US 20060200062A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2006/0200062 A1**

Saadat (43) **Pub. Date: Sep. 7, 2006**

(54) **MULTI-BARBED DEVICE FOR RETAINING TISSUE IN APPOSITION AND METHODS OF USE**

(75) Inventor: **Vahid Saadat**, Saratoga, CA (US)

Correspondence Address:
LEVINE BAGADE HAN LLP
2483 EAST BAYSHORE ROAD, SUITE 100
PALO ALTO, CA 94303 (US)

(73) Assignee: **USGI Medical Inc.**, San Clemente, CA (US)

(21) Appl. No.: **11/343,924**

(22) Filed: **Jan. 30, 2006**

Related U.S. Application Data

(63) Continuation of application No. 09/746,579, filed on Dec. 20, 2000, now Pat. No. 6,991,643.

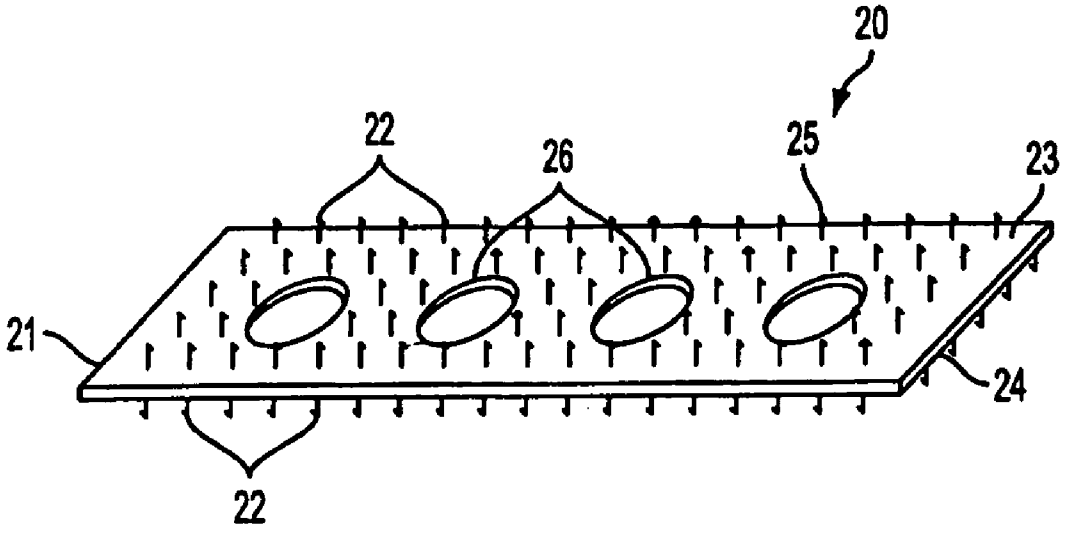
Publication Classification

(51) **Int. Cl.**
A61F 15/00 (2006.01)

(52) **U.S. Cl.** **602/41**

(57) **ABSTRACT**

A multi-barbed apparatus is provided, and methods of use, for penetrating two sides of a wound and holding the edges in apposition. The apparatus may be inserted within a wound or underneath the skin, and mechanically adheres the two sides of the wound together. The apparatus includes a biocompatible substrate carrying a multiplicity of tissue penetrating barbs on a least one side thereof, and may be formed as a rigid or flexible sheet, tube or other shape.



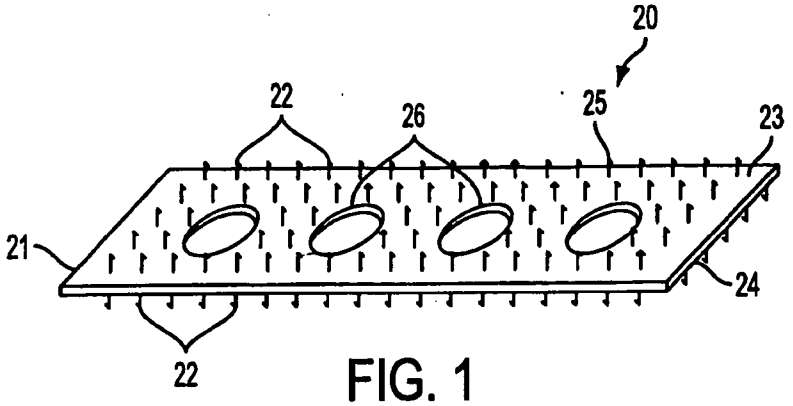


FIG. 1

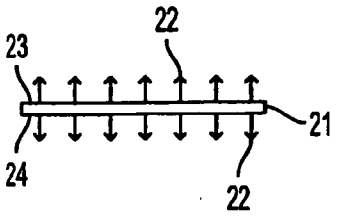


FIG. 2

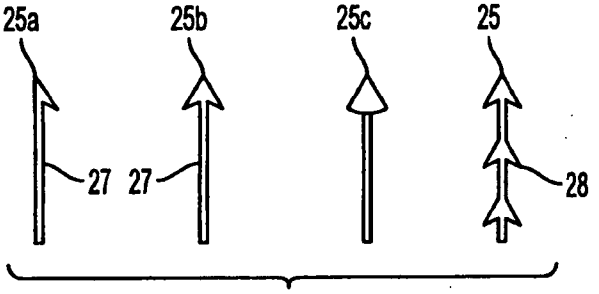


FIG. 3

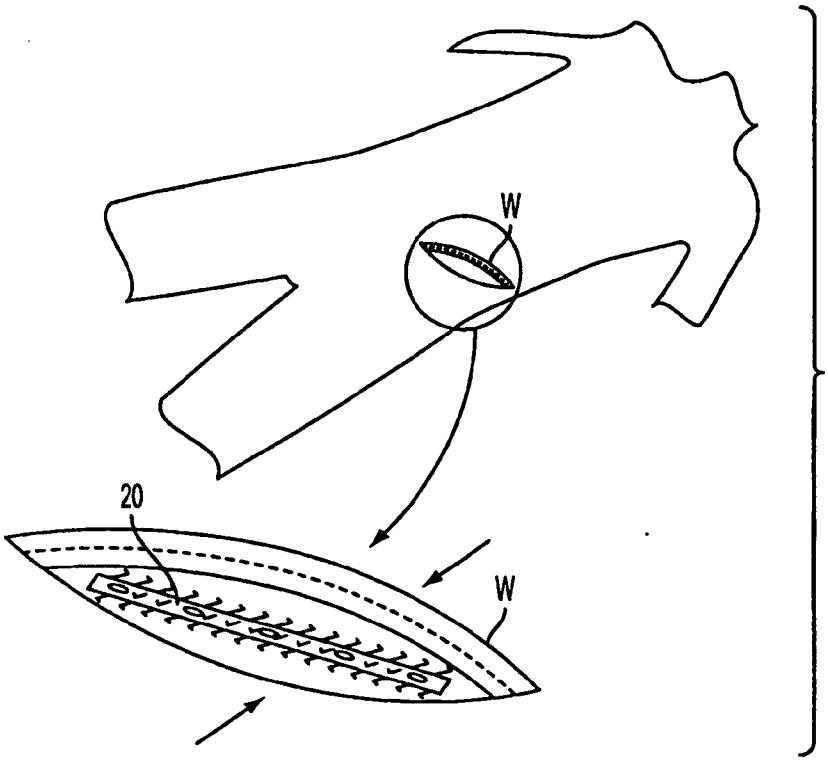


FIG. 4

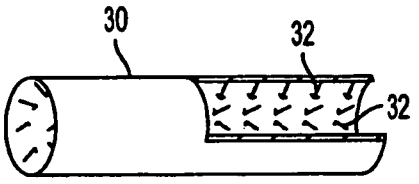


FIG. 5A

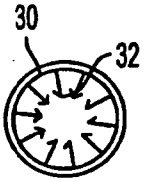


FIG. 5B

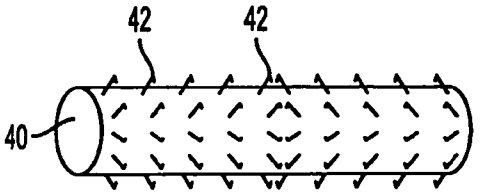


FIG. 6

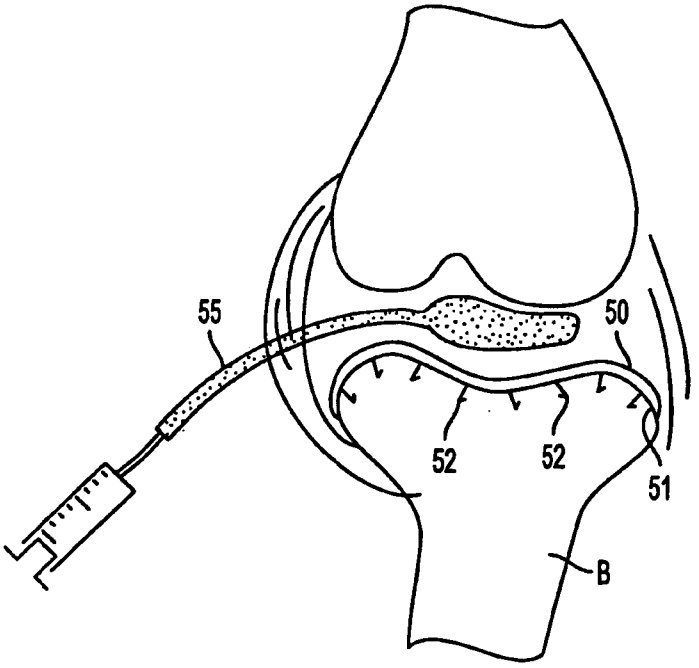


FIG. 7

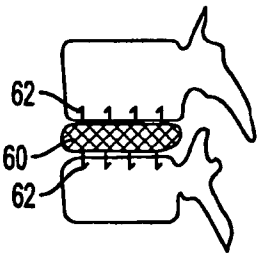


FIG. 8

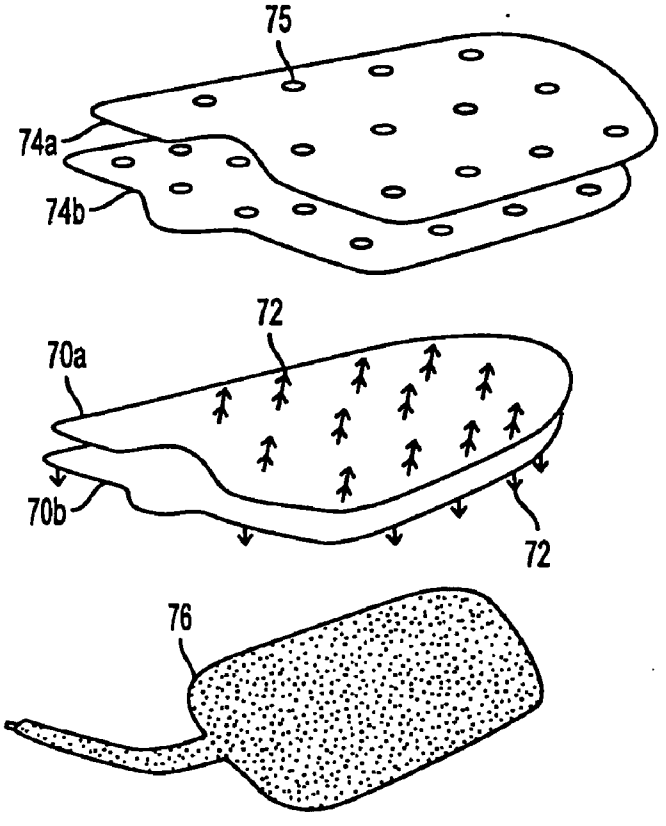


FIG. 9

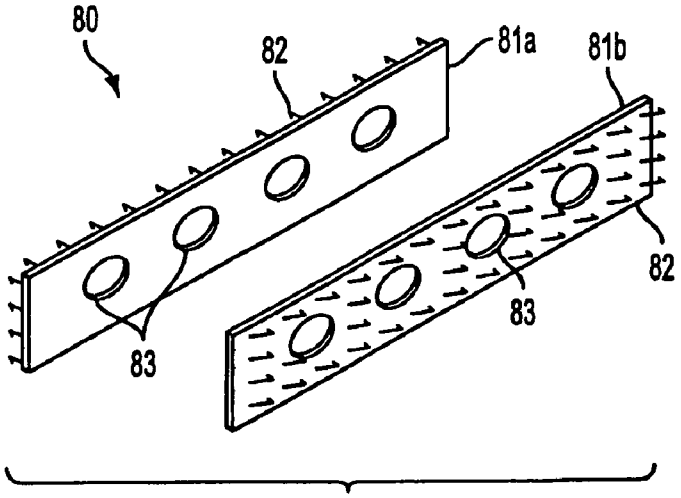


FIG. 10A

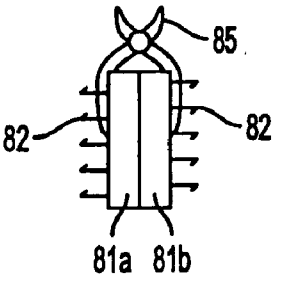


FIG. 10B

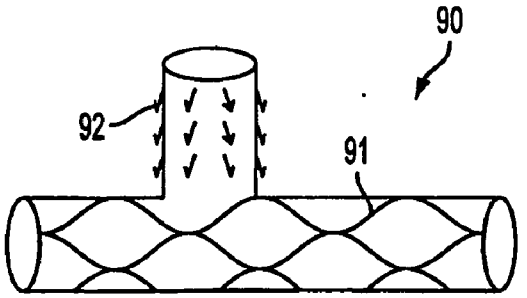


FIG. 11

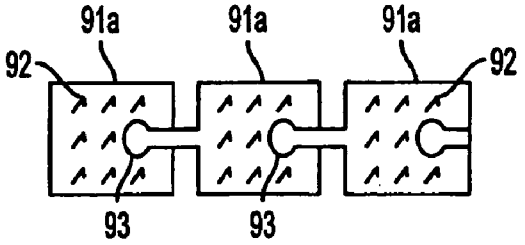


FIG. 12

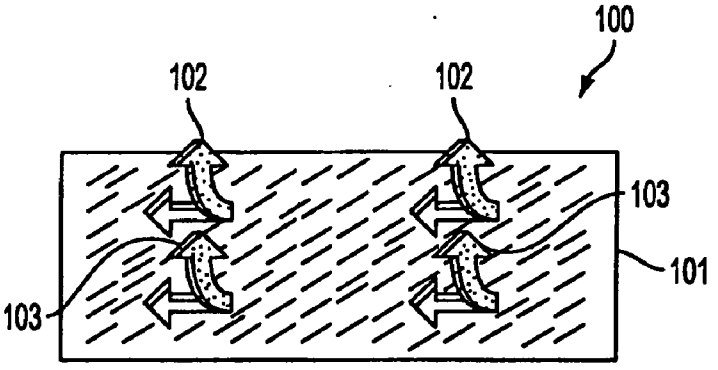


FIG. 13

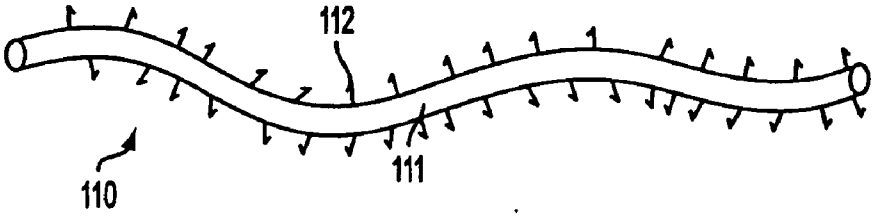


FIG. 14

MULTI-BARBED DEVICE FOR RETAINING TISSUE IN APPOSITION AND METHODS OF USE

FIELD OF THE INVENTION

[0001] The present invention relates generally to multi-barbed devices for maintaining tissue in apposition to promote wound closure and healing or for attaching tissue to adjacent structures or organs, and methods of use of such devices.

BACKGROUND OF THE INVENTION

[0002] Several types of wound closure devices and methods are known, and typically include sutures, staples, surgical tapes and tissue adhesives. Application of most of these wound closure devices is time consuming, and requires considerable manual dexterity and patience. In addition, while these methods are functionally adequate, some may take too long to provide effective wound closure, or be cosmetically unappealing.

[0003] Most prevalent is the use of needles and sutures. Sutures provide high tensile strength, a low incidence of reopening, and can provide minimal cosmetic scarring. Application of sutures is by far the slowest method of obtaining wound closure, the sutures typically require removal and the use of anesthetic and have the highest tissue reactivity and application cost.

[0004] Surgical staples have the advantages of rapid application, low tissue reactivity, low cost, and reduced risk of needle-sticks (and hence transmission of blood borne disease) to the surgeon and attending staff. Staples generally have low tensile strength than sutures, generally must be removed, and may interfere with certain imaging modalities, such as MRI or CT scanning. In addition, because staples typically present smaller contact areas to the tissue being closed, they present a higher risk of the wound being torn open.

[0005] Surgical tapes provide the least tissue reactivity, rapid application, low infection rates and low cost, reduced risk of needle-sticks, and a high degree of patient comfort. Because such tapes are topically applied, they provide much lower tensile strength than sutures, and thus the highest incidence of inadvertent reopening. In addition, such tapes generally cannot be used in hairy body areas, and must be kept dry.

[0006] Tissue adhesives and sealants offer advantages of rapid application, low cost, and a high degree of patient comfort. In addition, such adhesives do not need to be removed. Drawbacks associated with tissue adhesives include low tensile strength and high incidence of wound reopening when applied in areas subject to high tensile loads.

[0007] Most biologically derived sealants adhere to tissue by participating in the normal clotting cascade. Fibrin glues, for example, are generally used to control bleeding or to reinforce suture or staple lines rather than to make tissues adhere, thus functioning more as hemostatic agents than glues. While several new technologies are under development that offer the potential for use in diffuse bleeding sites, fibrin glues generally are most effective in areas of inactive bleeding.

[0008] Drawbacks common to many previously known wound closure techniques, such as sutures and staples, typically involve the skin in one way or another and therefore cause disfigurement of the skin (i.e. the suture penetration points). In addition, because such devices only hold the tissue together at certain points, they do not take advantage of the entire tissue surface area to create a strong bond.

[0009] Drawbacks associated with tissue adhesives and sealants are that most of these glues take several minutes to set, may not work in a wet environments and provide only limited tensile strength. Such glues work by binding with individual molecules on either side of the wound and therefore recruiting a large surface area in the act of binding the two surfaces together. This is an improvement over the needle and suture method where discrete "points" or tracks defined by the puncture sites of the needle where the suture passes through or the puncture site of the staple have the role of providing support for the coaptation of the two surfaces.

[0010] In view of the foregoing, it would be desirable to provide wound closure devices and methods that merge the desirable features of previously known wound closure systems, i.e. to take advantage of the entire surface in coaptation as well as utilizing a mechanical element to retain the tissue portions in apposition.

[0011] It further would be desirable to provide wound closure devices and methods that allow a surgeon to close a wound rapidly and effectively without damaging the skin surface adjacent the wound, thus creating a scar.

[0012] It also would be desirable to provide wound closure devices and methods that provide a high-tensile strength bond and are not visible from outside the skin.

[0013] It still further would be desirable to provide wound closure devices and methods that may be used not only to establish and retain tissue portions . . . in apposition, but which also may be used to provide adhesion to a large surface area, e.g., such as for hernia repair or attaching large skin grafts onto the surface of the body.

[0014] It also would be desirable to provide wound closure devices and methods wherein the devices may be configured in different shapes for different applications, including such shapes as a sheath, a cylinder, a ball a strip or a long rod like shape, and may be used intraoperatively or laparoscopically.

[0015] It yet further be desirable to provide wound closure devices and methods that can be used in wet or bleeding environments without significant loss of intended function.

[0016] It also would be desirable to provide wound closure devices that can be doped with a therapeutic agent, e.g., growth factor or thrombin, to aid wound healing or a clot enhancement.

SUMMARY OF THE INVENTION

[0017] In view of the foregoing, it is an object of the present invention to provide multi-barbed wound closure devices and methods for establishing and maintaining two sides of a wound in apposition.

[0018] It is another object of this invention to provide wound closure devices and methods that merge the desirable features of previously known wound closure systems, for

example, by taking advantage of the entire surface in coaptation as well as utilizing a mechanical element to retain the tissue portions in apposition.

[0019] It is another object of the present invention to provide wound closure devices and methods that allow a surgeon to close a wound rapidly and effectively without damaging the skin surface adjacent the wound.

[0020] It also is an object of this invention to provide wound closure devices and methods that provide a high-tensile strength bond and are not visible from outside the skin.

[0021] It further is an object of the present invention to provide wound closure devices and methods that may be used not only to establish and retain tissue portions in apposition, but which also may be used to provide adhesion to a large surface area, e.g., such as for hernia repair or attaching large skin grafts onto the surface of the body.

[0022] It still further is an object of the present invention to provide wound closure devices and methods wherein the devices may be configured in different shapes for different applications, including such shapes as a sheath, a cylinder, a ball a strip or a long rod like shape, and may be used intraoperatively or laparoscopically.

[0023] It yet further is an object of the present invention to provide wound closure devices and methods that can be used in wet or bleeding environments without significant loss of intended function.

[0024] It also is an object of this invention to provide wound closure devices that can be doped with a therapeutic agent, e.g., growth factor or thrombin, to aid wound healing or a clot enhancement.

[0025] In accordance with the principles of the present invention, the wound closure device comprises a substrate having a plurality of biodegradable barbs extending from at least one surface of the substrate. The multi-barbed device therefore permits closure of a wound in a timely, cosmetic and convenient manner.

[0026] The substrate generally is in the form of a thin strip of bioabsorbable polymer, and may be solid or have perforations forming a mesh. Where provided, the perforations allow the tissue and body fluids to contact the other side and enhance the healing process.

[0027] Where designed for applications in bringing the tissue edges of a wound into apposition and maintaining the tissue in fixed relation during healing, the substrate is provided with a multiplicity of barbs projecting from opposing sides of the substrate. The barbs have a sharpened distal end to facilitate tissue penetration, and hooks that grasp the tissue penetrated. Alternatively, the multiplicity of barbs may project from only one side of the substrate, for example, where the device is to be used to mend large areas of tissue, e.g., in hernia repair.

[0028] In accordance with the methods of the present invention, the multi-barbed device of the present invention is inserted within a wound or underneath the skin, and mechanically attaches to and brings the opposing tissue sides together.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] The above and other objects and advantages of the present invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

[0030] **FIG. 1** is a perspective view of an illustrative wound closure device constructed in accordance with the principles of the present invention;

[0031] **FIG. 2** is a side view of the device of **FIG. 1**;

[0032] **FIG. 3** is a detailed view of various embodiments of barbs suitable for use with the device of the present invention;

[0033] **FIG. 4** is a perspective view of a preferred method of employing the device of **FIG. 1** to close a wound in a human body;

[0034] **FIG. 5** is a perspective view, partly in section, of a tube constructed in accordance with the present invention;

[0035] **FIG. 6** is a perspective view of an alternative tube constructed in accordance with the present invention;

[0036] **FIG. 7** is a view showing insertion of an artificial cartilage including the multi-barbed device of the present invention within a human knee;

[0037] **FIG. 8** is a view showing placement of an intervertebral disk including the multi-barbed device of the present invention within a human vertebrae;

[0038] **FIG. 9** is a perspective view of several components of the present invention in the form of a clamshell;

[0039] **FIGS. 10A and 10B** are, respectively, perspective and side views of the present invention in the form of two halves that are attachable by sutures;

[0040] **FIG. 11** is a side view of an anastomosis device including the multi-barbed device of the present invention suitable for use in coronary artery bypass grafting;

[0041] **FIG. 12** is a side view of an embodiment of the present invention providing longitudinal flexibility;

[0042] **FIG. 13** is a perspective view of an alternative embodiment of the device of the present invention formed by stamping the barbs from the substrate material; and

[0043] **FIG. 14** is a side view of the alternative embodiment of the present invention in the form of a flexible rod coated with a plurality of the barbs.

DETAILED DESCRIPTION OF THE INVENTION

[0044] Referring to FIGS. **1** to **4**, a preferred embodiment of multi-barbed, multi-sided device **20** of the present invention is described for attaching coapting and maintaining two sides of a wound. Device **20** comprises substrate **21** having multiplicity of barbs **22** projecting from opposite sides **23** and **24**. Barbs **22** have sharpened distal ends **25** that enable the barbs to penetrate tissue.

[0045] Substrate **21** may be either rigid or flexible, and preferably comprises a thin sheet or strip of a bioabsorbable polymer that can be absorbed by the body such as polylactic acid, polyglycolic acid, polycaprolactone, polyethylene glycol, or other bioabsorbable polymers known in the art. Substrate **21** may by either solid or include mesh-like perforations **26** that permit the wound edges to communicate

with one another, thereby facilitating the healing process. Depending upon the intended application, substrate **21** may be made sufficiently flexible to conform to the tissue to be joined.

[**0046**] In the embodiment of **FIGS. 1-4**, barbs **22** project substantially orthogonally away from the plane of substrate **21**, and include distal tissue-piercing end **25** and shank **27**. Barbs **22** preferably are dull enough to not penetrate a surgical glove yet sharp enough to penetrate tissue. Distal ends **25** of barbs **22** may have a harpoon configuration (**25***a* in **FIG. 3**), an arrow configuration (**25***b* in **FIG. 3**) or being conically shaped (**25***c* in **FIG. 3**). In addition, barbs **22** may include additional ribs, hooks or projections **28** disposed along shanks **27** to further enhance the gripping ability of the barbs.

[**0047**] Barbs **22** preferably comprise a material that is sufficiently rigid to penetrate tissue during application, and is capable of withstanding the tensile forces expected during normal use, i.e., so the barbs cannot be pulled out and shanks **27** will not fracture in large numbers. Barbs **22** may comprise a bioabsorbable polymer, metal, or metal alloy. Barbs **22** may be made having shank lengths ranging from a fraction of a millimeter, e.g., for plastic surgery, to many millimeters, e.g., for large operations or veterinarian use.

[**0048**] Perforations **26** in device **20** reduce concerns that the substrate would be a barrier to healing, and instead allow the tissue edges and body fluids to contact one another across through substrate **21**, thereby accelerating the healing process. The perforations are passageways for the tissue and body fluids to have free communication from one side to the other. Perforations **26** may comprise up 90% or more of the area of substrate **21**.

[**0049**] In addition, substrate **21** and/or barbs **22** may be coated or impregnated with an anesthetic to reduce pain during wound healing. Alternatively, device **20** may include other drugs or therapeutic agents that provide some therapeutic effect during healing, for example, angiogenic agents or growth factors to facilitate wound healing, anti-inflammatory agents to reduce swelling or antibiotics to reduce infection.

[**0050**] Device **20**, and the alternative embodiments described hereinafter, have a number of applications, including:

[**0051**] Routine surgical wound closure;

[**0052**] Orthopedic procedures such as meniscal repair;

[**0053**] Wartime field use for fast wound closure;

[**0054**] Plastic surgery where it is cosmetically desirable to avoid the use of sutures; and

[**0055**] Grafting a large piece of planar tissue, such as fascia or skin, onto an area of the body.

[**0056**] Still referring to device **20** to **FIG. 1**, device **20** preferably comprises a biodegradable polymer such as polyglycolic acid or polylactic acid, and is preferably flexible to conform to curved surfaces. Barbs **22** may be constructed of the same material or a different material and preferably also are bioabsorbable. The whole device **20**, including substrate **21** and barbs **22**, may be molded out of one of the foregoing polymers. Perforations **26** enable the two sides of the wound to communicate with one another to facilitate healing of the wound, as described above.

[**0057**] In **FIG. 4**, device **20** is shown disposed within wound W. In accordance with a method of the present invention, device **29** is placed into the wound, and the two edges of the wound are approximated and squeezed together onto the multiplicity of barbs **22** so that tissue adhesion occurs. Barbs **22** thereby penetrate the tissue on both sides of substrate **21** and maintain the two edges of the wound firmly together.

[**0058**] Referring now to **FIGS. 5A and 5B**, an alternative embodiment of the present invention in form of a tube is described. Tube **30**, shown partly in section, includes a multiplicity of internal barbs **32** that project radially inward. The wall of tube **30** may comprise a solid material, such as a metallic or polymeric material, or may be in the form of a mesh.

[**0059**] Barbs **32** may be disposed only in regions adjacent to the ends of tube **30**, or as shown in **FIG. 5A**, may extend for along the entire length of the interior of tube **30**. Barbs **32** may project substantially orthogonally from the interior surface of tube **30**, or may in addition be angled towards the mid-point of the tube.

[**0060**] In accordance with the methods of the present invention, if a blood vessel or a tendon is inserted into tube **30**, it will be firmly engaged by the plurality of barbs **32**, and will be unable to come back out of the tube. Thus, two ends of a torn tendon may be inserted into the tube **30** to provide a strong connection.

[**0061**] In **FIG. 6**, an alternative embodiment is depicted in which the multiplicity of barbs is disposed on the exterior of the tube. Tube **40** may have a solid or hollow cross-section, and may comprise either a rigid or flexible material. Barbs **42** allow a tubular structure, such as a vessel, to be pulled over tube **40** like a sock and be firmly gripped. Examples of applications include rejoining of a fallopian tube or vas deferens anastomosis to reverse sterilization in a female or male subject.

[**0062**] In **FIG. 7**, an embodiment of the multi-barbed substrate of the present invention is described for use in joint repair to anchor artificial cartilage to the tibial chondyle. In this embodiment, artificial cartilage **50** is prepared having substrate **51** anchored to its lower surface. Substrate **51** includes multiplicity of barbs **52**, as described hereinabove, projecting from substrate **51**.

[**0063**] Artificial cartilage **50** is introduced arthroscopically in a contracted condition. Once disposed within in the knee space, artificial cartilage **50**, including substrate **51**, is unrolled over the tibial chondyle. High-pressure balloon **55**, or some other mechanical means, e.g., a mallet, is then used to apply a force on the surface of the artificial cartilage and substrate, thereby forcing the multiplicity of barbs **52** into engagement with bone B.

[**0064**] Similarly, **FIG. 8** depicts use of the structures and principles of the present invention for use in intervertebral disc replacement. Replacement disc **60** includes a multiplicity of barbs **62** on its upper and lower surfaces. Barbs **62** penetrate the vertebral end plate and stabilize it, thereby preventing rotation of the vertebrae and facilitating fusion. Replacement disc **60** preferably includes perforations, as

described above, to aid in bone migration. Additionally, replacement disc **60** or barbs **62**, or both, may be coated or impregnated with hydroxy apatite, as well as growth factors, to aid in the fusion process.

[**0065**] **FIG. 9** depicts another embodiment of a device constructed in accordance with the present invention, in which the barbs of the device are shielded until it is desired to implant the device. Substrate halves **70***a* and **70***b* each carry a multiplicity of barbs **72**. Substrate halves **70** are configured to be disposed within shield portions **74***a* and **74***b*. Shield portions **74***a* and **74***b* each include a multiplicity of openings **75** aligned with barbs **72**. Balloon **76** is configured to be disposed between substrate halves **70***a* and **70***b*, so that upon application of an outward force by balloon **76**, the barbs are driven through openings **75** in shield portions **74***a* and **74***b* and into the target tissue.

[**0066**] With respect to **FIGS. 10A and 10B**, another alternative embodiment is described. Device **80** includes substrate portions **81***a* and **81***b*, each carrying a multiplicity of barbs **82** as described above. Each of substrate halves **81***a* and **81***b* includes a plurality of suture eyelets **83**. In accordance with the methods of the present invention, device **80** is employed by individually adhering the substrate halves **81***a* and **81***b* to the edges of the wound. A suture **85** is then threaded through eyelets **83** in substrate halves **81***a* and **81***b*, and the wound is closed by pulling the suture connecting the two halves to bring substrate halves **81***a* and **81***b* into apposition, as depicted in **FIG. 10B**. Suture **85** is then knotted, and any excess suture material removed.

[**0067**] **FIG. 11** depicts an embodiment of the present invention wherein stent-like structure **90** is used to side anastomose a blood vessel. Structure **90** includes non-barbed section **91** that is inserted into the parent vessel. Barbed portion **92** is then used to attach a bypass graft vessel.

[**0068**] **FIG. 12** depicts yet another alternative embodiment of the wound closure device of the present invention. In this embodiment, substrate **91** comprises a rigid material including a multiplicity of barbs **92**. To ensure that the substrate is capable of flexing, however, substrate **91** is divided into a series of jointed and interlinked units **91***a*, **91***b* and **91***c*. Joints **92** enable units **91***a*-**91***c* to rotate relative to one another, thereby providing a degree of flexibility to the overall device.

[**0069**] **FIG. 13** depicts a method of manufacturing a multi-barbed device of the present invention. Device **100** comprises substrate **101** formed from a thin sheet of biocompatible polymer or metal alloy. Barbs **102** are die cut from substrate **101**, and then bent out of the plane of substrate **101** to expose sharpened distal ends **103**.

[**0070**] **FIG. 14** depicts an alternative embodiment to that shown in **FIG. 6**. Device **110**, which may made available for dispensing in the form of a reel, comprises flexible substrate **111** carrying a multiplicity of barbs **112** on its exterior surface. Device **110** therefore may be unrolled and cut to length depending upon the specific desired application. For example, for non-medical industrial applications, in which it is desired to adhere two separate sheets together quickly, substrate **111** may comprise a strong plastic, e.g., Nylon, and the barbs **112** may comprise stainless steel or another metal alloy.

[**0071**] With respect to the above description, it is to be realized that the optimum dimensional relationships for the parts of the invention, to include variations in size, materials, shape, form, function and manner of operation, assembly and use, are deemed readily apparent and obvious to one skilled in the art, and all equivalent relationships to those illustrated in the drawings and described in the specification are intended to be encompassed by the present invention.

[**0072**] Although preferred illustrative embodiments of the present invention are described above, it will be evident to one skilled in the art that various changes and modifications may be made without departing from the invention. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What is claimed is:

1. Apparatus for closing a wound comprising:

an elongated substrate comprising a biocompatible material, the elongated substrate having a first surface; and

a multiplicity of barbs projecting from the first surface, the multiplicity of barbs having tissue-penetrating distal ends.

* * * * *