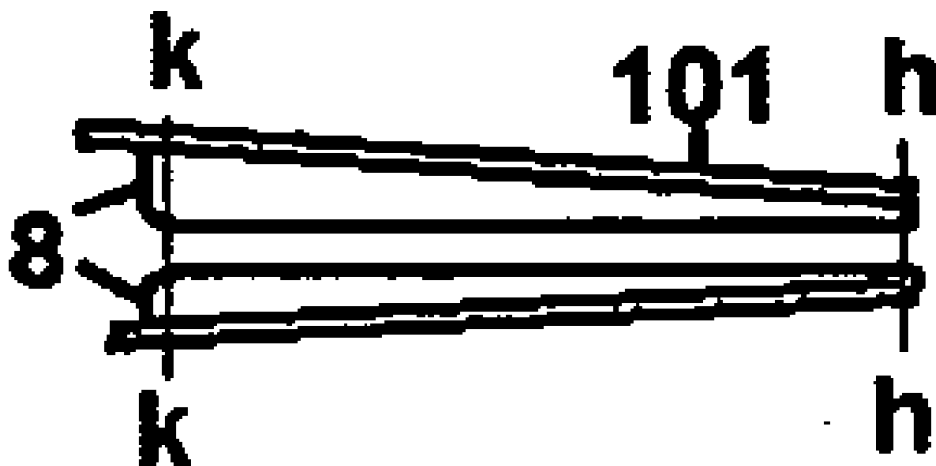


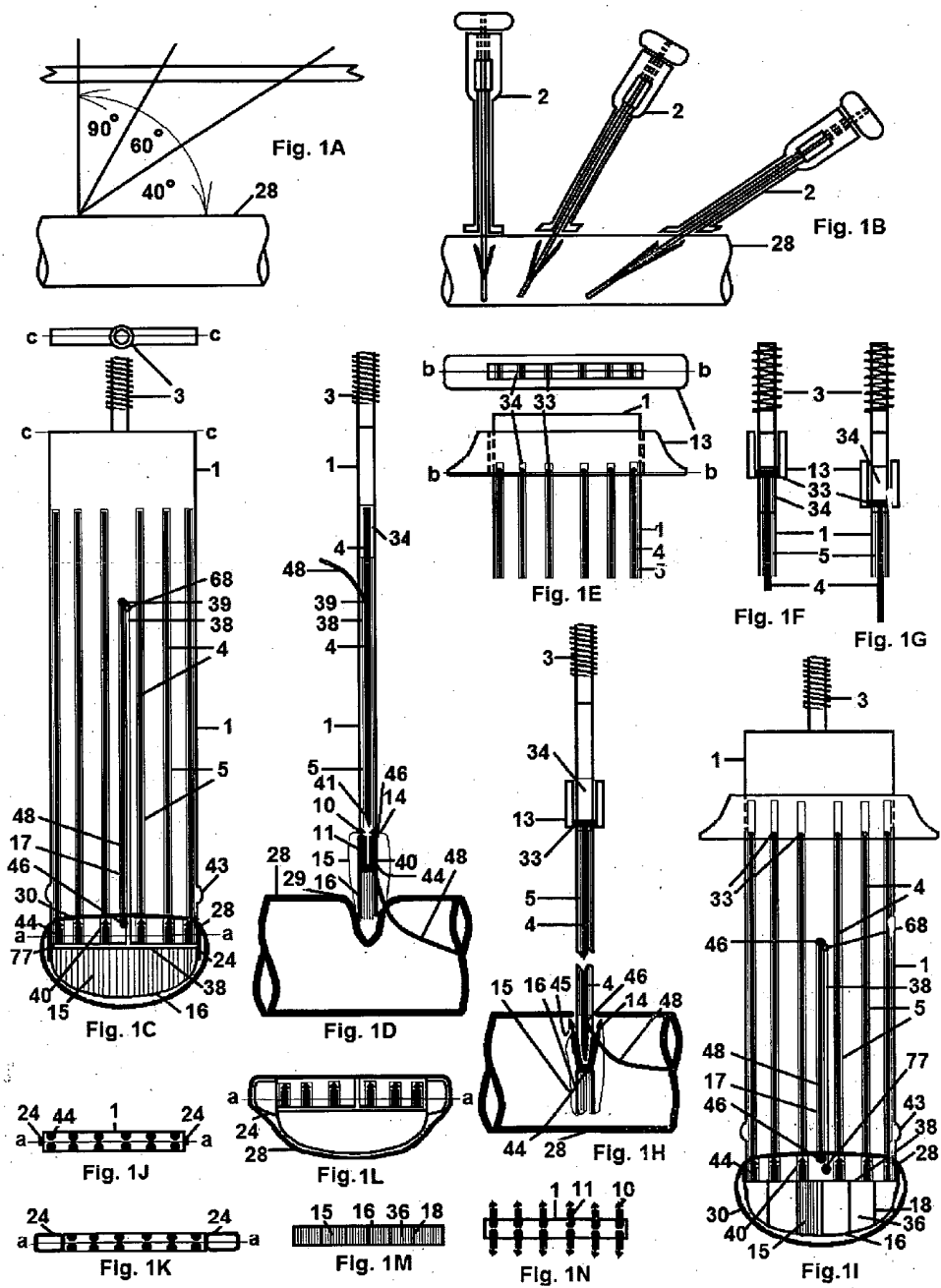


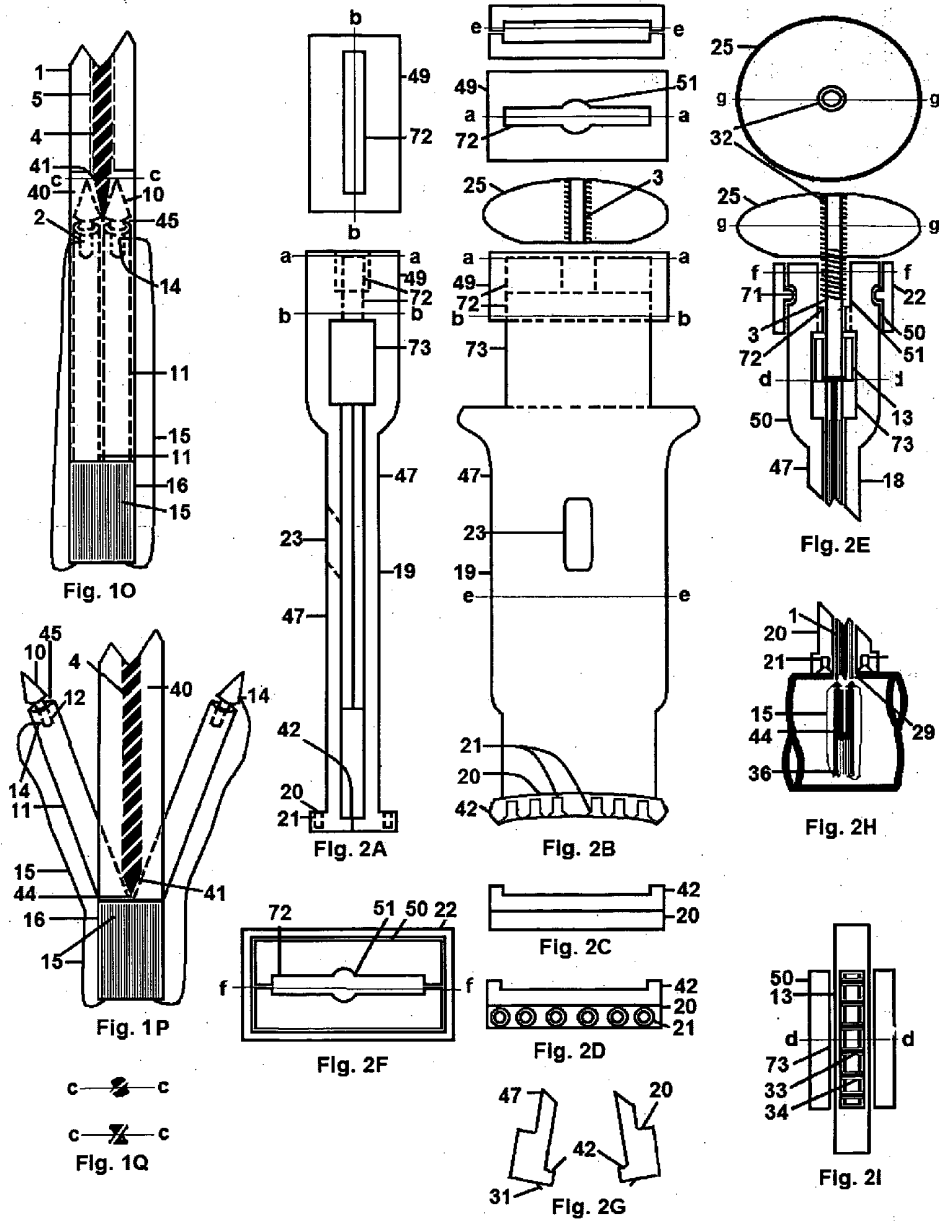
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(19) **United States**(12) **Patent Application Publication**
Shriver(10) **Pub. No.: US 2013/0178872 A1**(43) **Pub. Date: Jul. 11, 2013**(54) **INTRAVASCULAR SUTURING DEVICE FOR
SIMULTANEOUSLY PLACING 3-7 SUTURES
WITH IDEAL SPACING TO CLOSE LARGE
OPENINGS IN VESSELS INCLUDING
CALCIFIED**(76) Inventor: **Edgar Louis Shriver**, Aventura, FL
(US)(21) Appl. No.: **13/374,779**(22) Filed: **Jan. 11, 2012****Publication Classification**(51) **Int. Cl.**
A61B 17/04 (2006.01)(52) **U.S. Cl.**
USPC **606/148**(57) **ABSTRACT**

Centerboard entering vessel opening spreads it to a slit. Needle pairs in slots across centerboard width are at about 2 mm intervals inside vessel. Pushing a wedge or bridge wire between pairs spreads needle noses about 1 mm on either side of free edge of slit. Suture loop ends are attached to each pair. An outboard has legs on either side of centerboard with a foot on each leg that stands on either side of slit outside vessel. Needle nose housings in each foot are directly opposite needle noses. Operator turning a screw pushes needle noses through vessel wall overcoming resistance in calcified vessels and housings hold needle noses by detents. Removing device from body brings suture ends outside with suture loops across slit in ideal 2x2 pattern. Alternative configurations provide means of joining and cutting suture ends, with preformed knots slid to opening or clamping ends together with a clip.







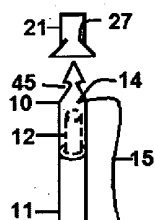


Fig. 3A

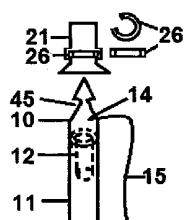


Fig. 3B

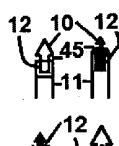


Fig. 3C

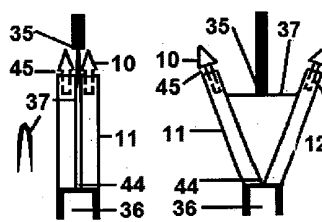


Fig. 3D

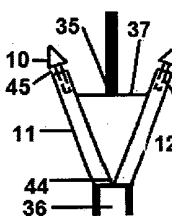


Fig. 3E

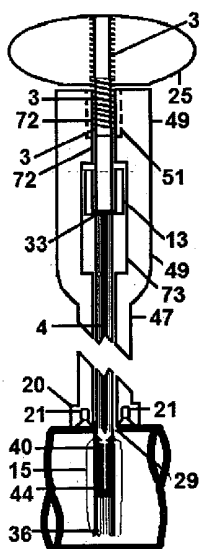


Fig. 4A

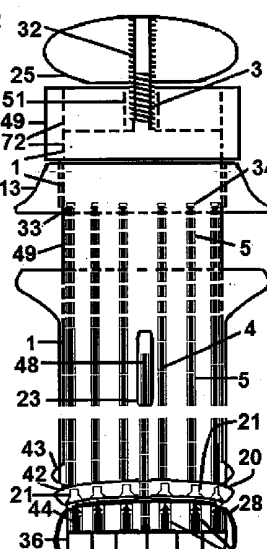


Fig. 4B

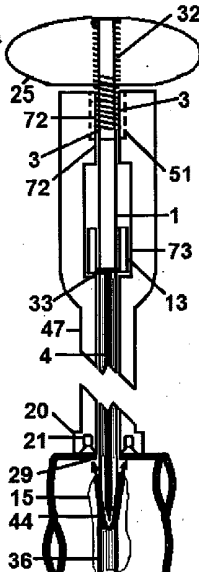


Fig. 4C

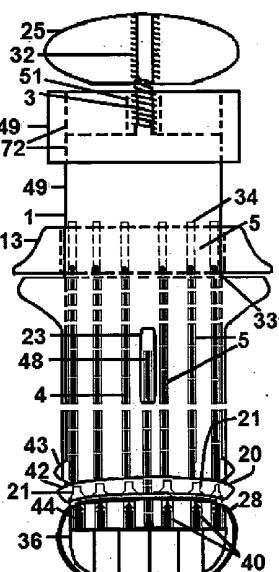


Fig. 4D

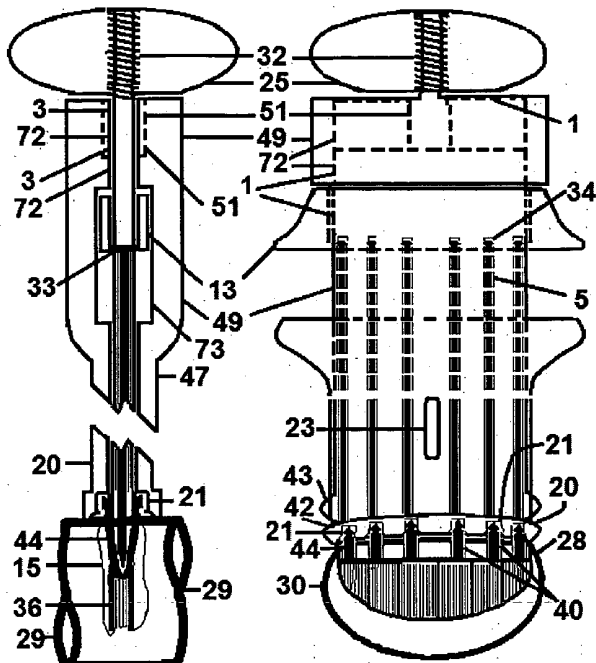


Fig. 4E

Fig. 4F

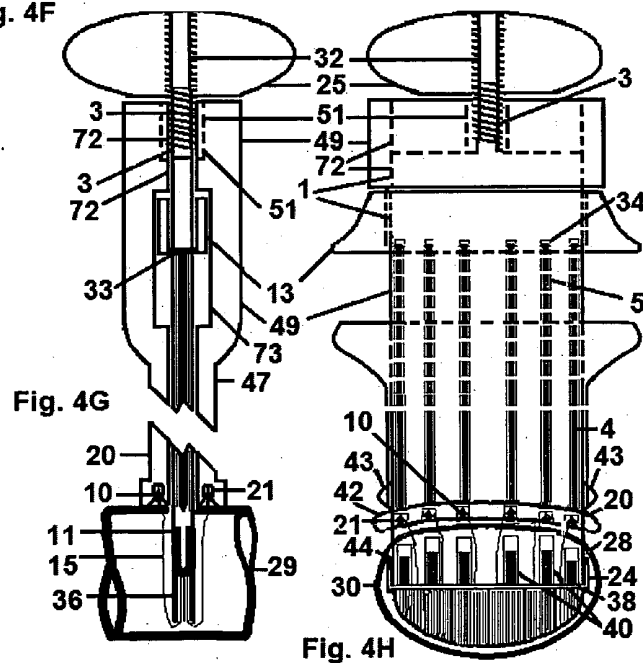
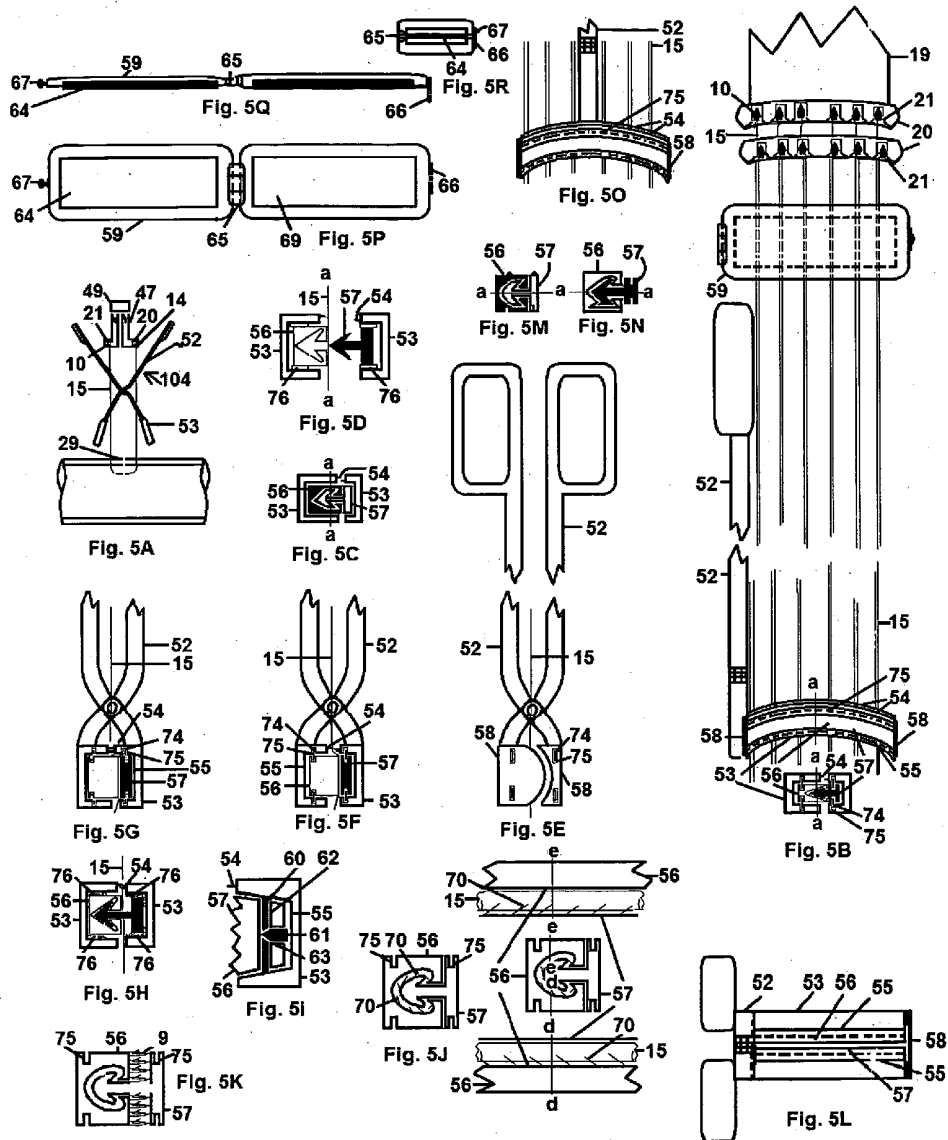
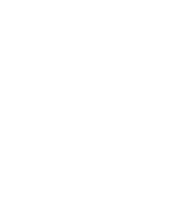
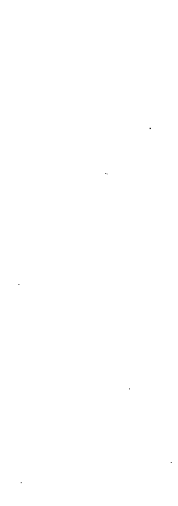
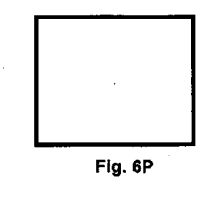
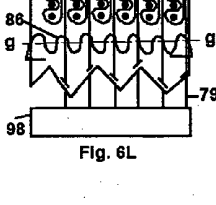
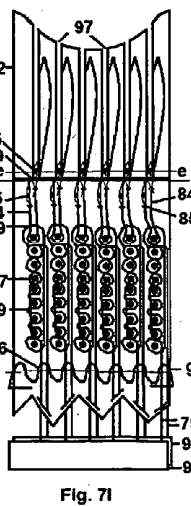
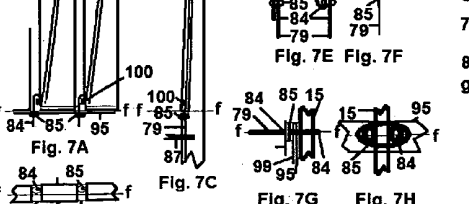
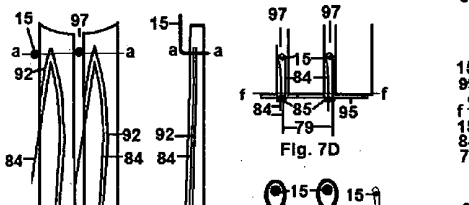
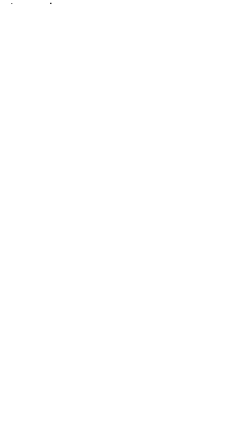
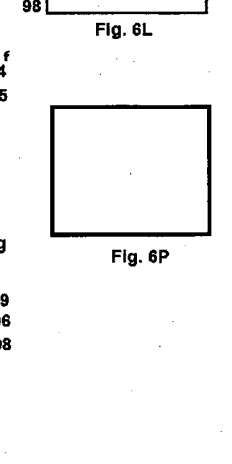
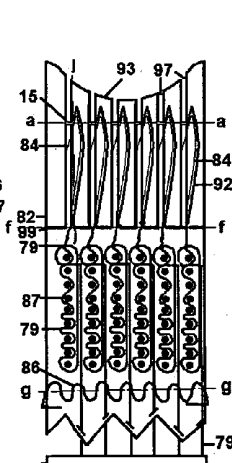
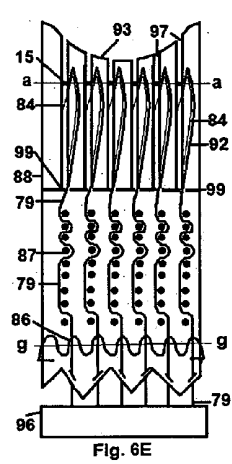
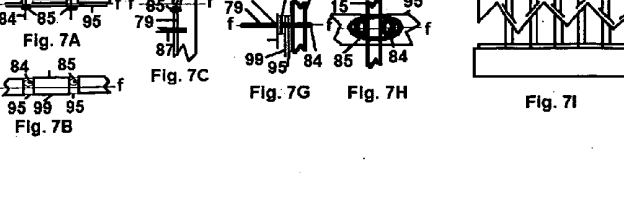
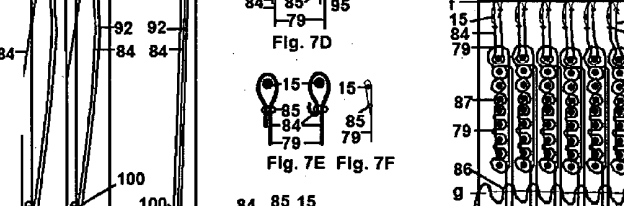
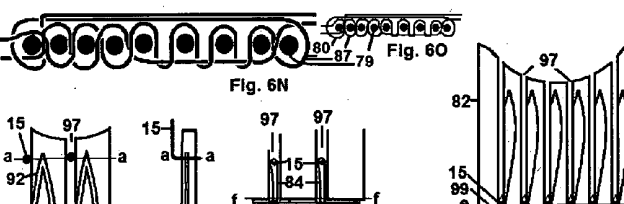
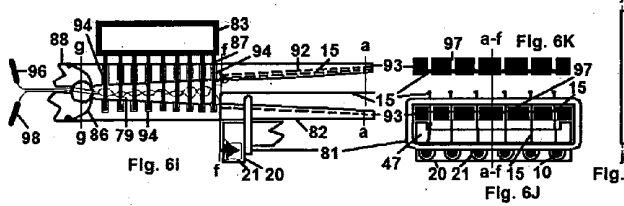
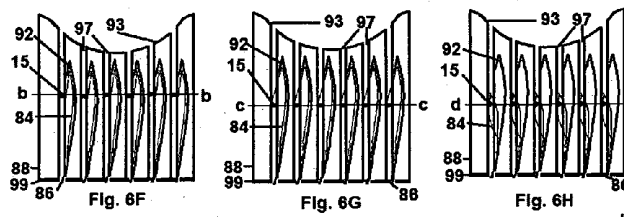
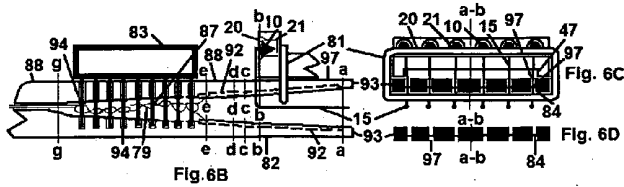
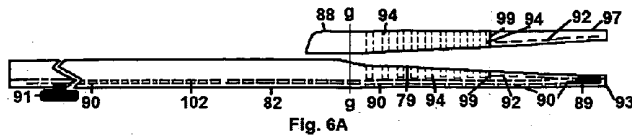
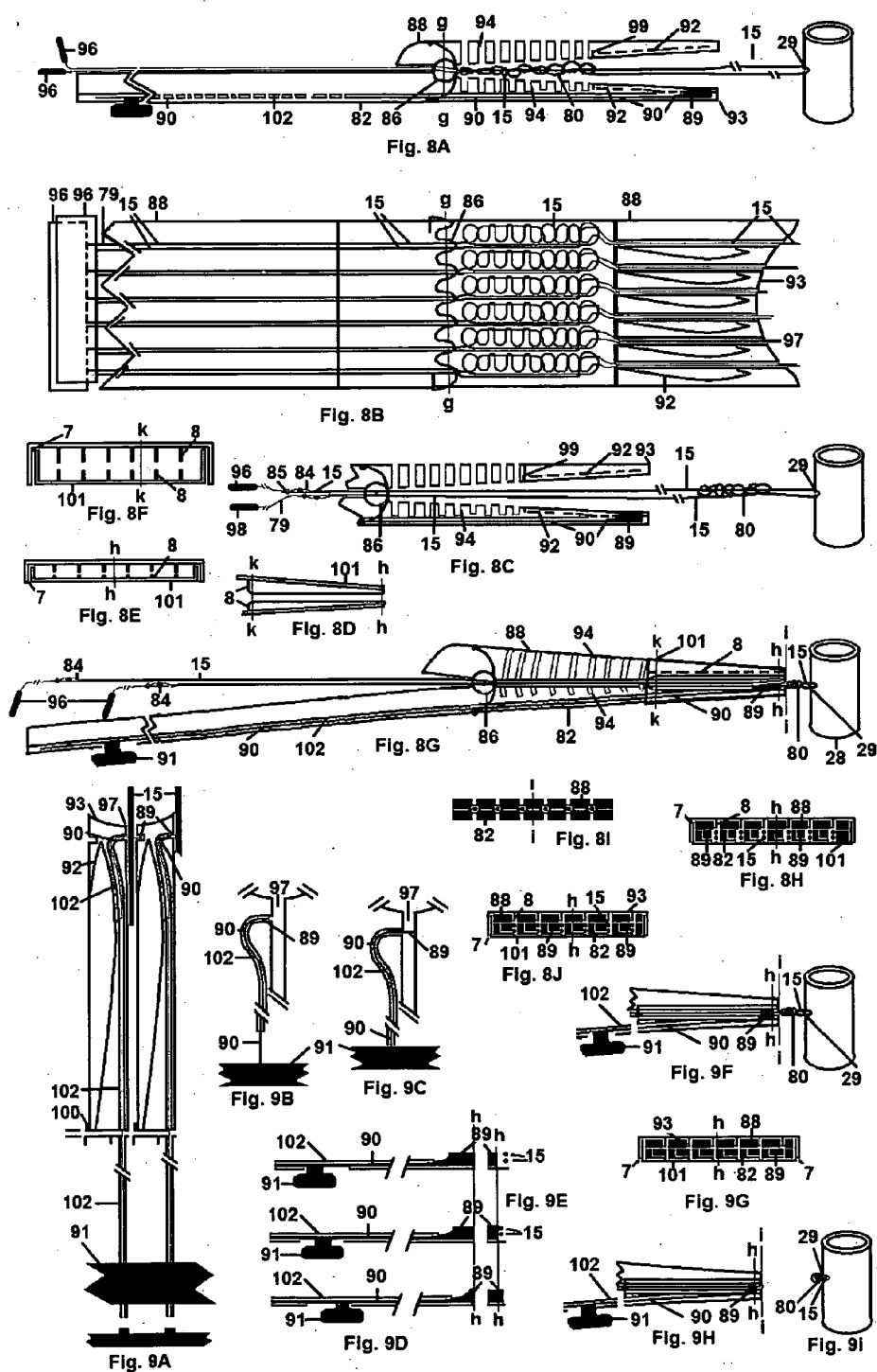


Fig. 4G

Fig. 4H







**INTRAVASCULAR SUTURING DEVICE FOR
SIMULTANEOUSLY PLACING 3-7 SUTURES
WITH IDEAL SPACING TO CLOSE LARGE
OPENINGS IN VESSELS INCLUDING
CALCIFIED**

**CROSS-REFERENCE TO RELATED
APPLICATIONS**

[0001] This is a new invention by the inventor of vascular devices disclosed in U.S. Pat. No. 7,771,442, U.S. Pat. No. 7,959,644, and U.S. Pat. No. 7,713,215, that require relatively large percutaneous openings in arteries for device entry; the object of the present patent application being to percutaneously close large openings such as 9 F to 32 F in vascular vessels; including calcified, with an ideal curved line of sutures placed simultaneously without tying and placing knots individually.

FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable

SEQUENCE LISTING OR PROGRAM

[0003] Not Applicable

BACKGROUND OF THE INVENTION

[0004] 1. Field of the Invention

[0005] The field generally relates to vascular closure devices that use plugs, mechanical pressure, or sutures to close percutaneous openings of size 3-10 F. Specifically, the present device provides a means for simultaneously placing an ideal pattern of sutures in a vascular vessel that may be calcified to close openings such as 9-32 F without surgery now required to achieve this object.

[0006] 2. Prior Art

3,470,875	October 1969	Johnson
3,665,926	May 1972	Flores
4,161,951	July 1979	Scanlon Jr.
4,553,543	November 1985	Amarasinghe
4,587,969	May 1986	Gillis
4,744,364	May 1988	Kensey
4,852,568	August 1989	Kensey
4,890,612	January 1990	Kensey
4,929,246	May 1990	Sinofsky
5,021,059	June 1991	Kensey, et al
5,049,138	September 1991	Chevalier
5,059,201	October 1991	Asnis
5,061,274	October 1991	Kensey
5,087,263	February 1992	Li
5,160,339	November 1992	Chen, et al
5,163,946	November 1992	Li
5,217,470	June 1993	Weston
5,171,251	December 1992	Bregen, et al
5,383,896	Jan 1995	Gershony
5,411,481	May 1995	Allen, et al
5,454,820	October 1995	Kammerer, et al
5,454,821	October 1995	Harm, et al
5,613,974	Mar 25 1997	Andreas et al
5,728,109	March 1998	Shultz, et al
5,769,862	June 1998	Kammerer, et al
5,776,150	July 1998	Nolan, et al
5,814,069	September 1998	Shultz, et al
6,090,130	Jul. 18, 2000	Nash et al
7,713,215	May 11 2010	Shriver

-continued

7,771,422	Aug. 10, 2010	Shriver
7,959,644	Jun. 14, 2011	Shriver

Devices and Procedures

[0007] Millions of percutaneous endovascular interventional procedures are performed each year to treat diseased coronary and peripheral arteries. The percutaneous method for entering arteries was described by Seldinger: the skin is punctured with a hollow needle pushed through a layer of subcutaneous adipose (fat) tissue to puncture an artery, usually the common femoral artery (CFA) in the groin. The angle of entry is generally between 40 degrees and 60 degrees. A guidewire is then advanced through the hollow needle to enter the artery lumen. The hollow needle is withdrawn and an introducer sheath advanced over the guidewire into the opening, thus forcing the opening to the size of the sheath. Introducer sheath has proximal end outside the body and distal end inside the artery lumen and a circumference large enough to introduce the size of tools and graft materials needed for the intended procedure on arteries of the heart or peripheral to the heart, e.g. in legs or neck. The opening forced by the sheath splits the artery from side to side rather than along the longitudinal axis. Since openings in the body are not perfect circles the French measurement system approximates the circumference of the opening's free edge in mm by expressing diameter in units that are $\frac{1}{3}$ mm. Thus an opening, sheath, or catheter that is 1 French (1 F) is $\frac{1}{3}^{rd}$ mm in diameter and approximately 1 mm in circumference, and 3 F is 1 mm in diameter and about 3 mm (an approximation of 3.14 mm) in circumference. Fluid pressure in the introducer sheath is maintained at a level that prevents blood pressure in the artery from causing blood to flow from the artery through the opening. When the procedure is finished tools and sheath must be removed and the opening closed.

[0008] The Seldinger method of closing is used for small openings such as 3 F. Pressure is applied manually on the skin opposite the opening after removing the sheath. The manual pressure must be greater than the blood pressure within the artery in order to maintain hemostasis while the natural elasticity of the blood vessel wall reduces the size of the opening until, after sufficient reduction, a blood clot forms to finally close the opening. The natural recoil of the vessel wall free edge around the opening might require 15 minutes of manual pressure for a 3 F opening but hours for an opening such as 6-8 F. And in older people the elasticity of vessel wall is less and thus recoil takes longer. Disadvantages of the pressure method include time and discomfort of patient but the advantage is minimal complications. Thus manual pressure is still the gold standard for access site management but the disadvantage of time required to ambulation has led to the evolution of many alternatives. None of these alternatives apply to openings larger than 8 F as the present invention does, so this background is only generally relevant to the present invention.

Mechanical Pressure

[0009] A certain type of device applies mechanical pressure to reduce the size of a larger opening to a smaller opening that can finally be closed by manual pressure. This type of device requires manual pressure to make the final closure

because a wire or tube remains in the path left by the sheath when it was removed and the opening cannot close until it is removed. These devices are not intended for use with openings larger than 6-8 F. Gershony in U.S. Pat. No. 5,383,896 reveals a balloon on a tube that is preferably not greater than 0.038 inches in outside diameter. The tube is advanced through the sheath so the balloon on the distal end can be inflated in the artery lumen. The balloon is pre-selected to be larger than the opening so it blocks blood and maintains hemostasis after the sheath is removed. A relatively large diameter fixation collar is located on the proximal end of the tube (shaft) and pressed against the skin opposite the opening to allow its place to be secure within the blood vessel. Another device for applying mechanical pressure is available under the commercial name Boomerang™. It utilizes site-specific compression, similar to that of the Gershony device. But instead of a balloon in the vessel lumen, this device has a collapsible wire mesh disc on the end of a wire. The collapsed disc is pushed through the sheath by the wire and adjusted into a flat disc inside the lumen. The flat wire disc is larger than the opening but is somewhat porous so does not seal the opening to achieve hemostasis. Hemostasis is achieved after the sheath is removed by clipping a detent on the wire against the skin where manual pressure is normally applied. The pressure can be adjusted by moving the detent more firmly against the skin—as manual pressure from a finger would be applied. This may be done in the cath lab in less than a minute to produce hemostasis. The patient can then be moved from the cath lab with the device in place. The opening relaxes around the wire by the natural process of elastic recoil while normal clotting mechanisms begin. The natural elastic recoil of the vessel wall occurs unless the patient's artery has lost so much elasticity that it does not fully recoil. When the size of the opening has reduced to the size of the wire, the wire disc is collapsed and the device removed. Normal manual pressure is then applied to close the remaining opening left by the removed wire.

Sealants/Plugs

[0010] There are a number of patented vascular closure devices (VCD) for placing a sealant or plug in the opening or in adjacent fat tissue with some success in the market. The invention revealed by Kensey in 4890612 describes the type of device that creates a plug for the opening. A relatively hard anchor disc is attached to a filament (string) introduced through an elongated tube with a plunger. This places the anchor disc in the artery lumen and the string is used to pull the plug against the opening while a biodegradable gel foam or collagen is pushed through the tube to surround the string and fill the opening. This maintains hemostasis and the plug biodegrades within a month or two. This device is handicapped by two properties inherent to the technology. First, the anchor placed inside is occasionally obstructive, either at the puncture site or with embolization. Second, it leaves a mass of collagen inside the tissue track and a filament (string) that extends from the arteriotomy to near the skin surface, which provides both a nidus and a wick for potential infection. There are other devices for placing plugs of this type without a string, e.g. Angio-Seal, a commercial device similar to the Kensey device still leaves a thrombosing agent in the tissue track. Another plug-type device uses a balloon as an alternative form of anchor disc. The balloon is opened in the lumen and held against the opening while the biodegradable seal substance is injected to plug the opening. There are also

various patches to place on the skin and chemical gels applied under the skin to counteract the effects of anticoagulants used during many percutaneous procedures to prevent clotting. These must be reversed when clotting is needed to close the opening. There are several reasons these VCDs have not displaced the simple pressure method to meet the need for a rapid, safe, and reliable hemostasis. They have not clearly been shown to reduce the incidence of bleeding, vascular complications or cost when compared with traditional compression but have been successful in decreasing time to ambulation. Obese patients are among the best candidates for these alternatives because direct pressure on the skin of an obese person may be transmitted laterally through fat layers and away from the opening, thus providing insufficient pressure at the vessel. These devices are used for closing openings up to 6 F.

Staples/Clips

[0011] Another type of closure device uses staples or clips to close the opening. The device called Starclose® advances a ring of barbs through the sheath and into the edge around the opening. The barbs are then turned inward to clip together the edge and thus close the opening. No manual compression is needed after using this device as it closes small openings completely. This device is not intended for use with large openings, there is relatively little experience with it and it is not in common use.

Intravascular Sutures

[0012] During the few minutes a suture is being placed, blood is stopped from flowing in the artery by applying pressure on the skin opposite. After a suture closes the opening, the suture provides hemostasis; there is no requirement for further pressure, sealants or lengthy time to ambulation. Other types of devices for maintaining hemostasis without sutures were briefly reviewed as general background. But there is only one device for closing percutaneous openings by a suture and it places one suture. It is based on U.S. Pat. No. 5,613,974 of Mar. 25, 1997 by Andreas et al, which is assigned to Perclose®, now owned by Abbott labs, and describes a type of intravascular suture closure device approved for placing one suture in an opening up to 8 F. That invention and those prior to it are included as potential prior art for the present invention of an intravascular suturing device that places a plurality of sutures in a particular ideal pattern. A common femoral artery is about 1 mm thick at an opening made for percutaneous procedures and an opening of 8 F is a little more than 8 mm in circumference. The free edge of that circumference folds to a slit of about half the circumference, or 4+ mm. Placing one suture across the free edge leaves about 2 mm on each side. When a surgeon has free access to place sutures, he/she will place the needle at a distance from the free edge that is equal to the thickness of the artery and place successive sutures twice this distance apart. Thus the Perclose device does this for openings up to 8 mm in circumference of 8 F, and that is the largest opening for which the device is approved for use.

Ideal Spacing of Sutures

[0013] The ideal spacing of sutures is 2 mm between sutures and 2 mm across free edge for an artery with wall thickness of 1 mm. Thus two sutures in the ideal pattern will close a slit of 6 mm (2 mm on each side and 2 mm between 2

sutures), 3 sutures will be required for a 8 mm slit, 4 for a 10 mm slit, 5 for a 12 mm, etc. A 24 F opening is about 24 mm in circumference so closes to a 12 mm slit that require 5 sutures 2 mm apart. The suturing pattern described as "ideal" is the result of numerous studies with animals and practice with human patients. There is a tendency for the lumen to be reduced along the line of suture across the artery. This reduction can be avoided by placing sutures 2 mm apart and 1 mm from the free edges of the slit with vessel wall thickness of 1 mm. This creates a slight increase in mass of tissue edges in opposition across each suture that exerts lateral pressure that counteracts the tendency to constrict the lumen, thus producing a curved line of sutures matching the original curvature of the vessel. This curved line of sutures is called a two-by-two as each puncture site is 2 mm from the one opposite it across the free edge and 2 mm from the adjacent. For a vein with thinner wall the distances should be closer to 3 by 3 mm. Vessel walls vary in both thickness and diameter among individuals but on average common femoral arteries (the usual site of percutaneous entry) are about 1 mm thick and about 7 to 11 mm in diameter, making artery circumference range from about 22 mm to 33 mm.

Larger Openings Required

[0014] There are procedures requiring openings of 24 F or even larger, e.g. aneurysms of the larger arteries of the legs such as abdominal aortic arch and of carotid arteries. Cut down for a surgeon to place sutures to close large opening has traditionally been used after these procedures so the surgeon can apply the ideal number and spacing of sutures manually. However open surgery has its own disadvantages and risks, so some exceptions are made to allow off-label use of a Prostar XL® device or two Perclose® devices to make a "purse-string" closure of the opening, pulling four points on the edge of the opening to the center and thus producing a closure that is not ideal, is technically difficult to perform, has some complications, and is usable only under certain conditions. Making the appropriate knot to tie suture ends also requires considerable skill and time so if alternative means can be invented to join suture ends by a faster, safer way than tying a knot in each, that would be an added advantage. Thus "off-label" is a workable solution for highly skilled practitioners but not a satisfactory long-term general solution for routinely closing large openings.

Device Characteristics for Meeting Future Needs

[0015] In addition to procedures that now require large openings, there are new procedures for replacing heart valves through large percutaneous openings, such as 24 F. These require highly skilled practitioners now but if they are to become generally usable a better means than off-label use of devices will be needed. And if devices for placing bypass grafts around occluded arteries of the heart and legs are to replace the less effective angioplasty devices that use balloons and stents, an effective, safe and easily performed means of closing the required large openings will be required. An approved device for closing larger openings by sutures that meet the ideal spacing criterion of surgically placed sutures would be preferred over a purse string pattern. Another problem of placing sutures in arteries is that they are frequently calcified making it difficult to push a suturing needle through the vessel wall even when the surgeon can manually access the artery. If a device can provide means for

pushing needles through calcified arteries more effectively than a surgeon can manually, that would be still another advantage. And if sutures can be placed simultaneously rather than sequentially as required with manual suturing and other devices, that is another major advantage by reducing time to perform. If the new device were to use pre-tied knots it would eliminate a difficult step reducing both the time and skill required. The availability of a device with any or all of these desired characteristics could be an important determinant of what type of other devices become practical for accomplishing future procedures such as transcatheter aortic valve implantation and transcatheter bypass graft placement. The present invention is expected to have all these advantages with its initial application being to closing large openings in common femoral arteries after completion of a percutaneous procedure requiring a large opening. It also applies to other vessels such as veins and even to skin, but the example used will be an artery in order to simplify the discussion. The device is designed as a means of placing sutures in the ideal 2x2 pattern in a curved line, provide means for penetrating calcified arteries with greater ease than a surgeon can achieve manually, place all sutures simultaneously with easily performed steps, and provide a quickly applied simple alternative to manual knot tying each knot individually and cutting all ends at opening simultaneously.

Advantages

[0016] 1. Millions of procedures are performed each year that require percutaneous openings of 3-6 F. Manual pressure is commonly used for closing openings of 3 F and there are numerous devices for closing openings up to 6 F, generally by plugging the opening with substances that are foreign to the body and thus not desirable. There are two devices for closing opening up to 8-10 F by placing one or two sutures in a cross pattern to make a purse string closure which has disadvantages with respect to ideal suture closures made with open surgery.

2. The Perclose® device is approved for placing one suture to close opening up to 8 F. The Prostar XL® device is approved for placing two sutures in a cross pattern for a purse string closure of openings up to 8-10 F. Open surgery places any number of sutures in the ideal pattern of 2x2 to close openings of 24 F or even larger, but has the disadvantage of more risk and greater trauma have devices for closing openings percutaneously.

3. The only currently approved means of closing openings of 11 to 24 F is with sutures manually placed by a surgeon, and this is done in the ideal configuration of sutures being 2 mm apart and 2 mm across the free edge of the slit produced by drawing the opening to half its circumference. It is called 2x2 and is ideal because it produces a curved line of sutures that matches the original vessel shape thus not narrowing the vessel. For veins of less than 1 mm thickness a distance of 3 mm apart and 3 mm across free edge is ideal, and called 3x3. There are increasing numbers of procedures that require larger openings and no device is approved for percutaneously closing openings larger than 8-10 F.

4. To avoid the risks and debilitation of open surgery for closing openings larger than 10 F, physicians sometimes use one Prostar XL® device with an unapproved technique or two Perclose® devices, also off-label, to place two sutures in a cross pattern thus making purse string closures of openings up to 24 F—or even larger. This off label use of devices is technically difficult, does not prevent narrowing the vessel, is

done only under restricted conditions, and has other complications, so cannot be long-term solutions for closing openings larger than 8-10 F.

5. The intravascular suturing device described and claimed herein is appropriate for percutaneously closing openings of 6-33 F with the ideal configuration of 2 to 7 sutures in a curved line that avoids narrowing the vessel. Thus the device avoids the risks of surgery while achieving the ideal suturing configuration and has other important advantages.

6. The device claimed herein places sutures simultaneously rather than sequentially. A skilled surgeon requires more than a minute to place one suture, or about the time required by the device to place all sutures. The other devices require even more than a minute to place each of two sutures in a cross pattern.

7. Another problem with placing sutures is the skill and time required to tie the ends of each suture with a special knot, run them individually to vessel wall and cut each with a special tool. The present intravascular suturing device provides pre-formed knots or clips to secure suture ends, runs knots to vessel wall and cuts knot ends at vessel wall simultaneously.

8. Still another problem with placing sutures is that arteries and veins are frequently calcified making it difficult to push a suturing needle through the wall and the wall stretches in the direction of applied needle force. The surgeon can't place a finger in front of the needle to prevent the stretching and has no other means of counteracting this tendency. The present device provides a needle housing outside the calcified vessel wall opposite the needle nose inside the vessel wall and they are forced together with the force of an inclined plane thereby piercing the calcified vessel wall between.

9. The advantages of this device are that it does not require surgery, closes large openings that other vascular closure devices cannot close or close less effectively, places sutures simultaneously in less time than other means and accomplishes this in calcified or non-calcified vessels in less time, more effectively and without the risks of manual suturing.

Key	
1.	Center board
2.	Suture placement component
3.	Threaded post
4.	Separator wire
5.	Separator wire channel
6.	Short snare groove
7.	Overlap
8.	Slot stopper
9.	Loops and hooks
10.	Needle nose
11.	Needle shaft
12.	Friction dowel
13.	Frame
14.	Suture end
15.	Suture loop
16.	Suture cove
17.	Guidewire channel
18.	Cove wall
19.	Outboard
20.	Foot
21.	Needle nose housing
22.	Surround
23.	Access slot
24.	Balloon
25.	Screw turner
26.	Spring clip
27.	Housing detent

-continued

Key	
28.	Vessel wall
29.	Free edge slit side
30.	Free edge slit across
31.	Spur
32.	Female threads
33.	Cross wire
34.	Cross slot
35.	Blunt end
36.	Suture compartment
37.	Bridge wire
38.	Fluid channel
39.	Proximal port
40.	Needle opening
41.	Wedge end
42.	Keeper
43.	Stopper
44.	Needle pair
45.	Nose indent
46.	Distal port
47.	Outboard legs
48.	Guidewire
49.	Blockhead
50.	Split blockhead
51.	Unthreaded hole
52.	Cross clamp
53.	Crossbar
54.	Scissors cutter
55.	Strip holder
56.	Female strip
57.	Male strip
58.	Suture shield
59.	Tension adjustor
60.	Slant end rod
61.	Release rod
62.	Slant channel
63.	Release channel
64.	Friction pad
65.	Hinge
66.	Clasp
67.	Clasp button
68.	Fluid port proximal
69.	Recessed area
70.	Barbs
71.	Tongue and groove
72.	Centerboard slot
73.	Frame slot
74.	Break away strip
75.	Holder slot
76.	Compression breaker
77.	Fluid port distal
78.	Fluid port edge
79.	Knot leader
80.	Slip knot
81.	Foot loop
82.	Long applicator
83.	Knot rod holder
84.	Wire snare
85.	Snare tightener
86.	Spring roller
87.	Knot rods
88.	Short applicator
89.	Cutter end
90.	Cutter pusher
91.	Push knob
92.	Snare holder
93.	Applicator nose
94.	Knot rod channels
95.	Resistance film
96.	Rail leader board
97.	Suture slots
98.	Loop leader board
99.	Tightener gate
100.	Snare detent
101.	Pinch sleeve
102.	Cutter channel

-continued

Key	
103.	Suture tying component
104.	Suture clip component

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1A is a schematic representation of angles of percutaneous entry from skin to vessel wall with angles between 40 and 90 degrees.

[0018] FIG. 1B shows shapes suture placement component of the present specification would have for alternative angles of entry of 40, 60 and 90 degrees.

[0019] FIG. 1C is a plan view at cross section c and a cross sectional front view of centerboard with components. (Cross sectional views are used so components interior to the faces need not be shown as dashed lines).

[0020] FIG. 1D is a cross sectional side view of a centerboard with components.

[0021] FIG. 1E is a plan view at cross section b and a cross sectional front view of frame containing cross wires located near proximal end of cross slots.

[0022] FIG. 1F is a cross sectional side view of frame before operator pushes it in the distal direction.

[0023] FIG. 1G is a cross sectional side view of frame after operator pushes it in the distal direction.

[0024] FIG. 1H is a cross sectional side view showing wedge end of separator wire between a needle pair after operator pushes frame in the distal direction.

[0025] FIG. 1I is a cross sectional front view of centerboard showing cross wires at distal end of cross slots after operator has pushed frame in distal direction.

[0026] FIG. 1J is a plan view of needle pairs and uninflated balloons at cross section a.

[0027] FIG. 1K is a plan view of needle pairs and inflated balloons at cross section a.

[0028] FIG. 1L is a frontal view of needles and inflated balloons inside vessel wall at cross section a.

[0029] FIG. 1M is a plan view of the distal end of centerboard with sutures in compartments.

[0030] FIG. 1N shows plan view of distal end of centerboard with needle pairs pushed apart.

[0031] FIG. 1O is a detail cross sectional side view of a needle pair in needle opening before wedge end of separator wire has been pushed between the pair.

[0032] FIG. 1P is a cross sectional side view of a needle pair after wedge end of separator wire has been moved distally to force needle pairs about 2 mm apart.

[0033] FIG. 1Q shows plan view of alternative configurations of wedge ends with sides curved to fit needle shafts at cross section c.

[0034] FIG. 2A is a side view of outboard with plan view at cross section b.

[0035] FIG. 2B is a frontal view of outboard and screw turner with plan views at cross sections a and e.

[0036] FIG. 2C is a plan view of a foot looking distally showing keepers

[0037] FIG. 2D is a plan view of a foot with keepers looking proximally showing open ends of needle nose housings.

[0038] FIG. 2E is a cross sectional side view of screw turner, proximal centerboard and outboard with split blockhead and surround plus a plan view at cross section g.

[0039] FIG. 2F is a plan view of split blockhead at cross section f.

[0040] FIG. 2G is a side view of outboard legs with each foot moved slightly apart and a spur on each foot.

[0041] FIG. 2H is a side view of distal portion of centerboard and outboard in free edge side slit before operator moves frame in distal direction.

[0042] FIG. 2I is a plan view of frame and cross wires between outboard legs at cross section d.

[0043] FIG. 3A is a cross sectional side view of needle shaft and nose with indent as held together by frictional dowel about to enter needle nose housing with detent.

[0044] FIG. 3B is a cross sectional side detail view of needle nose with spring clip indent as held to needle shaft by frictional dowel about to enter needle nose housing containing spring clip detent.

[0045] FIG. 3C shows four alternative configurations of friction dowels between needle shafts and noses.

[0046] FIG. 3D shows an alternate configuration for separating needle pairs by loop of bridge wire attached between a needle pair before separator wire has pushed bridge wire straight.

[0047] FIG. 3E shows needle pair pushed apart after separator wire pushes bridge wire straight.

[0048] FIG. 4A is a cross sectional side view of centerboard and outboard before operator pushes frame in distal direction.

[0049] FIG. 4B is a cross sectional frontal view of centerboard and outboard before operator pushes frame in distal direction.

[0050] FIG. 4C is a cross sectional side view of centerboard and outboard after operator pushes frame in the distal direction, pushing separator wedge between needle pairs.

[0051] FIG. 4D is a cross sectional frontal view of centerboard and outboard after operator pushes frame in distal direction, pushing separator wedge between needle pairs.

[0052] FIG. 4E is a cross sectional side view of centerboard and outboard after operator has turned screw turner to move needle noses through vessel wall and into needle housings.

[0053] FIG. 4F is a cross sectional frontal view of centerboard and outboard after operator has turned screw turner to move needle noses through vessel wall and into needle housings.

[0054] FIG. 4G is a cross sectional side view of centerboard and outboard after operator has turned screw turner in opposite direction leaving needle noses and suture ends in needle nose housings and needle shafts in centerboard.

[0055] FIG. 4H is a cross sectional front view of centerboard and outboard after operator has turned screw turner in opposite direction leaving needle noses and suture ends in needle nose housings and needle shafts in centerboard.

[0056] FIG. 5A shows a side view of a cross clamp open to collect suture loops running between free edge slit side and needle noses in the two feet of outboard legs.

[0057] FIG. 5B is a frontal view of the two feet and suture loops they hold running between cross clamp and tension adjuster, with cross sectional view at a-a showing male and female strips held by breakaway strips in strip holders.

[0058] FIG. 5C shows an alternative configuration of male and female strips in strip holders at cross section a, without compression breakers.

[0059] FIG. 5D shows an alternative configurations of male and female strips in strip holders at cross section a, with compression breakers.

[0060] FIG. 5E is a side view of cross clamp with the halves of suture shield on distal end that have holder slots through which breakaway strips are loaded.

[0061] FIG. 5F is the view of FIG. 5E with suture shield removed to show female and male strips held by breakaway strips. Strips have the same cross section at all points from apogee to perigee along curved crossbar so breakaway strips are shown without male and female strip shapes.

[0062] FIG. 5G is the same view as FIG. 5F with breakaway strips broken by cross clamp being partially closed.

[0063] FIG. 5H is the same view as FIG. 5G showing male and female strip shapes and an alternative configuration of compression breakers that turn into grains at their breaking tensile strength.

[0064] FIG. 5I is a cross section of strip holder and fragment representing female or male strip with slant end rod in slant channel and release rod in release channel.

[0065] FIG. 5J shows tiny barbs extending from the surface of male and female strips with one large scale and two small scale views of the same cross section as needed see how the tiny barbs are arranged on opposing surfaces.

[0066] FIG. 5K is an alternative configuration for preventing male strip from separating from female strip by attaching a plurality of hooks and loops to touching surfaces.

[0067] FIG. 5L is an end view of crossbars as viewed from the artery with suture shields on each end and male and female strips in strip holders.

[0068] FIG. 5M shows an alternative configuration of male and female strips.

[0069] FIG. 5N shows an alternative configuration of strips with sharp bends.

[0070] FIG. 5O shows cross clamp attached to middle of cross bar.

[0071] FIG. 5P shows plan view of a tension adjuster with friction pads.

[0072] FIG. 5Q is side view of an open tension adjuster with friction pads.

[0073] FIG. 5R is an end view of a closed tension adjuster with hinge.

[0074] FIG. 6A is a side view of short applicator and long applicator with components.

[0075] FIG. 6B is a side view of the distal portion of applicators with knot leaders, knot rods, and foot held on short applicator at cross sectional plane b by foot loop.

[0076] FIG. 6C is a frontal view along short applicator looking from cross section a to b showing foot, foot loop, and sutures coming from needle nose housings.

[0077] FIG. 6D is a frontal view looking proximally along long applicator from cross section a.

[0078] FIG. 6E is a plan view of short applicator including knot rods, knot leaders, wire snares, and snare holders with sutures (dots) in suture slots at cross section a.

[0079] FIG. 6F shows sutures moved in suture slots to cross sectional plane b where sutures push wire snares out of suture slots and into snare holders.

[0080] FIG. 6G shows sutures moved in suture slots to cross sectional plane c where sutures are no longer pushing wire snares out of suture slots so snares return into suture slots behind sutures.

[0081] FIG. 6H shows wire snares at cross section d where knot leaders surround sutures after operator pulls knot leader slightly to take it out of snare holder.

[0082] FIG. 6I is a side view of long and short applicators with spring roller holding them and a foot held by foot loop on long applicator at cross sectional plane f.

[0083] FIG. 6J is a frontal view looking from cross section a to f with foot loop holding foot with sutures coming from needle nose housings then turning toward viewer.

[0084] FIG. 6K shows sutures (as dots) in suture slots looking from a to f.

[0085] FIG. 6L is a plan view of long applicator distal to spring roller plus leader board.

[0086] FIG. 6M shows an alternative configuration of a shallow groove in the side of suture slot at cross section j.

[0087] FIG. 6N shows a plan view of crossing knot leaders from short applicator and long applicator combined in the pattern of a slip knot around knot rods.

[0088] FIG. 6O is a plan view of knot leaders in a slip knot not showing cross over.

[0089] FIG. 6P is a plan view of knot rod holder as the operator sees it.

[0090] FIG. 7A is a plan view of detail near and distal to tightener gate at cross section f.

[0091] FIG. 7B is a frontal view of details near tightener gate at f.

[0092] FIG. 7C is a side view of details near and distal to tightener gate at f.

[0093] FIG. 7D is a side view of the long side of wire snares in two suture slots being pulled by attached knot leader through snare tightener as short side enters snare tightener.

[0094] FIG. 7E shows unbent and bent short sides of snare wire in snare tightener.

[0095] FIG. 7F shows small scale snare wire with ends in snare tightener.

[0096] FIG. 7G is a side view of details of resistance film adhering to tightener gate and snare tightener.

[0097] FIG. 7H is a frontal view of details of resistance film adhering to tightener gate and snare tightener.

[0098] FIG. 7I is a plan view of overlaid short and long applicators with slip knot of knot leaders around knot rods and wire snares that hold sutures ready to be pulled by leader boards.

[0099] FIG. 8A is a side view of short applicator and long applicator after sutures have been pulled through knot rods and knot rod holder has removed knot rods.

[0100] FIG. 8B is a plan view of short and long applicators overlaid showing slip knots made with sutures and sutures extending distally through suture slots.

[0101] FIG. 8C shows sutures pulled from between short and long applicators by operator but still attached to leader boards and looped through vessel wall.

[0102] FIG. 8D shows a side view of pinch sleeve with slot stoppers between h and k as shown on short and long applicators in FIG. 8G.

[0103] FIG. 8E is a frontal view of pinch sleeve, slot stoppers and overlaps at section h.

[0104] FIG. 8F is a frontal view of pinch sleeve, slot stoppers and overlaps at section k.

[0105] FIG. 8G shows the effect of pinch sleeve forcing together short applicator and long applicator distal to spring roller and slip knot at cross section l where applicator ends have moved knot to vessel wall.

[0106] FIG. 8H is a frontal view of two sutures in long applicator suture slots and slot stoppers from pinch sleeve in short applicator suture slots at cross section h.

[0107] FIG. 8I shows frontal view of rail sutures coming toward viewer with loop sutures wrapped around them in slip knot distal to applicator ends at cross section I.

[0108] FIG. 8J shows frontal view of two sutures in long applicator suture slots at cross section h with cutter end about to cut sutures as described in FIGS. 9A-G.

[0109] FIG. 9A is plan view of portion of cutter channel that turns around snare holder to cross adjacent suture slot at right angle to cutter channel leading to push knob.

[0110] FIG. 9B is a detail plan view of cutter channel turning to cross adjacent suture slot at a right angle with cutter pusher pushed by push knob and cutter end ready to cross.

[0111] FIG. 9C is a plan view after operator pushes push knob to most distal position, thus pushing cutter end across suture slot.

[0112] FIG. 9D shows three side views of push knob pushing cutter pusher and cutter end moving in cutter channel around the right turn at cross section "h" thus disappearing from side view.

[0113] FIG. 9E shows three frontal views of cutter end at cross section h as it moves across suture slots to cut the two sutures.

[0114] FIG. 9F is side view of push knob and distal ends of short and long applicators after applicator ends have pushed slip knot to vessel and cutter end is about to cut sutures in suture slot at cross section h.

[0115] FIG. 9G is a frontal view of applicator ends at cross section h after cutter end has cut sutures in suture slots.

[0116] FIG. 9H is side view of push knob and distal ends of short and long applicators just after cutter end moves across suture slots and cut sutures in suture slots at cross section h.

[0117] FIG. 9I shows suture loops tied in vessel wall with knot which has been severed by cutter end thus freeing device for removal from body.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0118] Having thus described the figures, methods and means in accordance with the present invention are now described with reference thereto. It should be understood that steps described for each process may be omitted or the order changed or performed simultaneously without deviating from the spirit or scope of the invention. It should be understood that a specific application situation involving a vessel, such as an artery may have somewhat different characteristics than another application with another vessel, whether artery, vein or other tubular structure of the body such as urethra or even skin and each application situation may require somewhat different dimensions, numbers in a plurality, angle of entry, or other invention characteristics. Since the first applications are expected to be closing an opening in the common femoral artery, dimensions, numbers and terms used in the specification are consistent with an ideal sutured closing for that case without intent to limit dimensions, numbers, angles or terms to that case.

[0119] The following description of preferred embodiments should be read with reference to the drawings, in which the elements in different drawings are numbered in like fashion. The drawings, which are not necessarily to scale nor of exact shape, nor of actual angle of entry which in application varies with individual cases, thus depict or represent specific embodiments and are not intended to limit the scope of the invention. Distances between suturing elements are provided as examples based on ideal manual suturing practices with the

body open so all distances given should be considered approximate and illustrative. Examples of materials, construction, dimensions and manufacturing processes are provided for various elements but merely as a representation of current manufacturing practice which may change during the patent period. Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Reference to a singular item includes the possibility that there is a plurality of the same items present but not seen in the view being described. More specifically, as used herein and in the appended claims, the singular forms "a," "an," "said," and "the" include plural referents unless specifically stated otherwise. In many cases there is more than one of an element having a singular name and associated number key thus plural usage of a singular element is used to refer to "them" rather than "it" thus the articles allow for "at least one" of the subject item in the description above as well as the claims below. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

[0120] Without the use of such exclusive terminology, the term "comprising" in the claims shall allow for the inclusion of any additional element irrespective of whether a given number of elements are enumerated in the claim, or the addition of a feature could be regarded as transforming the nature of an element set forth in the claims. Except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity. Although the foregoing invention has been described in detail for purposes of clarity of understanding, it will be obvious that certain modifications may be practiced within the scope of the appended claims. Those skilled in the art will recognize that many of the examples provided here have suitable alternatives which may be used now and in the future.

[0121] FIG. 1A is a schematic representation of angles of entry for percutaneous devices between skin and vessel wall **28**. An intravascular device must generally follow the angle used by other devices for their prior entry though a deviation of 30 degrees or more from the original is possible—depending primarily on obesity of patient. The angle of entry of other devices from skin to vessel may be at any angle but 40-60 degrees is common.

[0122] FIG. 1B shows a generalized image of the present device as it would appear for use in angles of entry of 40, 60 and 90 degrees. It is evident that it is impractical to represent an intravascular suturing device in this specification for every possible angle and that each alternative is an obvious variation for other entry angles. Therefore the convention is applied to all figures in this specification that the angle of entry is 90 degrees. Though this angle of 90 degrees is not the most commonly used at the present it is easy to convert such an image to any entry angle that will be needed in practice. Practical considerations do not interfere with the conventions used in specifications to represent shapes, angles and sizes without specifying exact numbers.

[0123] FIG. 1C is a plan view at cross section c and a frontal view of the cross section between front face and back face of centerboard **1** (cross sectional views are used so components interior to the faces need not be shown as dashed lines).

Centerboard 1 has a length greater than width and width greater than thickness, the length having a distal end and a proximal end, the width terminating in edges, and the thickness being between front and back faces. Centerboard 1 has a longitudinal axis running in the proximal-distal direction equally distant from edges and faces. The ends and edges of centerboard 1 are straight and faces are flat except for protuberances and a semi-circular shaped suture cove 16 on distal end shaped to conform to the shape of vessel wall 28 and having a slot in thickness open to distal end from edge to edge suitable for storing suture loops. In an alternative configuration suture cove 16 is made of a soft elastic material such as polybutadiene to avoid injury to vessel wall 28 and may have greater thickness than hard material in centerboard also to avoid injury to vessel wall 28 opposite vessel opening to be closed. Centerboard 1 is made of high tensile strength metal, carbon fiber, or polymer, shaped and connected by processes appropriate for the material which may include injection molding, bending, cutting, drilling and bonding to form various openings, channels and attached components. The proximal end is located outside the body where an operator can manipulate it and the semi-circular distal end is located inside free edge slit across 30. The length of centerboard 1 must accommodate the size of the patient being treated but nominally be about 15-25 cm. Thickness of centerboard 1 is about 1 mm and width is pre-selected to be about one half the circumference of the free edge of the opening in vessel wall 28 that is to be closed. Thus when centerboard 1 is advanced into the vessel opening, the pre-selected width causes the free edge of the circumference of the opening to be stretched thereby closing it together into a relatively straight slit pressing against the front and back faces of centerboard 1. This shape is called free edge slit across 30 when view is looking along the longitudinal axis of vessel wall 28 and free edge slit side 29 when vessel wall 28 is viewed from the side. Openings in arteries or other vessels to be closed are not so large that this relatively straight line of free edge is as long as half the vessel circumference, so the vessel wall 28 opposite the opening retains some or all of its natural curvature. The semi-circular shape of suture cove 16 is to conform to this shape. One cue that the centerboard is in the vessel is the resistance of the semi-circular suture cove 16 of centerboard 1 pushing against vessel wall 28 on the side opposite the opening. Visual cues are discussed with contrast fluid below. Guidewire channel 17 is located along the longitudinal axis of centerboard 1, having a proximal end and distal end with lumen therebetween and being of smaller diameter than thickness of centerboard 1 and having a proximal port 39 at proximal end extending through the back face, and distal port 46 extending through front face near distal end but proximal to suture cove 16. A guidewire 48, not part of the device, is normally located in the artery and extends through the skin at the angle it was entered into the body. The operator is careful not to remove the guidewire while threading the guidewire through distal port 46, guidewire channel 17, and proximal port 39, then, with guidewire 48 already being within vessel wall 28 the operator advances centerboard 1 on guidewire 48 through opening in vessel wall 28 so distal end of centerboard 1 is inside vessel wall 28. A sheath, also not part of this device, but normally in the opening around guidewire 48 is removed before centerboard 1 is advanced on guidewire 48 because opening cannot be converted to a slit with the circular sheath in the opening. A fluid channel 38 is included in two alternative configurations, one configuration for introducing contrast fluid inside

vessel wall 28, the other for inflating two balloons 24 on either side of centerboard 1, which may be inflated with contrast fluid. Both alternative configurations provide visual images for use in determining when centerboard 1 is positioned properly within vessel wall 28. In both alternative configurations fluid channel 38 is located adjacent to guidewire channel 17 and has fluid port proximal 68 adjacent to proximal port 39. In the alternative configuration for introducing contrast fluid inside vessel wall 28 the fluid port distal 77 for fluid channel 38 is located adjacent distal port 46. In the alternative configuration for inflating two balloons 24, (shown in more detail in FIG. 1J) fluid channel 38 is divided immediately distal to the plurality of needle openings 40 into two sections of fluid channel 38 that turn at a right angle and run toward opposite edges of centerboard 1 where each section of fluid channel 38 has a fluid port edge 78. In the alternative configuration for placing contrast fluid within vessel wall 28, fluid port edge 78 is open to do this. In the alternative configuration where inflation fluid is introduced for inflating two balloons 24, fluid port edge 78 opens into balloons 24 attached to each of the two edges of centerboard 1 thus making the width of centerboard 1 more adjustable than the manufactured pre-selected width alone and providing the option of having contrast fluid in balloons 24 for visualization. Of course centerboard 1 is also dense enough to be fluoroscopically or ultrasonically visualized for purposes of properly positioning it within vessel wall 28. Threaded post 3 is a cylinder of about 1-2 mm diameter made of the same material of and being attached to or molded with centerboard 1 and extending proximally about 5-7 mm from the proximal end in line with the longitudinal axis and having male threads located around the cylinder that self-align with female threads 32 in a screw turner 25 as shown in FIG. 2B. In an alternative configuration there is a stopper 43, a small protrusion of generally semi-circular shape of about 1-2 mm radius located on each edge near the distal end of centerboard 1 and when centerboard 1 is properly placed between outboard legs 47 of outboard 19 the small protrusions of stopper 43 will stop distal movement of centerboard 1 within outboard 19 by engaging keeper 42 on outboard 19. Suture cove 16 is located distal to needle openings 40 and continues distally to the distal end of centerboard 1 and having a slot somewhat less in thickness than the thickness of, and extending from side to side of centerboard 1 provides a cove for storing suture loops 15. There is a plurality (six is the number used for illustration in this specification) of needle openings 40 about 2 mm apart along a straight or slightly bowed imaginary line across the width of centerboard 1 each needle opening 40 being an open cavity having a proximal end a distal end with length between about 1.5 and 4.5 and parallel to the longitudinal axis of centerboard 1, with width about 0.5 mm, and thickness equal to the thickness of centerboard 1 with distal ends immediately proximal to suture cove. There is a plurality of separator wire channels 5 having a distal end and proximal end with lumen therebetween being of round or oval cross section about 0.5 mm in diameter, running parallel to the longitudinal axis in line with and open to needle openings 40 on distal ends and cross slots 34 on proximal ends. Cross slots 34 have proximal ends and distal ends and are of the same shape, size and number as needle openings 40. A plurality of separator wires 4 are of slidably smaller diameter than separator wire channels 5, each having a distal and proximal end with high tensile strength metal wire therebetween and initially located in cross slots 34 and separator wire channels 5, and not in needle

openings 40 but with each distal end of each separator wire 4 having a wedge end 41 initially located at proximal end of needle openings 40. In each needle opening 40 there is a needle pair 44, one of a plurality of needle pairs having two needles and each needle having a needle nose 10 temporarily connected to a needle shaft 11 by a frictional dowel 12. Needle nose 10 is about 1 mm in length and tapering from about 0.5 mm diameter on distal end to a sharp point on proximal end and having a nose indent 45 located on the taper or, in an alternative configuration, between needle nose 10 and needle shaft 11. Needle shaft 11 is about 0.5 mm in diameter, length from about 1 to 4 mm and with distal end of each needle shaft 11 being attached to distal end of needle opening 40 in which each needle pair is located thus causing needle noses to point toward wedge ends of separator wires 4 in separator wire channels 5. The slightly curved shape of free edge slit across 30 is intended to represent the actual situation in a vessel. After suturing is completed this line will be curved as was the original curvature of the vessel, however before suturing the line will be relatively straight due to stretching. The exact shape will probably vary among individuals, so the slightly curved line used in drawing is an example, not intended to be an exact shape. Needle openings 40 are about 2 mm apart along a generally straight but somewhat curved line between edges, the generally straight line having the curvature of the free edge slit across 30 of actual vessels.

[0124] FIG. 1D is a cross section side view of centerboard 1 with the distal end of centerboard 1 shown entering free edge slit side 29. It is seen in this side view that cross slot 34 extends from front face to back face of centerboard 1 as do needle openings 40 and separator wire 4 is located in cross wire slot 34 and in separator wire channel 5 when in its most proximal position. In that most proximal position separator wire 4 is not in needle opening 40 but wedge end 41 is aligned between needle shafts 11 and needle noses 10 of needle pair. Suture cove 16 has a slot between centerboard faces starting on a line between edges where the distal ends of needle openings 40 are arrayed and continuing distally to the distal end of centerboard 1. A plurality of suture loops 15 are stored in suture cove 16 and suture ends 14 of each suture loop 15 are swaged or otherwise attached to a needle nose 10 or friction dowel 12 permanently attached to needle nose 10 of each needle pair 44. Operator has removed a sheath (not part of this device) from needle opening 40 in vessel wall 28 and placed guidewire 48 (also not part of this device but normally located inside vessel wall 28) in to and out of centerboard 1, entering through distal port 46, through guidewire channel 17 and leaving through proximal port 39. Then operator advances centerboard 1 on guidewire 28 through opening to be closed in vessel wall 28.

[0125] FIG. 1E is a cross section front and plan view at cross section b of frame 13 which is in the shape of a six-sided box with top and bottom removed, being made of the same material as centerboard 1, having inside dimensions slidably greater than the cross section of centerboard 1 and thus capable of sliding on the cross section of centerboard 1, and with sides about 3-4 mm in length parallel to the longitudinal axis of centerboard 1, thickness of sides adjacent faces of centerboard 1 being about 1-2 mm and thickness of sides adjacent edges of centerboard 1 being sufficient for an operator's fingers to grip and move frame 13 from position at proximal end to distal end of cross slots 34 a distance of about 2-5 mm on the length of centerboard 1. The proximal end of centerboard 1 is not shown in the plan view of this figure so

dotted lines are not required to show the plurality of cross wires 33 attached across frame 13 that are located within cross slots 34 with each being attached at the center, at a right angle to the proximal end of one of the plurality of separator wires 4.

[0126] FIG. 1F has a side view showing the situation before operator moves frame 13 distally on centerboard 1.

[0127] FIG. 1G has a side view showing the situation after operator moves frame 13 distally on centerboard 1 the length of cross slot 34 thus moving cross wire 33 through cross slot 34 and moving separator wires 4 the same distance. Movement may be in the distal or proximal direction.

[0128] FIG. 1H is a side view after frame 13 has been pushed to the distal position and shows the effects of that movement within free edge slit side 29. Cross wire 33 on frame 13 has moved distally in cross slot 34 and pushed separator wire 4 distally in separator wire channel 5 which causes wedge end 41 to move the same distance in needle opening 40 thus forcing needle pair apart at the pre-selected angle of wedge end 41 which places needle noses 10 of each needle pair about 2 mm apart with 1 mm on each side of free edge slit side 29. Each needle nose 10 has a nose indent 45 and an attached suture end 14.

[0129] FIG. 1I is a frontal view of centerboard 1 with frame 13 pushed to the distal position. This figure shows the alternative configuration for introducing contrast fluid into fluid port proximal 68, through and fluid channel 38 into artery through fluid port distal 77.

[0130] FIG. 1J is a plan view of needle openings 40 with needle shafts 11 and needle noses 10 in the unbent positions and with the alternate configuration of balloons 24 in uninflated state at cross section a.

[0131] FIG. 1K is a plan view of needle pairs in the unbent position and balloons 24 inflated at cross section a.

[0132] FIG. 1L is a frontal view at cross section a of needle pairs 44 and inflated balloons 24 within vessel wall 28. Since the length of the slit generally is not as long as half the circumference of the artery, the balloons 24 do not escape through the slit but take positions in "pockets" they form on either side of the vessel wall, thus tending to keep the distal end of centerboard 1 in artery 28.

[0133] FIG. 1M is a plan view that shows suture loops 15 in suture cove 16 where cove walls 18 are placed to form suture compartments 36 for suture loops 15 of each needle pair 44. Suture loops 15 are in suture compartments 36 with cove walls 18 between suture compartments 36, all within suture cove 16.

[0134] FIG. 1N shows a plan view of needle pairs spread apart.

[0135] FIG. 1O is a detail side view of needle pair showing two needle shafts 11 with friction dowel 12 holding needle noses 10 to needle shafts 11, and suture ends 14 of suture loop 15 swaged to or otherwise attached to a needle nose 10 of each needle pair or to friction dowel 12 permanently attached to needle nose 10. The suture loop 15 for this pair of needle noses 10 is seen in suture cove 16 which has an open distal end that allows suture ends 14 of suture loop 15 to be pulled out of suture cove 16 by movement of needle nose 10 but the suture loop 15 remains inside the artery while suture ends 14, attached to needle noses 10 in needle nose housings 21 are removed in each foot 20 of outboard 19 as they and centerboard 1 are removed from patient's body. Suture loops may be made of any material sutures are normally made of, may be non-biodegradable or biodegradable, and may be any stan-

standard size used to close openings in vessel being sutured. Separator wire 4 is seen in separator wire channel 5 about to enter needle opening 40 before operator moves frame 13 in the distal direction on centerboard 1.

[0136] FIG. 1P shows the situation after operator has moved frame 13 in the distal direction causing separator wire 4 to enter needle opening 40 and push wedge end 41 between needle shafts 11. Needle opening 40, being equal in thickness to centerboard 1 allows needle shaft 11 and needle nose 10 to be bent outside center board 1 on opposite sides of the approximately linear free edge of free edge slit side 29. Wedge end 43 has an angle preselected to bend needle shafts 11 apart so as to place needle noses 10 of a needle pair 44 about 1 mm from each side of free edge side slit 29. Nose indent 45 is shown between needle nose 10 and needle shaft 11 in this alternative configuration.

[0137] FIG. 1Q shows in cross section two shapes that separator wires 4 may take and how the cross section of wedge end 41 has a curved shape to fit the cylindrical shape of needle shaft 11.

[0138] FIG. 2A is a side view of outboard 19 which has a proximal end, a distal end and therebetween two outboard legs 47 and a contiguous blockhead 49 which joins outboard legs 47. Outboard 19 is made of high tensile strength metal, carbon fiber, or polymer, shaped and connected by processes appropriate for the material which may include injection molding, bending, cutting, drilling and bonding to form various openings, channels and attached components. Each outboard leg 47 has a length greater than width and width greater than thickness, the length having a distal end and a proximal end, the width terminating in edges, and the thickness being between front and back faces. The length of each outboard 19 must accommodate the size of the patient being treated but nominally be about 15-30 cm. Thickness of each outboard leg 47 is about 1 mm and width about 1 mm greater than width of centerboard 1 on each edge of each outboard leg 47. In an alternative configuration that portion of the edge that is about 1 mm greater than width of centerboard on each edge turns at a right angle and extends half way across the gap between outboard legs 47 from where blockhead 49 joins outboard legs 47 to about 10 mm proximal to the location of keeper 42 thus confining centerboard 1 within outboard legs 47 except near the distal end where stopper 43 moves in the distal-proximal direction for about 4-5 mm when centerboard 1 is moved between outboard legs 47. The turned edge also adds to rigidity of outboard 19, which may be further increased by joining touching edges with a temporary adhesive. This alternative configuration is shown in FIGS. 2A and in 2B, where it more easily seen in plan view, while the preferred configuration is shown in other figures. Foot 20 protrudes outward about 1-2 mm from the face of, and on the distal end of each outboard leg 47 and also extends about 1-2 mm outside each edge of outboard leg 47 and extends approximately 1-2 mm from distal end of outboard 19 in the proximal direction. Each foot 20 contains a plurality of needle nose housings 21, each being at a location that places it in line with one needle nose 10 when needle pair 44 is separated by wedge 41 thus placing each needle nose about 1 mm from each side of free edge slit across 30. In the extension of foot 20 outside the edges of outboard 47 there is a protrusion of about 0.5 mm, called keeper 42, protruding in the direction opposite that which foot 20 protrudes from face of outboard leg 47 thus filling the gap between outboard legs 47 that lies outside the edges of outboard legs 47. Keeper 42 is thus positioned to prevent center-

board 1 from moving outside the edge of outboard legs 47 on the distal end and provide a means for stopper 43 on the edge of centerboard 1 to prevent keeper 42 from moving past it in the distal direction. Thus when outboard 19 is properly placed with respect to centerboard 1, stopper 43 of centerboard 1 is immediately proximal to keeper 42 thus locating each needle nose housings 21 in each foot 20 is outside (adventitious to) free edge slit side 29 and about 1-2 mm from deployed needle noses 10 on the inside of free edge slit side 29 with vessel wall 28 between. Outboard legs 47 are joined by blockhead 49. Blockhead 49 is of irregular shape in exterior and interior dimension but is generally described as follows using the shapes shown in figures to assist in the description. Blockhead 49 extends from the proximal end of outboard 19 about 15 mm to outboard legs 47 with thickness about 5-6 mm and width being about 2-3 mm greater than the width of centerboard 1 for about 5 mm from proximal end then equal to width of centerboard 1 for another 8-10 mm to point where blockhead joins outboard legs so outboard legs 47 have a distance between that is slidably greater than thickness of centerboard 1. This equal width for 8-10 mm provides an area for operator to grip the protrusions on frame 13. The inside dimensions of blockhead 49 from the proximal end to the joining with outboard legs 47 are; (1) unthreaded hole 51 in the shape of an empty cylinder of circumference slidably greater than that of threaded post 3 and with centerline on the longitudinal axis of centerboard 1 extending about 4-5 mm in the distal direction from proximal end of outboard 19 to initial location of proximal end of centerboard 1, (2) centerboard slot 72, that has a thickness and width slidably greater than those of the proximal end of centerboard 1 and extending from proximal end of outboard 19 to for about 7-9 mm where frame 13 is initially located, (3) frame slot 73, slidably greater in cross section than cross section of frame 13 and extending within blockhead 49 from centerboard slot 72 about 3-4 mm a distance about equal to the distance frame moves which is the length of cross slot 33 and needle opening 40. This is the distance required to move wedge ends 41 of separator wires 4 from proximal ends to distal ends of needle openings 40 thus spreading needle noses across free edge side slit 29. Blockhead 49 joins outboard legs 47 immediately distal to frame slot 73 and being wider than outboard legs 47 in the section from proximal end of outboard 19 to frame slot 73 constitutes a barrier to the movement of centerboard 1 located in centerboard slot 72 to any point outside the edges of outboard legs 47.

[0139] FIG. 2B shows a cross sectional view of screw turner 25 and a front view of outboard 19 and plan views at cross sections a, b, and e. showing the alternative configuration of turned edges of outboard legs 47 that prevent centerboard 1 from moving outside the edges of outboard legs 47. Blockhead 49 has a width about 1-2 mm wider than centerboard 1 on each edge from proximal end of outboard 19 through centerboard slot 72 and is of the same width as centerboard 1 through the section having frame slot 73 which is slidably greater than the thickness of frame 13 which moves within frame slot 73. Blockhead 49 is the same shape in the preferred and alternative configuration of edges of outboard leg 47. Foot 20 is shown to contain tapered needle nose housings 21. The shape of needle nose housings 21 is that of an empty cylinder closed in foot 20 toward the proximal end of outboard legs 47 and open at the opposite end and being tapered to be larger near the open distal end thus providing a larger target for entry of needle nose 10 positioned opposite

the open end. Access slot 23 in outboard leg 47 is shown to be in position to align with proximal port 39 thus allowing guidewire 48 (with fluid channel with that alternative configuration) to emerge from centerboard 1. Shown in dashed lines within blockhead 49 are unthreaded hole 51, which allows passage of threaded post 3 into female threads 32 of screw turner 25, centerboard slot 72, and frame slot 73. Outboard legs 47 are shown with protrusions in this alternative configuration not shown in subsequent figures.

[0140] FIG. 2C is a plan view of foot 20 looking in the distal direction which shows the proximal end of needle nose housings 21 to be closed by foot 20 and shows protrusions, each called keeper 42 outside the two edges of outboard legs 47. Keeper 42 keeps edges of centerboard 1 from moving outside the edges of outboard legs 47 and also prevents stoppers 43 on the edges of centerboard 1 from moving distal to keeper 42, thus forcing needle nose housings 21, located outside vessel wall 28 to be at a distance from needle noses 10, located inside vessel wall 28, that is slightly greater than the thickness of vessel wall 28.

[0141] FIG. 2D is a plan view of foot 20 looking in the proximal direction. The open ends of the taper of needle nose housings 21 are seen as well as keepers 42. The taper on nose housings 21 is represented by two concentric circles to indicate a flare constituting a larger target for each aligned needle nose 10 to enter.

[0142] FIG. 2E is a plan view of screw turner 25 at cross section "g" and side view through a cross section of screw turner 25 and the proximal section of outboard 19 where split blockhead 50 holds outboard legs 47 apart to slidably contain centerboard 1 and frame 13. This is an alternative configuration in which split blockhead 50 is of the same material and replaces blockhead 49. Split blockhead 50 is divided in two halves along the plane midway between outboard legs 47, with each outboard leg 47 attached to one half of split blockhead 50 and having outside dimensions such as allow a flexible detachable surround 22 that is in the shape of 4 sides of a box with top and bottom removed to slidably fit around the proximal end of split blockhead 50 to hold the halves together. A tongue and groove 71 is located around surround 22 and split blockhead 50 to prevent surround 22 from accidentally being removed. Thus the alternative configurations of separated and un-separated outboard legs 47 are essentially equivalent except when surround 22 is not around the proximal end split blockhead 50, and outboard legs 47 may be moved slightly outward to engage spurs 31 on each foot 20, and each outboard leg 47 may be removed from the body independently of the other which may reduce the volume of what is removed at one time. Also shown is a front and plan view of screw turner 25 of generally cylindrical shape with female threads 32 on the centerline. Screw turner 25 may be made of the same material as centerboard 1. The female threads 32 fit the male threads of threaded post 3 and threads are held in contact for a short distance and are self-aligned before rotation starts. Rotation causes threaded post 3 to continue through female threads 32. Alternative configurations are obvious, including those that increase mechanical advantage with different thread pitch.

[0143] FIG. 2F is a cross section view at f of surround 22 around split blockhead 50 with unthreaded hole 51 and centerboard slot 72.

[0144] FIG. 2G shows outboard legs 47 slightly rotated outward from the faces of centerboard 1 which places the distal side of foot 20 slightly farther away from the free edge

of free edge slit side 29. One or more spurs 31, in the shape of wire-like protrusions of a stiff material that will adhere to the distal side of each foot 20 being about 0.1-0.3 mm in length and diameter and protruding at an acute angle with sides of acute angle opening toward faces of outboard legs 47 and being in planes that are at a right angle with respect to distal side of foot 20 will engage free edge slit side 29 and draw and hold free edges closer against centerboard 1 by a tweezers-like action.

[0145] FIG. 2H is a side view of the distal portion of suturing placement component 2 in free edge slit side 29 with centerboard 1 between the outboard legs 47 of outboard 19 showing frame 13 has not been moved to separate needle shafts 11 of needle pair 44 that are inside free edge slit side 29, but that needle nose housings 21 are positioned outside free edge slit side 29 to be aligned with needle noses 10 when needle shafts 11 are separated a pre-selected distance on the longitudinal axis by keeper 42 and stopper 43. Suture loop 15 is shown in suture compartment 36 with suture ends 14 swaged or otherwise attached to needle noses 10 of needle pair 44.

[0146] FIG. 2I is a cross section at d of plan view of frame 13 with attached cross wires 33 located in cross wire slots 34 between split blockhead 50.

[0147] FIG. 3A is a detail view of needle nose housing 21 and needle nose 10 held to needle shaft 11 by friction dowel 12. Friction dowel 12 is permanently attached to needle shaft 11 and frictionally to needle nose 10. Needle nose 10 has nose indent 45 in the nose in this figure, and not in the alternative configuration being between needle nose 10 and needle shaft 11 as was shown in FIG. 1G. Housing detent 27 is shown as one or more protrusions in needle nose housing 21 which are normally of the smaller diameter of indent 45 but are pushed back by the tapered point of needle nose 10 until the smaller diameter of nose indent 45 allows them to return to their normal constricted diameter which then prevents needle nose 10 from being removed from needle nose housing 21. Therefore, when needle shaft 11 is pushed in the proximal direction by reversing the direction of turning screw turner 25, needle shafts 11 are separated from needle noses 10 which remain in nose housings 21 with suture ends 14 while needle shafts 11 remain inside free edge slit side 29.

[0148] FIG. 3B shows an alternative configuration of the housing detent 27 and nose indent 45 in which friction dowel 12 is permanently attached to needle nose 10 and frictionally to needle shaft 11. In this arrangement nose indent 45 may be placed between needle nose 10 and needle shaft 11 but in this figure nose indent 45 is in the same location it was in FIG. 3B. Spring clip 26 is placed in needle nose housing 21 as the housing detent 27 that expands as needle nose 10 is pushed in needle nose housing 21 and then closes into nose indent 45 to capture needle nose 10. This spring clip 26 is ancient technology as are many means of trapping an object by a detent moving into an indent after the indent has moved through the detent like an arrow only to be prevented from backing up.

[0149] FIG. 3C shows alternative configurations of needle pairs with friction dowel 12 permanently attached to needle nose 10 and frictionally attached in needle shaft 11 or vice versa and nose indent 45 located in needle nose 10 and located between needle nose 10 and needle shaft 11, all being functionally equivalent ancient technologies.

[0150] FIG. 3D is an alternative configuration in which there is a plurality of blunt ends 35, one on the end of each separator wire 4 (rather than a wedge end 41) and blunt end 35

being connected to the center of bridge wire 37 which is initially in the shape of a loop made of a resilient material such as spring steel located between and attached to needle shafts 11 of each needle pair 44. Bridge wire 37 is not easily seen between needle shafts 11 of needle pair 44, so its shape is shown to the left and below the number 37.

[0151] FIG. 3E shows bridge wire 37 is of a length that when pushed straight by blunt end 35 of each separator wire 4 pushes needle shafts 11 a distance that places needle noses 10 of each needle pair about 1 mm away from each face of centerboard 1. This is shown in the figure where blunt end 35 is shown after being moved distally thus pushing bridge wire 37 to its straight length which causes needle shafts 11 to move apart the pre-selected distance equal to the length of separation bridge wire 37.

[0152] FIG. 4A is a cross section side view of centerboard 1 and outboard 19 as they are introduced into the body and through free edge slit side 29 in vessel wall 28 by operator. Screw turner 25 is also shown slightly screwed into threaded post 3.

[0153] FIG. 4B is a front view of centerboard 1 and outboard 19 as they are introduced into the body by operator is advancing them on guidewire 48 threaded through centerboard 1 from distal port 46 to proximal port 39 exiting outboard 19 at access slot 23. (The length is not to scale and erased sections are used to show this). An assistant applies pressure to the artery to maintain hemostasis while the physician performs the steps described in FIG. 1C to remove the sheath from the opening in vessel wall 28 and thread guidewire 48, that is already in the artery, through the centerboard and out access slot 23 in outboard then advance centerboard 1 and outboard 19 on guidewire 48 until distal end of centerboard 1 is inside vessel wall 28 where it is seen in free edge slit across 30. The entry of centerboard 1, with width pre-selected to force the vessel opening to close to a slit, and with each foot 20 outside vessel wall 28 on either side of the slit may be felt by operator to be in correct position but in addition other cues are available. Stopper 43 is touching keeper 42 which causes needle noses 10 to be the correct distance from each needle nose housing 21 in each foot 20, thus placing each foot 20 on the adventitial side of vessel wall 28 and apart from needle noses 10 by about the thickness of vessel wall 28. Keeper 42 also prevents centerboard 1 from moving outside outboard 19. Frame 13 is shown in the proximal position with separator wire 4 in separator wire channel 5 just proximal to needle opening 40 so needle pair has not been pushed apart. Also threaded post 3 is self-aligned in female threads 32 of screw turner 25 but screw turner 25 has not been turned to cause threaded post 3 to move centerboard 1 in the proximal direction within female threads 32. The alternative configuration with balloons 24 is not shown in this figure, but if the alternative configuration with balloons 24 (as shown in FIG. 4D) is being used they are inflated now to (in effect) extend the width of centerboard 1 by stretching free edge slit across 30 tighter.

[0154] FIG. 4C is a side view of suture placement component 2, namely centerboard 1 in outboard 19, after frame 13 has been pushed to the distal position. This causes cross wires 33 attached across frame 13 to move in cross slots 34 in the distal direction and separator wires 4 attached to the center of cross wire 33 are moved the distance distally which is the same as the length of needle opening 40 thus causing wedge 41 of separator wire 4 to enter needle opening 40 and separate needle pair 44 by a pre-selected distance so needle noses 10

become aligned with needle nose housings 21 outside (adventitial to) free edge slit side 29. Suture ends 14 are attached to needle noses 10 and suture loops 15 between suture ends 14 are stored in suture compartments 36 for each needle pair 44.

[0155] FIG. 4D is a front view of centerboard 1 and outboard 19 after frame 13 has been pushed to distal position. Cross wires 33 move distally in cross slots 34 causing attached separator wires 4 to move distally in separator wire channels 5 moving wedge end between needle pairs 44 in needle openings 40.

[0156] FIG. 4E is a side view after screw turner 25 has been turned a sufficient number of turns to cause threaded post 3 to enter female threads 32 thus drawing together centerboard 1 and outboard 19, and forcing needle noses 10 through vessel wall 28 and into needle housings 21 with the substantial force of the threads of an inclined plane needed to penetrate vessel walls 28 when they are calcified. Frame 13 moves with the movement of centerboard 1 to the proximal position it was originally in while wedge end 41 remains between needle pairs. This movement of centerboard 1 forces each needle nose 10 of each needle pair through vessel wall 28 where they are located about 1 mm from the free edge of free edge slit side 29. The needle nose housings 21 are outside (adventitial to) free edge slit side 29 immediately opposite each needle nose 10 so push with the same force against each needle nose 10. Having the mechanical advantage of a screw and the flanged opening of needle nose housings 21 positioned opposite and pushing with equal force creates a situation more conducive for a needle to pierce a calcified artery than a surgeon can create without the device. For arteries that are not calcified the procedure and device are the same though it is obvious that threads of greater pitch will move screw turner 25 the same distance with fewer turns and less mechanical advantage. The side view shows needle noses 10 in needle housings 21. Suture ends 14 attached to each needle nose are trapped with the needle noses 10 to which they are attached when housing detents 27 lodge in nose indents 45.

[0157] FIG. 4F is a front view of what is described in FIG. 4E.

[0158] FIG. 4G is a side view of suture placement component 2, with centerboard 1 moved in the distal direction within outboard 19 by operator turning screw turner 25 in the opposite direction while also holding frame 13 in the proximal position. This causes needle shafts 11 attached to moving centerboard 1 to disengage from needle noses 10 being held in needle nose housings 21 by breaking temporary friction connection of friction dowel 12. Also needle shafts 11 return to the position inside centerboard 1 as operator is holding frame 13 in proximal position thus preventing separator wires 4 with wedge ends 41 from moving distally with needle shafts 11. This view shows the alternative configuration with balloons 24 and fluid channel 38 which would be deflated at this time when those two alternative configurations are used. Centerboard 1 and outboard 19 are now ready for the operator to remove from the body and the physician releases pressure on vessel opening to determine if pressure of pulsing blood is reduced by free edge slit side 29 being held against centerboard 1 by suture loops 15 pulling on free edge of vessel opening. If so, centerboard 1 outboard 19 are removed from the body by physician pulling them out singly or together depending on the alternative configurations of split blockhead 50 or blockhead 49, but in either case needle noses 10 are drawn out of the patient's body in nose housings 21 with suture ends 14 attached to each needle nose 10 of each needle

pair 45 while suture loop 15 remains in the artery or other vessel. This device provides alternative configurations; suture tying component 103, and suture clip component 104, for simultaneously joining all suture ends 14 at free edge with either knots or clips.

[0159] FIG. 4H is a cross sectional front view of centerboard 1 and outboard 19 as described with FIG. 4G. This view shows the alternative configuration with balloons 24 and fluid channel 38 which would be deflated at this time when those two alternative configurations are used.

[0160] FIG. 5A shows suture clip component 1104 with a view of the situation after centerboard 1 and outboard 19 of intravascular placement device 2 are removed from the body and free edge slit side 29 is held together by a length of suture loop 15 with suture ends 14 attached to needle noses 10 in needle nose housings 21 in each foot 20 of outboard legs 47. The preferred configuration with blockhead 49 is shown but the alternate configuration with split blockhead 50 presents essentially the same situation. Cross clamp 52 is shown opened to place cross bars 53 extending from arms of cross clamp 52 on each side of suture loops 15. Cross clamp 52 and cross bars 53 are made of a high tension metal such as stainless steel. Cross clamp 52 is generally shaped like scissors that cross on an axle and have open handle loops for insertion of thumb on one arm and one or more fingers in the handle on the other arm and on the end opposite the handles on each arm is a cross bar 53 extending at a right angle from the plane of closing of the handles for a distance slightly greater than the width of the plurality of suture loops 15.

[0161] FIG. 5B is a frontal view of the situation shown in FIG. 5A with a cross sectional view of cross bar 53 at a-a and an alternative configuration of tension adjuster 59 for adjusting the length of each suture loop 15 so the straight line of sutures originally produced may be adjusted to form a curved line more consistent with the natural curvature of the artery and also to more conveniently hold suture loops 15 without having to hold the two outboard legs 47 and attached foot 20 with needle nose housings 21 and attached suture loops 15. Extending at a right angle to the plane of closure of cross clamp 52 are two curved cross bars 53, (one obscuring the other in this view). The curvature of cross bars 53 is pre-selected to be congruent with the natural curvature of the cross section of vessel wall 28. In an alternative configuration there are two suture shields 58, each in the shape of a planchet in two unequal halves separated by a curved line of separation, attached at a right angle to and on the ends of cross bars 53, one half on each end of cross bars 53 furthest from cross clamp 52 and one half of each of the other suture shield 58 on ends of cross bars 53 closest to cross clamp 52, thus the larger unequal half extends beyond the plane in which the plurality of suture loops 15 lie, constituting a barrier to the movement of any suture loop 15 outside suture shield 58, thus ensuring suture loops 15 will not slip outside the ends of cross bars 53. Suture shields 58 are shown in side view of FIG. 5D. Strip holder 55 is a recessed groove in facing sides of each cross bar 53 having straight rectangular sides and curved to run parallel to the curvature of cross bars 53 from one end of cross bar 53 to the other. One strip holder 55 holds female strip 56 and the other strip holder 55 holds male strip 57. Female strips 56 and male strips 57 are curved strips of metal or polymer material that may safely remain in the body, such as non-magnetic stainless steel or titanium or a biodegradable or non-biodegradable polymer. In cross section, as shown in a-a, each is shaped on one side to fit in strip holder 55 and shaped on the

other side so male strip 57 has the general shape of an arrow head that congruently fits in the shape of female strip 56 so the arrowhead cannot be removed once in. The surfaces of the arrowhead shape are almost touching and have a plurality of turns (e.g. three turns for the simple arrowhead shape) to prevent suture loops 15 trapped in the cross section from moving toward vessel wall 28 and keep male strip 57 and female strip 56 permanently joined after cross clamp 52 is opened for removal from the body. The joined male strip 57 and female strip 56 must be released from strip holders 55 after cross clamp 52 is opened and removed from the body. There are alternative configurations for release of male strip 57 and female strip 56 from strip holders 55, the simplest, and thus preferred, being making the width of strip holder 55 slidably greater than male strip 57 and likewise with female strip 56 to hold them in place until after they are pushed into each other trapping suture loops 15 between them—at which point strip holders 55 should release the joined male strip 57 and female strip 56.

[0162] Since strip holders 55 may fail to release one or both joined female strips 56 and male strips 57 when cross clamp 52 is opened for removal from the body, three alternative configurations are provided to ensure the release, one being shown in the cross section view a-a in this figure. Scissors cutter 54 is located slightly closer to the handles of cross clamp 52 than are strip holders 55 and are in the shape of two rectangular strips extending at right angles from cross bar 53 so placed as to slide past each other to cut suture loops 15 between them with an amount of applied pressure that is greater than that required to propel male strip 57 into female strip 56. Thus only after suture loops 15 are trapped and sealed between male strip 57 and female strip 56 are the ends of suture loops 15 cut. Break away strips 74 are used in the alternative configuration shown in this figure and compression breakers 76 in another alternative configuration. The third alternative is a mechanical means of release shown in FIG. 5H. Break away strips 74 and compression breakers 76 are made of a crystalline material that disintegrates into small grains when a pressure equal to its tensile strength is applied. This material must be one that can safely remain in the body. Salt is absorbable by the body and has a wide range of tensile strengths created as a function the temperature at which it is processed by melting and cooling. Sugar is an alternative crystalline material that is slightly more adhesive (sticky) but not as safe as salt for absorption by all patients. The pressure applied to force male strip 57 into female strip 56 may be used to cause the crystalline material of compression breaker 76 to break away and form grains or the additional pressure applied to force scissors cutters 54 to cut suture loops 15 after female strip 56 and male strip 57 are joined may be used to break the temporary crystalline bond of breakaway strips 74. The alternative configuration using holder slots 75 and breakaway strips 74 is shown in cross section a-a in this figure and the other alternative configurations are shown in FIG. 5C and FIG. 5H. Holder slots 75 are slots made at a right angle to and within the straight rectangular sides of strip holder 55 and in male strip 57 and female strip 56 at locations to align them with holder slots 75 in strip holders 55 as shown in a-a. Break away strips 74 are of the same curvature as and slidably smaller than strip holders 55 in which they are located, thereby holding male strip 57 and female strip 56 in strip holders 55. The alignment causes male strip 57 and female strip 56 to extend into strip holders 55 only so far that they do not completely fill the furthest extent of the closed end of strip

holders 55. Therefore, when cross bars 53 are squeezed the additional amount required to bring scissors cutters 54 past each other to cut suture loops 15, female strip 56 and male strip 57 are pushed to the end of strip holders 55, breaking break away strips 74 as shown in FIG. 5F. Before higher pressure is applied for joining male and female strips 56, the operator uses only slight pressure between male strip 57 and female strip 56, sufficient to keep suture loops 15 untangled while cross bar 53 is being pushed along suture loops 15 toward free edge slit across 30. Greater pressure is only applied after reaching vessel wall 28 to force male strip 57 into female strip 56 with sutures between, and still more pressure to cause the two blades of scissors cutter 54 to pass each other and cut suture loops 15 free of their length outside the body after suture loops 15 are trapped between the male strip 57 and female strip 56. The same additional pressure will break the alternative configuration of breakaway strips 74 in holder slots 75 which releases male strips 57 and female strips 56 from strip holders 55 so cross clamp 52 may be removed from the body with the assurance that it is not stuck to either male strip 57 or female strip 56 which remain in the body holding suture loops 15 together.

[0163] FIG. 5C shows the preferred configuration at cross section a for holding retaining male strip 57 and female strips 56 in strip holders 55 by friction only, and thus simpler and preferred. There are alternative configurations for release of male strip 57 and female strip 56 from strip holders 55, the simplest, and thus preferred, being making the width of strip holder 55 slidably greater than male strip 57 and likewise with female strip 56 to hold them in place until after they are pushed into each other trapping suture loops 15 between them—at which point strip holders 55 should release the joined male strip 57 and female strip 56. Since strip holders 55 may fail to release one or both joined female strips 56 and male strips 57 when cross clamp 52 is opened for removal from the body, three alternative configurations are provided to ensure the release.

[0164] FIG. 5D shows an alternative configuration in which compression breakers 76 are located between and touching strip holders 55 and the sides of male strips 57 and female strips 56 and thus provide the friction that holds female strip 56 and male strip 57 in their strip holders 55. Compression breakers 76 may be applied while in the liquid state or after being cooled in molds and slid between strip holders 55 and male strips 57 and female strips 56.

[0165] FIG. 5E shows the alternative configuration of two suture shields 58 in the shape of a planchet divided in two unequal halves by a curved line of separation being in the shape an arc with chord not centered on mid line between unequal halves and the separation being of sufficient width to allow cross clamp 52 to force male strip 57 into female strip 56 and for further closing to bring the two halves of scissors cutter 54 together to cut suture loops 15. Holder slots 75 are shown in one suture shield 58 to allow loading of breakaway strips 74 during manufacture and assembly when that alternative configuration is used with the alternative configuration of suture shields 58.

[0166] FIG. 5F is a view from the end of cross bar 53. The pre-determined curvature of cross bar 53 extending from a perigee at each end to the apogee at center applies also to male strip 57, female strip 56, strip holder 55, break away strip 74 holder slot 75 and compression breaker 76. The shapes of each have a cross section at each point along their extent but when viewed from the side the cross sections cannot be seen

but only a continuous stack of cross sections going from perigee to apogee as shown in FIGS. 5F and 5G. The same stacking view applies to scissors cutter 54, but it is not applied in FIGS. 5F and 5G as the purpose of these figures is to show how the added force that causes scissors cutter 54 to close and cut suture loops 15 also forces the joined male strip 57 and female strip 56 to be pushed farther into strip holder 55 thus breaking break away strip 74 into grains that do not inhibit the separation of strip holder 55 and male strip 57 and female strip 56 which are joined before the grains are produced by exceeding the tensile breaking strength of the material. Break away strips 74 are of the same curvature as and slidably smaller than strip holders 55 in which they are located, thereby holding male strip 57 and female strip 56 in strip holders 55. The alignment causes male strip 57 and female strip 56 to extend into strip holders 55 only so far that they do not completely fill the furthest extent of the closed end of strip holders 55. Therefore, when cross bars 53 are squeezed the additional amount required to bring scissors cutters 54 past each other to cut suture loops 15, female strip 56 and male strip 57 are pushed to the end of strip holders 55, breaking break away strips 74 as shown in FIG. 5G.

[0167] FIG. 5G is a view of the alternative configuration in which compression breakers 76, are located between male strip 57 and its strip holder 55 and between male strip 57 and its strip holder 55 to show how pressure forces male strip 57 and female strip 56 further into strip holders 55 either after or before they are joined thus matching the tensile strength of compression breakers 76 which can be pre-selected to be that of either the pressure required to cause male strip 57 to be forced into female strip 56 or the pressure required to cause scissors cutter 54 to cut suture loops 15 after male strip 57 has been forced into female strip 56. Either amount of pressure can be used to cause compression breakers 76 to disintegrate into grains that do not inhibit the separation of strip holder 55 and male strip 57 and female strip 56.

[0168] FIG. 5H is a view showing the effect of additional pressure that forces male strip 57 and female strip 56 further into strip holders 55 causing break away strip 74 to disintegrate into grains that do not inhibit the separation of strip holder 55 and male strip 57 and female strip 56 which were joined before the grains are produced by exceeding the tensile breaking strength of the material.

[0169] FIG. 5I shows an alternative configuration for ensuring the separation of strip holder 55 and female strip 56 and male strip 57 by mechanical means. A cross section of strip holder 55 and a fragment that represents both female strip 56 and male strip 57 is shown after sufficient pressure has been applied to join them. The sides of strip holder 55 are not rectangular with respect to the closed end but are tilted to become narrower toward the closed end. The shape of the sides of male strip 57 and female strip 56 adjacent the sides of strip holders 55 are tilted to conform to the adjacent sides of strip holders 55. At a plurality of locations along the length of female strip 56 and male strip 57 are slant channels 62, open cylinders extending from one side to the other of male strip 57 and female strip 56 where slant channels 62 open toward each side of strip holder 55. Two slant end rods 60 located in each slant channel 62 are slidably smaller and of the same cross section as slant channel 62 and movable only with the amount of force required to close scissors cutter 54. One end of each slant end rod 60 extends into the space between strip holders 55 and the sides of female strip 56 and male strip 57 adjacent to and touching the sides of strip holders 55. Thus the friction

for holding female strip **56** and male strip **57** in strip holders **55** is between these ends of slant end rods **60** and the sides of strip holders **55**. The other end of each slant end rod **60** is truncated to slant in the opposite direction from the other slant end rod **60** and is located congruently adjacent to release rod **61** which is truncated at two angles to be congruent with the ends of slant end rods **60** located contiguously with the truncation at two angles of release rod **61**. Release rod **61** is located in release channel **63** which is a cylinder that intersects with the center point of slant channel **62** and continues to the end of male strip **57** and female strip **56** facing the closed end of strip holder **55**. Since the end of release rod **61** is slanted to match the slants of each slant end rod **60** and the other end of release rod **61** is touching the closed end of strip holder **55**, the additional pressure required to close scissors cutter **54** is applied to the ends of slant end rods **60** providing the friction for holding female strip **56** and male strip **57** in strip holders **55** thus when female strip **56** and male strip **57** are moved by toward the closed end of strip holder **55** with sufficient force to move slant rods **77** in slant channel **62** the truncated end of release rod **61** is pushed against the closed end of strip holder **55** thus pushing female strip **56** and male strip **57** out of strip holder **55** as there is no longer any friction exerted between the ends of slant end rods **60** against the sides of strip holder **55**.

[0170] FIG. 5J is an example of an alternative configuration (to sharp turns) to prevent suture loops **15** from moving in the direction of vessel wall **28**. In this alternative configuration a plurality of barbs **70**, that are wire-like protrusions about 0.1-0.3 mm in length and diameter located in the cross section of separation between male strip **57** and female strip **56** where suture loops **15** are forced by male strip **57** entering female strip **56**. Barbs **70** are attached at an acute angle to a portion of the surfaces of female strip **56** and male strip **57** and sides of acute angle open in the direction opposite that of movement of suture loops **15** toward vessel wall **28**. Thus barbs **70** are attached to a portion of the surface of male strip **57** on one side of the separation and to a portion of the surface of female strip **56** on the other side of the separation as shown. Also, the direction of travel of male strip **57** into female strip **56** is not inhibited by barbs **70** since the acute angle of their attachment opens in the direction that is opposite to that of travel. Thus barbs **70** on female strip **56** and male strip **57** open from the acute angle of attachment in opposite directions with both being against the movement of suture loops **15** toward vessel wall **28** as shown.

[0171] FIG. 5K is an example of an alternative configuration to prevent male strip **57** from separating from female strip **56** by attaching a plurality of loops and hooks **9** made of material such as polyester or nylon about 0.1-0.3 mm in length and diameter located in the cross section of separation between male strip **57** and female strip **56** at touching surfaces of male strips **57** and female strips **56**. The plurality of loops and hooks **9** are not to scale.

[0172] FIG. 5L is a view from free edge slit across **30** as operator uses handles to push cross clamp **52** and cross bar **53** toward vessel wall **28** while holding suture loops **15** in sufficient tension to keep them untangled while also keeping free edge slit side **29** closed as can be determined by no blood spurting from the vessel opening plus the operator's sense of feel for the correct tension. When the physician feels the end come against the artery he/she takes the action of squeezing handles of cross clamp **52** thus forcing male strip **57** into female strip **56** and thus trapping one side of sutures **15**

between the small cross section of space between. This also cinches suture loop **15** tighter by the length of the small cross section of space suture loop **15** is pushed into, thus pulling tissue of free edge slit across **30** to create a slightly greater mass of tissue between adjacent sutures which tends to create lateral pressure on adjacent sutures which in turn causes the natural curvature of vessel wall **28** to return, thus avoiding constriction of artery lumen. Physicians will learn how much the sutures shorten when drawn through the pathway between male strip **57** and female strip **56** and this will vary with the alternative configuration pre-selected for the application.

[0173] FIG. 5M is a cross section view of an example of a shape joined female strips **56** and male strips **57** may take when their shapes have a plurality of sharp turns that suture loops **15** caught by the turns must take between male strip **57** and female strip **56** after joining. The suture loops **15** are located in the cross section between the almost touching surfaces of joined male strip **57** and female strip **56** but are not shown as doing so would add nothing but subtract from the clarity of the figure.

[0174] FIG. 5N shows the cross section has a plurality of sufficiently sharp turns to hold suture loops **15** without cutting but preventing suture loops **15** from moving in the cross section separation in the direction of the vessel opening.

[0175] FIG. 5O is a view of cross clamp **52** attached to middle of cross bar **53**, an alternative configuration that may be advantageous over attachment on end of cross clamp **52** in certain body shapes or certain size openings in vessel wall **28**.

[0176] FIG. 5P is a plan view of tension adjustor **59** in the shape of a six-sided box cut in two halves across the sides parallel to the ends of the box with the two halves held together on one side by hinge **65** and on the opposite side by clasp **66** and clasp button **67** that may be closed on each other when the box is placed in the closed position. The area within the box is recessed with respect to box sides and this recessed area **69** is where friction pads **64** are located in each half of tension adjustor **59**. The friction is pre-selected to be sufficient to prevent suture loops **15** from slipping through friction pads **64**. The length of tension adjustor **59** is pre-selected to be somewhat greater than the width of the plurality of suture loops **15**, the width less than the length and the thickness less than the width. The thickness may be on the order of 1-2 mm. The length of tension adjustor **59** is placed across the plurality of suture loops **15** and then closed and locked by placing clasp button **67** in clasp **66**. Friction pads press against each other with suture loops **15** between when tension adjustor **59** is closed on suture loops **15**. The fit and friction of friction pads is such that tension adjustor **59** holds suture loops **15** unless operator pulls on a specific pair of suture loops **15**, which causes that pair to move. Suture loops **15** may be cut free of their attachment to needle noses **10** when the alternative configuration of tension adjustor **59** is used.

[0177] FIG. 5Q is a side view of an open tension adjustor **59**.

[0178] FIG. 5R is an end view of a closed tension adjustor **59**.

[0179] FIG. 6A is a side view of short applicator **88** and long applicator **82**, each having a distal end and a proximal end with rectangular boards therebetween constructed of a hard, relatively inflexible, high tensile strength material such as metal or polymer and each having a longitudinal axis and being in the general shape of the two halves of a spring clothes pin, but long half being several times length of short half. The length of short applicator **88** being about 2-4 cm and long

applicator **82** pre-selected for patient size, but generally about 15-25 cm, width being less than length and pre-selected to be about as wide as $2\text{ mm} \times (1 + \text{number of sutures in plurality of sutures})$ which is also about the width of free edge of opening in vessel to be closed to a slit called free edge slit side **29**. Thickness of short applicator **88** and long applicator **82** is generally less than width and increasing from about 1-2 mm at distal end, called applicator nose **93**, to about 2-4 mm on proximal ends. A plurality of knot rod channels **94**, being empty cylinders located proximal to suture slots **97** (suture slots **97** are not seen in side view but in plan view of FIG. 6C) are at a right angle to longitudinal axis of and running through the thicknesses of short applicator **88** and concentrically running through about half the thickness long applicator **82**. Knot rod channels **94** are arranged in columns and rows each about 2 mm apart, with columns generally in line with suture slots **97**. In this example there are 9 knot rod channels **94** in column seen in side view as dotted lines, and there are adjacent columns not seen in a side view but seen in plan view of FIG. 6C. A plurality of snare holders **92** are located between a plurality of suture slots **97** that are not clearly visible in side view but are indicated by a dotted line that extends toward applicator nose **93** at distal end of short applicator **88** and long applicator **82**. They are discussed when clearly visible in plan view of FIG. 6C. Cutter **89**, cutter pusher **90**, and push knob **91** provide the means of cutting suture ends **14** after suture loops **15** have been tied in knots. They are shown here and discussed in association with FIGS. 9A-E.

[0180] FIG. 6B is a side view of short applicator **88** and long applicator **82**. Knot rods **87** are initially located in knot rod channels **94**. Diameter of knot rod channels **94** is slidably larger than knot rods **87** in short applicator **88** and sufficiently less in diameter in long applicator **82** to cause enough friction with knot rods **87** to prevent them from being easily removed once pushed in. Knot rod holder **83** is gripped by operator to slide knot rods **87** in and out of knot rod channels **94** simultaneously as one end of each knot rod **87** is attached to knot rod holder **83** which is a solid block of metal or polymer about 1 cm thick, and of sufficient length and width to hold all knot rods **87** that are arrayed in rows and columns as are knot rod channels **94**, each about 2 mm apart. Foot loop **81** loops around foot **20** and is an aid to transferring sutures from foot **20** to short applicator **88** by holding foot **20** as it is moved along the increasingly thick short applicator **88** to cross section planes a, b, c, d, e, and shown at b in this figure. Foot loop **81** is of a circumference sufficient to wrap around foot **20** and either short applicator **88** or long applicator **82** in cross section as shown, and made of an elastic material, such as polyisoprene or polybutadiene which may be attached to an inflexible material, such as stainless steel where the inflexible, portion is located between, and the flexible portion outside short applicator **88** and/or long applicator **82**. Foot **20** is seen in side and front views and is one of two which were removed from patient's body at end of procedure with suture placement component **2** and each contains a plurality of suture loops **15** attached to a plurality of needle noses **10** trapped in a plurality of needle nose housings **21**.

[0181] FIG. 6C is a frontal view of a generalized image looking from a to b along short applicator **88** that shows applicator nose **93** at distal ends of short applicator **88** and shows foot **20** and foot loop **81** as it appears [on short applicator **88**] from applicator nose **93**. Suture slots **97** are seen and they are about 2 mm apart along width. Sutures **15** extend from needle noses **10** in needle nose housings **21** in foot **20**

through suture slots **97** then turn at a right angle to run toward applicator nose **93**, (shown as a dot representing suture cross section.)

[0182] FIG. 6D is a view along long applicator **82** from a to b. Wire snares **84** are seen as lines across suture slots **97** but not discussed here.

[0183] FIG. 6E is a plan view of the distal portion of short applicator **88** and an extension of knot leaders **79** to rail leader board **96** where they are attached. A plurality of suture slots **97** extending from distal ends of short applicator **88** and long applicator **82** (long applicator not shown in this figure) about 3-8 mm toward proximal ends and being parallel to longitudinal axes each have a width of about 0.2-0.7 mm and thickness equal to thickness of short applicator **88** and long applicator **82** where suture slots **97** are located. The plurality of sutures **15** from foot **20** are pushed within suture slots **97** as foot **20** is moved along short applicator **88** here seen at cross section plane a. In the preferred configuration which does not include spring roller **86**, this is accomplished by operator holding short applicator **88** and long applicator **82** in his/her hands without aids. The dots labeled **15** in suture slots **97** represent sutures **15** in suture slots **97** as seen along the suture's own longitudinal axis. A plurality of wire snares **84** are positioned in snare holders **92** as the means of snaring sutures **15** as they are pushed proximally in suture slots **97** by movement of foot **20** and foot loop **81**. Snare holders **92** are depressions in the facing surfaces of short applicator **88** and long applicator **82**, located between suture slots **97** and distal to an alternative configuration named tightener gate **99** that is simply the proximal end of suture slots **97** with alternative configurations of snare tighteners **85**. The shape of a snare holder **92** is like that of a strung and bent simple "D" bow from handle located at tightener gate **99** to bow end near applicator nose **93** where the bow string is attached and bent back sharply as with a drawn bow string. A plurality of wire snares **84**, each having the same shape as and initially located in each snare holder **92**, have a proximal end located in snare holder **92** at tightener gate **99** and a distal end in snare holders **92** near applicator nose **93**. The side of wire snare **84** that is in the shape of a bent bow is longer than the short section in the shape of bow string. The short side extends into adjacent suture slot **97**. The long, bow shaped side of wire snare **84** is swaged or otherwise attached to the distal end of a knot leader **79**. The depression that is snare holder **92** in short applicator **88** is the same shape as the corresponding depression of snare holder **92** in long applicator **82** which have open faces facing each other. The short (bow string) side of wire snare **84** enters and crosses adjacent suture slot **97** at a point proximal to cross section plane a and this point is shown to be at cross section plane b in FIG. 6D. Each knot leader **79** has one end attached to the long side of a wire snare **84**, and extends proximally to bend around a plurality of knot rods **87** in a particular pattern that is one side of slip knot **80** then continue proximally to attached to rail leader board **96** which is a solid object of metal or polymer of planchet shape located proximal to short applicator **88**. In this specification a particular slip knot is used as example and it requires 9 knot rods **87**. Other slip knots may be used and such variants have names such as Roeder, Meltzer, Tayside, Tennessee slider, etc. Each has a different pattern that may require a different numbers of knot rods **87** to bend around, but all have one relatively straight side and the other side is wrapped around it. This straight side is sometimes called "rail" and sometimes "post". The other side is often called the "loop strand". The terms "rail" and "loop" will be

used here and the slip knot will have the generic name. The rail side of knot leader 79 is attached to wire snares 84 in short applicator 88 and attached to rail leader board 96 in this example but this could be reversed in another example. The loop sides of sutures 15 (shown in FIG. 6H) are snared by wire snares 84 in long applicator 82, extend through the same knot rods 87 around which rail sutures are bent, and are attached to loop leader board 98.

[0184] FIG. 6F shows sutures 15 moved in suture slots 97 in the proximal direction to the plane of cross section b. At cross section plane b, sutures 15 push wire snares 84 out of suture slots 97 and into snare holders 92.

[0185] FIG. 6G shows sutures 15 moved in suture slots 97 in the proximal direction to cross section plane c. At cross section plane c, sutures 15 are no longer pushing wire snares 84 out of suture slots 97 so wire snares 84 spring back to their previous positions in suture slots 97 but now sutures 15 are trapped by snare wires 84.

[0186] FIG. 6H shows wire snares 84 surrounding sutures 15 after knot leaders 79 with distal ends attached to wire snares 84 have been pulled a short distance by operator pulling rail leader board 96 attached to the proximal end of those knot leaders 79 thus drawing knot leader 79 and wire snares 84 in the proximal direction. Each suture 15 from short applicator 88 is snared by a wire snare 84 and moved proximally as shown and discussed in more detail in FIGS. 7A-D.

[0187] FIG. 6I is a side view of short applicator 88 and long applicator 82 with an alternative configuration that may provide greater assurance that they will be held together than does the friction of knot rods 87 in knot rod channels 94 of long applicator 82 thus making it easier for operator to handle. This alternative configuration provides a spring roller 86 located near the proximal end of short applicator 88 in shaped depressions in short applicator 88 and long applicator 82 corresponding to size of roll, thus constituting a rotational axis between short applicator 88 and long applicator 82, with wire in roll made of a springy metal, such as spring steel with diameter about 0.5-1 mm and roll having a plurality of turns of about 3 mm diameter. Number of turns may be equal to the plurality of suture loops 15 in foot 20. The wire ends of spring roller 86 are curved to wrap around, and bend back toward each other, outside short applicator 88 and long applicator 82 to hold them together as does the spring in a spring clothes pin. There may be shaped depressions outside short applicator 88 and/or long applicator 82 for the ends of spring roller 86 to fit in. This side view also shows the other foot 20 placed on long applicator 82 with foot loop 81 holding foot 20 as operator has pushed it proximally from cross section planes a to e and finally to cross section plane f which is the proximal end of suture slot 97 and location of an alternative configuration called tightener gate 99. In the side view, the pattern of knot leaders 79 is shown as a series of loops around knot rods 87. The knot leaders from long applicator 82 continue proximally, as do those from short applicator 88, (through loops of spring roller 86 when that alternative configuration is used) to be attached to loop leader board 98 a planchet of non-slippery material of a size that can be grasped between thumb and forefinger to pull attached knot leaders 79 simultaneously. Thus knot leaders in short applicator 88 are in the pattern of the rail side of slip knot 80 and attached to rail leader board 96 and knot leaders 79 in long applicator 82 are in pattern of loop side and attached to loop leader board 98 (or vice versa). The front view [is a generalized image looking from a to f that]

shows sutures 15 in short applicator 88 already placed in suture slots 97, snared by wire snares 84 and cut free of the foot 20.

[0188] FIG. 6J is a frontal view of a generalized image looking from cross section a to f along long applicator 82 that shows applicator nose 93, foot 20 held on long applicator 82 by foot loop 81 and sutures 15 extending from needle nose housings 21 in foot 20 and entering suture slots 97, which] are about 2 mm apart along width. Sutures 15 then turn at a right angle to run toward applicator nose 93, (shown as a dot representing suture cross section.).

[0189] FIG. 6K is a frontal view of short applicator 82 from a to f. Sutures 15 are seen as dots in suture slots 97. A wire snare 84 has snared each suture 15 but this cannot be seen in this view but snare details are shown in FIGS. 7A-H.]

[0190] FIG. 6L is a plan view of long applicator 82 distal to spring roller 86. Short applicator 88 and long applicator 82 have the same shape of wire snares 84 and snare holders 92 so the snaring situations for long applicator 82 are the same as for short applicator 88 from planes a-e, and thus are not repeated except the pattern of knot leader 79 around knot rods 87 is different for this loop side than for rail side in short applicator 88, and knot leaders 79 are attached to loop leader board 98 in long applicator 82 and to leader board 96 in short applicator 88.

[0191] FIG. 6M shows a short snare groove 6 that is an alternative configuration that may be provided in the side of suture slots 97 [along cross section j] for the end of the short side of wire snare 84 to move in and thus ensure that it does not catch on the rail or loop side of suture loop 15 as it passes to snare it.

[0192] FIG. 6N shows rail and loop knot leaders 79 from short applicator 88 and long applicator 82 combined in the pattern of slip knot 80 around knot rods 87. The image shows which knot leader 79 crosses over which other knot leader 79, where the knot leader 79 underneath is shown as erased and the knot leader 79 on top as continuous.

[0193] FIG. 6O is a small image that is used in other figures. It does not show the detail of which goes under and over but represents the over and under configuration shown in FIG. 6N. Other patterns of slip knot 80 may be used and they may require a different number of knot rods 87.

[0194] FIG. 6P is a plan view of knot rod holder 83, previously specified but not shown in plan view. The operator sees this view as he/she grips knot rod holder 83 to place knot rods 87, which are attached to the opposite side of knot rod holder 83.

[0195] FIG. 7A is a detail plan view of the area around alternative configuration tightener gate 99 and the area distal to tightener gate 99. Short applicator 88 and long applicator 82 each have snare holders 92, wire snares 84, snare detent 100, and the distal end of suture slots 97 which is tightener gate 99 when used in an alternative configuration. The components of the alternative configuration are snare tighteners 85, short snare groove 6, and resistance film 95 and all have the same structure and appearance in short applicator 88 and long applicator 82. FIG. 7A is used to represent both. The plurality of gates in tightener gate 99 are the proximal ends of suture slots 97 closed by resistance film 95 attached to the surface of tightener gate 99. Resistance film 95 is a thin film made of a high tensile strength material such as paralyne-polyxylylene or polyester polyethylene-teraphtalate (PET) and coated with an adhesive. The adhesive causes resistance film 95 to adhere to the surface of tightener gate 99 and to a

plurality of snare tighteners **85**. Each snare tightener **85** has the shape of an oval ring and is made of a material that will retain its shape and be harder than the material of wire snare **84**, such as stainless steel. Each snare tightener **85** is held by adhesion to resistance film **95** at the location of the proximal end of suture slots **97** which is a gate in tightener gate **99** when covered by resistance film **95** which is cut within the oval ring of each snare tightener **85** to allow the two arms of wire snare **84** to pass through unimpeded. Each knot leader **79** attached to long arm of wire snare **84** is initially located within the oval ring of snare tightener **85** and the short arm of wire snare **84** enters the oval ring when the long arm is pulled proximally by pulling knot leader **79** [as shown in FIG. 7D). Short snare groove **6**, shown in FIG. 6M allows short arm of wire snare **84** to pass around the side of suture loop **15** in suture slot **97** without becoming entangled. The two arms of each wire snare **84** fit tightly in the oval ring of snare tightener **85** and tighten on the side of suture loop **15** that is snared by wire snare **84** as the two arms are pulled within snare tightener **85**. Resistance film **95**, resists being torn apart or breaking adhesion and so holds snare tightener **85** in place as substantial force is exerted to force the arms of wire snare **84** together in the oval ring of snare tightener **85** but finally tears and/or loses adhesion, thus opening gates to passage of the rail or loop side of suture loop **15** in that gate. Wire snare **84** is made of a material such as titanium or a gold alloy that is sufficiently malleable to bend around knot rods **87** and sufficiently springy to be held under compressive tension in snare holder **92** and to spring behind that side of suture loop **15** to snare it after wire snare **84** was pushed aside. A plurality of wire snares **84**, each shaped like a bow with bowstring bent back from bow end, are initially located in a plurality of snare holder **92** and the bowstring portion of each is the short side initially extending from the bend back between bow and bow string into suture slot **97** as shown. The bow or long side of each wire snare **84** is held between snare detent **100** and distal end of snare holder **92** under slight compressive tension which holds it in snare holder **92**. The end of wire snare **84** that is detained by snare detent **100** is attached by swaging or other means to the distal end of one of a plurality of knot leaders **79**. Each knot leader **79** has a distal end and a proximal end with flexible material therebetween. The material may be any of those normally used for sutures including metal, cotton, silk, gut, and polymer.

[0196] FIG. 7B shows a detail frontal view of two suture slots near cross section f in which the long side of wire snare **84** is being pulled by attached knot leader **79** through snare tightener **85** while the short side of wire snare **84** has not yet started to enter snare tightener **85**.

[0197] FIG. 7C is a side view of a suture **15** in a suture slot **97** at cross section a before being snared by wire snare **84** as suture **15** is moved to cross section f. Snare detent **100** may be seen near cross section f holding wire snare **84** in snare holder **92** before operator pulls on knot leader **79** which will pull attached wire snare **84** around detent **100** and through snare tightener **85** toward knot rod **87**, shown as a fragment in this view.

[0198] FIG. 7D shows a detail plan view in two suture slots **97** near cross section f of the long side of wire snare **84** being pulled by attached knot leader **79** through snare tightener **85** which adheres to resistance film **95** while the short side of wire snare **84** starts to enter snare tightener **85** while tightening around the side of suture loop **15** in each snare

[0199] FIG. 7E shows two images in a detail view of both arms of wire snare **84** within snare tightener **85** making wire snare **84** tight around the side of suture **15** in that snare tightener. Comparing the two images shows that the short end on wire snare **84** may be intentionally or unintentionally bent back around snare tightener **85** and this does not impair the tightness of fit of wire snare **85** around suture **15**. The short end may be bent back as wire snare **84** is pulled around knot rods **87** or when there is no snare tightener **85** as in the preferred alternative configuration.

[0200] FIG. 7F A small image is shown to aid in recognition of wire snare **84** in figures that do not show the detail FIG. 7E does.

[0201] FIG. 7G is a side detail view of resistance film **95** adhering to tightener gate **99** and to snare tightener **85**. One side of suture loop **15** has been snared by wire snare **84** and snare tightener **85** is pulling the short and long sides of wire snare **84** tightly around that side of suture loop **15**. Sufficient pulling force has not yet been exerted on wire snare **84** to force resistance film **95** to tear and/or lose adhesion, so this is the final tightening of wire snare **84** before resistance film **95** is torn which then offers no more resistance in open gates of tightener gate **99** to suture loops **15**. At this point suture connections to foot **20** are severed by knife of scissors by operator, making suture loops **15** attached only to wire snares **84**.

[0202] FIG. 7H is a frontal view of what is shown in and discussed regarding FIG. 7G.

[0203] FIG. 7I is a plan view intended to represent both short applicator **88** and long applicator **82**. The portion[s] of short applicator **88** and long applicator **82** distal to tightener gate **99** are the same and directly in line with each other so one image represents both. The portion proximal to tightener gate **99** is common to short applicator **88** and long applicator **82** and shows wire snares **84** from short applicator **88** have been pulled out of their snare holders **92** and pulled through tightener gate **99** of short applicator **88** where they are located while wire snares **84** in long applicator **82** are being pulled out of their snare holders **92** and are passing through their tightener gate **99**. They will be pulled into the common area where knot leaders **79** from short applicator **88** have already been drawn and then both rail leader board **96**, and loop leader board **98** will be pulled drawing knot leaders with sutures snared in wire snares **84** from both short applicator **88** and long applicator **82** through the slip knot pattern around knot rods **87**. As this is done the pattern knot leaders have is transferred to suture loops **15**. Thus suture loops **15** when they have gone through knot rods **87** have the slip knot pattern that knot leaders **79** had. The rail leader board **96** and loop leader board **98** are pulled by operator pulls to draw each set of knot leaders **79** and snared sutures **15** into slip knots **80** made of suture loops **15**.

[0204] FIG. 8A is a side view of short applicator **88** and long applicator **82** after suture loops **15** have been drawn through knot rods **87** to form slip knot **80**. These are the rail and loop sides of suture loop **15** which is still located across free edge slit across **30** in vessel wall **28** as rail and loop sides extend proximally through rail leaders **79** to rail leader board **96** and loop leader board **98**. Operator has removed the knot rods **87**. Alternative configuration of spring roller **86** is shown at cross sectional plane g for holding short applicator **88** and long applicator **82** together like the spring roller on a spring clothes pin. Cutter channel **102**, cutter **89** and push knob **91** are shown but not described with this figure.

[0205] FIG. 8B is a plan view showing that shown in side view FIG. 8A without cutter components being shown. Slip knots **80** are made with sutures **15** and sutures **15** extend distally through suture slots **97** and proximally between loops of spring roller **86**, then, being interrupted by the symbol for discontinuity, continuing where sutures **15** are still snared by wire snares **84** attached to knot leaders **79** connected to rail leader board **96** and loop leader board **98**. These attachments are not all shown in the discontinuity.

[0206] FIG. 8C shows sutures **15** attached to knot leaders **79** by wire snares **84** and knot leaders **79** attached to rail leader boards **96** and loop leader board **98**. Operator has taken sutures **15** between his/her fingers and pulled them out from between short applicator **88** and long applicator **82** and slightly tightened the loop sides of slip knots **80** so loop side will slip on the rail side. This places slip knot **80** in position to be slipped down to artery side slit **29** after the distal ends short applicator **88** and long applicator **82** are pinched together on their distal ends by pinch sleeve **101**. Operator has removed knot rods **87** so distal ends of short applicator **88** and long applicator **82** can be pinched together on distal ends.

[0207] FIG. 8D shows pinch sleeve **101** which operator places around distal end of short applicator **88** and long applicator **82** to pinch them together. Pinch sleeve **101** is made of a relatively inflexible, tough, thin membrane of polymer shaped to fit around the slanting shape of short applicator **88** and long applicator **82** where suture slots **97** are located and to hold short applicator **88** and long applicator **82** together at that location by means of adhesive sides that are attached to surface where pinch sleeve **101** is applied. Another object of pinch sleeve **101** is to place slot stoppers **8** in suture slots **97** thus restricting rail and loop sides of suture loops **15** to a location in long applicator **82** in line with cutter ends **89**. Slot stoppers **8** are slidably less wide than suture slots **97** and attached to pinch sleeve **101** in such a manner that they are aligned with suture slots **97**. The shape of slot stoppers **8** is triangular in depth and the same length as suture slots **97** in which they are located. The triangular shaped suture stoppers increase in depth from cross sectional plane h to plane k. The triangular shapes of slot stoppers **8** entering suture slots **97** in short applicator **88** completely fill those suture slots **97** so sutures **15** cannot be located in slots **97** of short applicator **88**. The triangular shape and size of slot stoppers **8** entering suture slots **97** in long applicator **82** are such as to leave only space for rail and loop sides of suture loops **15** that are directly in line with cutter ends **89** as described with FIGS. 9A-E.

[0208] FIG. 8E shows a frontal view of pinch sleeve **101** at cross section h. The adhesive membrane has one or two overlaps **7** of adhesive surface to fasten applicators together.

[0209] FIG. 8F shows a frontal view of pinch sleeve **101** at cross section k. Slot stoppers **8** fill suture slots of short applicator **88** completely and partially fill suture slots of long applicator **82**.

[0210] FIG. 8G shows the effect of pinch sleeve **101** forcing the distal portion of short applicator **88** and long applicator **82** together. Rail and loop sides of suture loops **15** are forced into long applicator **82** by slot stoppers **8**. Slip knots **80**, being larger than, and outside suture slots **97** are pushed by applicator nose **93** of closed short applicator **88** and long applicator **82** to free edge slit side **29** and as slip knot **80** advances the "rail" sutures **15** are pulled in the distal direction by rail leader board **96** until slip knot **80** is pressing against open slit **29** in vessel wall **28**. Pulling rail leader board **96** and loop leader

board **98** at the same time makes slip knot **80** a permanent knot and ready to be cut loose from suture tying component **103**.

[0211] FIG. 8H shows a frontal view at cross sectional plane h where pinch sleeve **101** is around long applicator **88** and short applicator **82** with slot stoppers **8** filling suture slots **97** in short applicator **88** completely and partially filling suture slots **97** in long applicator **82** thus forcing rail and loop sides of suture loop **15** in the portion of suture slots **97** of long applicator **88** where cutter **89** will be pushed to cut sutures **15**.

[0212] FIG. 8I shows a frontal view of the "rail" side of suture loops **15** coming straight toward the viewer as dots and the loop sides of suture loops **15** as circles wrapped around the "rail" sides. Slip knots **80** are larger than and outside suture slots **97** thus applicator nose **93** pushes the loop side on the "rail" side to vessel wall **28**.

[0213] FIG. 8J shows the rail and loop sides of suture loops **15** at cross sectional plane h immediately proximal to cross section plane i where they are intertwined in slip knot **80**. Also represented at cross sectional plane h is cutter end **89** after it is moved from its position in FIG. 8H but before it is moved far enough to cut sutures **15** and thus only touching rail [and] loop side of any suture loop **15** in suture slot **97** of long applicator **82**. This representation of what occurs at cross sectional planes i and h is further described in FIGS. 9A-E.

[0214] FIG. 9A shows (two examples) of a plurality of cutter ends **89** and cutter pushers **90**, located in cutter channels **102**. Each cutter channel **102** is a rectangular channel in long applicator **82**, about 0.5 mm wide and 1-2 mm in depth, curved on one end in a question mark shape around distal end of snare holder **92** and crossing suture channel **97** at a right angle to push against the opposite side of suture channel **97**. Where the question mark shape is at a right angle to suture slots **97**, the depth of cutter channel **102** is increased in the direction of short applicator **88** making this portion of cutter channel **102** a groove in long applicator **82**. The other end of cutter channel **102** in long applicator **82** extends parallel to suture slot **97**, continuing in the proximal direction parallel to longitudinal axis of long applicator **82** and ends near proximal end of long applicator **82**. Near the proximal end of long applicator **82** the depth of cutter channel **102** increases in the direction opposite short applicator **88** for a length of about 2-4 mm thus becoming a groove with open side to the outside of long applicator **82**. Each cutter pusher **90** is a flexible strip of metal such as spring steel of the same shape but slidably smaller than cutter channel **102**, located in cutter channel **102**, having cutter end **89** near applicator nose **93**, and attached to push knob **91** where the depth of cutter channel **102** increases to the width of long applicator **82** and extending almost to the proximal end of cutter channel **102**. Cutter end **89** is the end of cutter pusher **90**, sufficient in depth to fill groove in cutter channel **102** around curve that turns to cross suture slot **97** and has a sharp end. Push knob **91** is a bar of high tensile strength metal or polymer that extends across the width of long applicator **82** with a plurality of protrusions that match the locations of and extend into the grooves created where cutter channel **102** increases to the width of long applicator **82** near proximal end. Thus operator pushes knob **91** to move cutter pushers **90** in cutter channels **102** thus causing cutter ends **89** to move in the groove across suture slots **97** in long applicator **82** where sides of suture loops **15** are located. A cross sectional view of push knob **91** with two protrusions as examples of a plurality of protrusions is shown.

[0215] FIG. 9B is a detail view of question mark shaped portion of cutter channel 102 before cutter pusher 90 is pushed by push knob 91 being pushed in the distal direction by operator so cutter end 89 has not crossed suture slot 97.

[0216] FIG. 9C is a detail view of the question mark shaped portion of cutter channel 102 after push knob 91 is pushed in the distal direction by operator thus causing the sharp cutter end 89 of cutter pusher 90 to cross suture slot 97, thus causing the sharp cutter end 89 of cutter pusher 90 to cross suture slot 97. No suture is shown in suture slot 97 so the detail can be seen but the object is to cut sutures 15 that are located in suture slot 97.

[0217] FIG. 9D includes three side views of the protrusion of push knob 91 attached to cutter pusher 90 being pushed to two more distal positions. Cutter end 89 being of greater depth than cutter pusher 90 fills cutter channel where it is a groove that turns to cross suture slot 97 in long applicator 82. Thus when operator pushes push knob 91 in the distal direction cutter 89 moves around the question mark shape of cutter channel 102 shown in this figure by decreasing the portion of cutter 89 that is seen at cross section h, thus representing cutter 89 moving around curve and "disappearing" to the side view.

[0218] FIG. 9E shows the three views shown in FIG. 9D but represented in the frontal view at cross section plane h by cutter 89 increasing in size or "reappearing" in the frontal view where cutter 89 is crossing suture slot 97. Two sides of suture loops 15 are represented by dots in suture slot 97 and these disappear when cutter 89 has been moved to its full extent across suture slot 97, representing the cutting of both rail and loop sides of suture loops 15.

[0219] FIG. 9F shows a side view of one of a plurality of slip knots 80 snugly fastened to close the opening of slit artery 29 after being pushed on "rail" side of suture loop 15 by applicator nose 93 now located at cross section plane i. Push knob 91 has been pushed to an intermediate position which advances cutter pusher 90 and cutter end 89 in cutter channel 102.

[0220] FIG. 9G is a frontal view at cross section h where cutter end 89 advances through cross section plane h and around the curved right angle to be seen in FIG. 9C. Applicator nose 93 surrounded by pinch sleeve 101 which causes slot stoppers 8 to keep both sides of suture loops 15 in line with cutter end 89 which is seen cutting both sides of suture loops 15 between cutter end 89 and opposite wall of suture channel 97, thus showing they have been cut.

[0221] FIG. 9H shows push knob 91 pushed to extreme distal position which advances cutter end 89 through cross section plane h and around the curved right angle to be seen in frontal view of applicator nose 93 to have cut both sides of suture loops 15 against opposite wall of suture channel 97.

[0222] FIG. 9I shows the remainder of suture loop 15 inside artery side slit 29 permanently tied by slip knot 80 being tightened to a permanent knot and the two sides of suture loops 15 in slip knot 80 have been cut loose from suture loops 15 still inside vessel thus completing the procedure and suture tying component 103 is removed from patient's body.

SUMMARY OF THE INVENTION

[0223] A centerboard in the shape of a rectangular board is located between two similar boards of an outboard, all made of high tensile strength metal, carbon fiber, or polymer. Length of centerboard is about 15-30 cm, thickness about 1 mm and width pre-selected to stretch the free edge of the

opening to an approximately straight slit, i.e. about 4-15 mm when centerboard is advanced on guidewire through opening into vessel. A plurality of needle pairs are located in a plurality of needle openings spaced 2 mm apart along centerboard width in vessel. Each needle of a pair has a shaft about 0.5 mm in diameter temporarily attached by friction to a needle nose and one end of a plurality of suture loops is attached to each needle nose. One end of each outboard is attached to a block-head that holds outboards, called legs, apart by the thickness of centerboard. Other end of each outboard leg has a foot projecting a right angle on the distal end which contains tapered needle housings, each with open end located opposite a needle nose located inside vessel wall while needle housing is located outside, making needle housings about 2 mm apart and about 1 mm from the free edge of the slit opening. The needle noses are pushed 1 mm to either side of the free edge by operator pushing a frame located around proximal end of centerboard which pushes longitudinal separator wires with a wedge end between each needle pair to bend needle noses apart by 2 mm across slit. A screw turner on proximal end of outboard has a center channel with female threads that receives a threaded post attached to proximal end of centerboard, thus forcing centerboard and

1. A suture placement component providing means of simultaneously placing a plurality of suture loops in the ideal 2x2 pattern across the free edge of an opening in a vascular vessel, which may be calcified, without opening the body, comprising,

- a. a centerboard in the shape of a flat board having a length greater than width and width greater than thickness, the length having a distal end and a proximal end, the width terminating in edges, the thickness being between front face and back face, and a longitudinal axis being equidistant from edges and faces, length about 15-30 cm, width pre-selected to be about one half the circumference of the free edge of the opening in the vessel to be closed, thickness about 1 mm, being made of high tensile strength material such as metal, carbon fiber or polymer, having a threaded post of about 1-2 mm diameter and 5-7 mm length protruding from proximal end, a semi-circular suture cove on distal end which has a slot between faces open on end from side-to-side, and a stopper of 1-2 mm protruding on each edge at a point about 1 mm proximal to distal end of needle openings,
- b. a plurality of needle openings located about 2 mm apart on an approximately straight line across width of centerboard immediately proximal to suture cove, each needle opening having a proximal end and a distal end with centerline therebetween, each centerline being parallel to longitudinal axis, length on centerline being about 1.5 to 4 mm, width slidably greater than needle diameter, or about 0.5 mm, and thickness equal to thickness of centerboard between faces, and having proximal end open to a separator wire channel,
- c. a plurality of needle pairs each having two needles, each needle being about 0.5 mm diameter and 2-3 mm length and in two parts, a needle nose and a needle shaft, held together by a temporary connection, having a nose indent, and needle shafts being attached to distal ends of needle openings with needle noses pointing toward separator wire channels,

- d. a plurality of separator wire channels each of oval or round cross section about 0.5 mm in diameter with one end open to needle openings and other end open to cross slots,
- e. a plurality of cross slots, each being a rectangular opening of same size, shape, and orientation as needle openings, located near distal end of centerboard and having distal end open to separator wire channel,
- f. a guidewire channel of smaller diameter than thickness of centerboard with ends at distal port on face near distal end and proximal port on face near proximal end,
- g. a plurality of separator wires, slidably smaller than and located in separator wire channels and having on distal end a wedge end shaped to separate needle noses by about 2 mm when pushed between a needle pair,
- h. a plurality of cross wires slidably smaller than and located in cross slots, each attached at their center point in a right angle to proximal end of a separator wire and having their ends attached to a frame,
- i. a frame of box shape with two extended sides to provide finger grips with interior cross section dimensions being slidably greater than cross section of centerboard and located so attached cross wires slide in cross slots,
- j. a plurality of suture loops stored in suture cove each having one end attached to one needle nose of each needle pair,
- k. an outboard with two legs and a blockhead, each leg being of a shape, size and material like centerboard and held slidably farther apart than centerboard thickness by a blockhead on proximal end. Distal ends are turned at a right angle away from thickness for about 1-2 mm, this protuberance being of greater width than outboard by about 1-2 mm and called a foot, and in the 1-2 mm where foot is of greater width than outboard, another protuberance called a keeper extends half way across distance centerboard legs are apart,
- l. a blockhead extending distally about 15 mm from proximal end of outboard to outboard legs, with thickness about 5 mm, and width being about 2-3 mm greater than the width of centerboard for about 5 mm from proximal end then equal to width of centerboard for another 8 mm where blockhead joins outboard legs so outboard legs have a distance between that is slidably greater than thickness of centerboard and blockhead having internal dimensions of an unthreaded hole in the shape of an empty cylinder, of circumference slidably greater than that of threaded post and extending on longitudinal axis from proximal end about 4-5 mm in the distal direction, a centerboard slot slidably greater than centerboard in thickness extending from proximal end about 5-7 mm and a frame slot extending from distal end of unthreaded hole and having a cross section slidably greater than that of frame,
- m. a plurality of needle nose housings, each being an empty cylinder of slidably greater diameter and length than a needle nose with proximal end in a foot and distal end opening in a tapered funnel shape outside foot, each needle nose housing located outside vessel wall directly opposite a needle nose inside vessel wall when each needle nose of each needle pair is separated by wedge end about 2 mm, and needle nose housings have housing detents that engage needle indents to hold needle noses that enter,

- n. a screw turner with threaded hole in center that self-aligns to engage threads on threaded post and drawing threaded post in threaded hole when turned,

whereby centerboard is located between outboard with keepers in foot immediately distal to but felt by operator to be touching stoppers on edges of centerboard thus making distance between foot on outside of opening the correct distance from needle pairs inside opening and keeping centerboard within keepers, operator places guidewire in centerboard and advances it into vessel opening thus closing opening to a slit as centerboard is of a width preselected to be about half that of free edge of vessel. Operator views centerboard which is opaque to fluoroscopy and ultrasound to determine when it is properly located within vessel wall. Operator then pushes frame distally causing cross wires to slide distally in cross slots thereby pushing separator wires through separator wire channels and into needle openings causing wedge ends to separate needle pairs so needle noses of each pair are spread 2 mm apart across free edge of slit, each attached to one end of a suture loop. Operator keeps stoppers against keepers thus insuring the needle housings are immediately outside slit and needles aligned inside slit whereupon operator turns screw turner causing threaded post to enter screw turner which causes needle noses to pierce calcified or non-calcified vessel wall and enter tapered open ends of needle nose housings in each foot outside vessel wall where housing detents engage needle indents to hold needle noses, while operator turning screw turner in opposite direction causes needle shafts to pull away from needle noses trapped in needle nose housings thus breaking temporary connections, operator pulling frame proximally causes needle shafts to return into needle openings and center board and outboard are removed from body bringing suture ends attached to needle noses in needle housings outside body with a plurality of sutures looped across free edge of slit opening in the ideal pattern of 2 mm apart and 2 mm across. The vessel opening is thus temporarily closed and an indication of this may be a cessation of blood spurting from opening, which is a cue for joining the sutures to make the closure permanent either before or after a procedure is performed, and alternative configurations of this device provide alternative means of joining suture ends,

2. The device of claim 1 wherein,

- a. a split blockhead being of the same material and shape as blockhead but being separated in two halves along the plane midway between outboard legs,
- b. a surround being in the shape of a 6-sided box with top and bottom removed and having dimensions to tightly surround split blockhead,
- c. a tongue and groove aligned between split blockhead and surround,

whereby split blockhead replaces blockhead when surround is in place but when not in place allows legs to be moved slightly away from centerboard to engage spurs on each foot and allows outboard legs to be removed separately from body while tongue and groove prevents surround from accidentally being removed from split blockhead.

3. The device of claim 1 further including,

- one or more spurs in the shape of wire-like protrusions of stiff material located on the distal side of each foot, being about 0.1-0.3 mm in length and diameter and protruding at an acute angle with sides of acute angle opening toward and being in a plane at a right angle to faces of outboard legs,

whereby operator can move foot away from outboard legs then move foot back toward outboard legs in a way that digs spurs into vessel wall and thus pulls free edge of artery toward outboard legs.

4. The device of claim 1 wherein,

- a. a plurality of blunt ends each on the distal end of a separator wire and being attached to the middle of a bridge wire,
- b. a plurality of bridge wires being in the shape of a loop made of a resilient material such as spring steel with ends attached to needle shafts of each pair and being of a length when straight that separates needle noses so each is about 1 mm outside front face and back face of centerboard,

whereby moving separator wires in the distal direction pushes blunt ends against bridge wires initially in the shape of a spring loop that straightens when pushed by blunt end thus forcing each needle pair apart by the length of straight bridge wire so each needle nose is approximately 1 mm from free edge of opening on each side of centerboard.

5. The device of claim 1, wherein,

- a. a spring clip made of spring steel and being in the shape of a disc with an open center and radial cut from open center to outside circumference,
- b. a circular slot in needle housing sized and shaped to receive spring clip,

whereby when spring clip is squeezed to a smaller circumference and placed in circular slot it expand to remain in slot after the squeezing force is removed and when a tapered needle nose is pushed into open center, spring clip expands until needle nose passes and a needle indent is in open center which allows open center to reduce in size and prevent needle nose from passing back through open center.

6. The device of claim 1 wherein,

- a. suture cove is of soft elastic material such as polybutadiene attached to hard material of centerboard,
- b. suture cove is about 1.5-3.5 mm in thickness and slot of 0.5 to 3 mm in thickness,

whereby suture cove tends not to penetrate vessel wall opposite opening when pressed against it, thus protecting vessel wall from injury and longer lengths of suture may be stored in slot.

7. The device of claim 1, further including,

- a. a fluid channel located adjacent to guidewire channel,
- b. a fluid port proximal of fluid channel located adjacent proximal port of guidewire channel,
- c. a fluid port distal located adjacent distal port of guidewire channel,

whereby contrast fluid introduced in proximal fluid port of fluid channel exits distal fluid port within vessel wall making vessel clearly visible on fluoroscope.

8. The device of claim 1, further including,

- a. a fluid channel located adjacent guidewire channel, that divides into two sections at a point immediately distal to needle openings and each of two sections turns at an opposite right angle and runs to opposite edges of centerboard,
- b. a fluid port proximal of fluid channel located adjacent proximal port of guidewire channel,
- c. two balloons attached to opposite edges of centerboard immediately distal to needle openings,

- d. two fluid port edge each located on an end of one of two sections of fluid channel on opposite edges of centerboard and each opening directly into one of two balloons.

whereby introducing contrast or non-contrast fluid in fluid port proximal causes it to flow through fluid channel divide to flow to each fluid port edge an inflate two balloons that have the effect of increasing the width of centerboard and may be clearly seen if inflated with contrast fluid.

9. The device of claim 1, wherein,

- a plurality of cove walls running parallel to longitudinal axis of centerboard and so spaced within suture cove as to produce a plurality of suture compartments of equal volume,

whereby each suture compartment of unequal length provides an equal volume for the suture coiled in the suture compartment that has its two ends attached to a needle pair.

10. A suture tying component for tying suture ends together in slip knots, sliding knots to vessel opening and cutting suture ends at opening after a suture placement device, such as described in claim 1 has placed suture loops across the opening and brought one end of each suture loop out of patient's body in one foot, the other end in another foot, comprising,

- a. a short applicator and long applicator, each having a distal end and a proximal end with boards therebetween constructed of a hard, high tensile strength material such as metal or polymer in the shape of the two halves of a spring clothes pin, the length of short applicator being about 2-4 cm. and long applicator about 15-30 cm, width being less than length and pre-selected to be about as wide as width of free edge of slit opening in blood vessel to be closed, and thickness generally less than width and increasing along longitudinal axis from about 1-2 mm on distal end to about 2-4 mm on proximal end,
- b. one or more foot loops of elastic material, such as polybutadiene attached to an inflexible material such as stainless steel which hold foot against while pushing sutures between short applicator and long applicator,
- c. a plurality of suture slots being about 2 mm apart, extending about 3-8 mm from distal ends of and parallel to longitudinal axis of short applicator and long applicator, being of a width slidably greater than the diameter of one suture and equal to thickness to short applicator and of long applicator where located,
- d. a plurality of knot rod channels of 0.5 to 1 mm diameter at right angles to longitudinal axis of and piercing short applicator and of sufficiently less diameter to create friction with knot rods concentric extension about half way through thickness of long applicator and being in an array of columns and rows each about 2 mm apart and columns generally in line with suture slots,
- e. a plurality of knot rods made of steel or polymer, slidably smaller than knot rod channels in which they are placed or removed by a knot rod holder attached to one end of each knot rod with knot rod holder being about 2 cm thick, with length and width sufficient to hold array of plurality of knot rods,
- f. a plurality of knot leaders each having a distal end and a proximal end and material therebetween being of suture material with half the knot leaders being the rail side and half being the loop side of slip knots intertwined around knot rods and proximal ends of loop sides being attached to a loop leader board and proximal ends of rail sides

being attached to a rail leader board and distal ends of one side being attached to wire snares in short applicator and distal ends of the other side attached to wire snares in long applicator,

- g. a loop leader board and a rail leader board, being planchets of a non-slippery material that can be grasped between thumb and forefinger and independently pulled by operator,
- h. a plurality of wire snares of a malleable but springy material, each shaped like a bow string and bow where the bent back short side is shaped the string and the long curved side like the bow from end to handle, each long side being attached to distal end of knot leaders and each short side extending into a suture slot, each being initially located in a similarly shaped snare holder,
- i. a plurality of snare holders being depressions in facing surfaces of short applicator and long applicator shaped like bow string and bow, located between suture slots with one side open to adjacent suture slot where short side of wire snare extends, and each having a snare detent that holds bow shaped side of wire snares in compressive tension until pulled out by knot leaders,
- j. a plurality of cutter channels, each having a rectangular cross section about 0.5 mm across width of, and 1-2 mm in thickness of and length extending from near proximal end to near distal end of long applicator, being offset from each suture slot and column of knot rods and being curved like a question mark to turn away from and then turn toward each adjacent suture slot so as to be at a right angle to adjacent suture slot immediately proximal to distal end, also increasing in depth around curve to become a groove open on side of long applicator face facing short applicator, with a like increase in depth also occurring for about 2-4 mm near proximal end of long applicator but with open side of groove facing away from short applicator, thus being on outside of long applicator,
- k. a plurality of cutter pushers having proximal ends and a distal ends with flexible strips of metal such as spring steel therebetween, being of the same shape but slidably smaller than and located in cutter channels and each being shaped into a sharp cutter on distal end where thickness of cutter may be equal to that of groove and each cutter pusher being attached to a push knob where channel is a groove near proximal end,
- l. a push knob in the shape of a bar with protrusions matching locations of each outside groove and protrusions being attached to cutter pusher,
- m. a pinch sleeve shaped to fit tightly over distal end of short applicator and long applicator in such a way as to force them to close tightly against each other and pinch sleeve having an adhesive side with overlap that keeps pinched sleeve from releasing closed distal ends and to adhesive side are attached a plurality of triangular shaped slot stoppers of length equal to and of width slidably smaller than suture slots, with which slot stoppers are aligned as pinch sleeve is attached by adhesion around distal end of short applicator and long applicator,

whereby the means of holding short applicator and long applicator together with distal ends apart is knot rods attached on one end to knot rod holder which is pushed against short applicator and other ends of knot rods held by friction in slightly smaller diameter knot rod channels in long applicator, a foot loop holds a foot with sutures extending from it as

foot is pushed proximally from distal end of short applicator with sutures located in suture slots of short applicator and other foot is likewise pushed across long applicator, causing each suture to push the short side of wire snares out of adjacent suture slots with short sides of wire snares springing back in suture slot after suture passes, thus being in position to snare the suture as the long side of wire snare is pulled by operator pulling the rail and/or loop leader board attached to proximal ends of rail and loop knot leaders that have their distal ends attached to long sides of wire snares and thus pulling wire snares around snare detents and out of snare holders and continued pulling of both leader boards causes sutures to be pulled through path of knot leaders among knot rods which is the intertwined path of a slip knot now transferred to sutures from knot leaders, whereupon operator pulls suture slip knots from between short and long applicators so slip knots are now distal to applicators with two sutures in suture slots, pulls knot rod holder to release frictionally held knot rods in long applicator, presses distal ends of short applicator and long applicator together and places pinch sleeve around them to keep them closed tightly on each other while also placing slot stoppers in suture slots so two suture sides of suture loop are limited in their location to being only in long applicator and directly in line with cutter. Operator positions each slip knot distal to each suture slot and being of a size larger than suture slots, slip knots are simultaneously pushed by applicator nose to opening in vessel as sutures attached to rail leader board are pulled, sutures are then both pulled by both leader boards to cinch slip knots into permanent knots and operator pushes push knob which moves cutter pushers in cutter channels and cutter across suture channel to cut suture ends releasing device which is removed.

11. The device of claim 10 further including,

- a. a spring roller made of a plurality of wire loops of springy wire about 0.5-1 mm diameter and loop about 3 mm diameter that fits in a
- b. two depressions shaped corresponding to spring roller, opposite each other in short applicator and long applicator, near proximal end of short applicator
- c. spring ends of spring roller that wrap around short applicator and long applicator and bend toward each other,
- d. two depression shaped like spring ends outside of short applicator and long applicator near depressions shaped like spring roller

whereby means of holding together while providing rotation between short applicator and long applicators is provided as does the cylindrical spring in spring clothes pins,

12. The device of claim 10 further including,

- a. a short snare groove in line with, slidably larger than diameter of, and located in side of suture slot where short side of wire snare touches opposite side of adjacent suture slot,

whereby short side of wire snare can pass around suture without becoming entangled with suture.

13. The device of claim 10 further including,

- a. two tightener gates at proximal end of suture slots, one in short applicator and the other in long applicator with gate openings aligned with suture slots,
- b. two resistance films each with an adhesive side that adheres to a tightener gate and to a plurality of snare tighteners aligned with gate openings and resistance film having holes in it for passage of a knot leader through snare tightener,

- c. a plurality of snare tighteners, each being in the shape of an oval ring slightly larger than two sides of and being made of a harder metal than the softer metal of wire snares and each being aligned in a gate opening by adhering to resistance films,

whereby as knot leader pulls long sides and then short sides of wire snares causing them to enter oval ring of snare tightener which resists movement because it is held in place by adhesive resistance film thus forcing oval ring far up wire snare sides toward suture being squeezed between sides, and being of harder metal tending to stick in cuts made in softer wire until resistance film tears thereby opening gate to passage of sutures thus ensuring sutures remain held by wire snares,

14. A suture clip component for simultaneously and permanently joining a plurality of sutures by a clip clamped across free edge of opening in a vascular vessel without opening the body for each suture to be tied manually or individually, comprising,

- a. a cross clamp of high tensile strength material such as stainless steel in the shape of crossed scissors arms having handles on one end and cross bars on the other end, with arms being of sufficient length to be pushed from outside the body to free edge of opening in vascular vessel and cross bars pre-selected to be of the same curvature as vascular vessel,
- b. two strip holders in the shape of curved grooves with straight rectangular sides, on facing sides of each cross bar and running parallel to the curve of cross bars between cross bar ends,
- c. a female strip and male strip made of metal or polymer material that may safely remain in the body, such as non-magnetic stainless steel or titanium or a biodegradable or non-biodegradable polymer, each being shaped to fit in holder strips on one side and shaped on the other side so male strip fits in female strip with the cross section of space between the almost touching surfaces having a plurality of sharp turns,
- d. a scissors cutter attached to cross bars that cuts sutures when sufficient additional pressure is applied by handles after joining of female and male strips,

whereby sutures are placed and loosely held between male strip and female strip and pushed from outside the body to free edge of opening by cross clamp which then is closed with pressure on handles to push male strip into female strip thus permanently holding sutures that have been trapped in the plurality of turns between the joined male and female strips and further pressure on handles cuts suture ends and male and female strips are pulled out of strip holders by opening of cross clamp.

15. The device of claim **14** further including,

- a plurality of sharp barbs in the shape of wire-like protrusions about 0.1-0.3 mm in length and diameter protruding at an acute angle from a portion of the surface of female strip and male strip in cross section separation between them when joined and acute angle having with sides opening in the direction that prevents sutures from moving toward vessel opening,

whereby sutures located within cross section separation are prevented from moving in the direction of the vessel opening.

16. The device of claim **14** further including,

- a plurality of loops and hooks, wire-like protrusions about 0.1-0.3 mm in length and diameter made of material such as polyester or nylon located in the cross section of

separation between and attached to touching surfaces of male strips and female strips,

whereby hooks and loops engage each other on being pressed together thus preventing touching surfaces from separating.

17. The device of claim **14** further including,

- a. two suture shields each in the shape of a planchet in two unequal halves separated by a curved line of separation, attached at a right angle to and on the ends of cross bars, one half on each of ends of cross bars furthest from cross clamp and one half of each of the other suture shield on ends of cross bars closest to cross clamp,
- b. a curved line of separation being in the shape an arc with chord not centered on mid line between unequal halves and line of separation being of sufficient width to allow cross clamp to bring scissors cutter together to cut sutures,
- c. unequal halves of suture shields may have openings in them in the shape of and in line with holder slots

whereby the larger unequal half extends beyond the plane in which the plurality of sutures lie thus constituting a barrier to the movement of any suture outside suture shield thus ensuring sutures will not slip outside the ends of cross bars.

18. The device of claim **14** further including,

- a. a plurality of holder slots being slots of the same curvature, but at a right angle to and in the rectangular sides of holder strips, and being aligned with holder slots in male strip and female strip,
- b. a plurality of break away strips made of crystalline material, that can safely remain in the body and disintegrate into tiny grains when a pressure equal to material tensile strength is applied, such as salt or sugar which have a wide range of tensile strengths created as a function the melting and curing temperatures with or without trace additives,
- c. break away strips being of the same shape and slidably smaller than holder slots in which they are located,
- d. pressure equal to tensile strength of material in break away strips being the same as that required to squeeze cross clamp with sufficient force for scissors cutters to cut sutures,

whereby male strips and female strips are held in place by breakaway strips until sufficient force is placed on them to break away into small grains thus freeing male and female strips from strip holders.

19. The device of claim **14** further including,

- a. a plurality of compression breakers made of crystalline material, that can safely remain in the body and disintegrate into tiny grains when a pressure equal to material tensile strength is applied, such as salt or sugar which have a wide range of tensile strengths created as a function the melting and curing temperatures with or without trace additives,
- b. crystalline material may be applied between rectangular sides of holder strips and male strip and female strip as a liquid before curing of as a solid after curing,
- c. the tensile strength for compression breakers to break into grains may be the pressure required to force male strip into female strip or the pressure required to force scissors cutters to cut sutures,

whereby male strips and female strips are held in place by compression breakers until sufficient force is placed on them to disintegrate into small grains thus freeing male and female strips from strip holders.

20. The device of claim 14 further including,

- a. holding strips having sides that are not rectangular but slightly tilted to become narrower toward closed end,
- b. female strip and male strip having their sides adjacent to sides of holding strip located toward closed end tilted to match the tilt of sides of holding strip,
- c. a plurality of slant channels in the shape of open cylinders extending from one side to the other side of male and female strips and opening toward each side of holder strip,
- d. two slant end rods being of the same shape, slidably smaller, and located in each of plurality of slant channels, and each having one end truncated to be of equal and opposite slant to that of the other slant end rod, and both slant end rods having the other end flat with plane at a right angle to the cylindrical shape of slant end rod, and flat end being lodged against side of holder strip and not movable with less force than that required to squeeze scissors cutter together to cut sutures,
- e. a plurality of release channels each intersecting one of plurality of slant channels in a "T" configuration and continuing in the shape of an empty cylinder to the end of female and male strips that are adjacent closed end of holder strip,
- f. a plurality of release rods, one for each release channel, slidably smaller than release channel, but slidable only with pressure equal to that required to close scissors cutter, the shape of one end of release rod being truncated with slant being congruent with facing truncated ends of slant end rods at "T" between release channel and slant channel, and other end being flat and touching closed end of holder strip before sufficient pressure is applied to close scissors cutter

whereby the friction of slant rods against sides of holding strip hold male and female strips in their holding strips until sufficient pressure is applied to close scissors cutter where-

upon slant rods push into "T" and no longer is there any friction exerted between the ends of slant end rods against the sides of holding strip and truncated ends squeeze release rod so as to push release rod against closed end of holder strip thus pushing male and female strips out of holder strips.

21. The device of claim 16, further including,

- a. a tension adjustor in the shape of a six-sided box cut in two halves across the sides parallel to the ends of the box with the two halves held together on one side by a hinge and on the opposite side by a clasp and clasp button that may be closed on each other when the box is placed in the closed position.
- b. the area within each half of tension adjustor is recessed with respect to box sides and friction pads are located in each,
- c. friction pads are of material having friction pre-selected to be sufficient to prevent plurality of sutures from slipping through friction pads when pressed between friction pads, but not sufficient to prevent operator from moving a suture pair by pulling a suture loop individually,
- d. the length of tension adjustor, from hinge to clasp, is pre-selected to be somewhat greater than the width of plurality of sutures, the width being less than the length and the thickness less than the width, with thickness being on the order of 2-5 mm.

whereby length of tension adjustor when placed across plurality of sutures and locked by placing clasp button in clasp, plurality of sutures are held between friction pads where the fit and friction of friction pads is such that tension adjustor holds sutures in place thus allowing operator to hold tension adjustor rather than the more awkward outboard legs and foot.

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专利名称(译)	血管内缝合装置，用于同时放置具有理想间距的3-7缝合线，以封闭包括钙化的血管中的大开口		
公开(公告)号	US20130178872A1	公开(公告)日	2013-07-11
申请号	US13/374779	申请日	2012-01-11
[标]申请(专利权)人(译)	施莱佛EDGAR LOUIS		
申请(专利权)人(译)	施莱佛，EDGAR LOUIS		
当前申请(专利权)人(译)	施莱佛，EDGAR LOUIS		
[标]发明人	SHRIVER EDGAR LOUIS		
发明人	SHRIVER, EDGAR LOUIS		
IPC分类号	A61B17/04		
CPC分类号	A61B17/0057 A61B2019/307 A61B17/0469 A61B17/0482 A61B17/0485 A61B17/0487 A61B17/0625 A61B2017/00557 A61B2017/00663 A61B2017/047 A61B2017/0472 A61B2017/0474 A61B2017/0475 A61B2017/0488 A61B2017/0496 A61B2017/06042 A61B17/0467 A61B2090/037		
其他公开文献	US8702730		
外部链接	Espacenet USPTO		

摘要(译)

进入容器开口的中心板将其扩展到狭缝。穿过中心板宽度的槽中的针对在容器内以约2mm的间隔。在两对之间推动楔形或桥接线在狭缝的自由边缘的任一侧上扩展约1mm的针鼻。缝线环末端连接到每对。舷外板在中心板的两侧各有一条腿，每条腿上有一只脚，位于船外切口的两侧。每只脚的针鼻罩直接与针鼻相对。操作者转动螺钉将针鼻穿过血管壁克服钙化血管中的阻力，并且外壳通过棘爪保持针鼻。从身体上移除装置会使缝合线末端在缝隙环外穿过狭缝，成为理想的2×2模式。替代构造提供了连接和切割缝合线端部的装置，其中预成形的结与夹子一起滑动到开口或夹紧端。

