva RF Controller and Minerva Disposable Handpiece are listed in **Table 15**.

Table 15: Symbols list

Minerva Disposable Handpiece		Minerva RF Controller	
STERILE R	Sterilized using irradiation		Power On
	Read Operator's Manual Prior To Use!	O	Power Off
	Do Not Reuse		Caution
	Do Not Resterilize		Equipotentiality
	Use By		Do Not Use in the Presence of Flammable Anesthetics
	Manufacturer		Type BF Applied Part
	Do Not Use if Package is Damaged		Risk of Electrical shock
	Keep Dry		Footswitch Connection
	Keep Away from Sunlight		Non-Ionizing Radiation
REF	Catalogue Number		Manufacturer
SN	Serial Number	FUSES: QTY. 2x TYPE "T" 5x20mm 5 A 250V	Fuses
LATEX	Not Made with Natural Rubber Latex	CO_2	Carbon Dioxide Canister
MR	MR Unsafe	AR	Argon Canister
			Date of Manufacture

Manufactured by:
Minerva Surgical, Inc.
101 Saginaw Dr.
Redwood City, CA 94063 USA
Phone: 1-855-646-7874
www.minervasurgical.com

Patents Pending

EXHIBIT B

US006872183B2

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

(10) **Patent No.: US 6,872,183 B2**
(45) **Date of Patent: *Mar. 29, 2005**

(54) **SYSTEM AND METHOD FOR DETECTING PERFORATIONS IN A BODY CAVITY**

(75) Inventors: **Russell M. Sampson**, Mountain View, CA (US); **Mike O'Hara**, Flasstaff, AZ (US); **Csaba Truckai**, Saratoga, CA (US); **Dean T. Miller**, Menlo Park, CA (US)

(73) Assignee: **Cytyc Surgical Product**, Palo Alto, CA (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.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/852,648**

(22) Filed: **May 24, 2004**

(65) **Prior Publication Data**

US 2004/0215099 A1 Oct. 28, 2004

Related U.S. Application Data

(63) Continuation of application No. 10/400,823, filed on Mar. 27, 2003, now Pat. No. 6,743,184, which is a continuation of application No. 09/710,102, filed on Nov. 10, 2000, now Pat. No. 6,554,780.

(60) Provisional application No. 60/164,482, filed on Nov. 10, 1999.

(51) **Int. Cl.**[7] **A61B 5/00**; A61M 31/00

(52) **U.S. Cl.** **600/561**; 600/560; 600/587

(58) **Field of Search** 600/560–562, 600/587–591, 593, 101, 104, 105, 135, 153, 156, 158; 606/27, 37, 40, 41, 45, 46, 49; 607/63, 96, 101, 105, 113, 115, 116, 138; 604/20, 23, 26, 27, 65–67, 114, 118, 500, 515, 920

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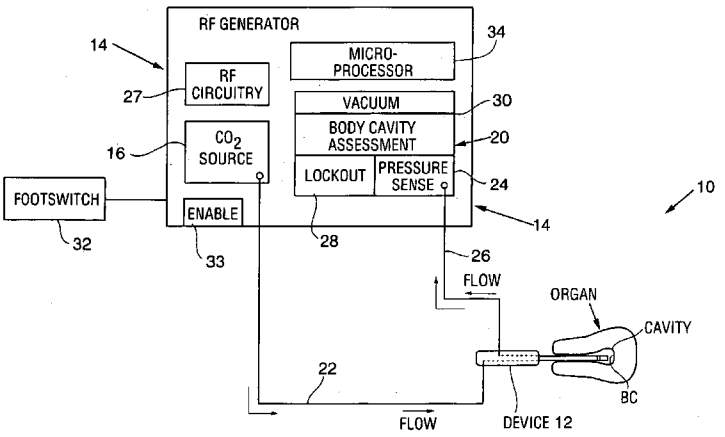
Primary Examiner—Charles Marmor
(74) *Attorney, Agent, or Firm*—Stallman & Pollock LLP

(57) **ABSTRACT**

A system and method for detecting perforations in a body cavity. In accordance with the method of the invention, a fluid (liquid or gas) is delivered into a body cavity to slightly pressurize the cavity. A pressure sensing system monitors the pressure within the cavity for a predetermined test period. If cavity pressure is not substantially sustained during the test period, the physician is alerted to further assess the cavity for perforations before initiating treatment within the cavity. In a preferred form of the system, a medical treatment system such as an RF ablation system is provided with perforation detection functionality. The system preferably includes a pre-test and post-test lockout system. The lockout system prevents RF power delivery unless, during a predetermined test period, the pressure sensing system determines that no perforation exists, or unless a previously performed perforation detection procedure determined a perforation was present but the lockout system was subsequently overridden by the physician.

15 Claims, 5 Drawing Sheets



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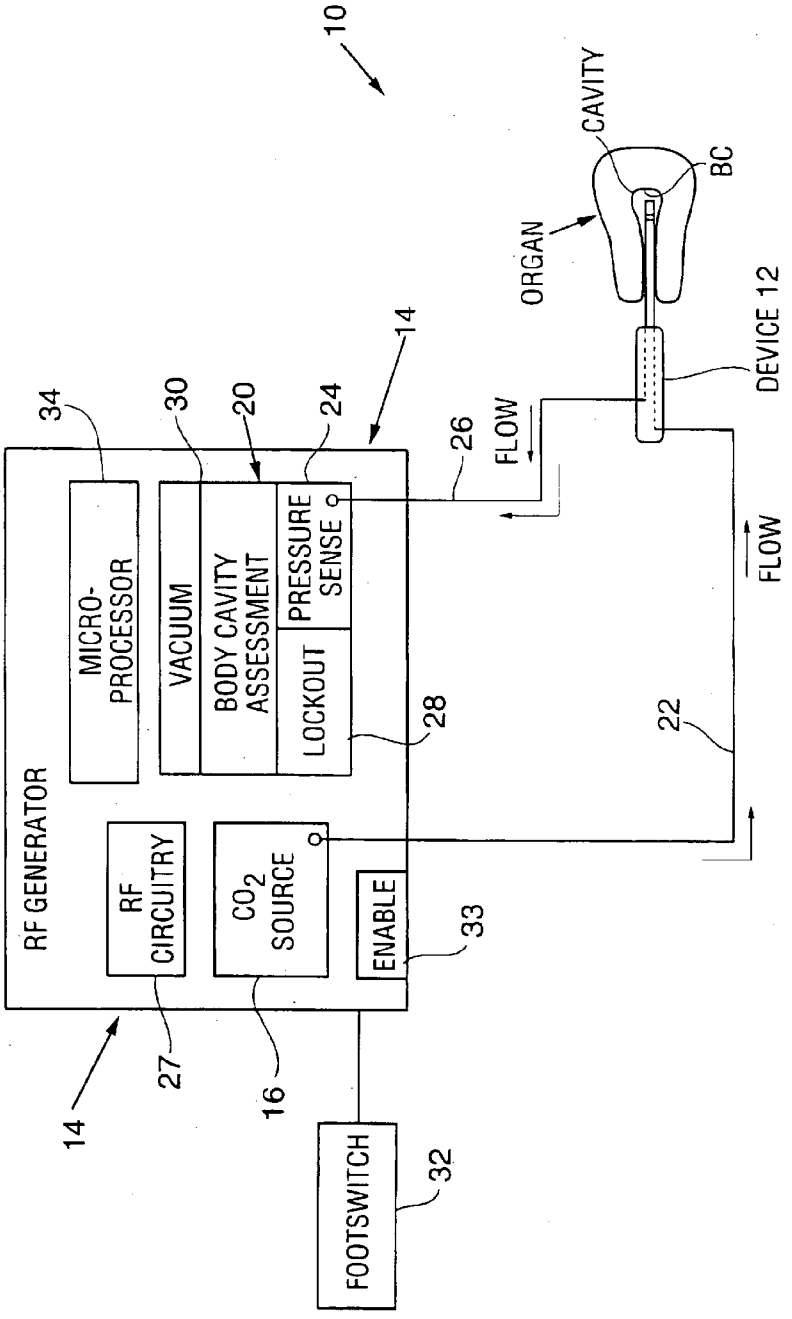
10
CAVITY
BC
ORGAN
DEVICE 12
14
34
30
20
24
26
FLOW
FLOW
MICRO-PROCESSOR
VACUUM
BODY CAVITY ASSESSMENT
PRESSURE SENSE
LOCKOUT
28
22
RF GENERATOR
RF CIRCUITRY
CO_2 SOURCE
ENABLE
33
14
27
16
FOOTSWITCH
32

FIG. 1

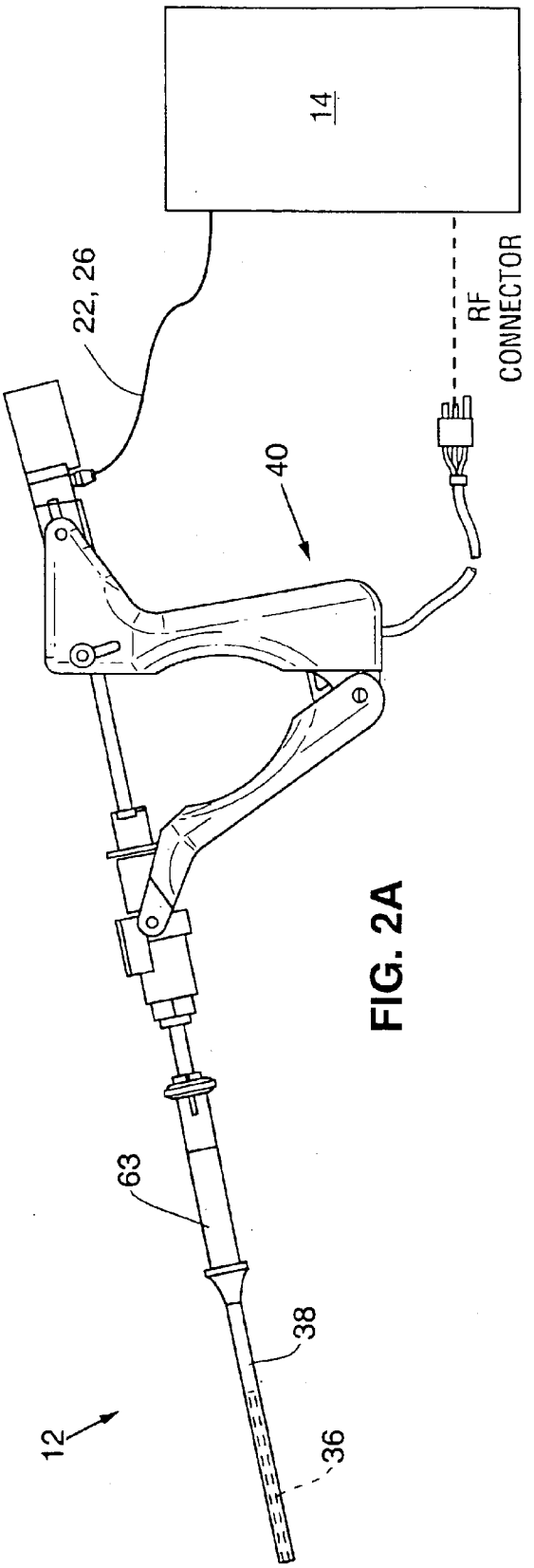

FIG. 2A

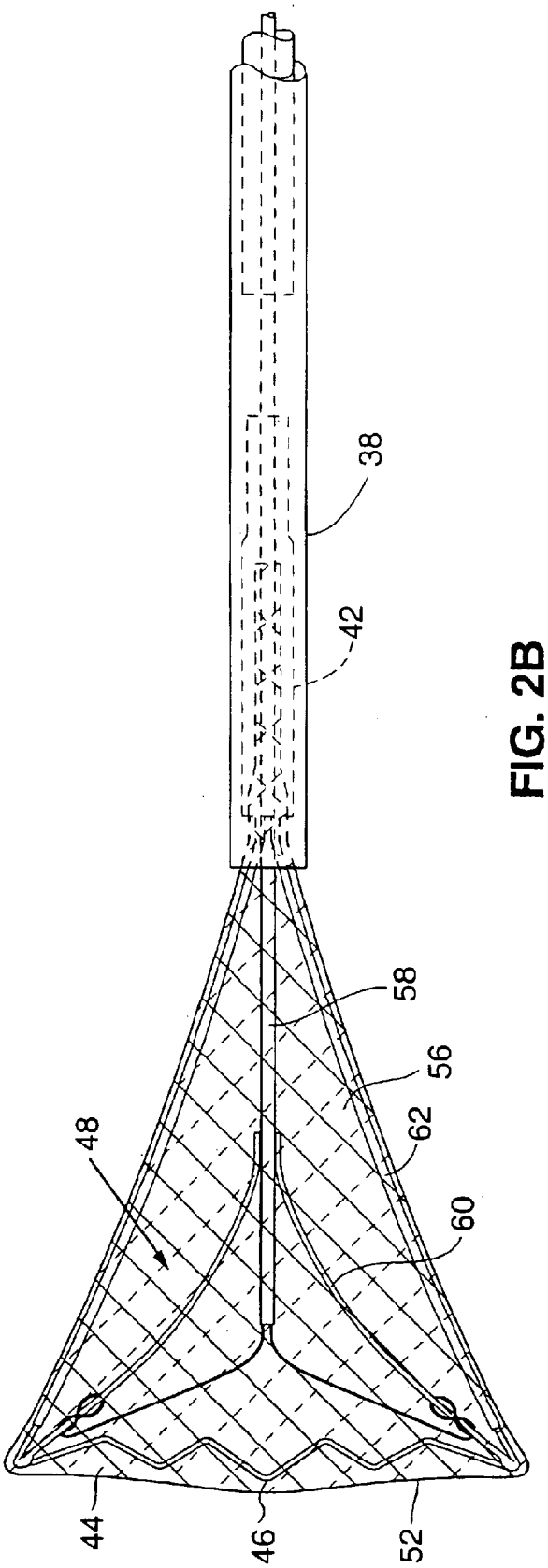

FIG. 2B

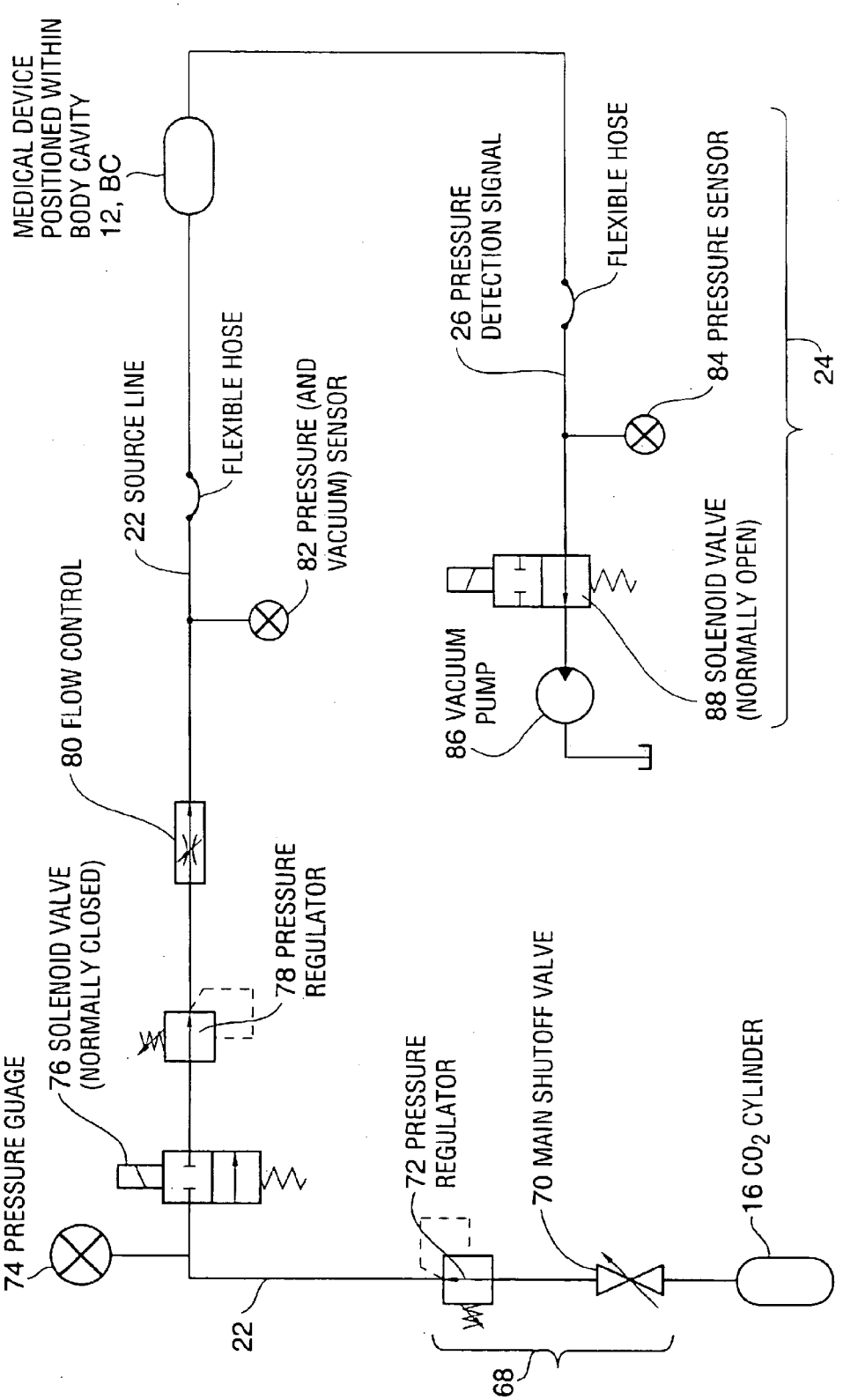
MEDICAL DEVICE POSITIONED WITHIN BODY CAVITY 12, BC
22 SOURCE LINE
FLEXIBLE HOSE
82 PRESSURE (AND VACUUM) SENSOR
80 FLOW CONTROL
78 PRESSURE REGULATOR
76 SOLENOID VALVE (NORMALLY CLOSED)
74 PRESSURE GUAGE
22
72 PRESSURE REGULATOR
70 MAIN SHUTOFF VALVE
68
16 CO_2 CYLINDER
26 PRESSURE DETECTION SIGNAL
FLEXIBLE HOSE
84 PRESSURE SENSOR
24
88 SOLENOID VALVE (NORMALLY OPEN)
86 VACUUM PUMP

FIG. 3

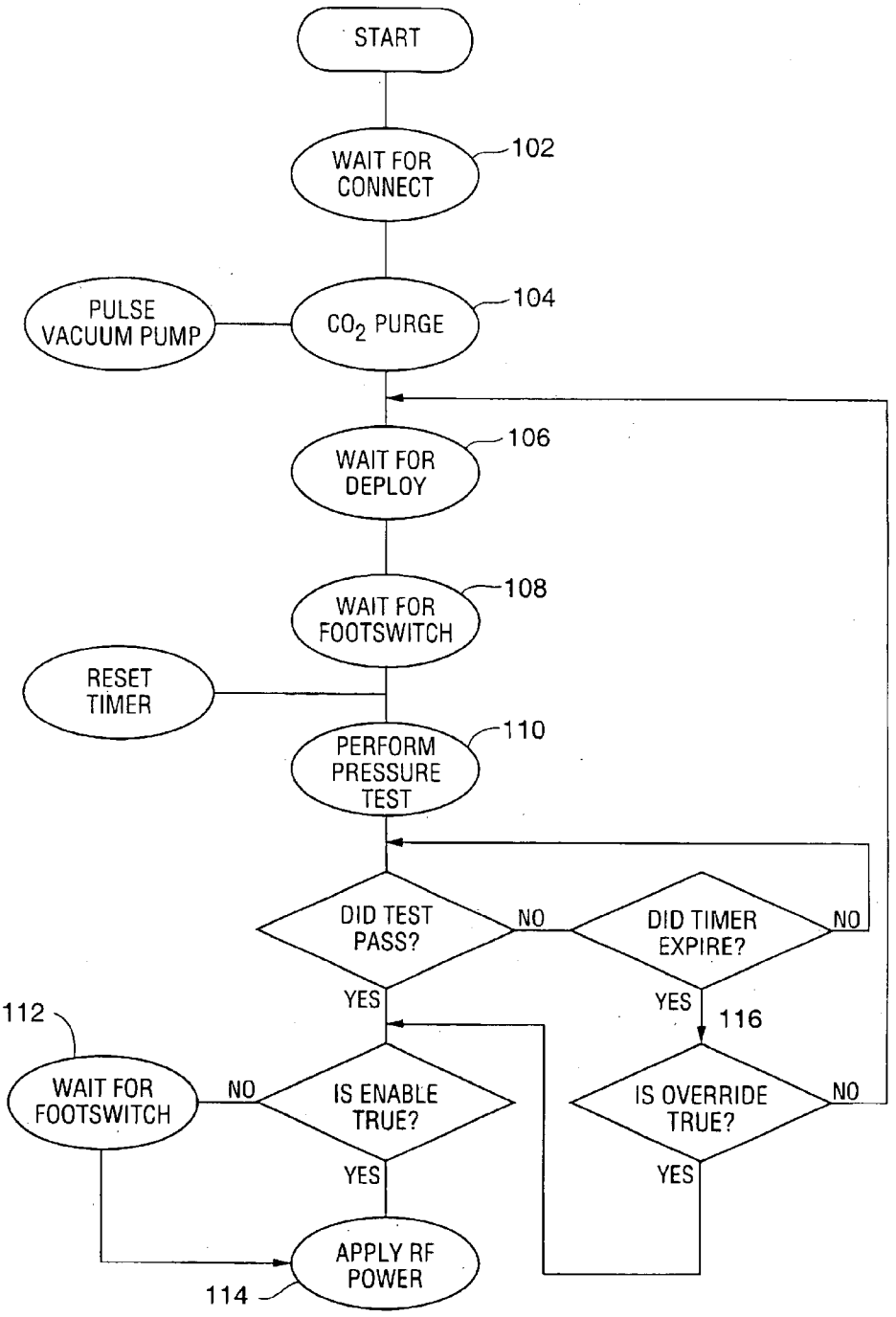
START
WAIT FOR CONNECT
102
PULSE VACUUM PUMP
CO_2 PURGE
104
WAIT FOR DEPLOY
106
WAIT FOR FOOTSWITCH
108
RESET TIMER
PERFORM PRESSURE TEST
110
DID TEST PASS?
NO
DID TIMER EXPIRE?
NO
YES
YES
116
112
WAIT FOR FOOTSWITCH
NO
IS ENABLE TRUE?
IS OVERRIDE TRUE?
NO
YES
YES
APPLY RF POWER
114

FIG. 4

SYSTEM AND METHOD FOR DETECTING PERFORATIONS IN A BODY CAVITY

This application continuation of U.S. application Ser. No. 10/400,823, filed Mar. 27, 2003, now U.S. Pat No. 6,743,184, which is a continuation of U.S. application Ser. No. 09/710,102, filed Nov. 10, 2000, now U.S. Pat. No. 6,554,780, which claims priority to U.S. Provisional Application No. 60/164,482, filed Nov. 10, 1999.

FIELD OF THE INVENTION

The present invention relates to the field of systems and methods for detecting the presence of perforations in body cavities. More particularly, the present invention relates to a system and method that pressurizes a body cavity and detects whether the body cavity can maintain a pressurized condition

BACKGROUND OF THE INVENTION

There are certain medical procedures that are carried out within a body cavity. One example of such a procedure is tissue ablation. Ablation of the interior lining of a body organ is a procedure which involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins. Such a procedure may be performed as a treatment to one of many conditions, such as chronic bleeding of the endometrial layer of the uterus or abnormalities of the mucosal layer of the gallbladder. Existing methods for effecting ablation include circulation of heated fluid inside the organ (either directly or inside a balloon), laser treatment of the organ lining, and resistive heating using application of RF energy to the tissue to be ablated.

Ablation procedures are often carried out without direct endoscopic visualization. For example, ablation of the endometrium typically involves insertion of an elongate ablation device into the patient's cervix without the use of a hysteroscope. As can be appreciated, the presence of a perforation in the uterus could result in inadvertent passage of the ablation device through the perforation and out of the uterus into the bowel. Although events of this nature are rare, the injury that could result from such occurrences make it highly desirable to provide a mechanism by which a physician can evaluate whether perforations are present in a body cavity before a treatment device such as an ablation device is used to deliver power.

SUMMARY OF THE INVENTION

The present invention is a system and method for detecting perforations in a body cavity. In accordance with the method of the invention, a fluid (either liquid or gas) is delivered into a body cavity to slightly pressurize the cavity. A pressure sensing system monitors the pressure within the cavity for a predetermined test period. If cavity pressure is not substantially sustained during the test period, the physician is alerted to further assess the cavity for perforations before initiating treatment within the cavity. In a preferred form of the system, a medical treatment system such as an RF ablation system is provided with perforation detection functionality. The system preferably includes a pre-test lockout feature that prevents RF power delivery unless a perforation detection procedure has been performed.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic representation of a perforation detection system utilizing principles of the present invention.

FIG. **2**A is a side elevation view of an ablation device that may be used with the system of FIG. **1**.

FIG. **2**B is a plan view of the RF applicator head of the ablation device of FIG. **2**A.

FIG. **3** is a schematic representation of the pneumatic subsystem of the system of FIG. **1**.

FIG. **4** is a simplified state diagram illustrating a mode of operation utilizing the perforation detection and lockout features of the present invention.

DETAILED DESCRIPTION

A perforation detection system **10** (also referred to as a "body cavity assessment system") utilizing principles of the present invention will be described herein as forming part of an RF ablation system used to ablate tissue within a body cavity such as a uterus. However, it. should be appreciated that the perforation detection system **10** may be provided with another type of system used for treatment, or it may be provided independently of a larger treatment system.

Generally speaking, perforation detection system **10** includes a medical ablation device **12** of a type used for tissue ablation, and an RF generator system **14** of the type used to deliver RF ablation energy to an electrode array on ablation device **12**. The RF generator unit, however, is provided with additional components that are used for the body cavity assessment function of the present invention. In particular, the RF generator unit is provided with a fluid/gas source **16** and a body cavity assessment system **20**. Fluid/gas source **16** is fluidly coupled to ablation device **12** via a source line **22**. The ablation device is positionable within a body cavity BC so as to deliver fluid/gas from source **16** through the source line **22** and the ablation device and into the body cavity.

Body cavity assessment system **20** includes a pressure sensing system **24** fluidly coupled to the medical device via pressure detection/signal line **26**. Pressure sensing system **24** monitors the pressure within the body cavity BC while fluid/gas is being (or after it has been) delivered to the body cavity, and detects whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ.

Body cavity assessment system **20** further includes a lockout system **28** that prevents treatment with the ablation device **12** unless body cavity assessment has been performed (pre-test lockout) and that prevents treatment if the body cavity assessment indicates a possible perforation (post-test lockout). The RF generator system **14** is additionally provided with a vacuum system **30** coupled to pressure detection/signal line **26**, RF circuitry **27**, and other components needed to perform the ablation function, A footswitch **32** or other input device controls operation of the RF generator system **14**. A microprocessor or programmable logic device **34** within the RF generator system **14** governs various functions, including the body cavity assessment, lockout, and RF ablation procedures.

Ablation Device

An example of an RF ablation device **12** that may be used with the system **10** is shown in FIG. **2**A and **2**B. Ablation devices of this type are shown and described in U.S. Pat. No. 5,769,880 and U.S. application Ser. No. 09/103,072, each of which are incorporated herein by reference. A similar device is the Novasure® ablation device available from Novacept, Inc., Palo Alto, Calif. Naturally the perforation detection system may be provided in combination with the other

medical devices as well. Such alternative devices include thermal ablation devices in which heated liquid is circulated through a balloon positioned within the body cavity of interest, or other device used for procedures besides ablation. Alternatively, the system may be provided with two medical devices, one for use in delivering inflation medium and another for use in treating body tissue. As a further alternative, a treatment device may be provided independent of the system **10**.

Ablation device **12** is configured to deliver RF ablation energy to the interior surface of a body cavity, while causing moisture (e.g. steam) generated during ablation to be withdrawn away from the body tissue preferably using suction. This moisture transport feature of the device **12** is advantageous in that removing steam from the ablation site minimizes the amount of thermal ablation that would otherwise be caused by the steam. Greater control over ablation depth is thus achieved by allowing ablation to occur only (or primarily) by RF energy rather than by thermal conduction.

The device **12** includes an RF applicator head **36**, a sheath **38**, and a handle **40**. The applicator head **36** is slidably disposed within the sheath **38** to give the appicator head **36** a streamlined profile (FIG. **2**A) to facilitate insertion of the device into a body cavity (e.g. the uterine cavity). Once the applicator head **36** has been inserted into the body cavity, handle **40** is manipulated to cause the applicator head **36** to extend from the distal end of the sheath **38** and to expand into the position shown in FIG. **2**B as to make contact with body tissue.

Referring to FIG. **2**B, applicator head **36** extends from the distal end of a length of tubing **42** which is slidably disposed within the sheath **3**B. Applicator head **36** includes an external electrode array **44** and an internal deflecting mechanism **46** used to expand and tension the array for positioning into contact with the tissue.

The array **44** is preferably formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material. In one array design, the knit is formed of three monofilaments of nylon knitted together with single yarns of spandex. Each yarn of spandex has a double helix of five nylon monofilaments coiled around it.

When in its expanded state, the array **44** includes a pair of broad faces **48** (one of which is shown in FIG. **2**B) spaced apart from one another, and narrower side faces (not shown) extending between the broad faces **48** along the sides and distal end of the applicator head **36**, and a distal face **52** extends between the broad faces **48** at the distal end of the applicator head **36**.

Insulating regions (not shown) formed by etching or other techniques on the applicator head divide the mesh into electrode regions.

The array may be divided by the insulated regions into a variety of electrode configurations. In a preferred configuration the insulating regions divide the applicator head into four electrodes by creating two electrodes on each of the broad faces.

Deflecting mechanism **46** and its deployment structure is enclosed within electrode array **44**. External hypotube **58** extends from tubing **42** and an internal hypotube **60** is slidably and co-axially disposed within hypotube **58**. Flexures **62** extend from the tubing **42** on opposite sides of external hypotube **58**. Hypotube **60** is a dual lumen tube that is coupled to the pneumatic subsystem as will be described below.

A plurality of longitudinally spaced apertures (not shown) are ford in each flexure **62**. During use, these apertures allow moisture to pass through the flexures and to be drawn into the exposed distal end of hypotube **58** using a vacuum source located in the RF generator system **14** and fluidly coupled to hypotube **58**.

Each flexure **62** preferably includes conductive regions that are electrically coupled to the array **44** for delivery of RF energy to the body tissue. For example, strips of copper tape (not shown) or other conductive material may extend along opposite surfaces of each flexure. Conductor leads (not shown) are electrically coupled to the strips and extend through tubing **42** to an electrical cable which is attachable to the RF generator.

During use of the ablation device, the applicator head **36** is inserted into the uterus with the sheath **38** covering the array **44** to compress the applicator head **36** into a streamlined condition. Once the applicator head is within the uterus, the handle is used to withdraw the sheath and to open the array into its deployed position. Vacuum source **30** (FIG. **1**) is activated, causing application of suction to hypotube **60**. Suction helps to draw uterine tissue into contact with the array **44**.

Ablation power is supplied to the electrode array **44** by the RF generator system **14**. The tissue is heated as the RF energy passes from electrodes **56** to the tissue, causing moisture to be released from the tissue. The vacuum source helps to draw moisture from the uterine cavity into the hypotube **60**. Moisture withdrawal is facilitated by the apertures formed in flexures, by preventing moisture from being trapped between the flexures and the lateral walls of the uterus.

Pneumatic Subsystem

The fluid/gas source **16**, pressure sensing system **24**, and associated components are shown in FIG. **3**. Each of the components of the pressure sensing system **24** is preferably coupled to microprocessor **34** of the RF generator system **14** although for clarity the microprocessor is not shown in FIG. **3**. All pressure transducers, solenoid valves, and the vacuum pump are controlled by the microprocessor. As discussed, a programmable logic device may be used in place of the microprocessor, although the term "microprocessor" will be used here for simplicity.

It is also important to note that in the embodiment described below the two lines (source One **22** and pressure detection/signal line **26**) play different roles during RF ablation than for perforation detection. Specifically, the signal line **26** for perforation detection serves as a suction line for ablation. The source line **22** for perforation serves as a vacuum signal line for ablation.

Components along the source line **22** will first be described. Fluid/gas source **16** is preferably a disposable CO_2 cylinder, and may be a 16 gm cylinder providing approximately 850 psi at 25 C. One such example is the Linde medical grade 16 gm cylinder. The cylinder is removably attached to a pressure regulator **68** such as the Leland Model 50033 or equivalent. Regulator **68** includes a main shutoff valve **70** and pressure regulation component **72** which has a control pressure of approximately 60 psi. A pressure gauge **74** such as SenSym model ASCX100DN or equivalent is fluidly coupled to source line **22**. Pressure gauge **74** monitors the pressure remaining in the fluid/gas source **16** so as to detect when a low volume of fluid/gas remains, or when the user has failed to open the valve **70**.

A solenoid valve **76** is positioned along the source line **22**, downstream of the pressure regulator **68**. Valve **76** remains in a dosed condition, preventing flow of gas through the line **22**, except when a cavity assessment procedure is being

carried out. A second pressure regulator **78**, such as an Airtrol R-920 series regulator, is positioned downstream of the valve **76** so as to reduce pressure in line **22** down to approximately 90+/−10 mmHg during a cavity assessment procedure. A flow control orifice **80**, positioned downstream of regulator **78**, limits flow in line **14** to 100+/−10 scc/min (standard cc/min). A pressure sensor **82** downstream of orifice **80** monitors whether the pressure limit (of, for example, approximately 100 mm Hg) has been exceeded. If the limit has been exceeded, an output signal from this sensor causes an audible alarm to be triggered and the solenoid valve **76** is turned off. Downstream of orifice **80**, source line **22** is coupled, using a flexible Tygon® tubing for example, to the introducer sheath **38** (FIG. **2**B) of the ablation device **12**. The introducer sheath is located at the internal surface of the body cavity BC (the internal os, for example, in the case of a uterine cavity) so as to deliver gas into the body cavity BC that is to be treated.

Turning to the components along the pressure detection line **26**, the pressure signal line **26** is fluidly coupled, using a Tygon® tubin for example, to the lumen of hypotube **60**. Downstream of the medical device **12** is a pressure sensor **84**, such as the Sensym ACSX05DN. During a cavity assessment procedure, sensor **84** monitors pressure in the pressure signal line **26** and delivers the signal to microprocessor **34**. Microprocessor **34** (or other electronic means such as the programmable logic device mentioned previously) then determines if pressure in the body cavity BC has failed to achieve a predetermined threshold (indicating a perforation in the body cavity) or if it has and maintained the threshold for a predetermined time period (indicating that the body cavity has no perforation). In this capacity, the microprocessor or (programmable logic device) serves as a feedback means that activates a notification signal to alert a user if the pressure monitored by the pressure sensor fails to rise and remain above a predetermined level during a predetermined amount of time. The microcroprocessor may initiate various forms of notification signals, such as visual or auditory signals.

Further downstream of the pressure sensor **84** is a vacuum pump **86**. While not needed for perforation detection, vacuum pump **86** is used to carry out the moisture transport function of the medical device **12** described in the section entitled Ablation Device above.

A second solenoid valve **88** lies upstream of the vacuum pump **86**. Valve **88** remains open at all times except during cavity assessment. Because the exhaust line of the vacuum pump may not be air-tight when it is not operating (including during the cavity assessment procedure) the valve **88** is provided to close the pressure signal line against leaks through the vacuum pump.

A simplified state diagram illustrating operation of the system is shown in FIG. **4**. Operation begins with valve **76** in the closed condition, and with valve **88** in the opened condition. In preparation for use of the system, a CO2 cylinder **16** is connected to the appropriate receiving device on the RF Generator's pneumatic subsystem (FIG. **3**). The power to the generator is switched on. Pressure gauge **74** detects the pressure in the portion of pressure/monitoring line **22** extending between CO_2 cylinder **16** and valve **76**. If the user has failed to open the main CO_2 shutoff valve **70**, or if the pressure detected by gauge **74** is less than the specified pressure, an audible alert will sound, indicating a low-gas condition. Assuming no low-gas condition is detected, the user will connect the ablation device **12** to the RF generator system **14**.

The system remains in a "WAIT FOR CONNECT" condition, step **102**, until the user connects the ablation device **12** to the RF generator system. When the ablation device is plugged in, it actuates a microswitch or similar feature, which alerts the microprocessor that the ablation device has been connected. Connection of the device automatically starts the "CO_2 PURGE" cycle, step **104**. During the purge cycle, valve **76** is opened to permit the flow of CO_2 through the device to drive air from the device. The purge cycle lasts for a duration sufficient to purge the air from the system, approximately 10 seconds. During the purging cycle the user is alerted by audible and visual indicators not to insert the device into the body cavity in order to prevent air from being delivered into the body. As a safety precaution, the vacuum pump that is,part of the RF Controller is pulsed every few seconds during purging. If the user has inserted the ablation device into a body cavity during purging, the vacuum pump will draw out air that is delivered to the body.

During the purge cycle and device insertion into the body cavity, the ablation device is dosed, such that the poles of the electrode array are in contact with each other. A low voltage signal is applied to the ablation device which senses that the poles are in contact by detecting a DC short. After the completion of the purging cycle the system waits for the device to be deployed within the patient, step **106**, by monitoring for the end of the DC short condition. Once the user inserts the device into the uterine cavity and opens the array, the system detects that a DC short condition is no longer present. As a safety precaution, the perforation detection cycle cannot be initiated until the DC short condition is eliminated. In this way the last operation to be performed before the application of RF energy is the perforation detection cycle.

From the completion of the purge cycle to the initiation of the perforation detection test, a continuous, low level flow of CO2 is circulated through the ablation device to keep the source and pressure signal lines open and free from blockage.

Next, the system waits for the user to depress the footswitch **32**, "WAIT FOR FOOTSWITCH", step **108**. Once the footswitch has been depressed, a 30-second timer is initialized ("RESET TIMER") and the perforation detection test, ("PERFORM PRESSURE TEST") 110 begins. Valve **88** is energized to close off the vacuum pump **86** to avoid loss of pressure through it. If it was not already opened, valve **76** is opened, allowing CO_2 to flow into the body cavity via medical device **12**. When the pressure at gauge **84** rises and remains above 50 mmHg for 4 seconds, the test has passed and the system moves to a "PASSTHROUGH" state. (It should be noted that the system may alternatively pressurize the cavity and then detect whether the monitored pressure falls below a predetermined level within a predetermined time period, indicating that a perforation may be present.) As illustrated in FIG. **4**, the "PASSTHROUGH" condition cannot be reached unless the body cavity assessment has been performed. In this capacity, the perforation detection system circuitry and logic components function as a pre-test lockout means.

In the "PASSTHROUGH" condition the CO_2 is turned off and the vacuum pump is re-enabled by re-opening valve **88**. If the ENABLE button **33** has been pressed (automatic mode), RF power **114** ("APPLY RF POWER") will be delivered automatically to the array **44** once the cavity assessment cycle has been completed and passed. If the ENABLE button has not been depressed (semiautomatic mode), the system moves through the "PASSTHROUGH" state and waits for footswitch actuation **112** ("WAIT FOR FOOTSWITCH"), The user must press the button to enable the RF generator and then press the foot switch **32** to deliver RF power **114**.

In the event the cavity assessment test is not passed after the **30** second timer has expired, an audible tone sounds and visual indicators flash. The system remains in a TEST FAIL state, step **116**, and awaits further action by the user. If the user presses the foot switch, the system re-sets to the initial ready state, step **108**, with the CO_2 flow off. The user may attempt the cavity assessment sequence as many times as desired. As FIG. **4** illustrates, the perforation detection system circuitry and logic components function as a post-test lockout means preventing delivery of RF power using the ablation device if the body cavity assessment is run but not passed.

Alternatively, after one or more cavity assessment procedures has been performed and failed, the user may choose to activate a form of override means to override the post-test lockout means and cause the system to deliver RF energy despite the cavity assessment test having been failed. To do so, the user will press and hold the ENABLE button **33** for six seconds. Note that the pressure check must be attempted at least one time before this feature is available. If the user overrides the cavity assessment, the system moves to the "PASSTHROUGH" state to wait for footswitch step **112**.

If at any time during the above sequence, the user should dose the ablation device, a DC short will be detected in the electrode array by the RF generators DC short detection circuitry. Closing the device causes the state of the perforation test to change to fail, and the system resets to the "WAIT FOR DEPLOY" state, step **106**. The system will then require that cavity assessment be performed again once the array is reopened. This assures that the last step performed before the application of RF energy is the perforation detection test: if the user, after having successfully completing the test, decides to close and remove the device for any reason, the perforation detection test must be performed again once the device is deployed in the body cavity. This requirement also prevents a user from abusing the system by running cavity assessment with the device outside the body, and then inserting the device, overriding the test, and ablating without having ever performed cavity assessment within the body cavity.

For additional safety, the perforation detection system preferentially uses CO2, though other gases or liquids, such as normal saline, may be used. The pressure and flow limits follow well known guidance documents for insufflators. In the case of uterine perforation detection, the limits follow hysteroflator guidance documents. Though other configurations are possible, the cavity to be assessed should be in series between the source and pressure signal lines. In this manner, any kinked tubing or other problems will not lead to a false test result. Additionally, the system is capable of detecting perforations exceeding the range of sizes of devices normally inserted into body cavities (from say 15 mm down to less than 1 mm diameter).

In order to reliably detect perforations in uterine cavities, the pressure threshold in that case is preferentially kept below the average cracking pressure of the fallopian tubes.

There are several features that improve the system's ease of use. Firstly, the physician can start or stop the perforation test at any time in the sequence. Secondly microprocessor **34** is capable of distinguishing the difference between a device that is closed versus a device that is undergoing slight motion in the body cavity, thus reducing the likelihood that a passed test condition will be overturned. Finally, the system includes a collar assembly **63** in FIG. **2***a* which is capable of sealing the entry into the body cavity BC if leaks are determined to exist, thus reducing the likelihood of a false test failure.

Although the forgoing description is with reference to a perforation detection system having a device usable to ablate tissue within a uterus, the present invention is applicable to perforation detection within other body cavities, and to perforation detection systems having medical devices useful for procedures other than ablation. In addition, although the system is described with reference to a particular embodiment, many other configurations are suitable for implementing the teachings of the invention. Those having ordinary skill in the art will certainly understand from the embodiment disclosed herein that many modifications are possible without departing from the teachings hereof. All such modifications are intended to be encompassed within the following claims.

What is claimed is:

1. A method of ablating a uterus, comprising the steps of:
inserting an ablation device into a uterus;
flowing an inflation medium into the uterus;
monitoring for the presence of a perforation in the uterus using a pressure sensor; and
treating the interior of the uterus using the ablation device.

2. The method of claim **1**, wherein the treating step includes delivering electrical energy to the tissue.

3. The method of claim **2**, wherein the electrical energy is RF energy.

4. The method of claim **1**, wherein the treating step includes delivering thermal energy to the tissue.

5. The method of claim **1**, wherein the flowing step includes:
passing an inflation medium through the ablation device and into the uterus; and
the monitoring step includes monitoring a pressure within the uterus for a predetermined amount of time.

6. The method of claim **1**, further including the step of:
if a perforation is detected in the monitoring step, providing feedback alerting a user to the presence of a preforation in the uterus.

7. The method of claim **1**, further including the step of preventing performance of the treating step until after the monitoring step has been carried out.

8. The method of claim **1**, further including the steps of:
suspending performance of the treating step if a perforation is detected in the monitoring step;
detecting an override signal from a user input device; and
permitting treatment of the uterus using the ablation device following detection of the override signal.

9. A method of detecting a perforation in a uterus, comprising the steps of:
passing an inflation medium into the uterus;
monitoring for the presence of a perforation in the uterus using a pressure sensor;
if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and
if a perforation is detected during the monitoring step, preventing ablation of the uterus.

10. The method of claim **9**, further including the step of:
if a perforation is detected during the monitoring step, detecting an override signal from a user input device and permitting treatment of the uterus using the ablation device following detection of the override signal.

11. The method of claim **9**, further including the step of:
if a perforation is detected during the monitoring step, activating a notification signal alerting the user to the presence of a perforation in the uterus.

12. The method of claim **9**, wherein the inflation medium is introduced using a medical device separate from the ablation device.

13. The method of claim **9**, wherein the inflation medium is introduced using the ablation device.

14. The method of claim **9**, wherein the ablation device is an RF ablation device.

15. The method of claim **9**, wherein the ablation device is a thermal ablation device.

* * * * *

EXHIBIT C

US008998898B2

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

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(54) **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

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(58) **Field of Classification Search**
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See application file for complete search history.

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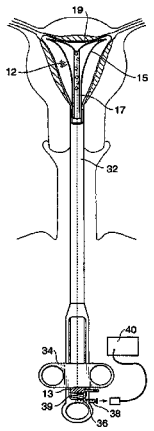
(57) **ABSTRACT**

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.

30 Claims, 18 Drawing Sheets



Related U.S. Application Data

10/959,771, filed on Oct. 6, 2004, now Pat. No. 7,604,633, which is a division of application No. 09/103,072, filed on Jun. 23, 1998, now Pat. No. 6,813,520, which is a continuation-in-part of application No. 08/632,516, filed on Apr. 12, 1996, now Pat. No. 5,769,880.

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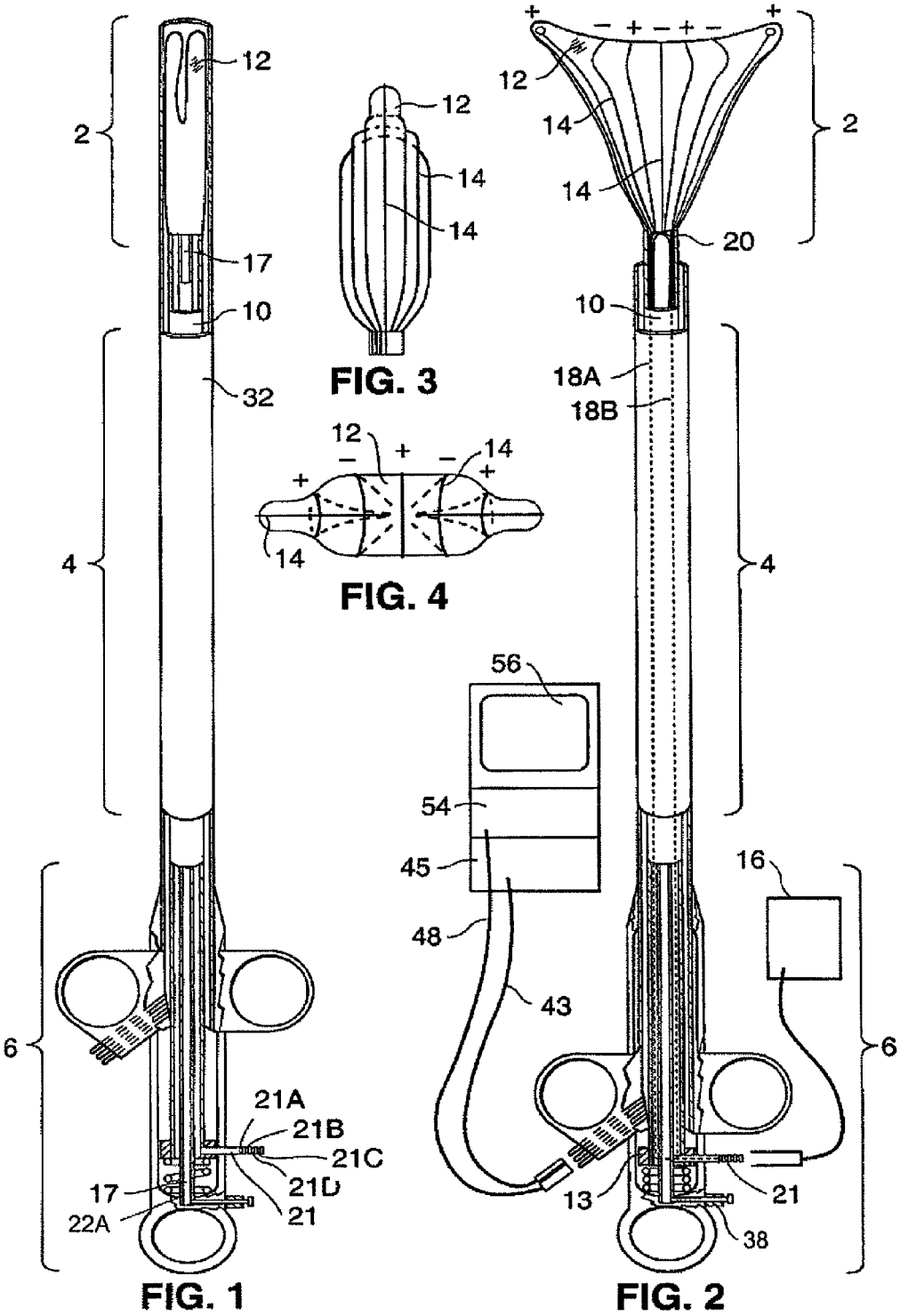
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FIG. 1
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FIG. 3
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FIG. 4
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18A
18B
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FIG. 2