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

ST. CROIX SURGICAL SYSTEMS, LLC, Plaintiff, v. CARDINAL HEALTH, INC., Defendant.	**Case No. 2:17-cv-00500-JRG-RSP (Lead)** Case No. 2:17-cv-00771-JRG-RSP (consolidated)

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff St. Croix Surgical Systems, LLC for its Complaint against Cardinal Health, Inc. for Civil Action No. 2:17-cv-771 alleges the following:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

THE PARTIES

2. St. Croix Surgical Systems, LLC ("St. Croix" or "Plaintiff") is a company organized and existing under the laws of the State of Minnesota, with an address at 8551 Yalta St. NE, Circle Pines, MN 55014.

3. On information and belief, Defendant Cardinal Health, Inc. ("Cardinal Health" or "Defendant") is a corporation organized and existing under the laws of the State of Ohio with its principal place of business at 7000 Cardinal Place, Dublin, Ohio 43017. Cardinal Health can be served via its registered agent CT Corporation System, 4400 Easton Commons Way, Suite 126, Columbus, Ohio 43219.

4. Defendant's website states that "[o]n May 12, 2014, Cardinal Health completed the acquisition of AccessClosure," the manufacturer of Mynx® Vascular Closure Devices.

JURISDICTION AND VENUE

5. On information and belief, Defendant maintains regular and established places of business of throughout Texas, including in the cities of Dallas, Fort Worth, and further including regular and established places of business in this District, including in the cities of Lewisville, Sherman, Texarkana, Roanoke, Jacksonville, and Grand Prairie.

6. In 2008, AccessClosure was sued for patent infringement in the Texarkana Division of the Western District of Arkansas. *St. Jude Medical, Inc., et. al. v. Access Closure, Inc.*, 4-08-cv-04101 (ARWD Texarkana). The case proceeded to trial in Texarkana, after which AccessClosure was found to have infringed the patents-in-suit.

7. Upon information and belief, Defendant sells and offers to sell products and services throughout the United States, including in this judicial district, and introduces products and services into the stream of commerce that incorporate infringing technology knowing that they would be sold in this judicial district and elsewhere in the United States.

8. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code, respectively.

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c), (d) and/or 1400(b).

10. On information and belief, Defendant conducts business in this district, the claims alleged in this Complaint arise in this District, and acts of infringement have taken place and are continuing to take place in this District.

11. On information and belief, Defendant is subject to this Court's general and specific personal jurisdiction because Defendant has sufficient minimum contacts within the State of Texas and this District, pursuant to due process and/or the Texas Long Arm Statute,

because Defendant purposefully availed itself of the privileges of conducting business in the State of Texas and in this District, because Defendant regularly conducts and solicits business within the State of Texas and within this District, and because St. Croix's causes of action arise directly from Defendant's business contacts and other activities in the State of Texas and this District. Further, this Court has personal jurisdiction over Defendant because it has purposely availed itself of the privileges and benefits of the laws of the State of Texas.

GENERAL ALLEGATIONS

12. Many surgical procedures such as heart catheterization involve insertion of a catheter into the patient though the artery in the patient's thigh, also known as the femoral artery. After the completion of the procedure, the catheter is removed and the puncture or hole in the artery must be sealed. However, due to the relatively high blood pressure and flow rate in the femoral artery, sealing the puncture (commonly called a "wound") in the artery can be quite challenging.

13. At least as early as 1996 Mr. Karol Nowakowski conceived of an idea of improving upon previous artery wound closure techniques by using a patient's own whole blood to seal an arterial wound. More particularly, Mr. Nowakowski conceived of using a gel-like mass comprised mostly of the patient's own whole blood to achieve hemostasis (the stoppage of bleeding or the flow of blood through a wound).

14. In his August 29, 1996 invention disclosure document filed with the United States Patent and Trademark Office, Mr. Nowakowski explained that his invention simulates a natural blood clot by using the patient's own clotted blood to seal the artery.

> For many years there has been strong interest in providing a method more efficient than applying direct pressure to close an arterial wound following procedures requiring transarterial access. This has led to numerous innovations involving sutures, balloons, clamps, collagen plugs and so on.

> None have gained wide acceptance to-date. Typically these innovations have problems such as excessive manufacturing complexity, high costs, patient incompatibility, or difficulty with regulatory approval.
>
> With this situation as background, a novel approach is proposed herein which overcomes difficulties cited with the prior art. . . .
>
> **The present invention emulates nature by using a mass of the patients own clotted blood to provide wound closure.** . . .
>
> In one method, the syringe filled with coagulated blood is connected to an appropriate introducer port and the coagulated blood is transferred through the sheath to where it exits around the inner shaft on the outside of the arterial wound. The sheath and inner shaft are removed thereby concluding the procedure.

Aug 29, 1996 Confidential Invention Disclosure, p. 1 (Exhibit 1 at 24-25) (emphasis added).

15. Mr. Nowakowski continued his development work at the office space of Huntter Medical, Inc. in Minnesota. Several months later he generated another invention disclosure summary which he also recorded at the United States Patent and Trademark Office. This disclosure reported on experiments using a porous matrix (cotton) to help coagulate the patient's own blood to form a clot which could be used to seal vascular holes.

> This disclosure continues on previous disclosures for a vascular sealing device. In previous disclosures inventions were presented which aimed to use the patient's own coagulated blood to seal an artery. **One objective was to develop a closed sterile system method and apparatus means of using the whole blood**. A second objective was to accomplish this using a catalytic means thereby avoiding things like having to mix in chemicals with the blood, thus avoiding difficult approval by the FDA. This differentiates my inventions from known prior art which adds materials like thrombin or silicates to the blood. It also differentiates my inventions from those proposing to break down the blood into its separate components for manufacture of fibrin glue or other products.
>
> **On March 4, 1997, experiments were performed at Huntter Medical, Inc. in Minnesota to attempt coagulation of my own blood within a syringe using cotton as a catalyst**. Coagulation worked but the blood also separated out into solid and serum-like portions. This is contrary to an express **design intent of my inventions which is to use the patient's own whole blood**, by methods always maintained in a sterile environment,

> and coagulated without chemical additives. Of course, in the practice of my inventions some humidity may be lost as evaporation of some water molecules from the blood may occur, some gases may migrate into the blood or out of it into the surrounding environment, and heat may be lost once it has been removed from the body. These changes however are not a fundamental change to the blood like addition of thrombin or silicates, or breakdown and separation of the blood's individual components for isolation and use in the manufacture of a sealing means.

March 5, 1997 Invention Disclosure (Ex. 1 at 51) (emphasis added).

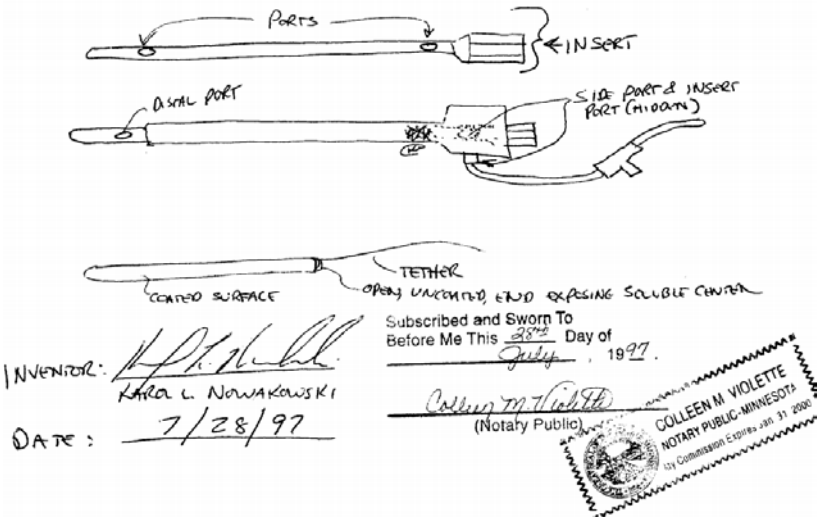
16. After performing additional experiments, Mr. Nowakowski prepared another invention disclosure which reported that use of a porous matrix (cotton) led to the formation of a homogeneous blood clot that could be used to achieve hemostasis.

> Experiments have shown cotton to be an excellent catalyst for activation of blood clotting. In vitro experiments show a relatively homogenous mass of coagulated blood may be generated. . . . Assuming that a **homogenous gel-like mass of blood like that achieved on the bench is the preferred form to have at the wound site**, it may be desirable to deliver the blood to the wound site shortly after activation of the clotting cascade by the catalyst. In this variation, the clot-activated but un-clotted blood would be pumped to the wound site where clotting would continue, thereby possibly forming the relatively **homogenous gel-like mass** observed in bench studies. Process steps remain fundamentally unchanged from previous disclosures but timing of process steps are altered to achieve the possibly desired effect . . .
>
> **If it is desired to return blood immediately to the wound site after activation by a clot inducing catalyst, it may be possible to eliminate the external collection reservoir altogether**. The process is now further simplified by allowing the blood to exit the vessel, traverse a catalyst and return directly to outside the wound site using arterial blood pressure. In effect, a controlled hematoma is being formed which is filled with blood having the clotting cascade activated. Flow is discontinued when an adequate volume has been transferred to the wound site. Numerous variations on an apparatus to accomplish this may be provided . . .
>
> Blood would flow out of the vessel, through the catalyst, and on to the wound site directly. Such an apparatus may be designed to fit within a hemostasis introducer and function similarly to the dilator-like devices of previous disclosures.

April 5, 1997 Invention Disclosure (Ex. 1 at 53) (emphasis added).

17. In the spring of 1997 Mr. Nowakowski designed devices that would be suitable to achieve hemostasis using a clot formed of the patient's own whole blood, in clotted form. He described the results of his development work in an invention disclosure that summer:

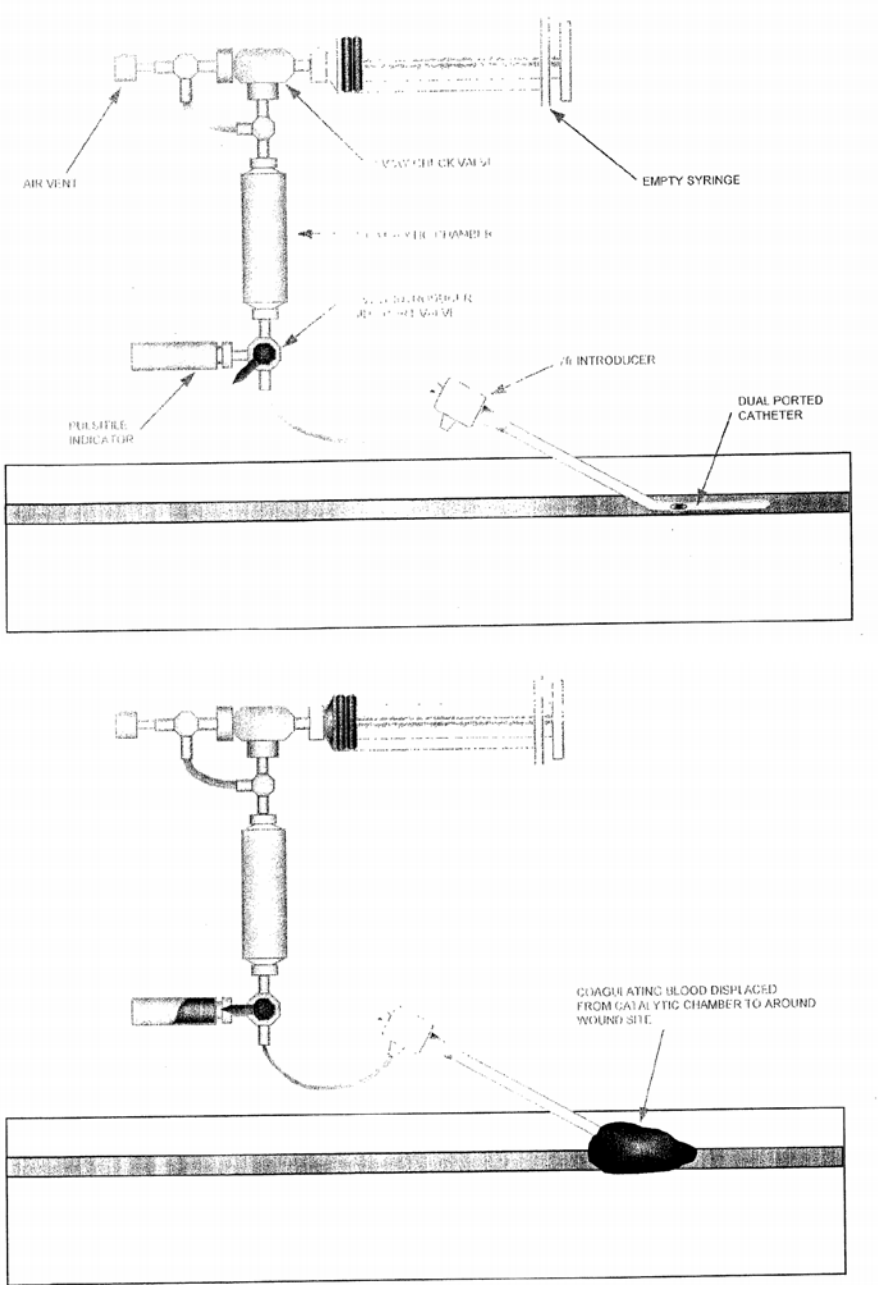
> The present invention relates two disclosures for devices suitable for use in vascular wound closure as described in the inventor's other disclosures. The first device is a dual ported hemostasis introducer insert. When the device is inserted into a hemostasis introducer the distal port is exposed beyond the end of the introducer sheath. The proximal port is within the introducer and in the area of the introducer's side port where it exit's the body of the introducer. In use, the insert's distal port allows blood to flow into its distal port and flow up to and out of the proximal port. From there, it may flow out through the side port of the introducer itself. This insert permits removal of the introducer from the artery while keeping the wound hole plugged. Blood may still flow out under controlled conditions to an external catalytic device as disclosed previously by the inventor. After blood has been removed the insert is backed out of the artery until further flow is not possible. This indicates the distal port is out of the artery. The most distal end of the insert is still in the artery where it plugs the wound site to prevent bleeding. With the distal port located outside the artery, activated blood or other sealant material may be forced down through the insert via the introducer sideport and proximal insert port to where it exits the distal port and fills the area about the wound site. See the illustration below.
>
> The second disclosure involves inserting a plug in the arterial wound. The plug is made of soluble material, such as a molded sugar. The plug is coated everywhere except the proximal end with an insoluble coating. As the sugar dissolves it is absorbed by the body without any risk of breaking off pieces in the artery thereby avoiding risk of embolism. The residual insoluble coating is removed at a later time by tether line or other means from the artery leaving the smallest possible wound hole to self seal.



July 28, 1997 Invention Disclosure (Ex. 1 at 52.)

18. In the fall of 1997 Mr. Nowakowski prepared a provisional patent application which described his innovation as using the patient's own blood to create a homogenous clot to achieve hemostasis at the arterial wound. Mr. Nowakowski's patent application also included detailed drawings of introducer devices that could be used to accomplish this goal.

> **The present invention advocates using the patient's own whole blood too [sic] create a homogenous clotted mass about an arterial wound site or other body location where a seal is desired**. . . .
>
> By activating the clotting cascade and then returning the blood to the wound site before a clot is fully developed, the blood can then form a homogenous clotted mass at the wound site.
>
> Numerous ways of activating the clotting cascade may be used. Experimentation thus far suggests that cotton balls work best. The cotton is placed in a cylinder to form the catalytic cartridge through which blood is passed. Once having been exposed to the cotton, blood clots as a nice homogenous mass. In contrast a material like Pyrex glass causes the blood to clot but causes it to separate out into clot and serum portions. Thus, it is believed that the cotton ball is more effective in not only activating clotting but causing the mass of blood to hold together.
>
> **Again, the invention advocates using the patient's own whole blood for wound sealing**. . . .



December 16, 1997 Provisional Patent Application (Ex. 1 at 5-12) (emphasis added).

19. Mr. Nowakowski filed a non-provisional application in due course. That application incorporated the foregoing materials by reference and expanded on a number of specific techniques and devices which could be used. Mr. Nowakowski explained at some length

that his invention could be implemented in various different ways, depending on the clinical situation and physician preference.

> The current invention concerns a novel method and apparatus for use in hemostatic closure of tissue wounds. The invention activates the clotting cascade of the blood fluid then transports the treated blood fluid to the wound in the patient such that the blood fluid can come into contact with the patient proximate the wound such that a clot is formed in the wound which prevents fluid from passing through the wound.
>
> The preferred embodiments of the apparatus of the present invention may be highly varied and is typically dependent on the individual application considering clinical situation, physician preference, and the like. As such, a clinical situation is selected and physician preference stated here for purposes of providing an illustrative example of one form of the invention apparatus. Presentation of this scenario is intended to be an instructive example of how the invention may be adapted to individual needs and should not be interpreted in a limited context as to how the invention applies. When used as a reference, those skilled in the art will be able to alter configurations and attributes of the apparatus to the same and other needs without departing from the scope and spirit of the present invention. The present example selected is that of post-introducer arterial wound closure following an angiographic procedure and the like. Post-introducer arterial wound closure typically involves the closure of a wound within an arterial wall such as the femoral artery, radial artery, and the like. Such wounds are typically subcutaneous in the sense that the artery is covered by tissue rather than being exposed by cut down through the tissue until the artery is visible to the practitioner. In the present illustration, an apparatus in configured for use typically with autologous whole blood. . . .
>
> FIG. 4 represents the placement of blood fluid having an activated clotting cascade at the wound site. Both the catheter and introducer are withdrawn from the patient until there is a cessation of movement within the blood fluid 39 within the pulsatile indicator thus indicating that the catheter's distal port is now outside the artery. Once this has been established, the syringe plunger is advanced thereby driving clot-activated blood fluid 40 out the distal catheter port and depositing it about the wound where clotting continues. As the blood fluid 40 continues to advance to a mature clot, proximal pressure is applied to the artery and both the introducer and catheter are fully removed from the patient. After typically 3 to 5 minutes, proximal direct pressure may be eliminated and the procedure considered complete. Although not presented in this example, anticlot inhibition may have also been used if desired as previously discussed.

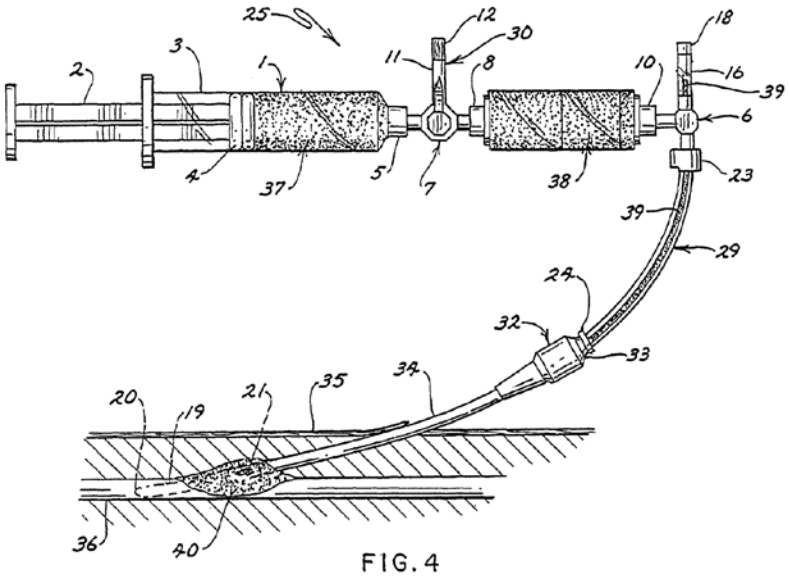


FIG. 4

(Exhibit 2 at 4:9-15, 7:4-27, 8:61-9:9 and Fig. 4.)

20. Mr. Nowakowski is a named inventor on U.S. Patent No. 6,159,232, the parent of the patent on which this Complaint is based, and U.S. Patent Nos. 8,568,448 (Exhibit 2), 8,652,168 (Exhibit 3), 9,669,131 (Exhibit 4) and 9,808,552 (Exhibit 7), which are in the same family.

21. In 1996, Mr. Nowakowski founded the company Closys, Inc. to commercialize his hemostatic wound closure device.

22. Mr. Nowakowski and his colleagues at Closys raised about $8,700,000 over the course of multiple rounds of financing.

23. Closys performed laboratory experiments on Mr. Nowakowski's innovation at Mayo Clinic, in Rochester Minnesota. Along the way, Mr. Nowakowski came to know Dr. Robert Schwartz, who as Professor of Cardiovascular Medicine for Mayo Medical School. Dr. Schwartz experimented with Mr. Nowakowski's invention in animal models and called it "impressive."

24. In a 2008 report by the leading industry publication, Life Science Intelligence, AccessClosure and Closys were identified as competitors in the vascular closure space. Newswires explained that the report "[e]stablished and emerging competitors are covered, including suppliers such as Abbott (ABT), AccessClosure, Cardiva Medical, CloSys, Datascope (DSCP), Marine Polymer Technologies, Medtronic (MDT), Morris Innovative Research, Possis Medical (POSS), Radi Medical Systems, Scion Cardiovascular, Therus, St. Jude Medical (STJ), Sutura (SUTU.OB), TZ Medical, and Vascular Solutions (VASC)." *Global Vascular Closure Device Market to Exceed $900 Million by 2013*, Business Wire (July 23, 2008), http://businesswire.com/news/home/20080723005770/en/Global-Vascular-Closure-Drvice-Market-to-Exceed-$900-Million-by-2013.

25. On information and belief, AccessClosure was aware of Closys and its patent portfolio at least as early as 2008. At a minimum, AccessClosure should have been aware of Closys' patent portfolio by that time.

26. On information and belief, by 2008 AccessClosure's sales of the Mynx® vascular closure devices reached about $50,000,000 annually.

27. Also in 2008, Saint Jude Medical sued AccessClosure for patent infringement in the Texarkana Division of the Western District of Arkansas. *St. Jude Medical, Inc., et. al. v. Access Closure, Inc.*, 4-08-cv-04101 (ARWD Texarkana). AccessClosure was found to have infringed Saint Jude's patents and a jury awarded St. Jude $27,000,000 in damages and granted an injunction. On appeal the Federal Circuit affirmed the district court's finding as to one of the two patent families. *St. Jude Medical, Inc. v. Access Closure, Inc.*, 729 F. 3d 1369 (Fed.Cir. 2013). Because that patent family had expired, AccessClosure was permitted to keep selling the Mynx® product.

28. In April 2014, AccessClosure was purchased by Cardinal Health, Inc. for $320,000,000 in cash. At that time, AccessClosure's sales of the Mynx® vascular closure device had reached $80,000,000 annually. http://www.prnewswire.com/news-releases/cardinal-health-completes-acquisition-of-accessclosure-258889211.html.

29. On information and belief, in or about September 2014, AccessClosure (then Cardinal Health) settled with Saint Jude Medical on terms which remain confidential.

30. In November 2013 the United States Patent and Trademark Office brought one of Mr. Nowakowski's patents to AccessClosure's attention. After AccessClosure filed a patent application directed to vascular wound closure, the patent examiner searched for relevant prior art that predated AccessClosure's work. One of the references cited by the Examiner was Mr. Nowakowski's U.S. Patent No. 6,159,232, the parent of the patents on which the counts of this complaint are based.

31. Mr. Nowakowski and his company Closys needed additional funding to take his innovation through clinical trials. However, that funding was not available due to presence of infringing Mynx® product on the market.

32. Due to the market penetration achieved by the infringing Mynx® devices, Closys was unable to successfully raise additional funds to commercialize its product.

33. In March 2015, Kevin Dillon, CEO of Closys, contacted Michael Duski, Senior Vice President of Cardinal Health, concerning the patents Mr. Nowakowski had been awarded for his invention. Exhibit 5. During a phone call Mr. Dillon explained that at least two of Mr. Nowakowski's patents, U.S. Patent Nos. 8,568,448 and 8,652,168, covered the Mynx® product. *Id*. at 2-3. Mr. Dillon sent Mr. Duski claim charts specifically demonstrating how the Mynx® products were covered by claims of the '448 patent. *Id.* at 2, 7-10.

34. Mr. Duski responded that Cardinal Health's attorneys had considered the patents and concluded that the term "cross-linked polymer" recited in the claim of the '448 patent did not cover the Mynx® polyethylene glycol (PEG) plug. *Id.* at 1. Cardinal Health did not dispute that PEG was a cross-linked polymer, as that term is generally understood. *Id.* Rather, Cardinal Health argued that Mr. Nowakowski's patent was limited to the preferred embodiment described in the non-provisional filing: an embodiment wherein the cross-linked polymer was fibrin polymer and the blood was extracted from the patient and collected in an external reservoir. *Id.*

35. However, Mr. Nowakowski's patents described embodiments which (i) omitted the step of externally collecting the blood, and (ii) used a cross-linked synthetic polymer to clot the blood. On the first point, Mr. Nowakowski's patent application stated that "[i]f it is desired to return blood immediately to the wound site after activation by a clot inducing catalyst, it may be possible to eliminate the external collection reservoir altogether." (Ex. 1 at 54.) On the second issue, Mr. Nowakowski's patent application specifically teaches that the procoagulant additionally includes synthetic porous material comprising a procoagulant including "polymers like dacron, nylon, polypropylene, silicone, and the like." (Ex. 2 at 4:66-5:2.) As is well known in the medical device industry, any silicone polymer in gel or solid form is cross-linked.

36. Moreover, as discussed above, Mr. Nowakowski was quite clear that the embodiments described were merely exemplary. (Ex. 2 at 7:4-7:13.) ("The preferred embodiments of the apparatus of the present invention may be highly varied and is typically dependent on the individual application considering clinical situation, physician preference, and the like. As such, a clinical situation is selected and physician preference stated here for purposes of providing an illustrative example of one form of the invention apparatus. Presentation of this scenario is intended to be an instructive example of how the invention may be adapted to

individual needs and should not be interpreted in a limited context as to how the invention applies.")

37. On information and belief, Cardinal Health's attorneys understood that it is axiomatic that patent claims are not limited to the preferred embodiment described by the inventor. "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Company v. Medrad, Inc.*, 358 F. 3d 898, 906 (Fed.Cir. 2004).

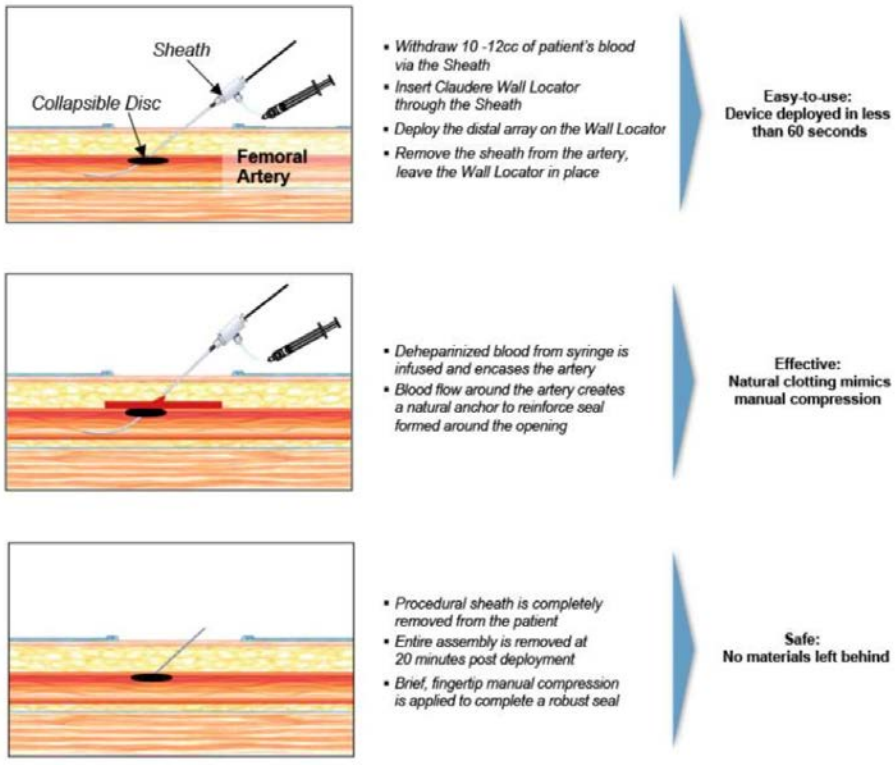
38. Turning to the second patent that was brought to Cardinal Health's attention, Cardinal Health "[took] a close look at" U.S. Patent No. 8,652,168 but did not offer any explanation as to why the Mynx® product did not infringe other than to suggest that the patent was somehow limited to "devices/procedures whereby a patient's blood is withdrawn from the body to initiate the clotting process." (Ex. 5 at 3.) Here again, Mr. Nowakowski's patent filings repeatedly stated that the described embodiments were merely exemplary.

39. At the conclusion of Mr. Duski's email, he stated that "our position has not changed and at this time, we are still not interested in moving forward with any further discussions concerning the Closys product and/or its Intellectual Property."

40. Cardinal Health lacked a good faith and reasonable belief that the Mynx® product did not infringe Mr. Nowakowski's patents.

41. Recently Closys reorganized as Claudere Vascular in a final attempt to penetrate the market notwithstanding Cardinal Health's willful infringement. Claudere Vascular's HD solution is shown below.

42. In Claudere's particular implementation of Mr. Nowakowski's invention, an inflatable disc is used to locate the catheter at the arterial wound site. Thereafter a hydrogel comprising the patient's whole blood is positioned at the wound site, after which the artery is sealed as the blood completely clots.



43. Claudere Vascular has been unable to penetrate the market due to Cardinal Health's widespread infringement. Claudere has largely ceased business operations.

44. Mr. Nowakowski's company St. Croix Surgical Systems has duly acquired his patents from Claudere Vascular.

45. The United States Patent and Trademark Office (USPTO) recently granted Mr. Nowakowski yet another patent on his invention and, in so doing, reaffirmed the breadth of Mr. Nowakowski's inventive concept. Mr. Nowakowski presented to the USPTO claims which recite "homogenously reacting the patient's arterial whole blood in a porous matrix that is not of biological origin." So as to make it clear that his invention was not limited to the preferred embodiments described in the non-provisional application, Mr. Nowakowski explained repeatedly that his claimed invention was not limited to the preferred embodiments of the non-provisional application's specification. In his March 8, 2017 communication to the USPTO, Mr. Nowakowski explained that

> Applicant also would like to bring to the Examiner's attention the following portions of originally filed specification. Provisional Application Serial No. 60/069,834 at page 53 of 54 teaches that "[i]f it is desired to return blood immediately to the wound site after activation by a clot inducing catalyst, it may be possible to eliminate the external collection reservoir altogether." That is consistent with application's broad teaching that "[t]the present invention advocates using the patient's own whole blood too [sic] create a homogenous clotted mass about an arterial wound site or other body location where a seal is desired." *Id.* at page 5 of 54. Accordingly, the innovation recited in claim 62 does not require external collection of the blood. In contrast, dependent claims 66 and 68 positively recite that the exposing step occurs outside the patient or that the cross-linked polymer is transported from a position outside the body.

March 8, 2017 response to non-final office action at 8-9.

46. The USPTO agreed that the claimed subject matter was patentable as broadly claimed and described by Mr. Nowakowski. In her notice of allowance, the Examiner raised no

objection to Mr. Nowakowski's characterization of the breadth of his innovation. May 1, 2017 Notice of Allowance.

47. The USPTO has duly issued Mr. Nowakowski U.S. Patent No. 9,669,131.

48. After filing of the original Complaint, the USPTO granted U.S. Patent No. 9,808,552 (issued November 7, 2017) to Mr. Nowakowski. Mr. Nowakowski has now been issued eight patents, each of which covers different aspects and embodiments of his innovation: 6,159,232, 6,478,808, 6,989,022, 8,652,168, 8,568,448, 8,652,169, 9,669,131, 9,808,552 and 9,839,716.

COUNT I:
CARDINAL HEALTH'S INFRINGEMENT OF U.S. PATENT NO. 9,808,552

49. St. Croix repeats the allegations of paragraphs 1-48 above as though fully set forth herein.

50. On November 7, 2017, U.S. Patent No. 9,808,552 ("the '552 patent"), entitled "Apparatus for Closing Wounds," was duly and legally issued by the United States Patent and Trademark Office. A true and correct copy of the '552 patent is attached as Exhibit 7.

51. St. Croix is the assignee and owner of the right, title and interest in and to the '552 patent, including the right to assert all causes of action arising under said patent and the right to any remedies for infringement of them.

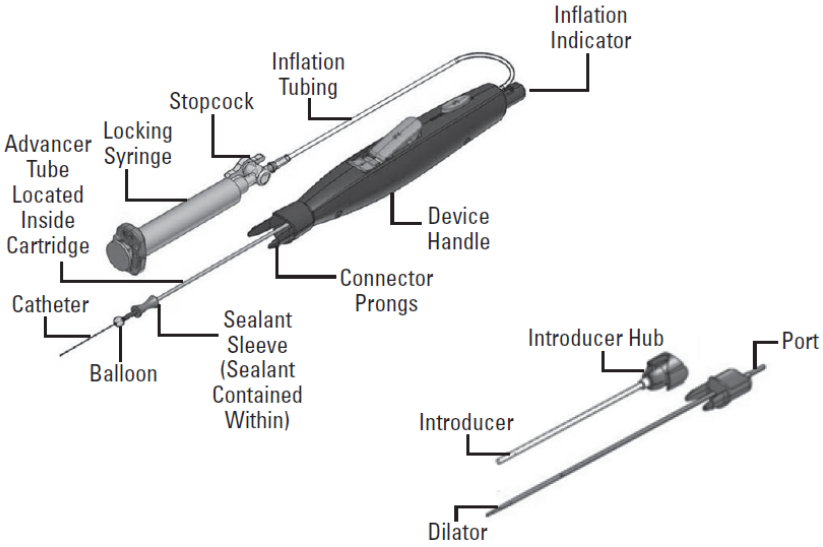
52. Upon information and belief, Cardinal Health has and continues to directly and indirectly infringe at least claims 1-4, 7-14, and 16-20 of the '552 patent by making, using, selling, importing and/or providing and causing to be used the Mynx® devices.

53. Claim 1 of the '552 patent recites an "apparatus for using a volume of a patient's whole blood to close a subcutaneous arterial wound in the patient." According to Cardinal Health's website, "[t]he MYNX® product family utilizes the proprietary GRIP™ sealant to seal

the arteriotomy. The GRIP™ sealant, comprised of Polyethylene Glycol (PEG), grips the artery, providing a secure close." http://www.cardinalhealth.com/en/product-solutions/medical/cardiovascular/mynx-vascular-closure-devices.html. As shown in the Mynx® video available on YouTube, the platelets accumulate in the porous matrix, after which the blood clots. https://www.youtube.com/watch?v=_kcJM1lnQo8 ("Platelets and blood cells continue to collect inside the Mynx® sealant's porous matrix, causing the sealant to swell three to four times its original size. Together the Mynx® sealant and the grip tip provide a durable hemostasis and a platform for natural vessel healing.") *See also* https://www.youtube.com/watch?v=4rXGfe5xX9g.

54. Claim 1 next recites "a syringe." As discussed and shown above, the Mynx® catheter is introduced through the wall of the artery, after which the balloon is inflated and pulled back so that it seats against the artery wall at the site of the puncture. Saline is delivered via a syringe to inflate the balloon.

Figure 1: Mynx Ace Vascular Closure Device

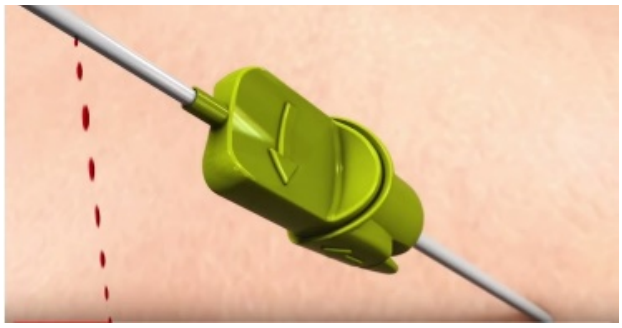


(Exhibit 8 at 12.)

55. Claim 1 also recites "a valve coupled to the syringe." As illustrated in Figure 1,

reproduced above, the locking syringe is coupled with a stopcock. (*Id.*)

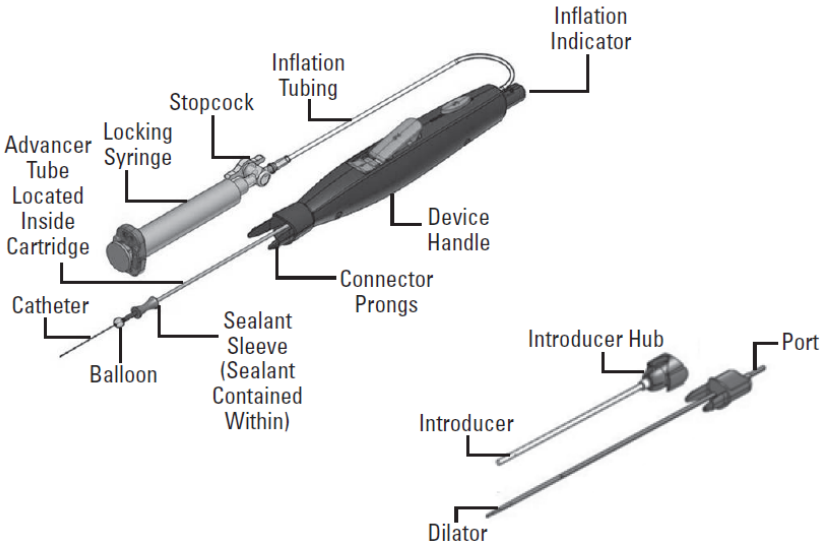
56. Claim 1 further recites "a pulsatile indicator". The Mynx® Instruction Guide instructs the user to "[a]dvance the introducer over the guidewire until pulsatile blood flow is observed through the port at the proximal end of the dilator." (Ex. 8 at 14, see also FIG. 1 above). Further, the Mynx® video illustrates blood releasing from the pulsatile indicator:



https://www.youtube.com/watch?v=-FVR3gokZik

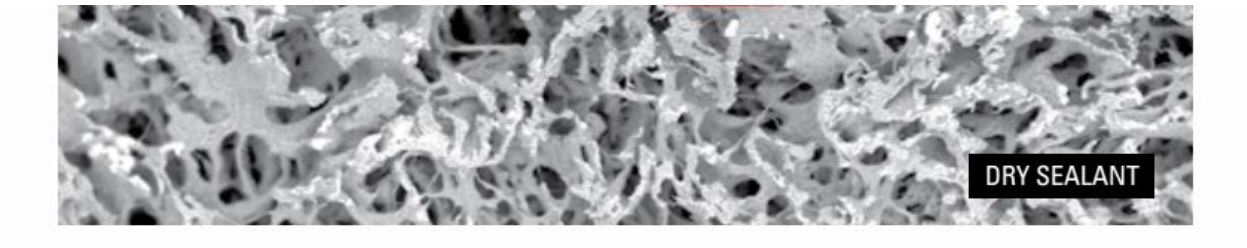
57. Claim 1 next recites "a tube having a proximal end and a distal end." As illustrated in the Mynx® Instruction Manual, reproduced below, a tubular catheter is provided between a proximal end connected to the handle of the Mynx® product and a distal end configured to enter the arterial wound:

Figure 1: Mynx Ace Vascular Closure Device



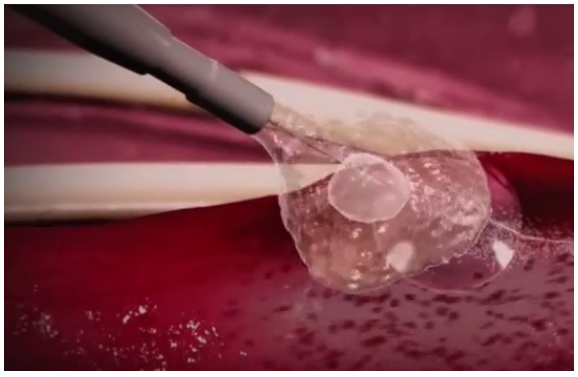
(Ex. 8 at 12).

58. Claim 1 also recites "a porous matrix." As explained and shown above, the Mynx® product forms a clot by exposing the patient's whole blood to a porous matrix of Mynx® sealant. A picture of the porous matrix is provided in one of AccessClosure's brochures:



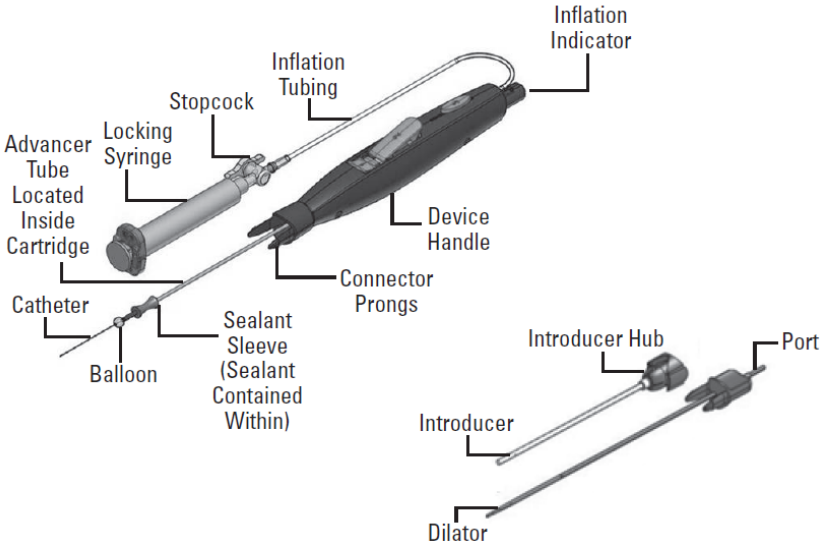
(Exhibit 6 at 2).

59. Claim 1 further recites "a cylindrical enclosure coupled to the tube and at least partially surrounding the porous matrix and configured to, in cooperation with the tube, effect homogenous exposure of the patient's whole blood to the porous matrix to initiate a clotting cascade in the patient's whole blood." The Mynx® Ace marketing video illustrates a cylindrical enclosure (sealant sleeve) surrounding the porous matrix (Mynx® sealant) and pushing out the porous matrix:



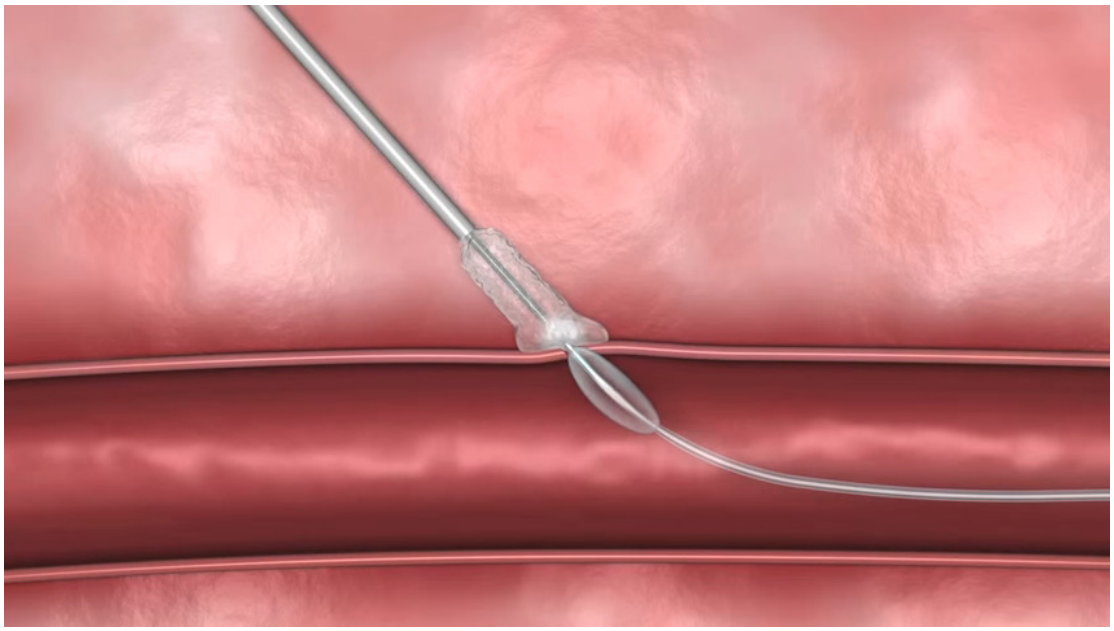
As illustrated above, the cylindrical enclosure extends from the tube (catheter). The coupling of the sealant sleeve with the catheter is illustrated in Figure 1 of the Mynx® Instruction Guide, reproduced below:

Figure 1: Mynx Ace Vascular Closure Device

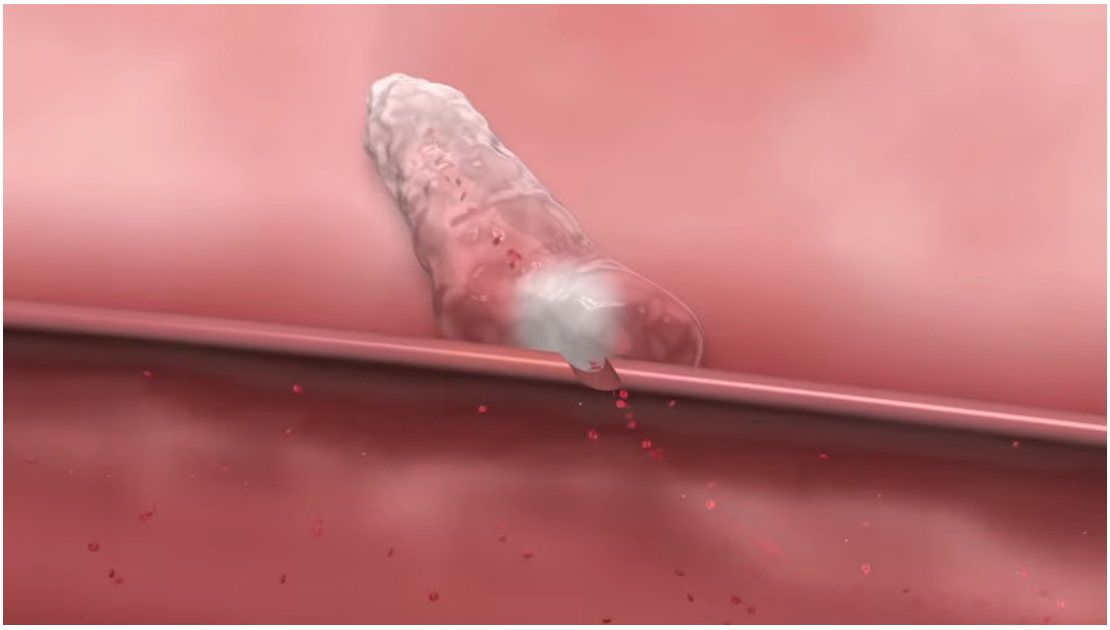


(Ex. 8 at 12). The closure is accomplished by exposing the whole blood to the porous matrix that holds the platelets in proximity to one another, thereby allowing a clotting cascade to occur and forming a blood clot that achieves hemostasis.

60. Claim 1 next recites "wherein the tube and porous matrix are further configured to situate the patient's whole blood at a position proximate the arterial wound as the patient's whole blood is clotting in order to form a hemostatic closure comprising the patient's whole blood." According to the video and as depicted in the screenshots below, "[t]emporary hemostasis is achieved first by placing an intra-arterial balloon, followed immediately by delivery of the Mynx® Grip sealant, which is positioned on surface of the artery."



The sealant and the balloon are both delivered via the tube (e.g., catheter). According to the video and as depicted in the screenshot below, "[p]latelets and blood cells continue to collect inside the Mynx® sealant's porous matrix, causing the sealant to swell three to four times its original size." https://www.youtube.com/watch?v=_kcJM1lnQo8.

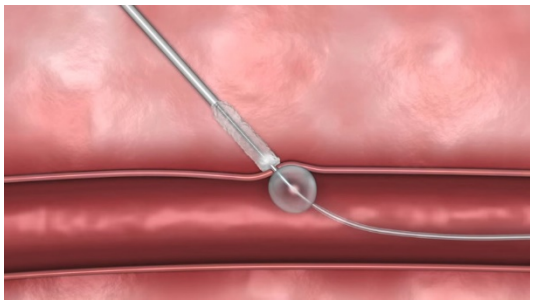


"As blood collects in the sealant's matrix, it clots producing a durable hemostasis." In other

words, the hemostasis is achieved by the patient's clotted whole blood. https://www.youtube.com/watch?v=4rXGfe5xX9g. Meanwhile, the Mynx® Grip Tip portion of the sealant holds the clot-activated blood at the site until the clotting cascade has completed.

61. Claim 2 recites "the hemostatic closure comprises cross-linked polymer." As discussed above, the Mynx® sealant comprises cross-linked polyethylene glycol. Moreover, a blood clot is formed by converting fibrinogen to a fibrin monomer, then fibrin polymer which ultimately becomes a crosslinked fibrin polymer.

62. Claim 3 recites that the "apparatus is configured to establish the hemostatic closure about a surface of the artery comprising the subcutaneous arterial wound." According to the video and as depicted in the screenshots below, "[t]emporary hemostasis is achieved first by placing an intra-arterial balloon, followed immediately by delivery of the Mynx Grip® sealant, which is positioned on surface of the artery." https://www.youtube.com/watch?v=_kcJM1lnQo8.



63. Claim 4 recites "the porous matrix is not of biological origin." Cross-linked polyethylene glycol is not of biological origin.

64. Claim 7 recites that the "porous matrix is configured to homogenously receive the patient's whole blood." As discussed and shown above, the final mass is comprised of an even distribution of platelets and PEG gel. Upon expansion, the Mynx® sealant forms a hydrogel mass that is comprised of 5% PEG and 95% whole blood.

65. Claim 8 recites that the "hemostatic closure comprises a gel-like mass." The

MynxAce instruction for use describes the sealant as a hydrogel. (Ex. 8 at 2 ("The balloon catheter is loaded with a single Hydrogel sealant. Reuse of the device would result in no delivery of Hydrogel sealant.").)

66. Claim 9 recites that the "gel-like mass comprises fibrin polymer and at least 90% of the available fibrin polymer is cross-linked." As discussed above, the hydrogel mass is comprised of 95% whole blood. The clotting cascade causes cross-linking of at least 90% of the available fibrin polymer within the whole blood.

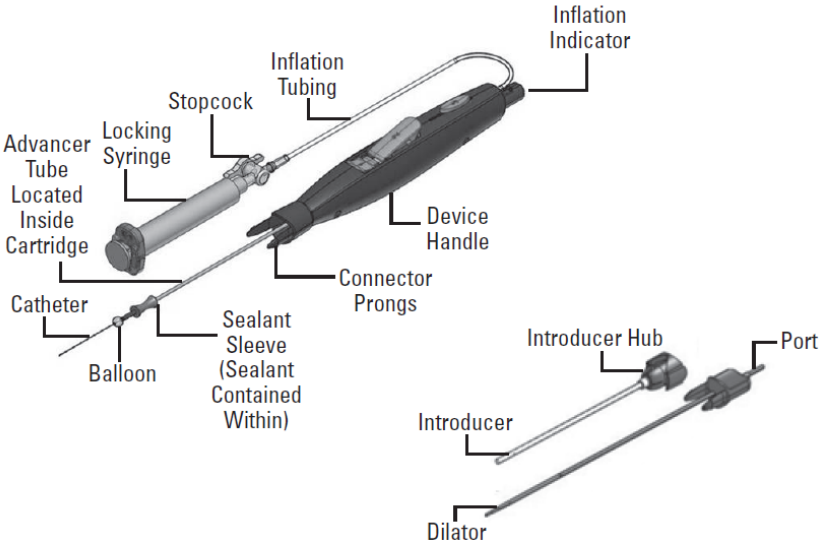
67. Claim 10 recites that the "syringe, tube and cylindrical enclosure are configured to cooperate to situate a cross-linked polymer at a position outside the artery." As discussed in relation to claim 1, the Mynx Ace marketing video illustrates the cylindrical enclosure (extending from within the catheter) surrounding the Mynx® sealant (e.g., cross-linked polymer) and pushing out the Mynx® sealant. https://www.youtube.com/watch?v=_kcJM1lnQo8. Meanwhile, the saline provided from the syringe has inflated the balloon, physically blocking the Mynx® sealant from entering the wound site and thereby aligning the Mynx® sealant at a position outside the artery. *Id*. The patient's whole blood enters the Mynx® sealant and cross-links during a clotting cascade into cross-linked fibrin polymer.

68. Claim 11 recites "an arterial wound closure apparatus." According to Cardinal Health's website, "[t]he MYNX® product family utilizes the proprietary GRIP™ sealant to seal the arteriotomy. The GRIP™ sealant, comprised of Polyethylene Glycol (PEG), grips the artery, providing a secure close." http://www.cardinalhealth.com/en/product-solutions/medical/cardiovascular/mynx-vascular-closure-devices.html.

69. Claim 11 next recites "a syringe." As discussed and shown above, the Mynx® catheter is introduced through the wall of the artery, after which the balloon is inflated and pulled

back so that it seats against the artery wall at the site of the puncture. Saline is delivered via a syringe to inflate the balloon.

Figure 1: Mynx Ace Vascular Closure Device

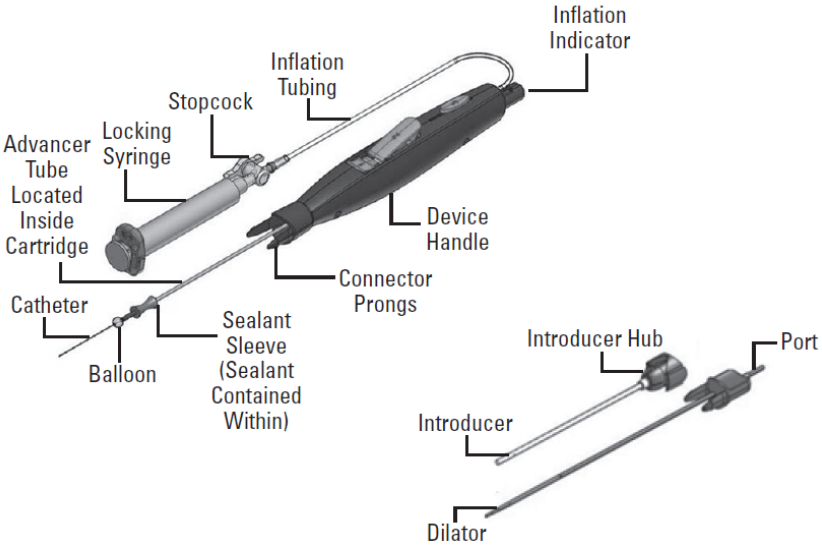


(Ex. 8 at 12.)

70. Claim 11 also recites "a valve coupled to the syringe." As illustrated in Figure 1, reproduced above, the locking syringe is coupled with a stopcock. (*Id.*)

71. Claim 11 next recites "a tube having a proximal end and a distal end." As illustrated in the Mynx® Instruction Manual, reproduced below, a tubular catheter is provided between a proximal end connected to the device handle of the Mynx® product and a distal end configured to enter the arterial wound:

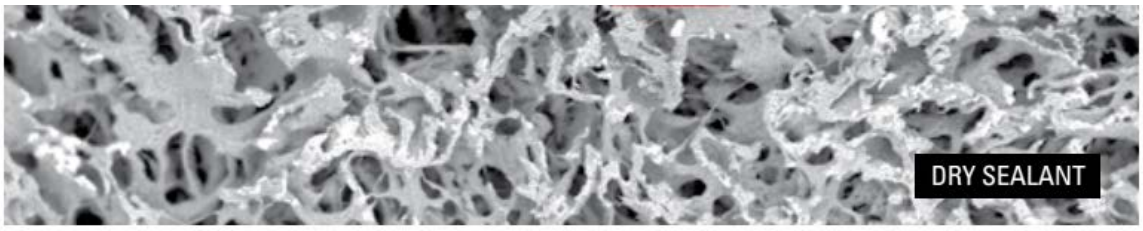
Figure 1: Mynx Ace Vascular Closure Device



(Ex. 8 at 12).

72. Claim 11 further recites an "introducer configured to receive the tube." As illustrated in FIG. 1, reproduced above, the Mynx® product includes an introducer.

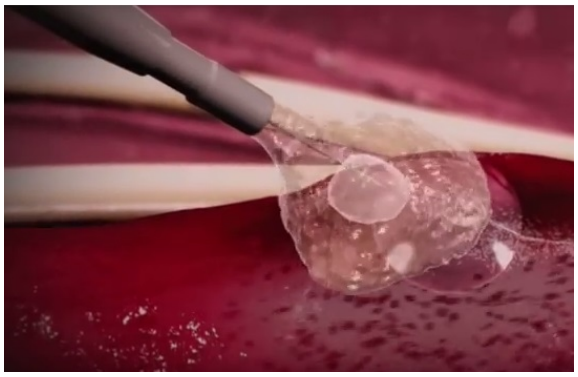
73. Claim 11 next recites "a porous matrix". As explained and shown above, the Mynx® product forms a clot by exposing the patient's whole blood to a porous matrix of Mynx® sealant. A picture of the porous matrix is provided in one of AccessClosure's brochures:



(Ex. 6 at 2).

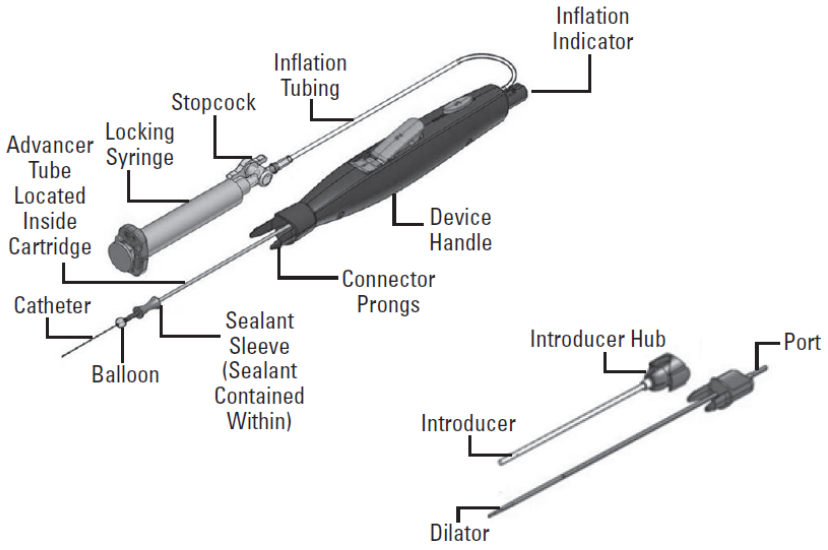
74. Claim 11 additionally recites an "enclosure coupled to the tube and retaining the porous matrix and further configured to, in cooperation with the tube, effect homogenous exposure of a patient's whole blood to the porous matrix to initiate a clotting cascade in the patient's whole blood." The Mynx® Ace marketing video illustrates an enclosure (sealant sleeve)

surrounding the porous matrix (Mynx® sealant) and pushing out the porous matrix:



As illustrated above, the enclosure extends from the tube (catheter). The coupling of the sealant sleeve with the catheter is illustrated in Figure 1 of the Mynx® Instruction Guide, reproduced below:

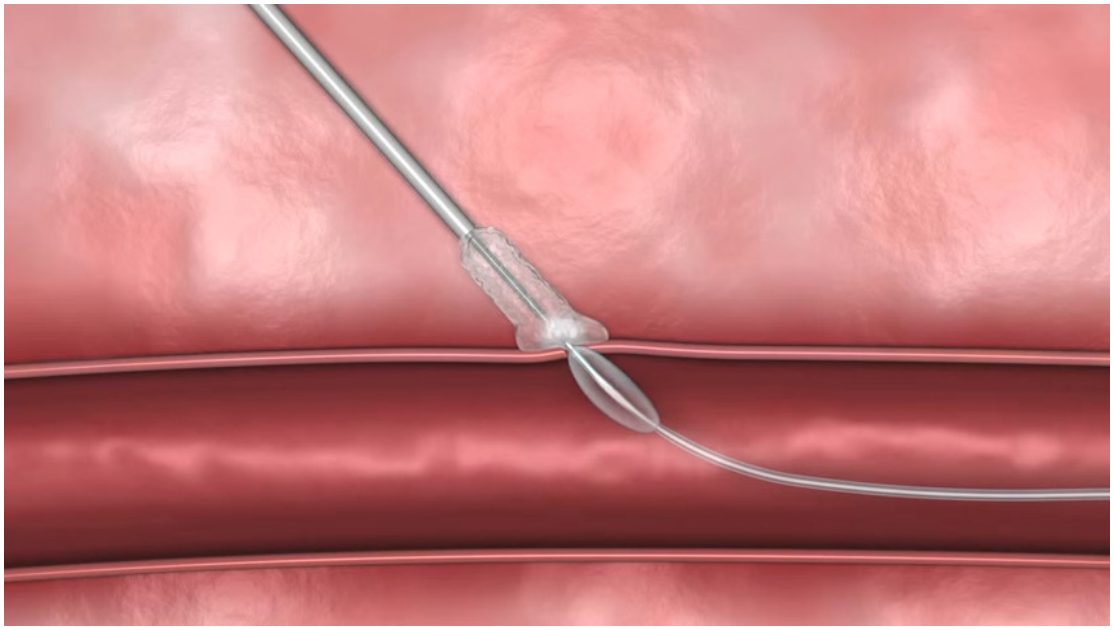
Figure 1: Mynx Ace Vascular Closure Device



(Ex. 8 at 12). The closure is accomplished by exposing the whole blood to the porous matrix that holds the platelets in proximity to one another, thereby allowing a clotting cascade to occur and forming a blood clot that achieves hemostasis.

75. Claim 11 finally recites that the "tube, introducer and porous matrix are further configured to situate the patient's whole blood at a position proximate the subcutaneous arterial wound as the patient's whole blood is clotting in order to form a hemostatic closure comprising

the patient's whole blood. The Instruction Manual states that the "Mynx Ace Vascular Closure Device (Mynx Ace) is designed to **achieve femoral artery hemostasis** via delivery of Grip Technology, an extravascular, water-soluble synthetic sealant, **using a balloon catheter in conjunction with a custom introducer** sheath." (Ex. 8 at 2, emphasis added.) According to the video and as depicted in the screenshots below, "[t]emporary hemostasis is achieved first by placing an intra-arterial balloon, followed immediately by delivery of the Mynx® Grip sealant, which is positioned on surface of the artery." https://www.youtube.com/watch?v=_kcJM1lnQo8.

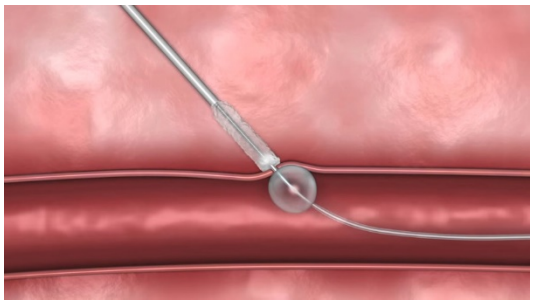


The sealant and the balloon are both delivered via the tube (e.g., catheter) which is inserted through the introducer. According to the video and as depicted in the screenshot below, "[p]latelets and blood cells continue to collect inside the Mynx® sealant's porous matrix, causing the sealant to swell three to four times its original size." https://www.youtube.com/watch?v=_kcJM1lnQo8.

"As blood collects in the sealant's matrix, it clots producing a durable hemostasis." https://www.youtube.com/watch?v=4rXGfe5xX9g. In other words, the hemostasis is achieved by the patient's clotted whole blood. Meanwhile, the Mynx® Grip Tip portion of the sealant holds the clot-activated blood at the site until the clotting cascade has completed.

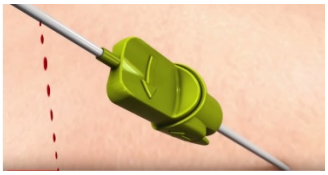
76. Claim 12 recites that the "hemostatic closure comprises cross-linked polymer." As discussed above, the Mynx® sealant comprises cross-linked polyethylene glycol. Moreover, a blood clot is formed by converting fibrinogen to a fibrin monomer, then fibrin polymer which ultimately becomes a crosslinked fibrin polymer.

77. Claim 13 recites that the "apparatus is configured to establish the hemostatic closure about a surface of the artery comprising the subcutaneous arterial wound." According to the video and as depicted in the screenshots below, "[t]emporary hemostasis is achieved first by placing an intra-arterial balloon, followed immediately by delivery of the Mynx Grip® sealant, which is positioned on surface of the artery." https://www.youtube.com/watch?v=_kcJM1lnQo8.



78. Claim 14 recites that the "porous matrix is not of biological origin." Cross-linked polyethylene glycol is not of biological origin.

79. Claim 16 recites a "pulsatile indicator." The Mynx® Instruction Guide instructs the user to "[a]dvance the introducer over the guidewire until pulsatile blood flow is observed through the port at the proximal end of the dilator." (Ex. 8 at 14, see also FIG. 1 above). Further, the Mynx® video on YouTube illustrates blood releasing from the pulsatile indicator:



https://www.youtube.com/watch?v=-FVR3gokZik

80. Claim 17 recites that the "porous matrix is configured to homogenously receive the patient's whole blood." As discussed and shown above, the final mass is comprised of an even distribution of platelets and PEG gel. Upon expansion, the Mynx® sealant forms a hydrogel mass that is comprised of 5% PEG and 95% whole blood.

81. Claim 18 recites that the "hemostatic closure comprises a gel-like mass." The Mynx Ace instruction for use describe the sealant as a hydrogel. (Ex. 8 at 2 ("The balloon catheter is loaded with a single Hydrogel sealant. Reuse of the device would result in no delivery of Hydrogel sealant.").)

82. Claim 19 recites that the "gel-like mass comprises fibrin polymer and at least 90%

of the available fibrin polymer is cross-linked." As discussed above, the hydrogel mass is comprised of 95% whole blood. The clotting cascade causes cross-linking of at least 90% of the available fibrin polymer within the whole blood.

83. Claim 20 recites that the "syringe, tube and enclosure are configured to cooperate to situate a cross-linked polymer at a position outside the artery." As discussed in relation to claim 11, the Mynx Ace marketing video illustrates the enclosure (extending from within the catheter) surrounding the Mynx® sealant (e.g., cross-linked polymer) and pushing out the Mynx® sealant. https://www.youtube.com/watch?v=_kcJM1lnQo8. Meanwhile, the saline provided from the syringe has inflated the balloon, physically blocking the Mynx® sealant from entering the wound site and thereby maintaining the Mynx® sealant at a position outside the artery. The patient's whole blood enters the Mynx® sealant and cross-links during a clotting cascade into cross-linked fibrin polymer.

84. On information and belief, the Infringing Instrumentalities are marketed, provided to, and/or used by or for Defendant's partners, clients, customers and end users across the country and in this District.

85. Cardinal Health's infringement of the '552 patent is and continues to be knowing, intentional, and willful, in whole or in part at least as of the filing date of this Complaint.

86. On information and belief, Cardinal Health has known of the existence of the '552 patent since its issuance, and its acts of infringement have been willful and in disregard for the '552 patent without any reasonable basis for believing that it had the right to engage in the infringing conduct.

87. Upon information and belief, since at least the time Defendant has been made aware of the '552 patent, Defendant has induced and continues to induce others to infringe at

least one claim of the '552 patent under 35 U.S.C. § 271(b) by, among other things, and with specific intent or willful blindness, actively aiding and abetting others to infringe, including but not limited to Defendant's partners, clients, customers, and end users, whose use of the Infringing Instrumentalities constitutes direct infringement of at least one claim of the '552 patent.

88. In particular, Defendant's actions that aid and abet others such as its partners, customers, clients, and end users to infringe include advertising and distributing the Infringing Instrumentalities and providing instruction materials, training, and services regarding the Infringing Instrumentalities. On information and belief, Defendant has engaged in such actions with specific intent to cause infringement or with willful blindness to the resulting infringement because Defendant has had actual knowledge of the '552 patent and knowledge that its acts were inducing infringement of the '552 patent since at least the date Defendant received notice that such activities infringed the '552 patent.

89. Upon information and belief, Defendant is liable as a contributory infringer of the '552 patent under 35 U.S.C. § 271(c) by offering to sell, selling and importing into the United States Mynx® devices especially made or adapted for use in an infringement of the '552 patent. The Infringing Instrumentalities are a material component for use in practicing the '552 patent and are specifically made and are not a staple article of commerce suitable for substantial non-infringing use.

90. St. Croix has suffered and will continue to suffer damages as a result of Cardinal Health's infringing activities. On information and belief, Cardinal Health has been infringing, and will, unless enjoined by this Court, continue to infringe the '552 patent by making, using, selling, offering to sell, and/or importing, at a minimum, its Mynx® devices.

91. Cardinal Health's acts of infringement of the '552 patent have caused and will continue to cause St. Croix damages for which St. Croix is entitled to compensation pursuant to 35 U.S.C. § 284.

92. Cardinal Health's acts of infringement of the '552 patent have caused and will continue to cause St. Croix immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. St. Croix has no adequate remedy at law.

93. This case is exceptional and, therefore, St. Croix is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT II:
CARDINAL HEALTH'S INFRINGEMENT OF U.S. PATENT NO. 9,839,716

94. St. Croix repeats the allegations of paragraphs 1-93 above as though fully set forth herein.

95. On December 12, 2017, U.S. Patent No. 9,839,716 ("the '716 patent"), entitled "Methods of Closing Wounds," was duly and legally issued by the United States Patent and Trademark Office. A true and correct copy of the '716 patent is attached as Exhibit 9.

96. St. Croix is the assignee and *owner* of the right, title and interest in and to the '716 patent, including the right to assert all causes of action arising under said patent and the right to any remedies for infringement of them.

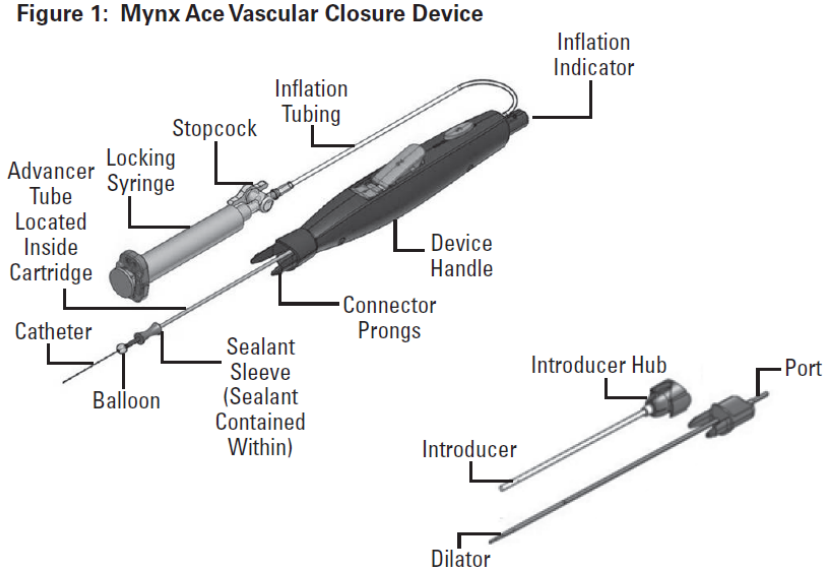
97. Upon information and belief, Cardinal Health has and continues to directly and indirectly infringe at least claims 1-7 and 9-18 of the '716 patent by making, using, selling, importing and/or providing and causing to be used the Mynx® devices.

98. Claim 1 of the '716 patent recites "a method for using a volume of a patient's whole blood to close a subcutaneous arterial wound in the patient." According to Cardinal Health's website, "[t]he MYNX® product family utilizes the proprietary GRIP™ sealant to seal

the arteriotomy. The GRIP™ sealant, comprised of Polyethylene Glycol (PEG), grips the artery, providing a secure close." http://www.cardinalhealth.com/en/product-solutions/medical/cardiovascular/mynx-vascular-closure-devices.html. As shown in the Mynx® video available on YouTube, the platelets accumulate in the porous matrix, after which the blood clots. https://www.youtube.com/watch?v=_kcJM1lnQo8 ("**Platelets and blood cells continue to collect** inside the Mynx® sealant's porous matrix, causing the sealant to swell three to four times its original size. Together the Mynx® sealant and the grip tip provide a durable hemostasis and a platform for natural vessel healing.")

99. Claim 1 next recites "introducing a catheter percutaneously into an artery of the patient." As discussed and shown above, the Mynx® catheter is introduced through the wall of the artery, after which the balloon is inflated and pulled back so that it seats against the artery wall at the site of the puncture. Saline is delivered via a syringe to inflate the balloon.

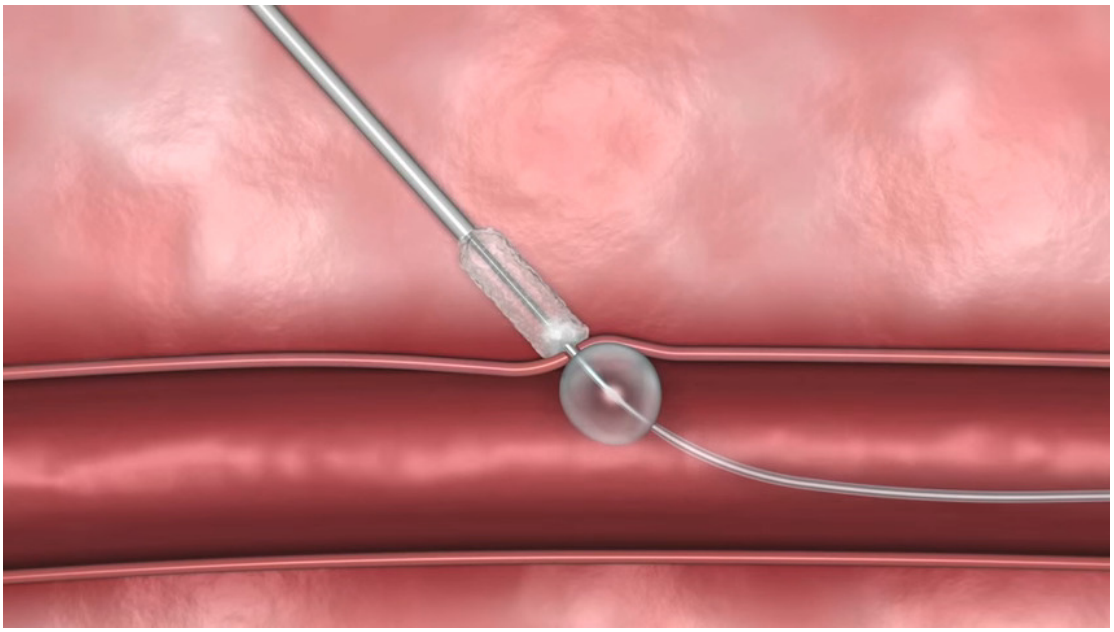
Figure 1: Mynx Ace Vascular Closure Device



(Ex. 8 at 12.)

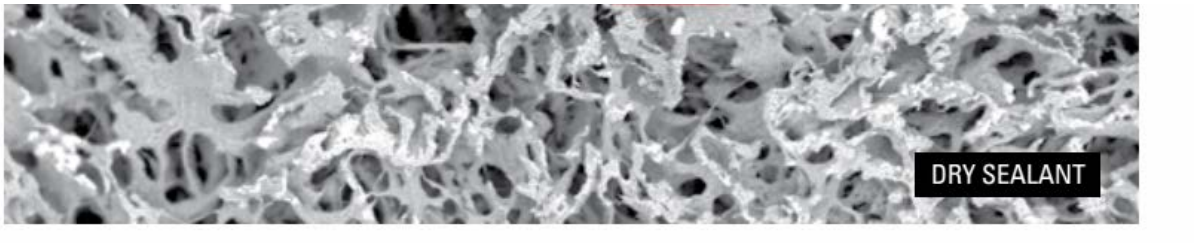
100. Claim 1 also recites "locating an external wall of an artery comprising the subcutaneous arterial wound." According to the video and as depicted in the screen shot below, a

balloon device is used to locate the puncture in the artery and position theMynx sealant proximate the puncture, and "after delivery, the Mynx® Grip sealant is compressed, accelerating expansion and adhesion to the vessel wall." https://www.youtube.com/watch?v=_kcJM1lnQo8.



101. Claim 1 further recites "providing a porous matrix;" As shown in the screen shot below, "[p]latelets and blood cells continue to collect inside the Mynx® sealant's porous matrix, causing the sealant to swell three to four times its original size." https://www.youtube.com/watch?v=_kcJM1lnQo8.

Further, as explained and shown above, the Mynx® product forms a clot by exposing the patient's whole blood to a porous matrix of Mynx® sealant. A picture of the porous matrix is provided in one of AccessClosure's brochures:



(Ex. 6 at 3).

102. Claim 1 next recites "homogenously exposing the patient's whole blood to the porous matrix to initiate a clotting cascade in the whole blood." As discussed and shown above, the Mynx® product forms a clot by exposing the patient's whole blood to a porous matrix of Mynx® sealant. The video referenced herein also shows the platelets accumulate in the porous matrix, after which the blood clots. https://www.youtube.com/watch?v=_kcJM1lnQo8 ("Platelets and blood cells continue to collect inside the Mynx® sealant's **porous matrix**, causing the sealant to swell three to four times its original size. Together the Mynx® sealant and the grip

tip provide a durable hemostasis and a platform for natural vessel healing.") (Ex. 6 at 3.) In sum, the closure is accomplished by exposing the whole blood to an agent (the porous matrix called the Mynx® sealant) that holds the platelets in proximity to one another, thereby allowing a clotting cascade to occur and forming a blood clot that achieves hemostasis.

103. Claim 1 also recites "situating the patient's whole blood at a position proximate the wound as the patient's whole blood is clotting." "The MYNX® product family utilizes the proprietary GRIP™ sealant to seal the arteriotomy. The GRIP™ sealant, comprised of Polyethylene Glycol (PEG), grips the artery, providing a secure close." http://www.cardinalhealth.com/en/product-olutions/medical/cardiovascular/mynx-vascular-closure-devices.html. Meanwhile, the Mynx® Grip Tip portion of the sealant holds the clot-activated blood at the site until the clotting cascade has completed. (Ex. 8 at 13). The closure is accomplished by exposing the whole blood to the porous matrix that holds the platelets in proximity to one another, thereby allowing a clotting cascade to occur and forming a blood clot that achieves hemostasis.

104. Claim 1 also recites "removing the catheter from the artery as the patient's whole blood is clotting." After the initial sealant expansion, the balloon is deflated and the device is removed." https://www.youtube.com/watch?v=_kcJM1lnQo8.

105. Claim 1 further recites "holding a subcutaneous mass comprising the patient's whole blood in position proximate the arterial wound as the patient's whole blood continues to clot." As shown and explained above, closure with the Mynx® device is accomplished by exposing the whole blood to the porous matrix that holds the platelets in proximity to one another, thereby allowing a clotting cascade to occur and forming a blood clot that achieves hemostasis. (Id.) Additionally, "The MYNX® product family utilizes the proprietary GRIP™

sealant to seal the arteriotomy. The GRIP™ sealant, comprised of Polyethylene Glycol (PEG), grips the artery, providing a secure close." http://www.cardinalhealth.com/en/product-olutions/medical/cardiovascular/mynx-vascular-closure-devices.html. Also, the Mynx instructions for use provide that after the device is removed fingertip compress should be applied to the wound. (Ex. 7 at 17 ("Continue to apply fingertip compression for up to 1 minute or as needed. If hemostasis is not achieved, apply additional compression as necessary.").)

106. Claim 2 recites "the method of claim 1, wherein the hemostatic closure comprises cross-linked polymer." As discussed and shown above, the Mynx® sealant comprises cross-linked polyethylene glycol. Moreover, a blood clot is formed by converting fibrinogen to a fibrin monomer, then fibrin polymer which ultimately becomes a crosslinked fibrin polymer.

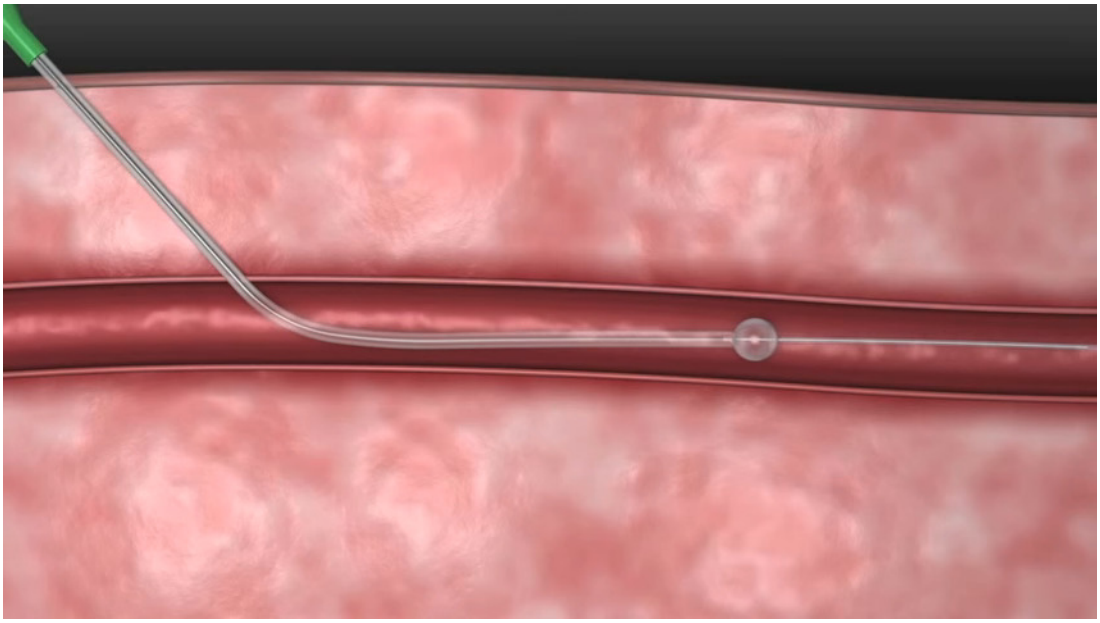
107. Claim 3 recites "the method of claim 1, wherein the introducing is performed prior to the homogenously exposing." As described above, the Mynx® sealant is introduced at the wound site, then "[p]latelets and blood cells … collect inside the Mynx® sealant's porous matrix, causing the sealant to swell three to four times its original size." https://www.youtube.com/watch?v=_kcJM1lnQo8.

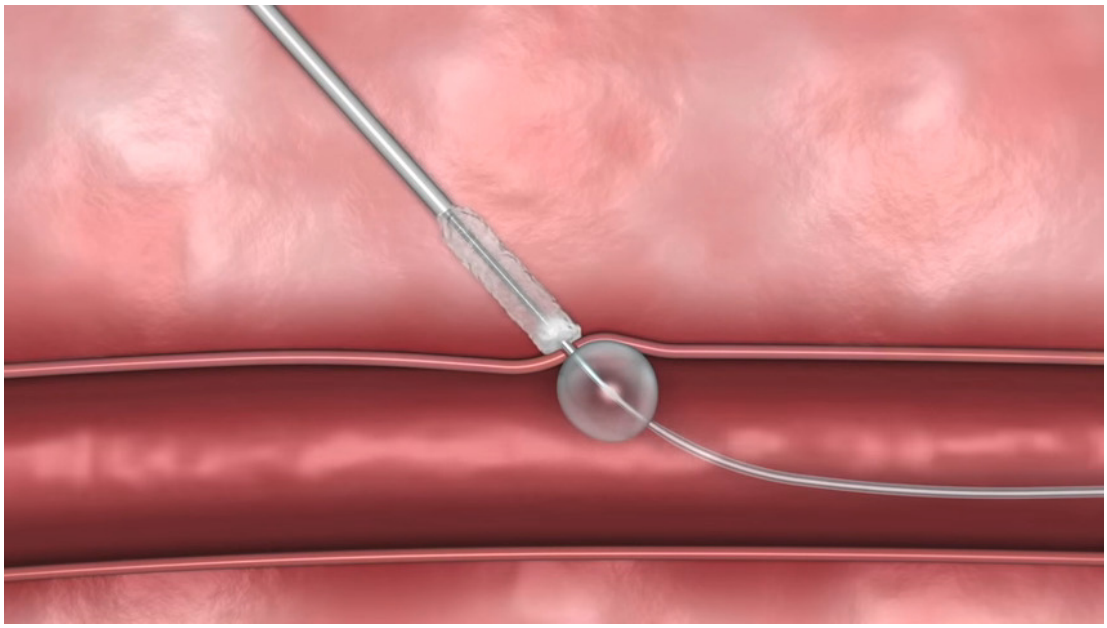
108. Claim 4 recites "the method of claim 1, wherein the locating is performed prior to the homogenously exposing." As described above, a balloon device is used to locate the puncture in the artery and position the Mynx® sealant proximate the puncture, after which "[p]latelets and blood cells … collect inside the Mynx® sealant's porous matrix, causing the sealant to swell three to four times its original size." https://www.youtube.com/watch?v=_kcJM1lnQo8.

109. Claim 5 recites "the method of claim 1, wherein the providing is performed prior to the homogenously exposing. As described above, the porous matrix called the Mynx® sealant is provided to the wound site via a catheter. Then, closure is accomplished by exposing the

whole blood to the Mynx® sealant that holds the platelets in proximity to one another, thereby allowing a clotting cascade to occur and forming a blood clot that achieves hemostasis.

110. Claim 6 recites that the "the method of claim 1, wherein the hemostatic closure is established about a surface of the artery comprising the arterial wound." According to the video and as depicted in the screenshots below, "[t]emporary hemostasis is achieved first by placing an intra-arterial balloon, followed immediately by delivery of the Mynx® Grip sealant, which is positioned on surface of the artery."





111. Claim 7 recites "the method of claim 1, wherein the porous matrix is not of biological origin." Cross-linked polyethylene glycol is not of biological origin.

112. Claim 9 recites "the method of claim 1, wherein the hemostatic closure is biodegradable." According to the Mynx® video, "[t]he sealant dissolves naturally, through hydrolysis. Within thirty days the sealant is complete reabsorbed, leaving nothing behind but a sealed artery. Mynx Grip® grips on contact and leaves without a trace." https://www.youtube.com/watch?v=_kcJM1lnQo8.

113. Claim 10 recites "the method of claim 1, wherein the patient's whole blood comprises an anticoagulant." The article sponsored by AccessClosure explains that the device is particularly well suited for use in anticoagulated patients. (Ex. 5 at 32 ("The 99% clinical success rate in a cohort of 774 patients that included a high percentage of interventional procedures in anticoagulated patients suggests potentially broader utility for MynxGrip in complex patients.").)

114. Claim 11 recites "the method of claim 1, wherein the hemostatic closure comprises a gel-like mass." The MynxAce instructions for use describe the sealant as a hydrogel. (Ex. 7 at 2 ("The balloon catheter is loaded with a single Hydrogel sealant. Reuse of the device

would result in no delivery of Hydrogel sealant.").)

115. Claim 12 recites "the method of claim 11, wherein the gel-like mass comprises fibrin polymer and at least 90% of the available fibrin polymer is cross-linked." As discussed above, the hydrogel mass is comprised of 95% whole blood. The clotting cascade causes cross-linking of at least 90% of the available fibrin polymer within the whole blood.

116. Claim 13 recites "the method of claim 12, wherein the step of holding the subcutaneous mass comprises holding the patient's whole blood in position outside the artery as the patient's whole blood continues to clot." "As blood collects in the sealant's matrix, it clots producing a durable hemostasis." https://www.youtube.com/watch?v=4rXGfe5xX9g. In other words, the hemostasis is achieved by the patient's clotted whole blood. Meanwhile, the Mynx® Grip Tip portion of the sealant holds the clot-activated blood at the site until the clotting cascade has completed. Also, the Mynx instructions for use provide that after the device is removed fingertip compress should be applied to the wound. (Ex. 7 at 17 ("Continue to apply fingertip compression for up to 1 minute or as needed. If hemostasis is not achieved, apply additional compression as necessary.").)

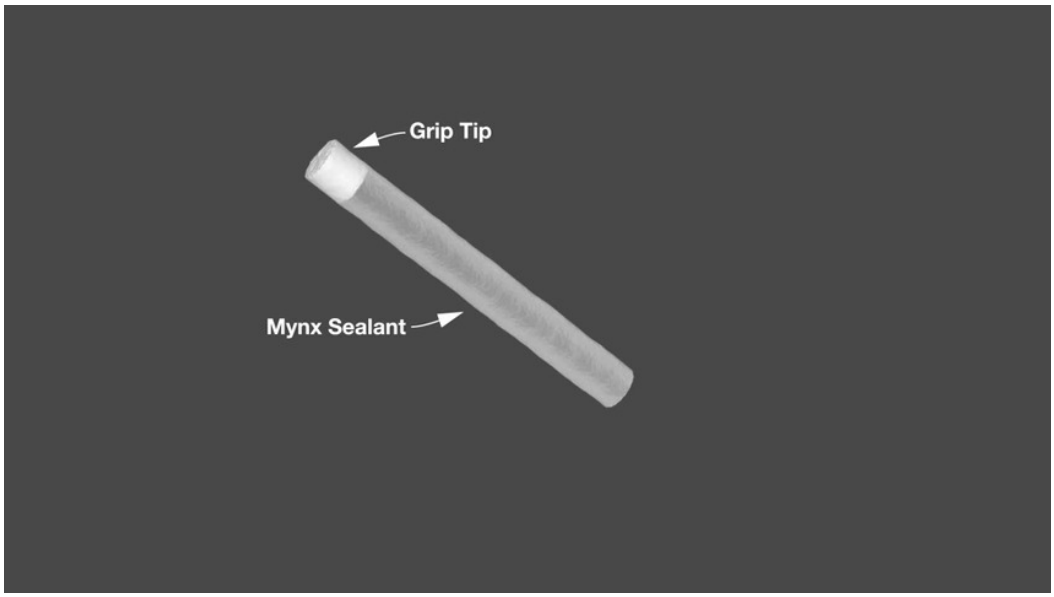
117. Claim 14 recites "the method of claim 13, wherein the hemostatic closure comprising the patient's whole blood is formed by holding the subcutaneous mass comprising the patient's whole blood adjacent to and outside the arterial wound." As discussed and shown above, the mass is formed between the skin of a patient and adjacent the puncture in the artery that is to be sealed. As described and depicted above, a balloon device is used to locate the puncture in the artery and position the Mynx sealant adjacent to and outside the arterial wound.

118. Claim 15 recites "the method of claim 11, wherein the step of holding the subcutaneous mass comprises holding the patient's whole blood in position outside the artery as

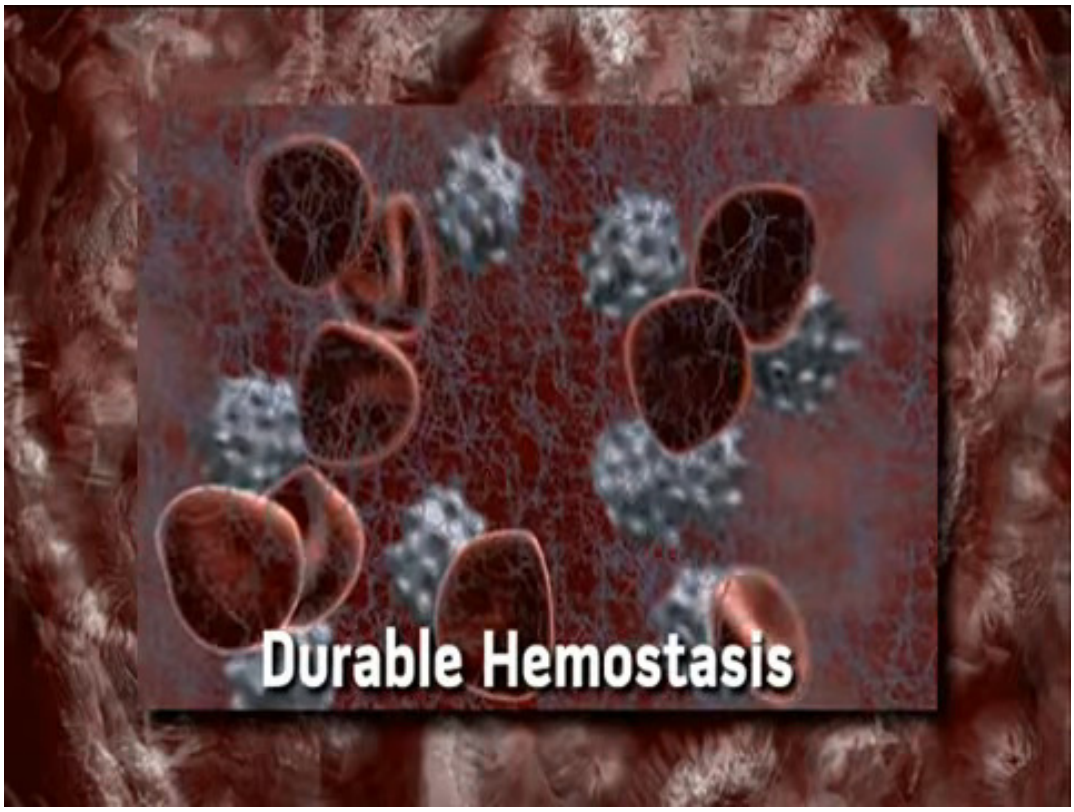
the patient's whole blood continues to clot." "As blood collects in the sealant's matrix, it clots producing a durable hemostasis." https://www.youtube.com/watch?v=4rXGfe5xX9g. In other words, the hemostasis is achieved by the patient's clotted whole blood. Meanwhile, the Mynx® Grip Tip portion of the sealant holds the clot-activated blood at the site until the clotting cascade has completed. Also, the Mynx instructions for use provide that after the device is removed fingertip compress should be applied to the wound. (Ex. 7 at 17 ("Continue to apply fingertip compression for up to 1 minute or as needed. If hemostasis is not achieved, apply additional compression as necessary.").)

119. Claim 16 recites "the method of claim 15, wherein the hemostatic closure comprising the patient's whole blood is formed by holding the subcutaneous mass comprising the patient's whole blood adjacent to and outside the arterial wound." As discussed and shown above, the mass is formed between the skin of a patient and adjacent the puncture in the artery that is to be sealed. As described and depicted above, a balloon device is used to locate the puncture in the artery and position the Mynx sealant adjacent to and outside the arterial wound.

120. Claim 17 recites "the method of claim 1, wherein the step of holding the subcutaneous mass comprises holding the patient's whole blood in position outside the artery as the patient's whole blood continues to clot." The "Mynx® Sealant" portion is crosslinked outside the patient prior to the procedure. (Ex. 7, *The MynxGrip™ Vascular Closure Device - Initial experience with active extravascular arteriotomy closure*, at p. 29.)



According to the video and as shown below, as blood collects in the sealant's matrix, it clots producing a durable hemostasis."



When fully expanded, the gel-like mass consists mostly of whole blood. AccessClosure's product literature reports that the mass is comprised of about 95% whole blood and 5%

polyethylene glycol (PEG):

> When delivered to the tissue tract, the freeze-dried Mynx sealant instantly absorbs blood and fluids from the arteriotomy and conforms to the tract. The hydrated, porous sealant provides immediate hemostasis by swelling 3-4 times its size. When fully expanded, the sealant is 95% blood and fluids and 5% PEG.

(Exhibit 6 at 3.)

121. Claim 18 recites "The method of claim 17, wherein the hemostatic closure comprising the patient's whole blood is formed by holding the subcutaneous mass comprising the patient's whole blood adjacent to and outside the arterial wound." As discussed and shown above, the mass formed between the skin of a patient and adjacent the puncture in the artery that is to be sealed.

122. On information and belief, the Infringing Instrumentalities are marketed, provided to, and/or used by or for Defendant's partners, clients, customers and end users across the country and in this District.

123. Cardinal Health's infringement of the '716 patent is and continues to be knowing, intentional, and willful, in whole or in part at least as of the filing date of this Amended Complaint.

124. On information and belief, Cardinal Health has known of the existence of the '716 patent since its issuance, and its acts of infringement have been willful and in disregard for the '716 patent without any reasonable basis for believing that it had the right to engage in the infringing conduct.

125. Upon information and belief, since at least the time Defendant has been made aware of the '716 patent, Defendant has induced and continues to induce others to infringe at least one claim of the '716 patent under 35 U.S.C. § 271(b) by, among other things, and with

specific intent or willful blindness, actively aiding and abetting others to infringe, including but not limited to Defendant's partners, clients, customers, and end users, whose use of the Infringing Instrumentalities constitutes direct infringement of at least one claim of the '716 patent.

126. In particular, Defendant's actions that aid and abet others such as its partners, customers, clients, and end users to infringe include advertising and distributing the Infringing Instrumentalities and providing instruction materials, training, and services regarding the Infringing Instrumentalities. On information and belief, Defendant has engaged in such actions with specific intent to cause infringement or with willful blindness to the resulting infringement because Defendant has had actual knowledge of the '716 patent and knowledge that its acts were inducing infringement of the '716 patent since at least the date Defendant received notice that such activities infringed the '716 patent.

127. Upon information and belief, Defendant is liable as a contributory infringer of the '716 patent under 35 U.S.C. § 271(c) by offering to sell, selling and importing into the United States Mynx® devices especially made or adapted for use in an infringement of the '716 patent. The Infringing Instrumentalities are a material component for use in practicing the '716 patent and are specifically made and are not a staple article of commerce suitable for substantial non-infringing use.

128. St. Croix has suffered and will continue to suffer damages as a result of Cardinal Health's infringing activities. On information and belief, Cardinal Health has been infringing, and will, unless enjoined by this Court, continue to infringe the '716 patent by making, using, selling, offering to sell, and/or importing, at a minimum, its Mynx® devices.

129. Cardinal Health's acts of infringement of the '716 patent have caused and will

continue to cause St. Croix damages for which St. Croix is entitled to compensation pursuant to 35 U.S.C. § 284.

130. Cardinal Health's acts of infringement of the '716 patent have caused and will continue to cause St. Croix immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. St. Croix has no adequate remedy at law.

131. This case is exceptional and, therefore, St. Croix is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all issues triable as such.

PRAYER FOR RELIEF

WHEREFORE, St. Croix respectfully requests that the Court enter judgment against Cardinal Health as follows:

A. An adjudication that Cardinal Health has infringed the '552 and '716 patents in violation of 35 U.S.C. § 271;

B. A granting of an injunction permanently enjoining Cardinal Health, its employees, agents, officers, directors, attorneys, successors, affiliates, subsidiaries and assigns, and all of those in active concert and participation with any of the foregoing persons or entities from infringing, contributing to the infringement of, or inducing infringement of the '552 and '716 patents;

C. An order to Cardinal Health to account and pay damages adequate to compensate St. Croix for Cardinal Health's infringement of the '552 and '716 patents, with pre-judgment and

post-judgment interest and costs, pursuant to 35 U.S.C. § 284, and an accounting of all infringing acts not presented at trial;

D. An order that the damages award be increased up to three times the actual amount assessed, pursuant to 35 U.S.C. § 284;

E. A declaration that this case is exceptional under 35 U.S.C. § 285, and an award of St. Croix's reasonable costs and fees, including attorneys' fees, with interest; and

F. An award to St. Croix of such other and further relief as this Court deems just and proper.

Dated: January 30, 2018

DEVLIN LAW FIRM LLC

/s/ Timothy Devlin
Timothy Devlin (#4241)
tdevlin@devlinlawfirm.com
1306 N. Broom St., 1st Floor
Wilmington, Delaware 19806

Telephone: (302) 449-9010
Facsimile: (302) 353-4251

GARDELLA GRACE P.A.

/s/ Greg H. Gardella
Greg H. Gardella (*pro hac vice* to be filed)
ggardella@gardellagrace.com
Natalie J. Grace (*pro hac vice* to be filed)
ngrace@gardellagrace.com
Gardella Grace P.A.
455 Massachusetts Ave. N.W.
Suite 507
Washington, DC 20001

Telephone: (703) 556-9600
Facsimile: (703) 740-4541

Attorneys for Plaintiff
St. Croix Surgical Systems, LLC