US 20020123758A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2002/0123758 A1

Bachman et al. (43) Pub. Date: Sep. 5, 2002

(54) SURGICAL KNOT PUSHING DEVICE AND METHOD OF USE

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(21) Appl. No.: **09/797,964**

(22) Filed: **Mar. 2, 2001**

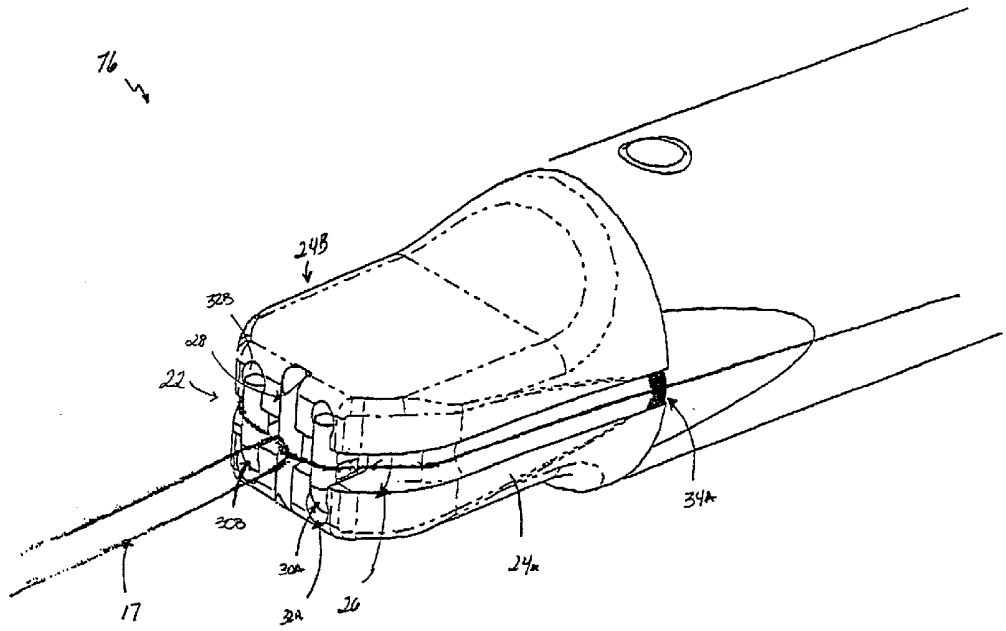
**Publication Classification**

(51) **Int. Cl.**[7] ..... **A61B 17/04**

(52) **U.S. Cl.** ..... **606/148**

(57) **ABSTRACT**

A surgical knot pushing device is described which has a knot pushing interface mounted on the distal portion of an elongated body and an actuation handle located on the proximal portion of the elongated body. The knot pushing interface has a suture receiving recess formed thereon, and a knot positioning member which traverses the suture receiving interface. At least one extendable knot retaining member is further positioned on the pushing interface, the at least one extendable retaining member capable of engaging suture material. The knot pushing interface also comprises at least one suture cutting member which is in communication with the actuation handle. The present invention is particularly well suited for use in minimally invasive surgical procedures. The present invention also teaches a method of forming a knot in suture material, retaining a knot with a knot pushing device, advancing and applying a knot to an area of interest, and cutting excess suture material.




Normal Run-down

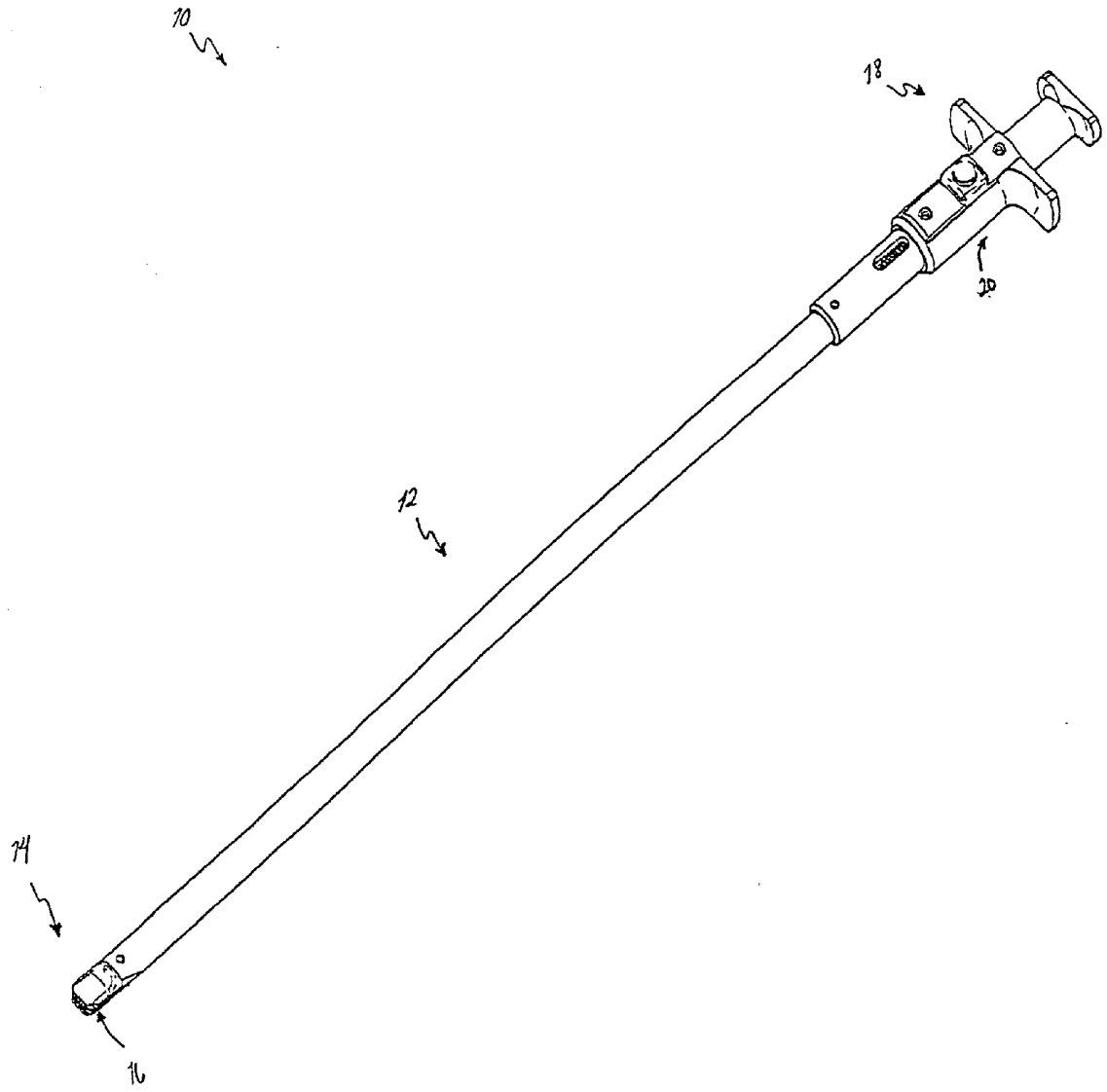
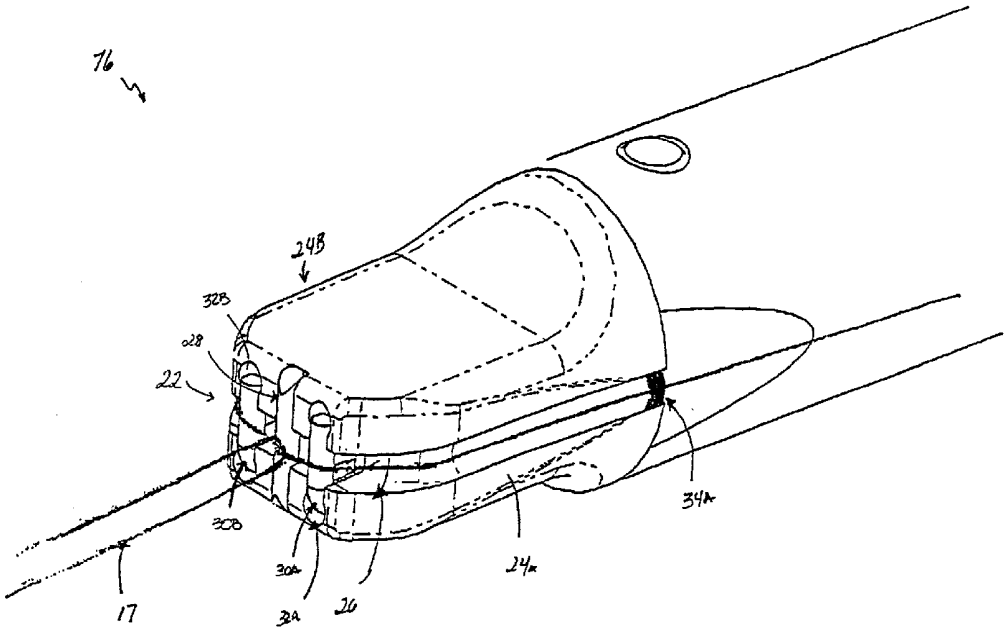
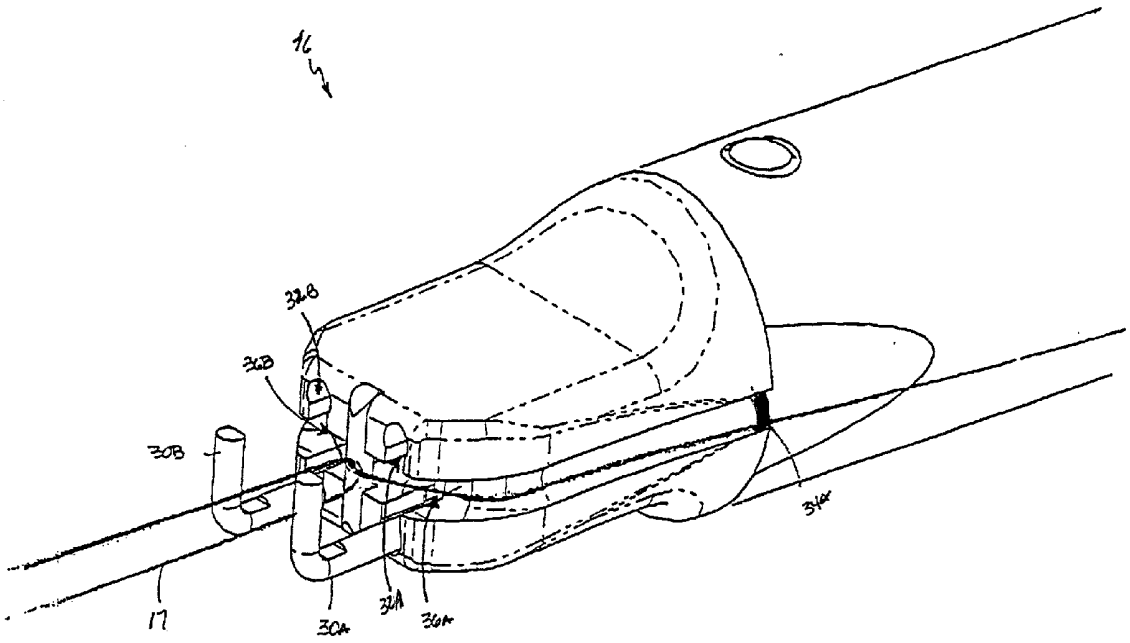



FIGURE 1



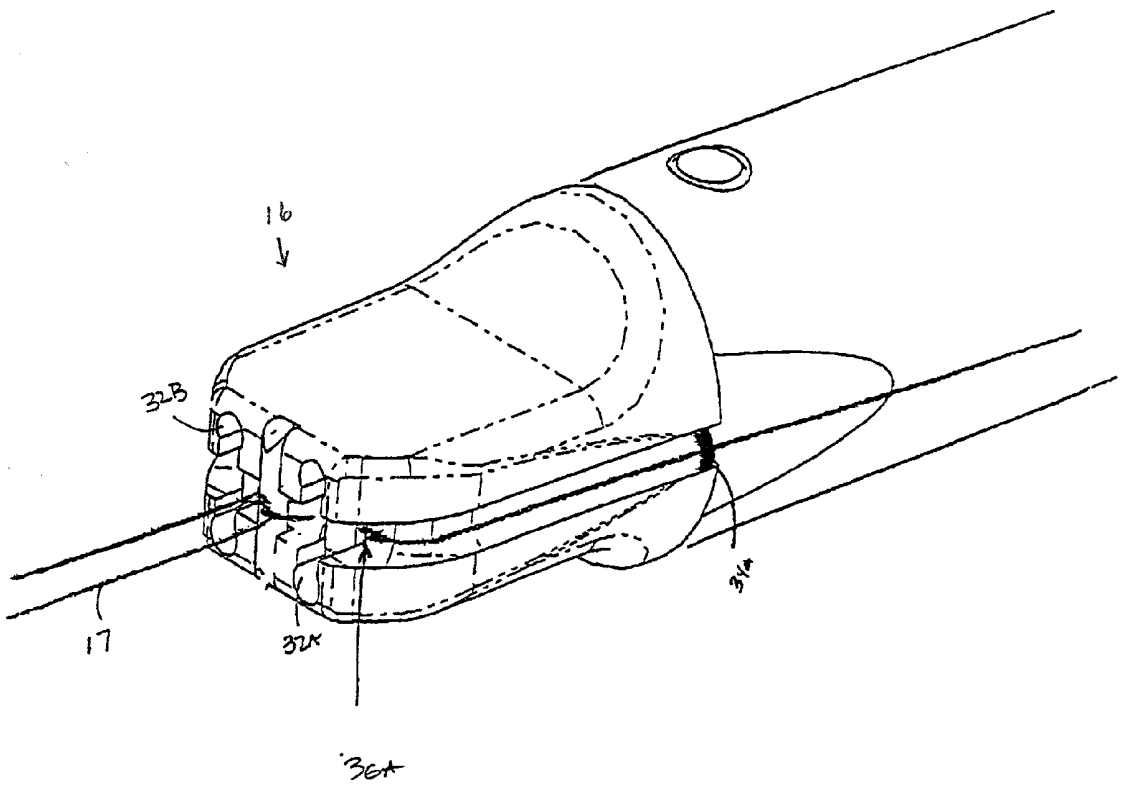

Normal Run-down

FIGURE 2




Preparing to cut

FIGURE 3




Cutting

FIGURE 4

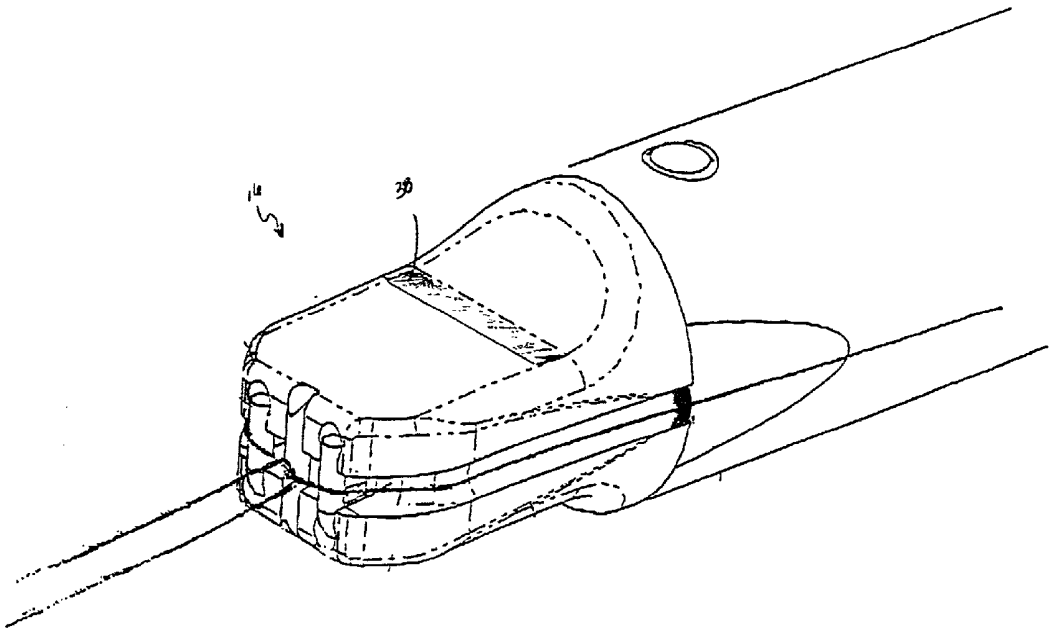


FIGURE 5

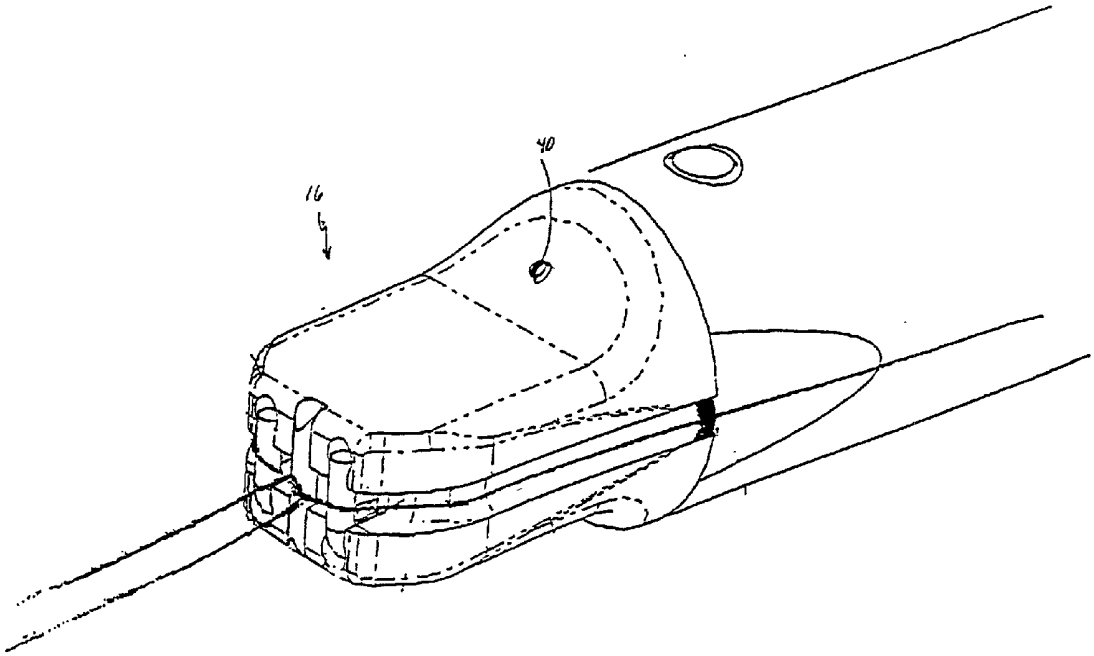



FIGURE 6

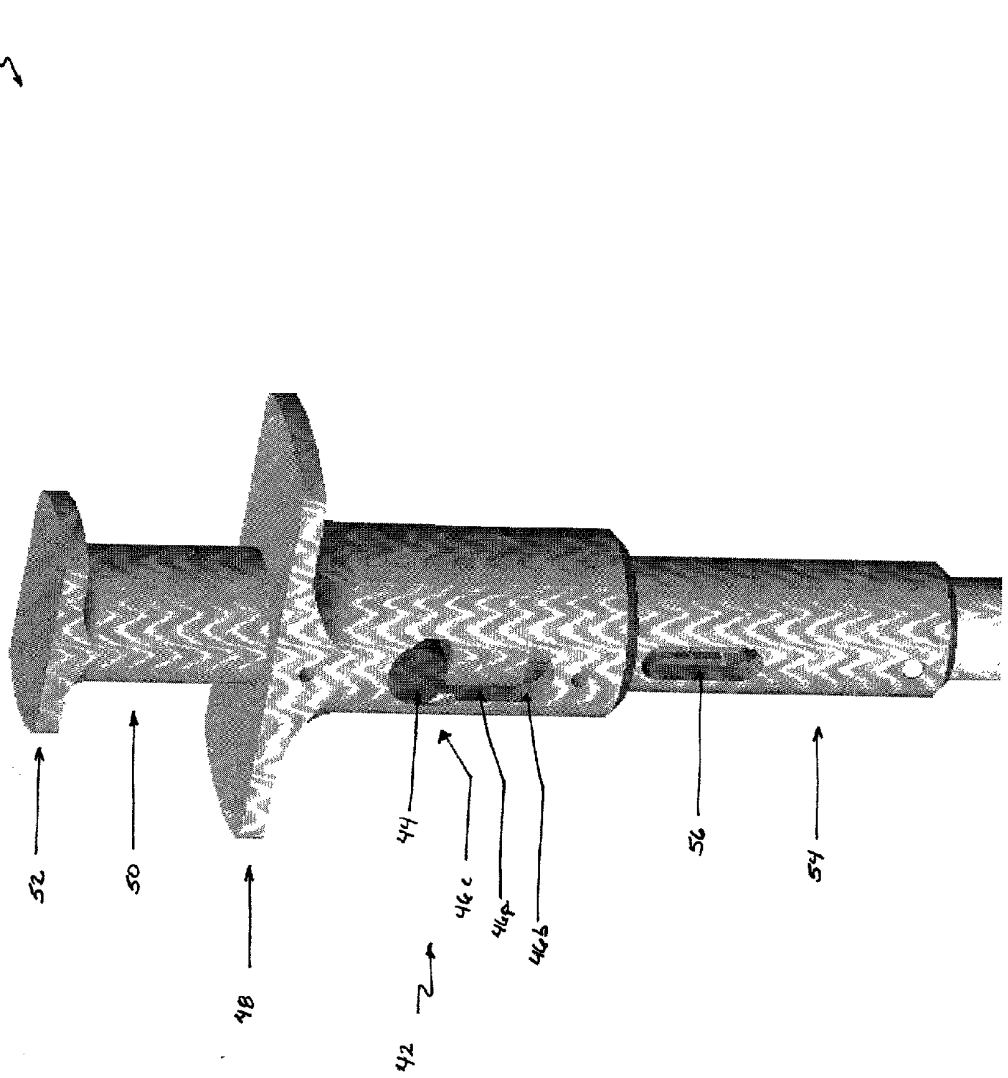



Figure 7

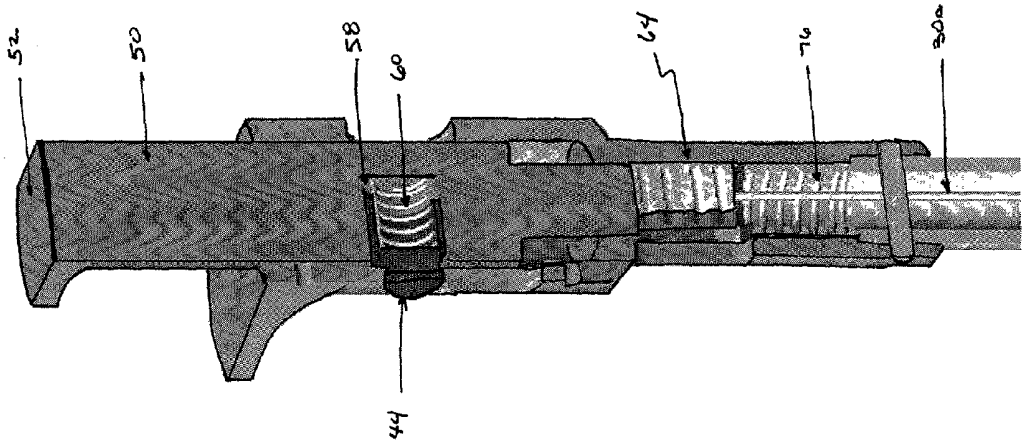



Figure 8

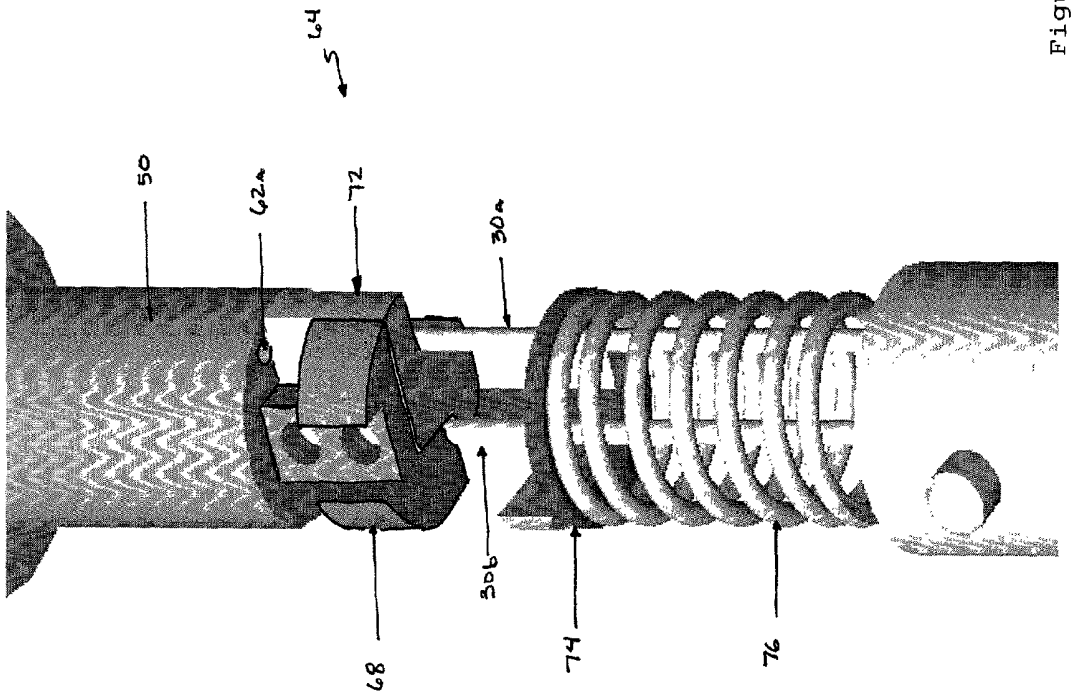



Figure 9

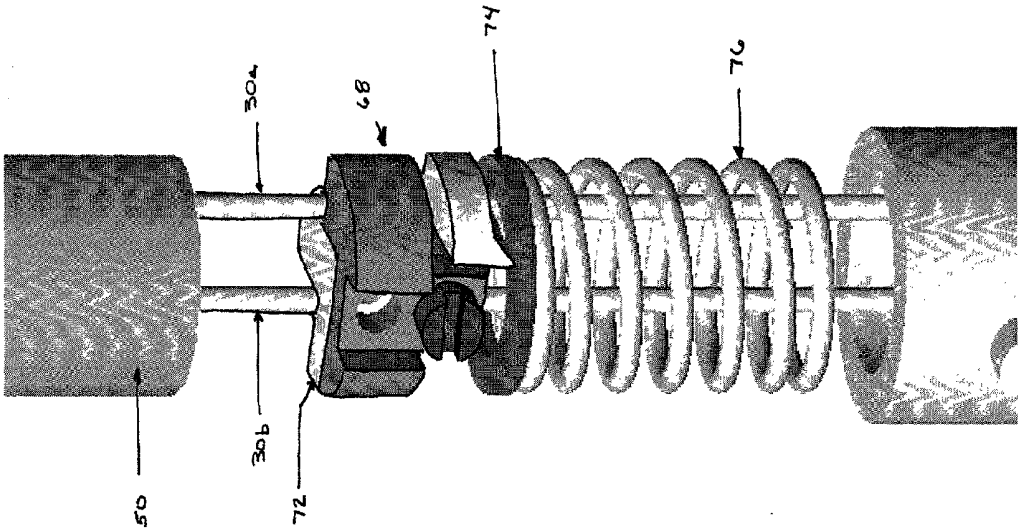



Figure 10

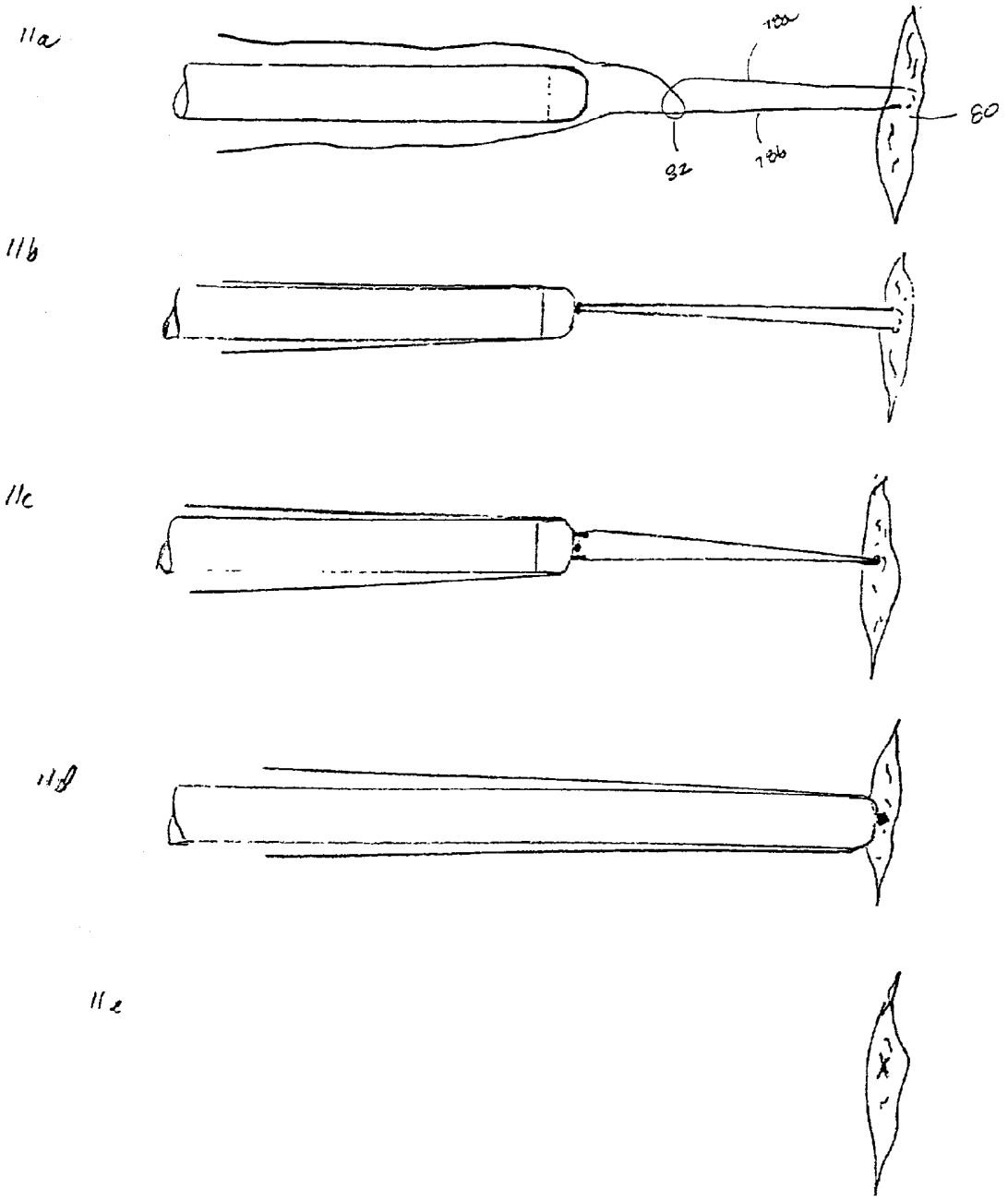



FIGURE 11

# SURGICAL KNOT PUSHING DEVICE AND METHOD OF USE

## BACKGROUND OF THE INVENTION

[0001] Minimally invasive surgical techniques have emerged as an alternative to conventional surgical techniques to perform a plurality of surgical procedures. Minimally invasive procedures differ from conventional surgical procedures in that a plurality of devices may be introduced into the body through a small incision. As a result, trauma to the body is greatly reduced, thereby decreasing the recovery time of the patient.

[0002] Many conventional surgical procedures have been performed using minimally invasive techniques. One challenge presented when performing a heretofore conventional surgical procedure using a minimally invasive technique is to remotely position and apply sutures to an area of interest. Commonly, a suture will be required to approximate at least two pieces of tissue. In conventional surgical techniques, the surgeon will approximate the tissue pieces by forcing a needle and suture material through various portions of the tissue to be approximated, and tying a knot in the suture material resulting in approximation. In contrast, in minimally invasive surgical techniques the surgeon's access to the approximation site is greatly reduced. Commonly, a surgical device will attach the suture material to the tissue. The surgeon will remotely form a knot in the suture material and advance the knot to the area of interest with a "knot pusher," thereby approximating the tissue. Thereafter, the knot pusher is removed from the body and a suture cutting device is inserted to cut the surplus suture material.

[0003] Several knot pushing devices are known. These devices permit an operator to push suture knots which have been formed extracorporeally towards tissue to be sutured. For example, U.S. Pat. No. 5,769,863, issued to Garrison et al., discloses a surgical knot pusher having an elongated body connected to a pushing head. The pushing head engages a portion of suture material containing a knot and is advanced to the area of interest, thereby "throwing" the knot. Once the suture knot is placed the knot pushing device is removed and a cutting implement is introduced into the body and cuts the remaining suture material. The remaining suture material is then removed. The device disclosed therein failed to effectively address the cutting of superfluous suture material, instead requiring the use of a supplemental cutting implement to be precisely positioned proximate the suture knot.

[0004] With respect to the aforementioned devices, it is desirable to have a system capable of intracorporeally positioning and applying a suture knot to an area of interest. Additionally, it is desirable to have a knot pushing system wherein the operator may cut and remove surplus suture material using the knot pushing device.

## BRIEF SUMMARY OF THE INVENTION

[0005] The present invention solves the problem of effectively delivering a knot formed outside the body from surgical suture material to a location proximate to a repair site in vivo. Additionally, the present invention provides a device capable of delivering the suture knot to a intracorporeal location and cutting excess suture material, thereby effectively approximating tissue pieces.

[0006] The knot pushing device of the present invention is optimized for use in minimally invasive surgical procedures wherein the surgeon's access to the area of interest is greatly reduced. Additionally, the knot pushing device of the present invention may be used to advance a plurality of bi-manually formed surgical knots utilized in conventional surgical procedures. The knot pushing device disclosed herein may be further used to sequentially advance multiple knots or "throws" to the repair area.

[0007] In one aspect, the present invention provides a knot pushing device comprising an elongated body having a distal portion attached to a pushing interface and a proximal portion attached to an actuation handle. The elongated body may be manufactured from a plurality of materials depending on the desired use.

[0008] The pushing interface comprises at least one suture cutting member which is in communication with the actuation handle. The at least one suture cutting member enables an operator to deliver a suture to a site of repair, apply the suture, and remove excess suture material with one device.

[0009] Also disclosed herein is a knot pushing device capable of mechanically retaining the suture knot and suture material, advancing the knot down the suture material, applying the knot to an area of interest, and removing excess suture material. The present embodiment comprises an elongated body having a distal portion attached to a pushing interface and a proximal portion attached to an actuation handle. The pushing interface comprises at least one cutting member and at least one extendable retaining member capable of capturing, retaining, and releasing suture material.

[0010] The present invention further discloses a method of forming a knot from surgical suture material, advancing the knot to a location in vivo, applying the suture to an area of repair, and removing excess suture material.

[0011] Other objects and further features of the present invention will become apparent from the following description when read in conjunction with the attached drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1** is an elevated view of the surgical knot pushing device of the present invention;

[0013] **FIG. 2** is an elevated view of the pushing interface of the surgical knot pushing device engaging suture material;

[0014] **FIG. 3** is an elevated view of the pushing interface of the surgical knot pushing device having two extendable retaining members extended with suture material disposed thereon;

[0015] **FIG. 4** is an elevated view of the pushing interface of the surgical knot pushing device retaining and cutting suture material;

[0016] **FIG. 5** is an elevated view of an alternate embodiment of the pushing interface of the surgical knot pushing device having a visualization device disposed thereon;

[0017] **FIG. 6** is an elevated view of an alternate embodiment of the pushing interface of the surgical knot pushing device having a medicament application device disposed thereon;

[0018] **FIG. 7** is an elevated view of the actuation handle of the surgical knot pushing device;

[0019] **FIG. 8** is an sectional view of the actuation handle of the surgical knot pushing device showing the internal components;

[0020] **FIG. 9** is a perspective sectional view of the actuation handle of the surgical knot pushing device showing the internal components of the actuation system;

[0021] **FIG. 10** is an elevated sectional view of the actuation handle of the surgical knot pushing device showing the internal components of the actuation system;

[0022] **FIG. 11***a* is a side view of the knot pushing device of the present invention preparing to engage a knot being formed in suture material;

[0023] **FIG. 11***b* is a side view of the knot pushing device of the present invention preparing to engage the knot formed in suture material;

[0024] **FIG. 11***c* is a side view of the knot pushing device of the present invention preparing to retain a knot formed in suture material;

[0025] **FIG. 11***d* is a side view of the knot pushing device of the present invention preparing to cut a knot formed in suture material; and

[0026] **FIG. 11***e* is a side view of the approximated tissue.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

[0027] Disclosed herein is a description of various illustrated embodiments of the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention. The section titles and overall organization of the present description are for the purpose of convenience only and are not intended to limit the present invention.

[0028] The knot pushing device of the present invention is generally used in minimally invasive surgical procedures, which typically utilize relatively small incisions, to precisely apply and position a knot. The device and method disclosed herein are of particular value when a surgeon or other clinician is unable to tie a suture knot directly at the surgical site. The device has particular relevance to the surgical procedures disclosed in co-pending U.S. patent application Ser. No. 09/562,406 filed on May 1, 2000 entitled Minimally Invasive Mitral Valve Repair System and Method and U.S. Patent Application entitled Method And System For Tissue Repair Using Dual Catheters filed on Feb. 6, 2001, both of which have been assigned to the assignee of the present invention and which are incorporated by reference as if set forth herein in their entirety. Those skilled in the art will appreciate, however, that the device and method are relevant to a variety of procedures wherein a surgeon's hands cannot directly reach the surgical site.

[0029] As those skilled in the art will appreciate, the present invention may be utilized as a handheld device or, in the alternative, as a catheter delivered implement. It is anticipated as being within the scope of the present invention to produce a knot pusher capable of functionally delivering knots formed with a plurality of suture sizes to various locations within a body.

[0030] Referring to **FIG. 1** of the drawings, the device **10** comprises an elongated body member **12** having a distal portion **14** attached to a pushing interface **16** and a proximal portion **18** having an actuation handle **20** attached thereto. The elongated body member **12** of the present invention may be manufactured in a plurality of lengths, as required.

[0031] Those skilled in the art will appreciate that the elongated body member **12** may be manufactured from a plurality of materials, including, for example, polycarbonate or polyacetate, thereby providing a relatively rigid device. In an alternative embodiment of the present invention, the elongated body member **12** may be manufactured from moderately flexible materials such as, for example, polyvinyl chloride or braided cable, thereby enabling catheter-based applications. Alternatively, the elongated body **12** of the present invention may contain at least one internal lumen.

[0032] **FIG. 2** shows the pushing interface **16** of the present invention engaging a portion of suture material **17**. As shown in **FIG. 2**, the pushing interface **16** comprises a distal face **22** and first and second sidewalls **24***a* and **24***b*. A suture receiving recess **26** containing suture material **17** extends from the first sidewall **24***a*, across the distal face **22**, and traverses the second sidewall **24***b*. A knot positioning member **28**, which is located on the distal face **22**, is in communication with the suture receiving recess **26**. In the illustrated embodiment, the knot pushing member **28** is a transverse member which engages and stabilizes a knot positioned thereon. During use, pulling tension is applied to the suture material **17** by the operator ensuring that the knot remains positioned on the knot positioning member **28**, thereby permitting accurate knot placement. The distal face **22** further comprises at least one extendable retaining member. As illustrated in **FIG. 2**, two extendable retaining members **30***a* and **30***b*, shown in a retracted position, are positioned within retaining member receivers **32***a* and **32***b*, respectively. The elongated body **12** or pushing interface **16** may also be constructed with suture ports **34***a* and **34***b*, if desired. The suture ports **34***a* and **34***b*, if included, provide a barrier preventing the suture material **17** from becoming dislodged or displaced from the suture receiving recess **26**.

[0033] The pushing interface **16** shown in **FIG. 2** may be manufactured from a plurality of materials including, for example, stainless steel, titanium, ceramic, reinforced plastic, or other rigid biologically compatible materials capable of withstanding sterilization. In an alternate embodiment of the device **10**, different materials may be used to manufacture various component of the pushing interface **16**. For example, the pushing interface **16** may be manufactured from a reinforced plastic and the extendable retaining members **30***a* and **30***b* may be manufactured from stainless steel. Alternatively, the pushing interface **16** may include coatings, such as Teflon®, to reduce friction.

[0034] **FIG. 3** shows the pushing interface **16** of the present invention having the extendable retaining members **30***a* and **30***b* extended, thereby preparing to retain suture material **17**. As shown in **FIG. 3, a** pair of cutting members **36***a* and **36***b* are located within the retaining member receivers **32***a* and **32***b*. The cutting members **36***a* and **36***b* may be manufactured from a plurality of materials, including, without limitation, titanium, stainless steel, ceramic, or reinforced plastic. As shown in **FIG. 3**, the extendable retaining

members **30***a* and **30***b* cooperatively engage the cutting members **36***a* and **36***b*, thereby ensuring effective cutting of any material positioned therebetween.

[**0035**] As illustrated in FIGS. **2-4**, the extendable retaining members **30***a* and **30***b* have three positions: a retracted position wherein the retaining members **30***a* and **30***b* are positioned within the receiving recesses **32***a* and **32***b* as shown in **FIG. 2**; an extended position wherein said retaining members **30***a* and **30***b* extend beyond the distal portion of the pushing head **16** as shown in **FIG. 3**; and a cutting position wherein said retaining -members **30***a* and **30***b* are retracted further within the retaining member receivers **32***a* and **32***b* to engage the cutting members **36***a* and **36***b* as shown in **FIG. 4**. As shown in **FIG. 4**, the extendable retaining members **30***a* and **30***b* are retracted further within the retaining member recesses **32***a* and **32***b*, thereby forcing the suture material **17** to engage the cutting members **36***a* and **36***b*.

[**0036**] Those skilled in the art of minimally invasive surgery will appreciate that the pushing interface **16** may comprise additional devices. As shown in **FIG. 5, a** visualization **38** device may be disposed on the pushing interface **16**, thereby enabling the operator to visualize the suture placement. The visualization device **38** may be passive in the form of a radio-opaque or echo-genic material for visualization by x-ray or ultrasound. In an alternate embodiment, the visualization may be achieved with an ultrasonic or fiber optic probe coupled to the device. In an alternative embodiment as shown in **FIG. 6**, the pushing interface **16** may further comprise a medicament applicator **40** in communication with at least one medicament lumen (not shown) located within the elongated body **12**, thereby enabling the delivery and application of a medicament to the tissue containing or surrounding the suture.

[**0037**] **FIG. 7** shows the exterior of the actuation handle **20** of the present invention. The actuation handle **20** comprises a handle body **42** having a cutting actuator **44** positioned within a cutting actuator receiver **46**, an integral stop **48**, a slidable actuation piston **50** having a pusher **52**, and an actuation assembly **54** having an adjustment recess **56** formed therein. The actuation piston **50** is slidably coupled to the handle body **42** and is in communication with the extendable retaining members **30***a* and **30***b*. The cutting actuator receiver **46** forms a multiple lobe orifice having a first position **46***a* which corresponds to the extendable retaining members **30***a* and **30***b* being in a retained position; a second position **46***b* which corresponds to the extendable retaining members **30***a* and **30***b* being in an extended position; and a third position **46***c* which corresponds to the extendable retaining members **30***a* and **30***b* being in a cutting position. The adjustment recess **56** provides user access to the adjustment screws **66** and **70** (see **FIG. 10**), and the retaining members clamping assembly **64** (see **FIGS. 9 and 10**) positioned within the actuation handle. Those skilled in the art will appreciate that the actuation handle of the present invention may be manufactured from a plurality of materials, including, for example, reinforced plastic, various metals, and biologically compatible elastomers.

[**0038**] **FIG. 8** shows the internal components of the cutting actuation assembly positioned within the actuation handle **42**. As shown in **FIG. 8**, the cutting actuator **44** is positioned within a cutting actuator channel **58** formed within the slidable actuation piston **50**, and in communication with a cutting actuator biasing member **60** positioned therein.

[**0039**] **FIG. 9-10** show two angular views of the internal actuation assembly of the present invention. As shown in **FIG. 9**, two retaining member ports **62***a* and **62***b* formed in the slidable actuation piston **58** receive the extendable retaining members **30***a* and **30***b*. The retaining members clamping assembly **64** comprises a first adjustment screw **66** coupled to a first clamp portion **68** and a second adjustment screw **70** coupled to a second clamp portion **72**. The adjustment screws **66** and **70** permit the operator to adjust the extension and retraction action of the extendable retaining members **30***a* and **30***b* individually. For example, an operator may loosen the first adjustment screw **66** and manually retract the extendable retaining member **30***b* further into the actuation handle **20**, thereby causing the extendable retaining member **30***b* to engage the cutting member **36***b* before the other extendable retaining member **30***a* engages the other cutting member **36***a*. Those skilled in the art will appreciate the capability to individually adjust the extendable retaining members **30***a* and **30***b* enables a consistent cutting action by the device. The retaining members clamping assembly **64** is positioned on the extendable retaining members **30***a* and **30***b*, proximate a washer **74** and a biasing member **76**. The first clamp portion **68** and second clamp portion **72** cooperatively position and secure the retaining members **30***a* and **30***b* respectively. Retaining members **30***a* and **30***b* are secured between the first clamping portion **68** and the second clamping portion **70**. The first and second clamping portions **68** and **72** are attached to each other with the adjustment screws **66** and **70** such that tightening the adjustment screws **66** and **70** decreases the distance between the first and second clamping portions **68** and **72**, thereby securing the extendable retaining members **30***a* and **30***b* positioned therebetween. The bifurcated clamping assembly allows the operator to adjust the engagement of the extendable retaining member **30***a* and **30***b* relative to the cutting members (not shown), thereby ensuring effective cutting of the suture. The washer **74** and biasing member **76** forcibly bias the slidable actuation piston **50** to position the retaining members **30***a* and **30***b* is a retracted position.

[**0040**] The present invention further teaches various methods of using the knot pushing device disclosed herein. In a first embodiment, the device can be used to advance, or "throw" a knot to the approximated tissue. As shown in **FIGS. 11***a*-**1***b*, a portion of suture material **78**, having opposite end portions **78***a* and **78***b*, is secured to various tissue pieces **80** to be approximated. A knot **82** is extracorporeally formed in the suture material **78** using a standard bimanual technique. The excess suture material **78***a* and **78***b* is then positioned within the suture receiving recess **26** along the pushing interface sidewalls **24***a* and **24***b* such that the knot **82** is positioned proximate the knot positioning member **28**, and a pulling tension is applied by the operator to the suture material **78***a* and **78***b*. The device **10** is then advanced down the taunt suture material **78***a* and **78***b* to a position proximal the tissue **80** being approximated, thereby "throwing" the knot **82**.

[**0041**] The device can also be used to first retain the suture material prior to advancing the knot to the approximated tissue. Referring to **FIGS. 3, 7**, and **11***c*, the knot **82** may be retained in position by engaging the suture material **78***a* and

78*b* with the extendable retaining members **30***a* and **30***b*. To actuate the extendable retaining members **30***a* and **30***b*, the operator advances the pusher **52** towards the integral stop **48** thereby resulting in the slidable actuation piston **50** advancing into the handle body **42**. The extendable retaining members **30***a* and **30***b*, which are in communication with the slidable actuation piston **50**, are extended beyond the distal face **22** of the pushing interface **16**. As the pusher **52** is advanced the cutting actuator **44** moves from the first position **46***a* within the cutting actuator receiver **46** to the second position **46***b*. As shown in **FIG. 11***c*, the operator may then engage the suture material **78***a* and **78***b* with the retaining member **30***a* and **30***b* by positioning the excess suture material **78***a* and **78***b* within the suture receiving recess **26** along the pushing interface sidewalls **24***a* and **24***b*. Again the knot **82** is positioned proximate the knot positioning member **28**, and a pulling tension is applied by the operator to the suture material **78***a* and **78***b*. In this embodiment, however, suture material **78***a* and **78***b* are placed between retaining members **30***a* and **30***b* and knot positioning member **28** as shown in **FIG. 3**. Once the retaining members **30***a* and **30***b* have engaged the suture material **78***a* and **78***b*, the operator releases the pressure applied to the pusher **52**, thereby permitting the biasing member **76** to retract the retaining members **30***a* and **30***b* into the retaining member receivers **32***a* and **32***b* with the knot **82** and suture material **78***a* and **78***b*. Retraction of the retaining members **30***a* and **30***b* results in the cutting actuator **44**, positioned within the cutting actuator receiver **46**, retracting from the second position **46***b* to the first position **46***a*. Thereafter, the knot **82** is advanced or "thrown" proximal" the tissue **80** to be approximated. To release the device **10** from the attached suture the operator extends the retaining members **30***a* and **30***b* and disengages the suture material **78***a* and **78***b*. The device **10** may then be removed.

[**0042**] Referring to **FIGS. 4, 7**, and **11***d*-**11***e*, the present invention discloses a method of using the same device to extracorporeally form a knot, advance and attach the knot to an area of interest in vivo, and thereafter cut superfluous suture material. A portion of suture material **78***a* and **78***b* is secured to various tissue pieces **80** to be approximated. As shown in **FIG. 11***a*, a knot **82** is extracorporeally formed in the suture material **78** using a standard bimanual technique. As detailed above, the knot **82** is retained by the retaining members **30***a* and **30***b* and advanced to a positioned proximal the tissue **80** to be repaired. To cut the surplus suture material **78***a* and **78***b*, the operator depresses the cutting actuator **44**, thereby compressing the cuffing actuator biasing member **60** within the cutting actuator channel **58**. The cutting actuator **44** is permitted to retract from a first position within the cutting actuator receiver **46***a* to a third position **46***c*. The biasing member **76** forces the slidable actuation piston **50** away from the handle body **42**. The extendable retaining members further retract from into the retaining member receivers **32***a* and **32***b* and engage the cutting members **36***a* and **36***b*, resulting in the suture material **78***a* and **78***b* being cut. The device **10** and terminated suture material may then be removed from the body. **FIG. 11***e* shows the approximated tissue.

[**0043**] In closing it is understood that the embodiments of the invention disclosed herein are illustrative of the principles of the invention. Accordingly, the present invention is not limited to that precisely as shown and described in the present invention.

What is claimed is:

**1**. A knot pushing device, comprising:

an elongated body having a distal portion and a proximal portion, said distal portion comprising a pushing interface, said proximal portion attached to an actuation handle; and

said pushing interface comprising at least one cutting member capable of cutting suture material positioned thereon.

**2**. The device of claim 1 wherein said elongated body is rigid.

**3**. The device of claim 1 wherein said elongated body is flexible.

**4**. The device of claim 1 wherein said elongated body is a catheter.

**5**. The device of claim 1 wherein said elongated body contains at least one lumen therein.

**6**. The device of claim 1 wherein said pushing interface further comprises a suture receiving recess.

**7**. The device of claim 1 wherein said pushing interface further comprises a knot positioning member.

**8**. The device of claim 1 wherein said pushing interface further comprises at least one extendable retaining member, wherein said at least one extendable retaining member is positionable between an extended position, a retain position, and a cutting position.

**9**. The device of claim 8 wherein said at least one extendable retaining member is capable of engaging said at least one cutting member when positioned in said cutting position.

**10**. The device of claim 8 wherein said pushing interface further comprises at least one retainer member receiver.

**11**. The device of claim 10 wherein said at least one cutting member is positioned within said at least one retaining member receiver.

**12**. The device of claim 1 wherein said at least one cutting member comprises a blade.

**13**. The device of claim 1 wherein said pushing interface further comprises a visualization device.

**14**. The device of claim 13 wherein said visualization device comprises echo-genic material.

**15**. The device of claim 13 wherein said visualization device comprises radio-opaque material.

**16**. The device of claim 13 wherein said visualization device comprises an ultrasonic probe.

**17**. The device of claim 1 wherein said pushing interface further comprises a medicament applicator.

**18**. A knot pusher, comprising:

an elongated body having a distal portion and a proximal portion, said distal portion comprising a pushing interface, said proximal portion attached to an actuation handle;

wherein said pushing interface comprises at least one extendable retaining member and at least one cutting member capable of cutting suture material positioned thereon;

wherein said at least one extendable retaining member is in communication with said actuation handle and is extendable from said pushing interface and retractable towards said pushing interface; and

wherein said at least one extendable retaining member is engageable with said at least one cutting member.

**19**. A method of applying a knot to a surgical site in vivo, comprising:

placing suture material through tissue to be approximated;

forming a knot extracorporeally in suture material;

advancing said knot along said suture material with a knot pushing device;

positioning said knot proximate tissue to be approximated with said knot pushing device; and,

using said knot pushing device to cut surplus suture material from said knot.

**20**. The method of claim 18 further comprising retaining said knot with retaining members positioned on said knot pushing device.

**21**. The method of claim 18 further comprising cutting said surplus suture material with cutting members positioned on said knot pushing device.

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|---|---|---|---|
| 专利名称(译) | 手术结推动装置和使用方法 | | |
| 公开(公告)号 | US20020123758A1 | 公开(公告)日 | 2002-09-05 |
| 申请号 | US09/797964 | 申请日 | 2001-03-02 |
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| IPC分类号 | A61B17/04 A61B19/00 | | |
| CPC分类号 | A61B17/0469 A61B19/54 A61B2017/0474 A61B2019/5425 A61B90/39 A61B2090/3925 | | |
| 其他公开文献 | US6860890 | | |
| 外部链接 | Espacenet USPTO | | |


摘要(译)

描述了一种外科结推动装置，其具有安装在细长主体的远侧部分上的结推动界面和位于细长主体的近侧部分上的致动手柄。结推动界面具有形成在其上的缝合线接收凹槽，以及横穿缝合线接收界面的结定位构件。至少一个可伸展的结保持构件进一步定位在推动界面上，所述至少一个可伸展的保持构件能够接合缝合材料。结推动界面还包括至少一个缝合线切割构件，该缝合线切割构件与致动手柄连通。本发明特别适用于微创外科手术。本发明还教导了一种在缝合材料中形成结，用结推动装置保持结，向所关注区域推进和施加结，以及切割多余缝合材料的方法。