(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 November 2006 (09.11.2006)

PCT

(10) International Publication Number
WO 2006/119487 A2

(51) International Patent Classification:
*A61B 17/08* (2006.01)

(21) International Application Number:
PCT/US2006/017348

(22) International Filing Date: 3 May 2006 (03.05.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

| | | |
|---|---|---|
| 60/677,863 | 4 May 2005 (04.05.2005) | US |
| 60/688,510 | 7 June 2005 (07.06.2005) | US |
| 60/723,878 | 5 October 2005 (05.10.2005) | US |
| 11/245,956 | 7 October 2005 (07.10.2005) | US |
| 11/332,784 | 12 January 2006 (12.01.2006) | US |

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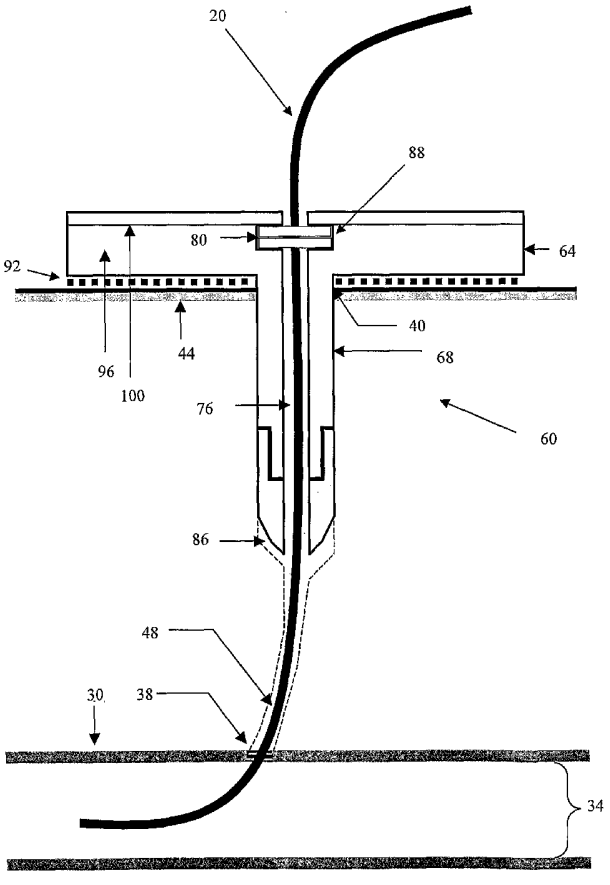
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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,

*[Continued on next page]*

(54) Title: HEMOSTATIC WIRE GUIDED BANDAGE AND METHOD OF USE




(57) Abstract: Some embodiments of the invention provide an apparatus for achieving hemostasis in a puncture tract that is created during a medical procedure. The puncture typically extends from the epidermis to the vasculature in a living organism. In some embodiments, the apparatus includes (1) a plug for subcutaneous placement within the puncture tract, and (2) a delivery mechanism for delivering and maintaining the plug within the puncture tract until hemostasis is achieved. The apparatus also includes in some embodiments a lubricious sheath that is placed around the plug to facilitate the insertion of the plug into the puncture tract.

WO 2006/119487 A2

RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# HEMOSTATIC WIRE GUIDED BANDAGE AND METHOD OF USE

## REFERENCE TO RELATED APPLICATIONS

This application claims priority to United States Provisional Application filed on May 4, 2005, assigned serial number 60,677,863 and titled "Vascular Closure System," United States Provisional Application filed on June 7, 2005, assigned serial number 60/688,510 and titled "Hemostatic Wire Guided Bandage" and also to United States Provisional Application filed on October 5, 2005, assigned serial number 60/723,878 and titled "Vascular Puncture Sealing Mechanism and Method of Use." This application also claims priority to United States Patent Application 11/245,956, entitled "Hemostatic Wire Guided Bandage and Method of Use," filed October 7, 2005 and United States Patent Application 11/332,784, entitled "Hemostatic Wire Guided Bandage and Method of Use," filed January 12, 2006. All the above applications are incorporated herein by reference.

## FIELD OF THE INVENTION

The invention is directed towards a wire guided hemostatic bandage normally placed subcutaneously and a method of using the same.

## BACKGROUND OF THE INVENTION

Numerous medical diagnostic and therapeutic procedures require access to the internal organs of a living organism. Some of these procedures can be performed without traditional surgical incisions by utilizing catheter-based apparatus to enter blood vessels. Usually, catheter-based apparatus require a needle to be inserted through the skin and directed into a blood vessel.

This provides a conduit for extending a metal or polymer guide wire through the needle and into the vasculature. After positioning the guide wire in the conduit, the needle can be removed and replaced with a hollow tube or catheter directed over the guide wire into the blood vessel. The tube or catheter provides access for administration of certain substances and/or for passage of additional equipment that will be used to perform manipulations within the vasculature or within other organ systems accessible through the vasculature.

To prevent bleeding upon completion of a catheter-based intravascular procedure, the catheter must be removed and the puncture site sealed. In the low-pressure environment of the venous system, a small needle puncture is readily sealed by the brief application of pressure to the site and application of a light dressing, such as a bandage. This method is widely utilized after needle stick procedures such as blood drawings.

However, when punctures are created with larger caliber apparatus (such as catheters) in the high-pressure environment of arteries, the puncture created will not readily seal with the application of brief pressure. Prolonged external pressure may be required for fifteen to thirty minutes and may lead to substantial discomfort at the puncture site for the patient and/or a significant failure rate with late bleeding and hematoma formation.

In the past, several methods have been proposed to address this problem. For instance, one prior apparatus utilizes a marker to indicate the position of the bandage with respect to the wound to be treated in order to position externally applied pressure at or near a puncture site. Another apparatus uses a pad which, when moistened by fluid from a wound, expands and exerts pressure against a wound.

Another apparatus utilizes laser energy directed through a balloon tipped catheter into the vascular tract and positioned just outside the outer wall of the blood vessel. The balloon is used to create a covering for the vascular puncture. The laser is used to create a laser "weld" or seal in the adjacent tissue.

Another apparatus uses both a balloon tipped catheter and an absorbable plug. The plug is used to occlude the vascular access tract and provide hemostasis. The balloon tipped catheter serves as a positioning anchor for antegrade insertion of the vascular plug and must be removed from the patient after plug deployment.

Yet another apparatus uses a balloon tipped catheter arranged so as to pass into the vascular lumen by means of the extant access sheath. After this procedure it is withdrawn to the intraluminal side of the blood vessel puncture to provide temporary hemostasis. A pro-coagulant slurry is then injected into the vascular access tract to promote coagulation. During this time, the balloon tipped catheter remains inflated. After a suitable period of time necessary to promote blood coagulation, the balloon tipped catheter is deflated and withdrawn from the access tract.

Each of these approaches has its own unique set of shortcomings. The prior apparatus lack both a means for precise positioning of a pressure-generating component against a puncture tract and a structure designed to optimize the pressure that is to be applied to such a site. Therefore, there is a need in the art for an apparatus that hemostatically closes a vascular puncture site without leaving a hematoma within the puncture tract, while minimizing patient discomfort. Ideally, such an apparatus would quickly, painlessly and reliably achieve hemostasis upon withdrawal of vascular catheters, and consequently reduce patient discomfort, staff time and the unfavorable failure rate associated with vascular hemostasis and the risk of hematoma formation.

## SUMMARY OF THE INVENTION

Some embodiments of the invention provide an apparatus for achieving hemostasis in a puncture tract that is created during a medical procedure. The puncture typically extends from the epidermis to the vasculature in a living organism. In some embodiments, the apparatus includes (1) a plug for subcutaneous placement within the puncture tract, and (2) a delivery mechanism for delivering and maintaining the plug within the puncture tract until hemostasis is achieved. The apparatus also includes in some embodiments a lubricious sheath that is placed around the plug to facilitate the insertion of the plug into the puncture tract.

In some embodiments, the delivery mechanism and its associated plug are removed after hemostasis has been achieved. In this manner, the delivery mechanism and its associated plug act as a disposable bandage. The plug is the component of the disposable bandage that is inserted into the puncture tract to achieve hemostasis. The plug can have many shapes. Also, in some embodiments, the plug includes one or more materials (e.g., Chitosan) designed to promote coagulation and thereby achieve hemostasis. In some embodiments, the delivery mechanism allows an operator to apply pressure to maintain the plug in the puncture tract until hemostasis is achieved. In some embodiments, the delivery mechanism also occludes the opening of the puncture tract.

## BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth in the appended claims. However, for purpose of explanation, several embodiments of the invention are set forth in the following Figures.

Figure **1** illustrates a side elevation showing in cross section, a hemostasis sheath placed over a guide wire within a blood vessel through the epidermis and subcutaneous tissue of a living being.

Figure **2** illustrates a side elevation view showing in cross section, a guide wire in place with the hemostasis sheath removed.

Figure **3** illustrates a side elevation view showing in cross section, an occlusive plug and the hemostatic bandage being passed over the guidewire and into the puncture wound.

Figure **4** illustrates a side elevation view showing in cross section, the occlusive plug in place with the guide wire removed and the hemostatic bandage secured within the puncture tract.

Figure **5** illustrates a side elevation view of the component parts of the occlusive plug.

Figure **6** illustrates an oblique three dimensional exploded view of the component parts of the occlusive plug.

Figure **7** illustrates side plan view of the hemostatic apparatus according to some embodiments of the invention.

Figure **8** illustrates a bottom perspective view of the hemostatic apparatus of some embodiments.

Figure **9** illustrates a top perspective view of the hemostatic apparatus of some embodiments.

Figure **10** illustrates an exploded and compacted view of the hemostatic apparatus of some embodiments.

Figure **11** illustrates a cross sectional view of the cover pad and bandage of the hemostatic apparatus of some embodiments.

## DETAILED DESCRIPTION OF THE INVENTION

In the following description, numerous details are set forth to provide a better understanding of the various embodiments of the invention. However, one of reasonable skill in the art will realize that the invention may be practiced without the use of the specific details presented herein. In some instances of describing the invention, well-known structures and apparatus may be shown in block diagram form to avoid obscuring the description of the invention with unnecessary detail. Therefore, the examples provided herein for clarification and understanding should not be read into and thereby limit the language of the claims.

Some embodiments of the invention provide an apparatus for achieving hemostasis in a puncture tract that is created during a medical procedure. The puncture typically extends from the epidermis to the vasculature in a living organism. In some embodiments, the apparatus includes (1) a plug for subcutaneous placement within the puncture tract, and (2) a delivery mechanism for delivering and maintaining the plug within the puncture tract until hemostasis is achieved. The apparatus also includes in some embodiments a lubricious sheath that is placed around the plug to facilitate the insertion of the plug into the puncture tract.

In some embodiments, the delivery mechanism and its associated plug are removed after hemostasis has been achieved. In this manner, the delivery mechanism and its associated plug act as a disposable bandage. The plug is the component of the disposable bandage that is inserted into the puncture tract to achieve hemostasis. The plug can have many shapes. Also, in some embodiments, the plug include one or more materials (e.g., Chitosan) designed to promote coagulation and thereby hemostasis. In some embodiments, the delivery mechanism allows an operator to apply pressure to maintain the plug in the puncture tract until hemostasis is achieved. In some embodiments, the delivery mechanism also occludes the opening of the puncture tract.

Several more detailed embodiments of the invention are discussed in Section III and IV. These embodiments provide a hemostatic bandage and a hemostatic wire-guided bandage delivery system. Before discussing these embodiments, it is helpful to understand relevant terminology and some environments in which the hemostatic bandage and its associated delivery system are used. Therefore, Section I presents relevant terminology, while Section II provides an overview of intravascular procedures, which are one type of procedure in which some embodiments can be used.

## I. TERMS AND TERMINOLOGY

An opening in the skin is called a percutaneous opening because it passes through the skin. The subcutaneous layer is the layer immediately below the skin, which is composed of the epidermal and dermal layers. The hole from the percutaneous opening to the blood vessel is the puncture tract or access tract. The opening in the blood vessel wall is a vascular puncture or vascular opening. The open space within the blood vessel is called the vascular lumen. As used in the following discussion, a "lumen" is an opening, such as the cavity of a tubular organ or the bore of a tube (as of a hollow needle or catheter). The term "bandage" is used generically to refer to an apparatus that assists in achieving hemostasis of a wound.

## II. AN EXEMPLARY INTRAVASCULAR PROCEDURE

Some embodiments of the invention have particular utility when utilized in conjunction with intravascular procedures. Today, intravascular procedures are performed by many physicians, such as radiologists and cardiologists. Examples of intravascular procedures include angiography, angioplasty, vascular stenting and stent graft placement, arterial thrombectomy, arterial embolization, intra-arterial drug administration, etc. These procedures normally involve

the insertion of a hollow needle (e.g., an 18 gauge thin walled needle) through the skin. The needle is advanced through the body tissue overlying a blood vessel and continued through the proximal side of the vascular wall until the distal tip of the needle enters the vascular lumen. A brisk return of blood through the needle hub signals entry of the needle into the vascular lumen.

Figures **1** and **2** illustrate an exemplary intravascular procedure that commonly uses an access sheath **10** placed in the access tract **48** to facilitate entry into the vascular lumen **34** by diagnostic and therapeutic tools. Figure **1** illustrates the hemostasis access sheath **10** threaded onto a guide wire **20** and placed within the access tract **48.**

To install the access sheath **10,** the operator first creates an access path to the blood vessel **28** by cutting a percutaneous opening **40** in the epidermal layer **44** at a point that is favorable to accessing the blood vessel **28.** A needle (or other cutting tool) is typically advanced through a percutaneous opening **40,** an epidermal layer **44,** a subcutaneous layer **52** and a vascular wall **30.** It continues through the vascular wall **30** (creating a vascular puncture **38)** and into a vascular lumen **34** of a blood vessel **28.** This creates the access tract **48.**

After creating the access tract **48,** the operator typically threads a guidewire **20** longitudinally through the needle. After positioning the guidewire **20** within the access tract **48,** the needle may be removed while maintaining the guidewire **20** in position. Normally, an access sheath **10** is later placed within the access tract **48** to prevent the tract **48** from closing during the procedure. The access sheath **10** is typically threaded onto the guidewire **20** and inserted into the access tract **48,** using the guidewire **20** to precisely position the sheath **10** into place. When positioned at its final location, one end of the sheath **10** is within the vascular lumen **34** while the opposing end is outside of the organism. Once the access sheath **10** is in place, other apparatus

and/or materials can pass through the access sheath **10** and advance into the blood vessel **28** to the area of interest within the body, in order to perform the intravascular procedure.

Upon completion of the intravascular procedure, the catheters and other apparatus used in the procedure are removed from the blood vessel **28**. This is generally followed by the removal of the sheath **10** over the guide wire **20,** leaving the guide wire **20** in place within the access tract **48** and leaving the access tract **48** open. Figure **2** presents a longitudinal cross-sectional side view of the access tract **48** with the guidewire **20** in place after the removal of the access sheath **10**.

The removal of tools from the access tract **48** causes the access tract to gradually close upon any objects remaining within the tract **48.** If hemostasis is not quickly attained, vigorous bleeding can occur. Therefore, the vascular puncture **38** and the access tract **48** must be sealed as quickly and as efficiently as possible. One method of doing so uses a hemostatic wire guided bandage delivery and placement apparatus of some embodiments of the invention.

## III. HEMOSTATIC BANDAGE AND WIRE-GUIDED DELIVERY SYSTEM FOR DELIVERING THE HEMOSTATIC BANDAGE IN A PUNCTURE TRACT

Some embodiments provide a hemostatic bandage for achieving hemostasis in a puncture tract that is created during a medical procedure. Some embodiments also include a wire-guided delivery mechanism for delivering the bandage into the puncture tract and for maintaining the bandage in the puncture tract until hemostasis is achieved. In some embodiments, the mechanism not only positions the bandage, but also occludes the opening of the puncture tract. Although some embodiments of a hemostatic wire guided bandage delivery and placement apparatus achieve hemostasis at or near a vascular puncture site in a living organism, the apparatus' construction and use also has widespread applicability in analogous non-vascular settings.

Figures **3** through **5** illustrate a hemostatic apparatus **60** of some embodiments of the invention. This apparatus includes a hemostatic bandage and its associated wire guided delivery apparatus. As shown in Figure **3**, the apparatus **60** includes (1) a cover pad **64**, (2) a stem **68** affixed to the cover pad **64** and extending at a angle downwards from the bottom side of the cover pad **64**, (3) a bandage **85** attached to the distal end of the stem **68**, and (4) a central lumen **76** defined from the top of the cover pad downwards through the center of the stem **68** and through the center of the bandage **85**. As shown in this figure, the cover pad includes a hemostatic valve **80**.

As shown in Figure **3**, the apparatus **60** positions the bandage **85** subcutaneously to provide hemostasis within a puncture tract. In use, the cover pad of the apparatus **60** covers and/or occludes the access tract **48** percutaneously. The cover pad's hemostatic valve prevents blood from flowing back through the central lumen and out of the patient, while allowing for the passage of the guidewire **20** through the central lumen.

The stem **68** positions the bandage **85** within the access tract **48** to achieve hemostasis. As mentioned above, the stem extends downwards at an angle from the bottom side of the cover pad **64**. This angle corresponds to the angle of the puncture tract. In some embodiments, the angle at which the stem extends downwards from the cover pad is adjustable to match angle of the puncture tract.

While Figure **3** presents the guidewire **20** threaded through the apparatus **60**, Figure **4** presents the apparatus **60** after the guidewire **20** has been removed. The guidewire **20** is used to properly guide the bandage **85** as the apparatus **60** is advanced into the access tract **48**. After the apparatus **60** is in place, the guidewire **20** may be removed, as shown in Figure **4**. Its removal from the access tract **48** causes the access tract to gradually close further.

The cover pad **64**, hemostatic valve **80**, a stem **68** and bandage **85** of the apparatus **60** are discussed in detail in Section A, immediately below. This discussion is followed in Section B by a description of how the apparatus **60** is used in some embodiments to place a hemostasis bandage subcutaneously within a puncture tract.

## A. The Components of a Bandage Delivery and Placement Apparatus

### 1. The Cover Pad

In some embodiments, the cover pad **64** provides a mechanism (1) to push the stem **68** into the access tract **48**, (2) to occlude the percutaneous opening **40**, and (3) affix the apparatus **60** to the epidermal layer **44** during recovery. Figure **5** presents a more detailed view of the apparatus **60**. As shown in this figure, the apparatus **60** in some embodiments includes a multi-layered cover pad **64**. The layers include a first adhesive layer **92**, a second central layer **96** and a third surface layer **100**. The cover pad in some embodiments includes a fourth layer (not shown in Figure **5**) that covers the first adhesive layer **92** as further described below. Although Figure **5** shows a particular multi-layered cover pad, a person skilled in the art will realize that the cover pad **64** in other embodiments might be constructed differently (e.g., with more or less layers).

As mentioned above, the first layer **92** of the cover pad **64** in some embodiments is an adhesive layer that is applied to the bottom side of the second central layer **96**. The first adhesive layer **92** is covered by a fourth layer (not shown) when the bandage has not been deployed. The fourth layer protects the adhesive layer from degradation before the bandage has been deployed. As further described below, the fourth layer is removed from the first layer **92** when the bandage is being deployed, in order to enable the first layer to affix the apparatus **60** to the patient's skin during the operation.

The second layer **96** has a lumen **88** defined about the central lumen **76**, which passes through the second layer. The hemostatic valve **80** is seated with the second lumen **88**, which is larger than, and concentric to, the central lumen **76** and is shaped to receive the valve **80**. With the valve **80** seated in the second lumen **88**, the third layer **100** covers the second layer **96** (including the valve **80**) to immobilize the valve **80** within the second lumen **88**. The third layer **100** contains a third lumen 101 that is concentric to the central lumen **76** and shaped to cooperate with and receive a portion of the hemostatic valve **80** seated in the second lumen **88**.

Figure **6** illustrates an exploded view of the cover pad **64** of some embodiments of the invention. As shown in this figure, the second lumen **88** of the second central layer **96** is larger than the third lumen 101 of the third layer **100**. This figure also shows that in some embodiments the hemostatic valve **80** is formed by two circular pads **105** and **110**.

The circular pads **105** and **110** are formed of a soft rubber material in some embodiments, while they might be formed by other materials in other embodiments. The pads have two slits **115** and **120** at a 90° angle with each other. These two slits allow the guide wire **20** to pass through the central lumen **76**. However, the 90° arrangement of the slits plus the composition of the pads **105** and **110** limit the back flow of blood from the central lumen. Although the valve **80** is formed by two pads **105** and **110** in some embodiments, one of ordinary skill will realize that the valve **80** is formed differently (e.g., with different number of pads, different composition for the pads, different shaped pads, etc.) in other embodiments.

### 2. The Stem

As mentioned above, the stem **68** allows the bandage **85** affixed to the stem **68** to be placed in the subcutaneous tissue and within the access tract **48**. In some embodiments, the stem

68 is roughly cylindrical and includes a proximal end and an opposing distal end. The proximal end is affixed to the cover pad 64. The distal end cooperates with the bandage 85 placed subcutaneously within the access tract 48. In different versions of the apparatus 60, the stem 68 may have different lengths, in order to position the bandage 85 at different depths within the access tract 48 based upon patient's circumstances. Alternatively, in some embodiments, the stem 68 is capable of different lengths by means of telescoping the stem. In other embodiments, the stem 68 may be sectioned and joined together, one section at a time, to create an appropriate length for each individual need.

The stem 68 allows the bandage 85 to be placed within the access tract 48 without causing the bandage 85 to flatten near the epidermal layer 44. In so doing, the bandage 85 is placed closer to the vascular puncture 38 and the chance of hematoma or other undesirable effects is reduced.

### 3. The Bandage

As mentioned above, the bandage 85 is located at the distal end of the stem 68. The bandage serves to occlude the access tract 48 and provide hemostasis within the access tract 48 without undesirable side effects. In some embodiments, the bandage 85 is a plug that contains a central lumen designed to accept the guidewire 20 and is a component of the delivery apparatus 60. As shown in Figures 3-6, the plug 85 has a tapered tip in some embodiments to facilitate entry into the puncture tracts. The depth at which the plug 85 is positioned in the access tract 48 will be approximately the length of the stem 68. In some embodiments, the circumference of the plug 68 is approximately the diameter of the access tract 48.

Some of the embodiments of the bandage **85** may be made from, or coated with, one or more coagulating materials. Coagulating agents facilitate coagulation and hemostasis. One such pro-coagulation material is Chitosan. By including one or more pro-coagulating agents within the bandage, hemostasis is achieved earlier than it would be otherwise achievable. By varying the composition of the bandage **85**, the hemostasis rate may be controlled or varied. In this manner, the hemostasis rate may be controlled to fit the needs of each individual circumstance.

**B. Method of Use**

As discussed previously, removing the access sheath **10** from the access tract **48** at the completion of an intravascular procedure causes the access tract **48** to naturally collapse onto the guidewire **20**. Therefore, the apparatus **60** should be inserted into the access tract **48** before the tissue collapses onto the access tract **48**. To be most effective, the operator should be able to insert the apparatus **60** quickly, easily and efficiently.

At the conclusion of an intravascular medical procedure, most of the instrumentation used in the procedure is typically removed from the blood vessel and the access tract. For instance, all the instrumentation except the access sheath **10** might be removed from the blood vessel and the access tract. Next, a guidewire **20** is re-inserted into the access tract (e.g., re-inserted through the access sheath) and the sheath **10** is then removed.

To insert the apparatus **60**, the apparatus is first threaded onto the guidewire **20** by inserting the side of the guidewire **20** that is out of the patient through the hole in the tip of the plug **85**, through the central lumen **76**, through the slits **115** and **120** of the valve **80**, and out of the cover pad. The cover for the adhesive layer **92** of the pad **64** is removed to reveal the adhesive layer **92**. Next, the apparatus **60** is advanced into the access tract **48** until the bandage

**85** is properly placed subcutaneously and the adhesive layer **92** comes in contact with the epidermis **44**. With the adhesive layer exposed, the cover pad **64** can firmly adhere to the epidermal layer **44** to prevent the bandage **85** from moving within the access tract **48**. With the apparatus **60** properly positioned, the guidewire **20** can be removed, as shown in Figure **4**.

With the apparatus **60** in place, the hemostasis valve **80** prevents back bleeding through the central lumen **76**. The bandage **85** acts to seal the remaining portion of the access tract. By placing the apparatus **60** within the access tract **48**, the bandage **85** and the cover pad **64** both obstruct the flow of blood from the vascular puncture **38**.

In some embodiments, the bandage **85** is coated with, contains, or is completely composed of Chitosan or other pro-coagulant material. The use of coagulating agents in the bandage **85** further impedes the blood flow. Next, the removal of the guidewire **20** causes the access tract **48** to collapse. Also, the tissue exerts force on the tapered tip of the bandage to close the hole at this tip. The insertion of the bandage, the use of the coagulating agent, and the collapse of the tissue restrict the flow of blood from the blood vessel **28** and thereby quickly and efficiently result in hemostasis. To achieve hemostasis, a physician might also exert minimal pressure on the cover pad in some cases for a small duration of time (e.g., thirty to sixty seconds). Also, the bandage **85** has to remain in the patient for a suitable amount of time to achieve hemostasis. This amount can be as little as 30 to 60 minutes in some cases.

After a suitable period to allow for recovery and healing, the bandage **85** is removed from the living organism by pulling the cover pad away from the patient. After the removal of apparatus **60**, a light topical dressing is then applied to the wound.

## IV. HEMOSTATIC BANDAGE WITH LUBRICIOUS SHEATH

Figures **7-11** illustrate another example of a hemostatic apparatus **260** of some embodiments of the invention. The hemostatic apparatus **260** has many of the same features as the hemostatic apparatus **60** illustrated in Figures **3-5**. For instance, as illustrated in Figures **7-10**, the apparatus **260** includes (1) a cover pad **264**, (2) a stem **268** affixed to the cover pad **264** and extending downwards from the bottom side of the cover pad **264**, and (3) a bandage **285** attached to the distal end of the stem **268**. Like the bandage **85** of apparatus **60**, the bandage **285** of apparatus **260** has a tapered tip. The bandage **285** or its tapered tip is coated with, contains, or is completely comprised of Chitosan or other pro-coagulant material in some embodiments. Also, like the apparatus **60**, the apparatus **260** has a central lumen **276** defined from the top of the cover pad downwards through the center of the stem **268** and through the center of the bandage **285**, as illustrated in Figure **11**.

In addition to these components, the apparatus **260** includes (1) two slots **290** in the cover pad **264**, (2) a sheath **210**, and (3) a holding pad **292** with two slots **291**. The sheath **210** is coated with, or is composed partially or entirely of, a lubricious material, such as a hydrophilic polymeric film or other hydrophilic material. The lubricious sheath **210** has a hollow tip **294** that surrounds the bandage **285** (i.e., surrounds the tip **285**). The sheath also has two flaring finger **296** that extend from the hollow tip **294**. As illustrated in Figures **7-9**, these two fingers **296** pass through the two slots **290** of the cover pad **264** and the two slots **291** of the holding pad **292**, which rests on top of the cover pad **264**. In this manner, the two fingers **296** maintain the lubricious sheath's hollow tip around the bandage **285**. The central lumen **276** of the apparatus **260** is defined through the sheath **290** and the holding pad **292**.

The apparatus **260** of Figures **7-9** operates in a similar manner to the apparatus **60** of Figures **3-5**. Specifically, the stem **268** and the bandage **285** of the apparatus **260** is pushed into a puncture tract by passing the central lumen **276** of the apparatus **260** over a guidewire that is positioned in the access tract.

The lubricious sheath **210** assists in positioning the bandage **285** into the puncture tract. Without this sheath, a surgical-team member might have a hard time inserting the bandage **285** into the puncture tract. However, with the sheath, the bandage can be inserted much easier into the tract, as the lubricious sheath becomes slick when it contacts liquids in the tract.

Once the bandage **285** has been placed in its desired position within the tract, the operator removes the sheath **210** from the puncture tract. The sheath **210** has slits **295** on the exterior surface of its hollow tip **294**. To remove the sheath **210** from the puncture tract, the operator pulls the holding pad **292** away from the cover pad **264**. This pulling causes the hollow tip **294** to tear typically along the position of the slits **295**. This tearing breaks the enclosure of the tip **294** around the bandage **285**, and thereby allows the sheath to slide out of the puncture tract.

With the sheath removed, the pro-coagulant material of the bandage **285** achieves hemostasis in a few minutes. Specifically, as mentioned above, the bandage **285** is coated with, contains, or is completely composed of Chitosan or other pro-coagulant material in some embodiments. The use of coagulating agents in the bandage **285** impedes the blood flow almost immediately after the removal of the sheath. In addition, before or after the removal of the sheath, the guidewire is removed, and this removal causes the access tract to collapse. Also, the tissue exerts force on the tapered tip of the bandage to close the hole at this tip. Accordingly, the insertion of the bandage, the use of the coagulating agent, and the collapse of the tissue restrict the flow of blood from the blood vessel and thereby quickly and efficiently result in hemostasis.

To achieve hemostasis, a physician might also exert minimal pressure on the cover pad in some cases for a small duration of time (e.g., thirty to sixty seconds). Also, the bandage **285** has to remain in the patient for a suitable amount of time to achieve hemostasis. This amount can be as little as 30 to 60 minutes in some cases. After a suitable period to allow for recovery and healing, the bandage **285** is removed from the living organism by pulling the cover pad away from the patient. After the removal of apparatus **260**, a light topical dressing might be applied to the wound.

The delivery apparatus and bandage of some embodiments constitute a significant advance in the fields of cardiology, radiology and vascular surgery as it significantly improves upon the art by providing an effective means of completely sealing a vascular access puncture site, even in anti-coagulated patients, without bleeding and hematoma formation. Compared with the topical application of a bandage as used in the prior art without the precise guide wire directed positioning of the invention's insertion bandage tip, the probability of hematoma formation and the need for prolonged application of external pressure is greatly reduced by using the apparatus. The apparatus will reduce patient discomfort, improve sheath related complication rates due to bleeding and hematoma formation, eliminate intra-arterial trauma, reduce hospitalization time and allow rapid mobilization and earlier discharge of patients following catheter based vascular procedures.

While the invention has been described herein with reference to numerous specific details, one of ordinary skill in the art will recognize that the invention can be embodied in forms without departing from the spirit of the invention. For instance, in some cases, the invention's bandage will be used for hemostasis of the radial artery in the wrist. The same guide wire delivery will apply, but the device will be secured by a wrist strap rather than an adhesive

bandage. In addition, in the case of the very superficial radial puncture, the device can be placed on but not within a subcutaneous tract, as the tract at the radial site is very short and cannot be entered with a device. Thus, one of ordinary skill in the art would understand that the invention is not to be limited by the illustrative details contained herein, but rather is to be defined by the appended claims.

## CLAIMS

What is claimed is:

1. An apparatus for achieving hemostasis in a puncture tract that is created during a medical procedure on a patient, the apparatus comprising:

(a) a plug for placement within the puncture tract,

(b) a delivery mechanism for delivering the plug into the puncture tract until hemostasis is achieved; and

(c) a lubricious sheath placed around the plug to facilitate insertion of the plug into the puncture tract.

2. The apparatus of claim 1, wherein the plug includes at least one coagulating material.

3. The apparatus of claim 1, wherein the plug is at least one section that is entirely composed of Chitosan.

4. The apparatus of claim 1, wherein the plug is coated with Chitosan.

5. The apparatus of claim 1, wherein the plug includes Chitosan.

6. The apparatus of claim 1 further comprising a lumen that is defined through the plug and the delivery mechanism, said lumen for passing a wire through the plug and the delivery mechanism in order to guide the plug into the puncture tract.

7. The apparatus of claim 6 further comprising a valve for preventing blood from flowing out of the patient through the lumen while allowing the wire to pass through the lumen.

8. The apparatus of claim 1 further comprising an adhesive material for affixing the delivery mechanism to the patient while the plug is within the puncture tract.

9. The apparatus of claim 1, wherein the plug has a tapered tip for easy insertion into the puncture tract.

10. The apparatus of claim 1, wherein the delivery mechanism has a pad for abutting the patient.

11. The apparatus of claim 10, wherein the pad provides a surface for a person to apply pressure to maintain the plug within the puncture tract after the plug has entered the puncture tract.

12. The apparatus of claim 1, wherein the delivery mechanism and the plug are removed from the puncture tract after hemostasis has been achieved.

13. A method of achieving hemostasis in a puncture tract that is created during a medical procedure on a patient, the method comprising:

(a) inserting a plug for placement within the puncture tract, said plug surrounded by a lubricious sheath;

(b) removing the sheath from the puncture tract; and

(c) maintaining the plug in the puncture tract until hemostasis is achieved.

14. The method of claim 13 further comprising removing the plug from the puncture tract after hemostasis has been achieved.

15. The method of claim 13, wherein the plug includes at least one coagulating material.

16. The method of claim 13 passing a wire through a passageway that is defined in the plug in order to guide the plug into the puncture tract.

17. The method of claim 16 passing the wire through a valve coupled to the plug, said valve preventing blood from flowing out of the patient through the passageway while allowing the wire to pass through the passageway.

18. The method of claim 13, wherein inserting the plug comprises using a delivery mechanism, to which the plug is affixed, to insert the plug into the puncture tract, wherein the method further comprises affixing the delivery mechanism to the patient while the plug is within the puncture tract.

19. The method of claim 13, wherein the plug has a tapered tip for easy insertion into the puncture tract.

20. A method of performing a medical operation, the method comprising:

a) defining a puncture tract to access a blood vessel in a patient;

b) inserting a plug for placement within the puncture tract, said plug surrounded by a lubricious sheath;

c) removing the sheath from the puncture tract; and

d) maintaining a plug in the puncture tract until hemostasis is achieved;

e) removing the plug from the puncture tract after hemostasis has been achieved.

21. An apparatus for achieving hemostasis in a puncture tract that is created during a medical procedure on a patient, the apparatus comprising:

(a) a plug for placement within the puncture tract, said plug having at least one section that includes Chitosan.

(b) a delivery mechanism for delivering the plug into the puncture tract until hemostasis is achieved.

22. The apparatus of claim 21, the section is entirely composed of Chitosan.

23. The apparatus of claim 21, wherein the plug's section is coated with Chitosan.

24. An apparatus for achieving hemostasis in a puncture tract that is created during a medical procedure on a patient, the apparatus comprising:

(a) a plug for placement within the puncture tract, and

(b) a delivery mechanism for delivering the plug into the puncture tract until hemostasis is achieved.

25. The apparatus of claim 24, wherein the delivery mechanism and the plug are removed from the puncture tract after hemostasis has been achieved.

26. The apparatus of claim 24, wherein the plug includes at least one coagulating material.

27. The apparatus of claim 24 further comprising a lumen that is defined through the plug and the delivery mechanism, said lumen for passing a wire through the plug and the delivery mechanism in order to guide the plug into the puncture tract.

28. The apparatus of claim 27 further comprising a valve for preventing blood from flowing out of the patient through the lumen while allowing the wire to pass through the lumen.

29. The apparatus of claim 24 further comprising an adhesive material for affixing the delivery mechanism to the patient while the plug is within the puncture tract.

30. The apparatus of claim 24, wherein the plug has a tapered tip for easy insertion into the puncture tract.

31. The apparatus of claim 24, wherein the delivery mechanism has a pad for abutting the patient.

32. The apparatus of claim 31, wherein the pad provides a surface for a person to apply pressure to maintain the plug within the puncture tract after the plug has entered the puncture tract.

33. A method of achieving hemostasis in a puncture tract that is created during a medical procedure on a patient, the method comprising:

(a) inserting a plug for placement within the puncture tract, and

(b) maintaining the plug in the puncture tract until hemostasis is achieved.

34. The method of claim 33 further comprising removing the plug from the puncture tract after hemostasis has been achieved.

35. The method of claim 33, wherein the plug includes at least one coagulating material.

36. The method of claim 33 passing a wire through a passageway that is defined in the plug in order to guide the plug into the puncture tract.

37. The method of claim 36 passing the wire through a valve coupled to the plug, said valve preventing blood from flowing out of the patient through the passageway while allowing the wire to pass through the passageway.

38. The method of claim 33, wherein inserting the plug comprises using a delivery mechanism, to which the plug is affixed, to insert the plug into the puncture tract, wherein the method further comprises affixing the delivery mechanism to the patient while the plug is within the puncture tract.

39. The method of claim 33, wherein the plug has a tapered tip for easy insertion into the puncture tract.

40. A method of performing a medical operation, the method comprising:

a) defining a puncture tract to access a blood vessel in a patient;

b) maintaining the plug in the puncture tract until hemostasis is achieved.

41. The method of claim 40 further comprising removing the plug from the puncture tract after hemostasis has been achieved.

42. The method of claim 40, wherein the plug includes at least one coagulating material.

Figure 1

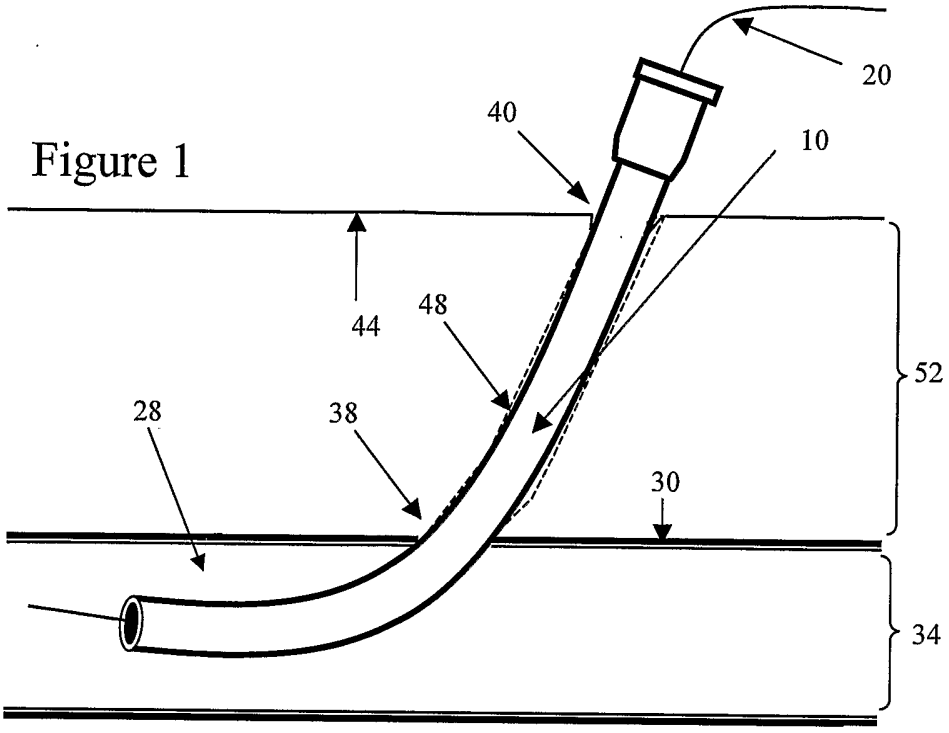



Figure 2

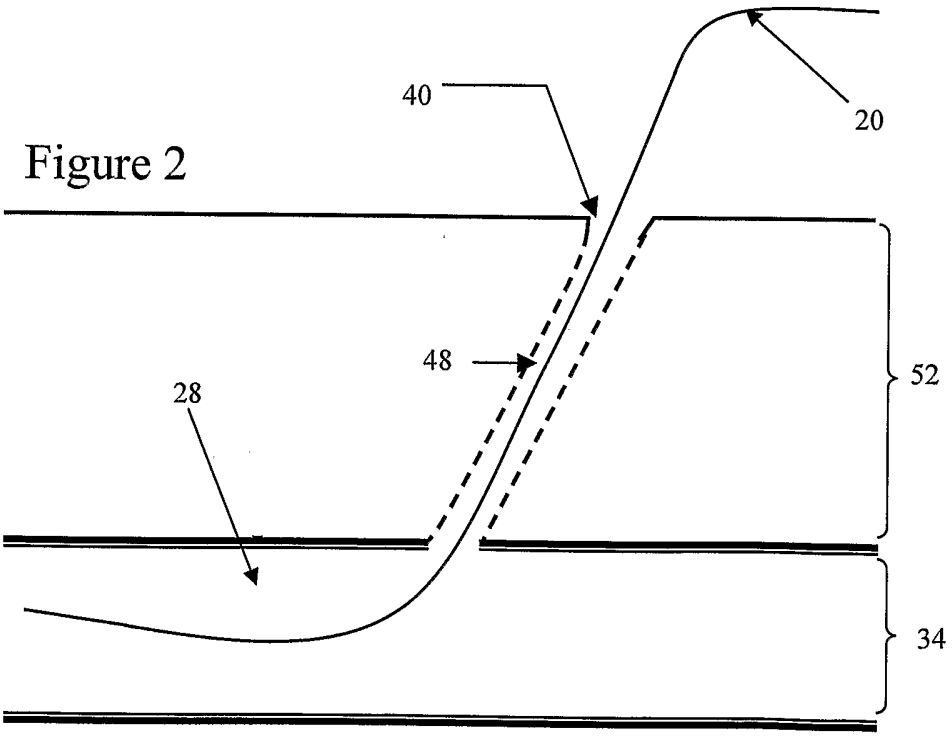


Figure 3

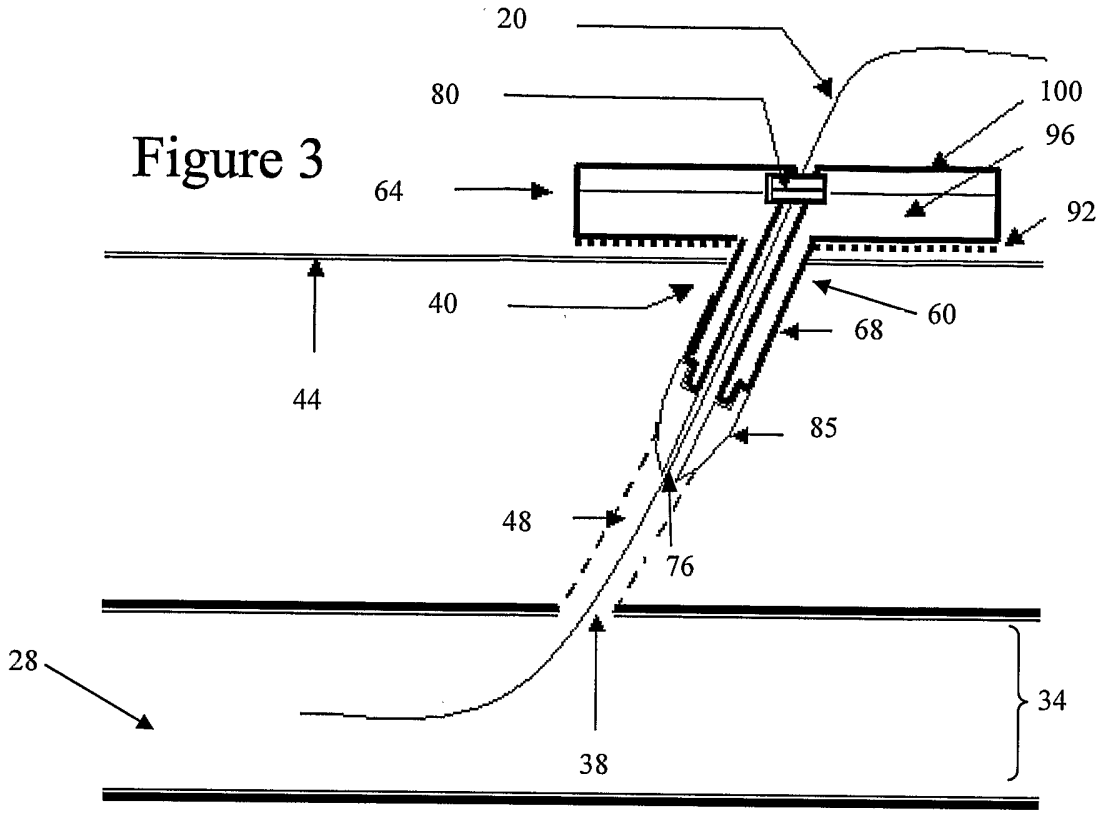
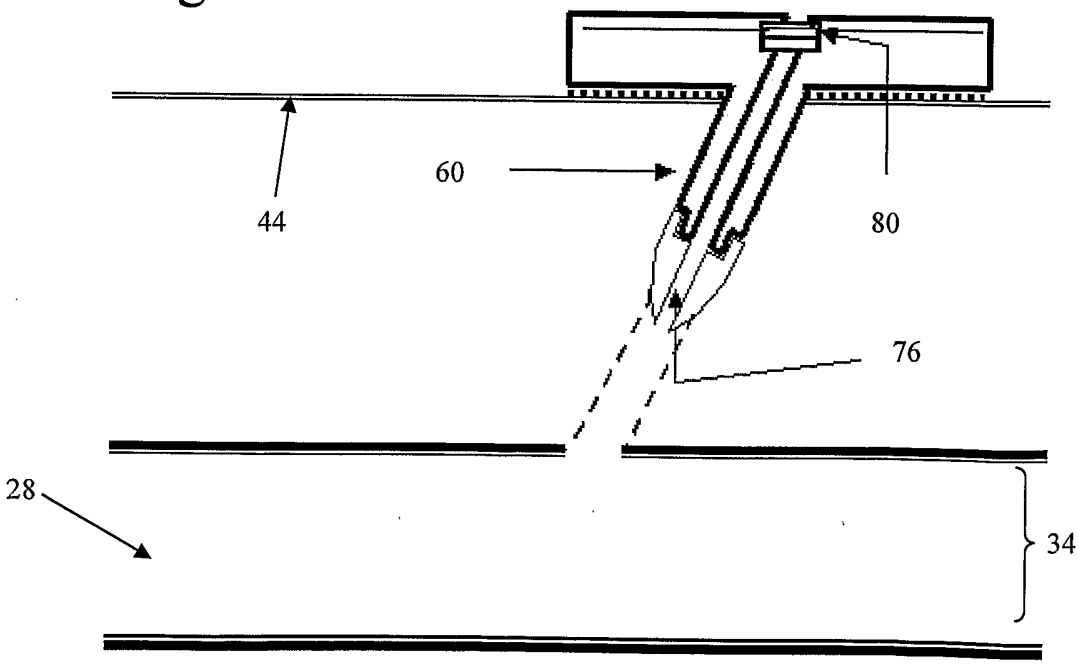



Figure 4



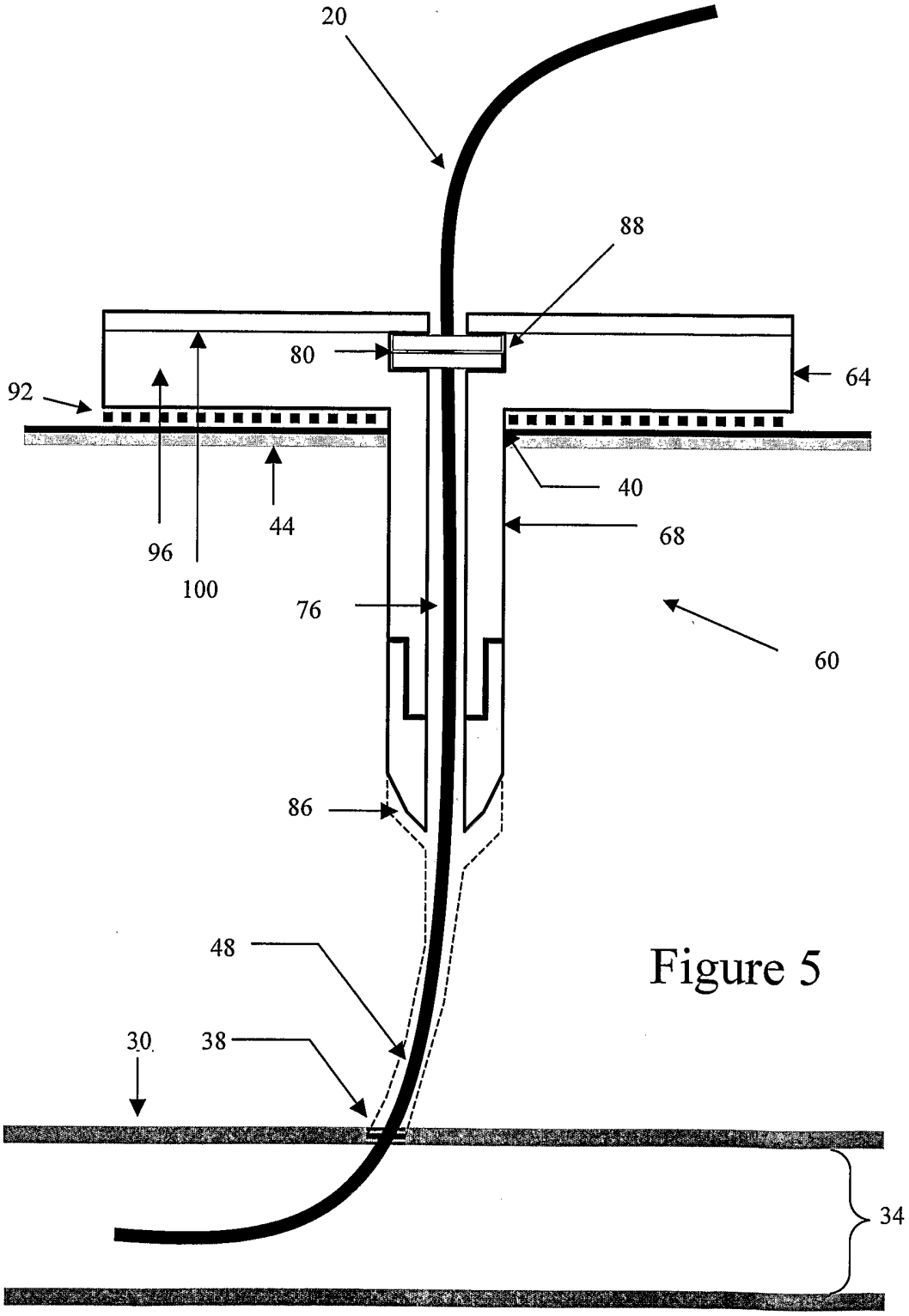



Figure 5

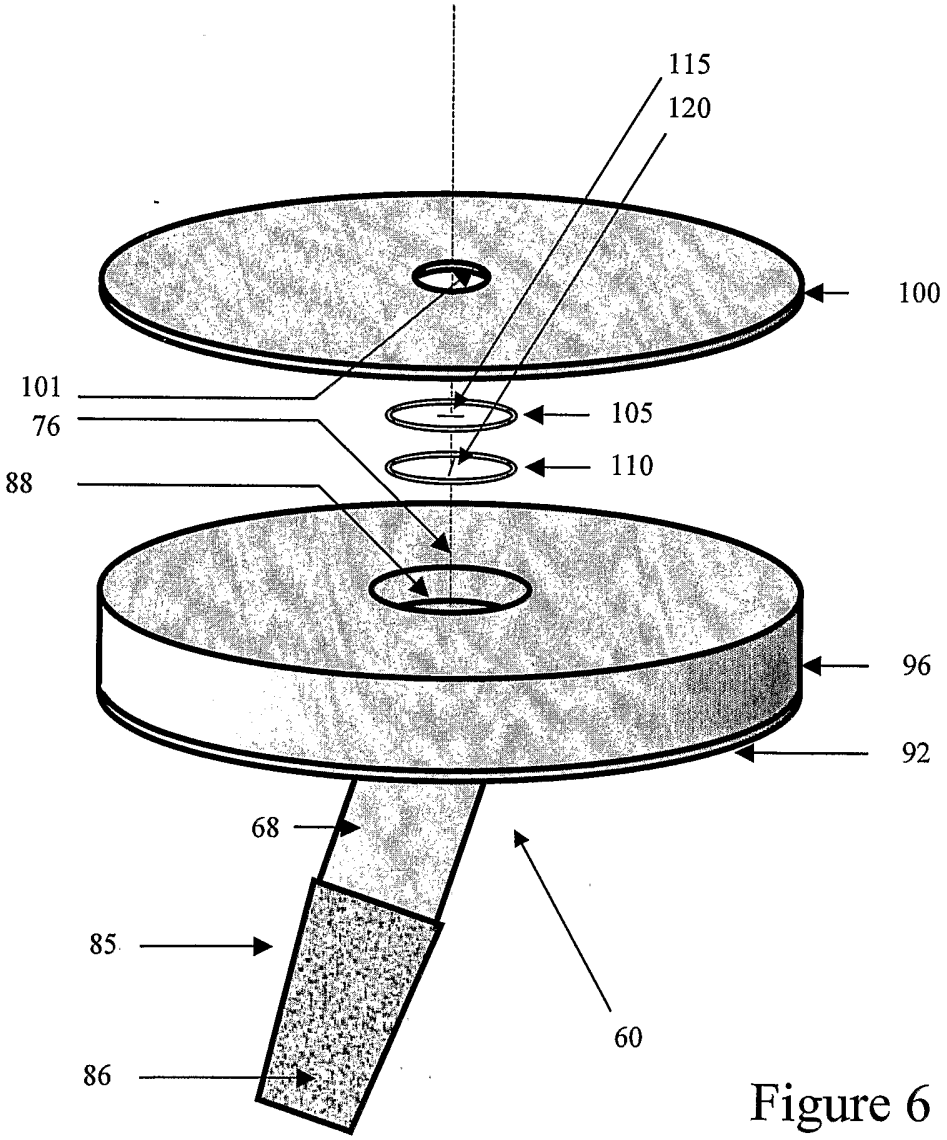



Figure 6

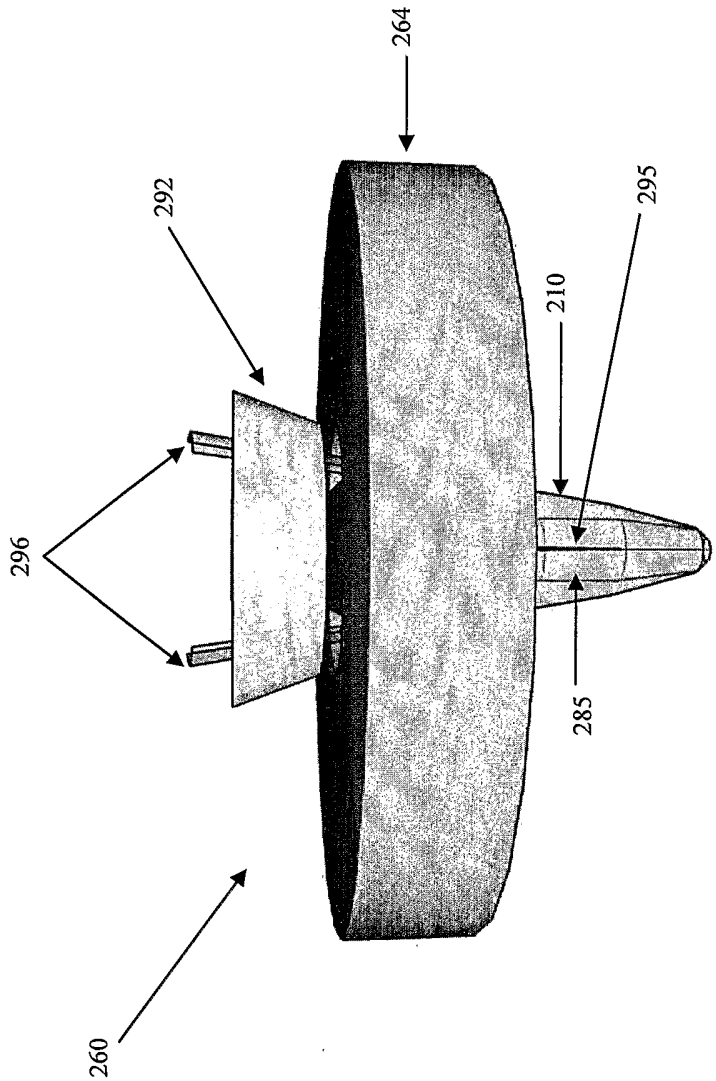



*Figure 7*

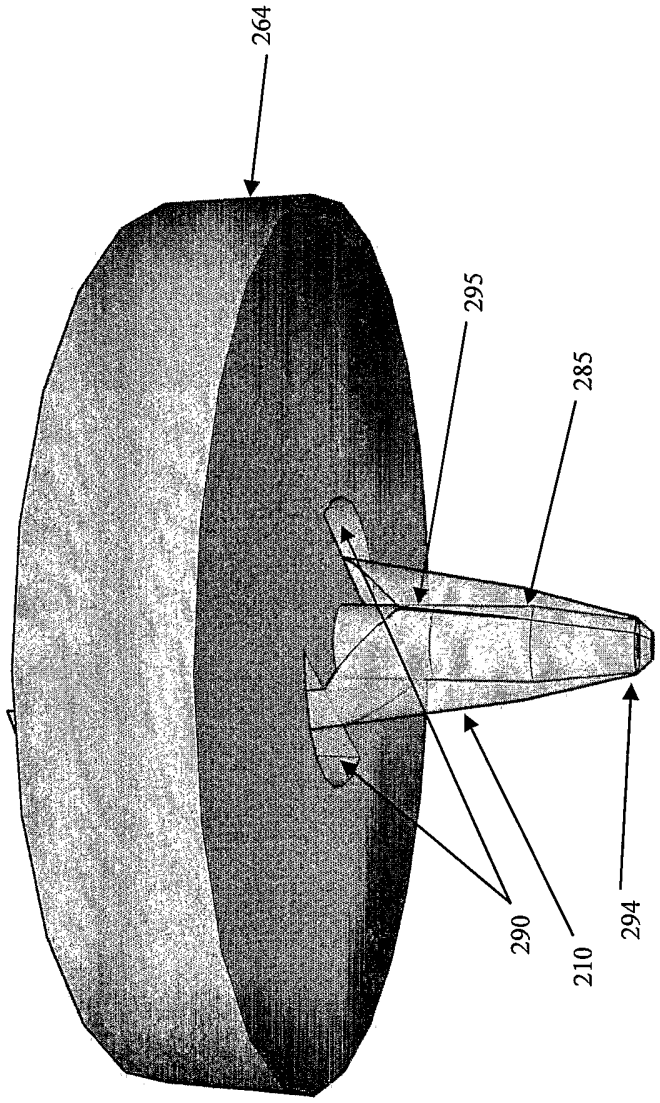



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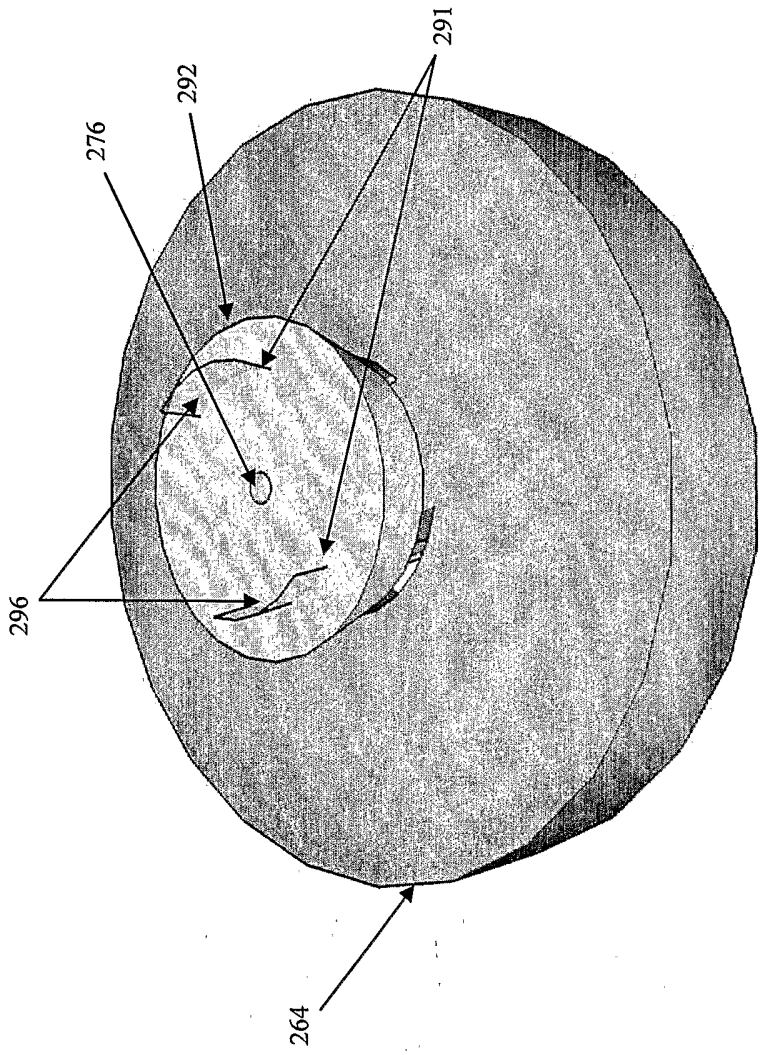



*Figure 9*

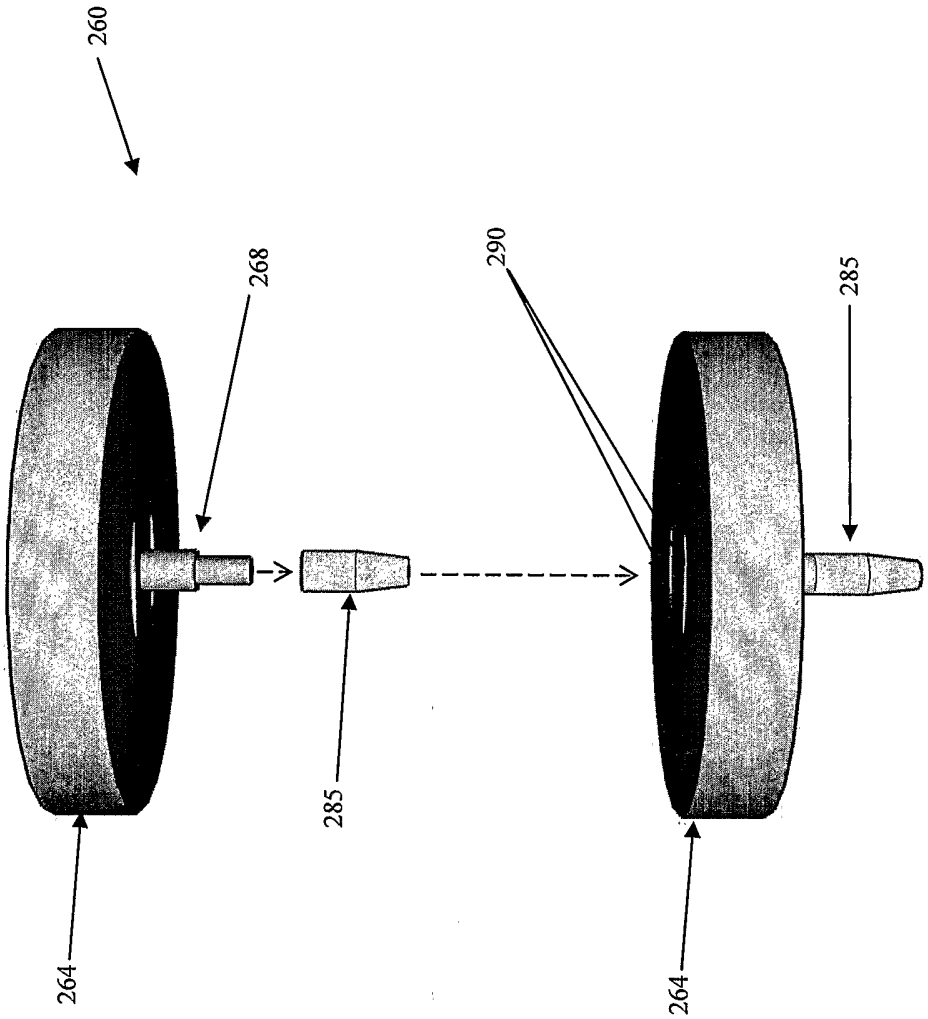



*Figure 10*

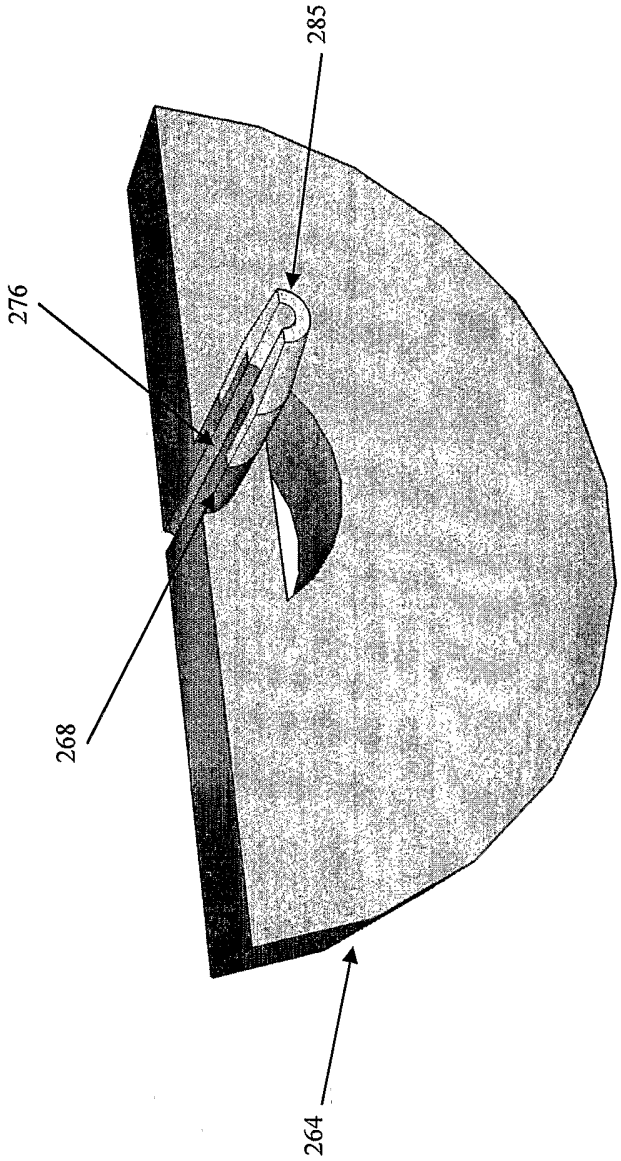



*Figure 11*