

[54] **HEMOSTATIC VASCULAR CUFF**

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[51] Int. Cl. A61b 17/12

[58] Field of Search 128/325, 326, 327, 128/337, 334 C, 303 A, 346, 89, 79

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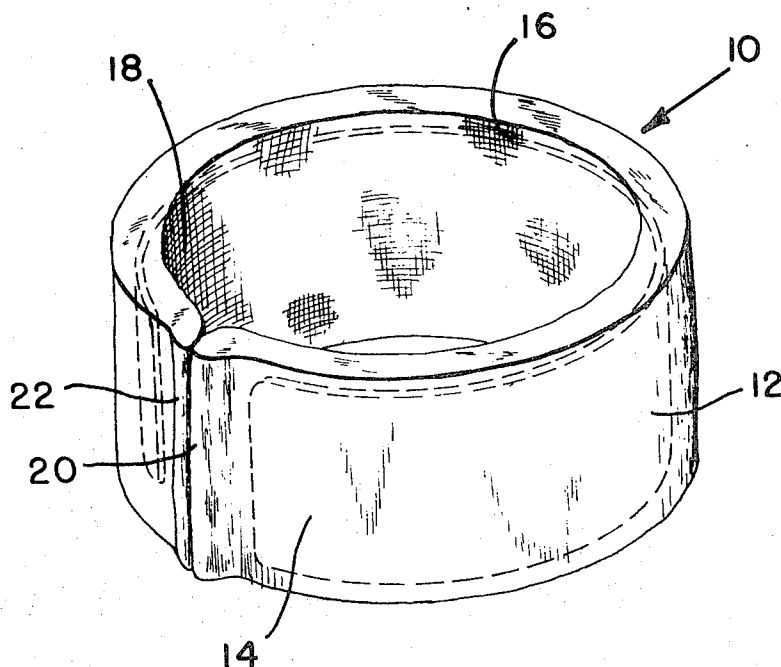
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[57] **ABSTRACT**

A hemostatic vascular cuff for controlling hemorrhage to induce tissue healing and reinforcing vessel walls embodying preferably an open section and resilient annulus which is non-reactive to biological tissues. The cuff can be constructed to encircle and remain secured to blood vessels and organs during expansion and contraction and yet continually exert gentle pressure thereagainst. The cuff may be provided with an inner antiskid surface for contact with slippery vessel or organ walls and may be further secured about the vessel or organ by connecting the free ends of the annulus with dissolvable sutures or other suitable means.

3 Claims, 10 Drawing Figures



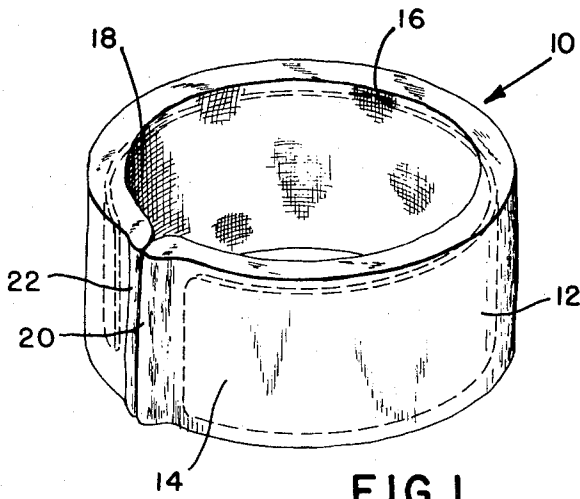


FIG. 1

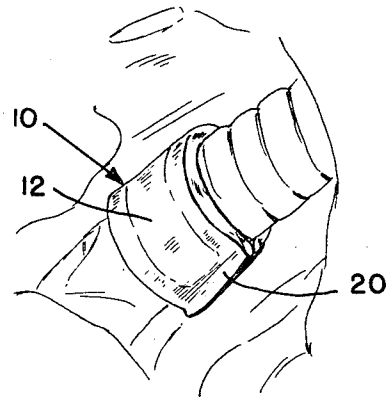


FIG. 2

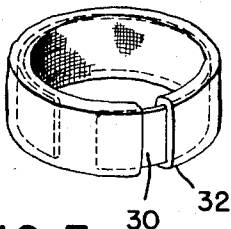


FIG. 3

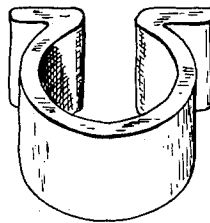


FIG. 4

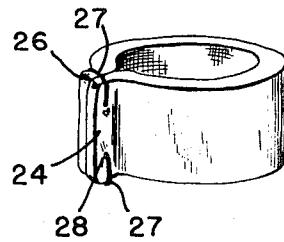


FIG. 5

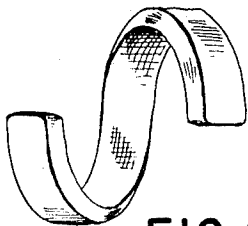


FIG. 6

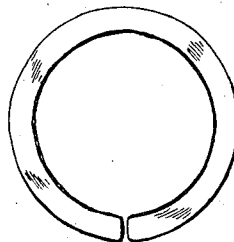


FIG. 7

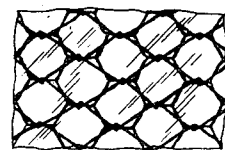


FIG. 8

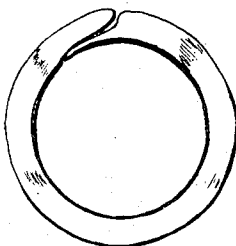


FIG. 9

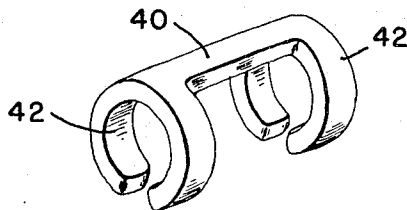


FIG. 10 BY

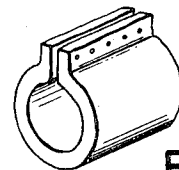


FIG. 11

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HEMOSTATIC VASCULAR CUFF

BACKGROUND, BRIEF SUMMARY AND OBJECTIVES OF THE INVENTION

Difficulties have long been experienced in controlling hemorrhage after vascular surgery because vessel walls do not coact and mend readily. Where vessels have been sliced or cut and sutured, blood leakage is very difficult to control particularly since the stitches along the suture line tend to pucker and thus gap open and permit blood seepage.

It is oftentimes desirable to reinforce vessel walls along an old closed suture line or when the vessel tissue is weak. Failure to take such precautions can result in subsequent vessel rupture.

Conventional techniques to control the numerous jets and seepage of blood passing between and about sutures include placement of packing or direct digital pressure until clotting occurs. This, of course, increases operative time and blood loss in high-risk patients. Additionally, subsequent hemorrhage may occur from such areas.

The present invention is a hemostatic vascular cuff formed of a resilient material which is non-reactive with and non-disruptive to biological tissues and which is positioned to encircle the anastomosis temporarily or permanently in such a way as to control the suture line blood seepage problem.

The cuff consists preferably of an open section annulus having a body portion constructed preferably, but not necessarily, of silicone rubber, a good material because of its non-reactivity. Resilience may be induced by a semi-rigid core within the silicone rubber body portion. The ends of the open cuff may be slightly everted and joined by sutures if more retentive characteristics are necessary. This design feature also relieves the high local pressures which may be exerted on the vessel walls by straight-cut ends. The inner surface of the cuff may be provided with slippage resistant means such as Dacron fabric which provides an antiskid surface for contact with vessel or organ walls.

Other cuff designs include a convoluted embodiment capable of completely encircling the vessel without additional securing means, a substantially flat embodiment especially suited for longitudinal vascular sutures and a substantially linear embodiment suited to be wrapped and secured about a vessel.

The cuff may be used on a variety of vessel or organ suture lines, and its natural resilience allows it to expand and contract with the pulsations of the vessel or organ which it encircles while still providing constant pressure on the suture line. This resilience also permits the cuff to remain in position for long periods of time without erosion of the vessel wall as might otherwise occur if a more rigid device were used. Extra pressure may be temporarily achieved by tightening the cuff using sutures or other equally acceptable means. The duration of increased pressure may be limited by using absorbable sutures or cuff material.

It is therefore an object of the present invention to provide a hemostatic vascular cuff for preventing or controlling bleeding about vascular suture lines.

Another object of the present invention is to provide a vascular cuff of the type described which is designed for short-term or long-term implantation within a patient and as an acute operative device.

Yet another object of the present invention is to provide a vascular cuff of the type described which is designed to encircle a vessel or organ and exert constant pressure to control vessel hemorrhage.

Yet still another object of the present invention is to provide a cuff of the type described having antislippage means included along its inner, vessel-engaging surface.

A further object of the present invention is to provide a cuff of the type described which can function to reinforce previously sutured or weakened vessel walls.

Yet still another object of the present invention is to provide a cuff of the type described which may be made to conform to suture lines where bleeding is to be controlled.

These and other objects of the present invention will become more apparent after a consideration of the following detailed specification taken in conjunction with the accompanying drawings wherein like characters of reference designate like parts throughout the several views.

FIGURE DESCRIPTION

FIG. 1 is a perspective view of the hemostatic vascular cuff embodying the present invention showing the annulus and its interior slippage resistant surface.

FIG. 2 is a perspective view of the hemostatic vascular cuff embodying the present invention in position on a vessel suture line.

FIG. 3 is a perspective view of an alternative embodiment of the cuff constituting the present invention utilizing an external sleeve movable over a resilient annular core.

FIG. 4 is a perspective view of another embodiment of the cuff comprising the present invention suitably shaped to partially encircle a vessel for those applications where circumferential encirclement is not desired.

FIG. 5 is a perspective view of yet another embodiment of the cuff comprising the present invention having pronounced everted annular ends adapted for securement by sutures or other suitable means.

FIG. 6 is a perspective view of yet still another embodiment of the cuff comprising the present invention which has a spiral configuration adaptable for positioning on oblique vessel suture lines.

FIG. 7 is a plan view of the cuff illustrated in FIG. 1 showing the positioning of the inner slippage resistant material.

FIG. 8 is an enlarged plan and fragmentary view of an antiskid material such as Dacron mesh material which can be joined to the inner surface of the annulus.

FIG. 9 is a plan view of a convoluted embodiment of the cuff comprising the present invention which completely encircles the vessel.

FIG. 10 is a perspective view of another embodiment of the cuff comprising the present invention which is particularly adapted for use with longitudinal vascular sutures.

DETAILED DESCRIPTION OF THE DISCLOSURE

Referring now to the drawings and particularly to FIG. 1, the hemostatic cuff comprising the present invention is shown generally as 10 and is fabricated in preferred form from an open section annulus 12 having

a body portion formed from a material which is non-reactive to biological tissues such as silicone rubber. The annulus 12 may be held to a generally circular configuration by a core 14 preferably formed within the body portion and from a resilient material such as nylon or polypropylene. The annulus formed is thus suitable to encircle and remain secured to blood vessels and organs since the resilience achieved from the core 14 or by utilizing the natural properties of the rubber generally permits the expansion and contraction caused by pulsations of the encircled vessel or organ while still providing a constant and gentle pressure thereagainst.

Because the arterial and vessel walls are slippery, it is sometimes advantageous to provide the inner surface 16 of the body portion of the annulus 12 with some means to resist slippage once the cuff is positioned for use. A lining 18 of an antiskid material such as Dacron mesh (FIG. 8) may be used to enhance the frictional characteristics of the cuff. Certainly a number of other materials such as Teflon, silicone or the like can be used as an interface to regulate and maintain the cuff's position, and it is possible to corrugate or groove the inner face of the annulus body portion to overcome slippage without using a separate lining.

the annulus 12 may be formed with slightly everted ends 20 and 22 which may be contiguous with each other when the cuff is positioned about a vessel or organ. These ends may be used to hold sutures that further contain or regulate pressure of the cuff about the vessel wall, and this design feature is effective to relieve the high local pressures which may be exerted on the vessel wall by cuffs having straight-cut ends. A more pronounced illustration of this design is shown in FIG. 5 wherein the everted ends 24 and 26 may be held together by sutures 27, medical adhesives or other suitable means. Additionally, suturing eyelets 28 can be provided for chronic applications.

A very successful construction is achieved by placing a polypropylene pre-shaped resilient core between two layers of Dacron mesh sleeving and filling the remaining air space inside the sleeving with silicone rubber. The outside of the core and sleeving is then covered and shaped with additional silicone rubber. Obviously the cuff normally has a substantially circular configuration, but as the application requires, it can be shaped ovaly, spirally, angularly or substantially linearly as desired. FIGS. 4, 6 and 7 illustrate various configurations attainable with the present inventive concept.

Another variation of cuff design is shown in FIG. 3 wherein a resiliently shaped core 30 is covered by flexible tubing 32 in such a way that the tubing will be movable to close the open section of the core and form a completely closed circular cuff. This embodiment obviously eliminates the need of any suture or other end-securing means to regulate the attachment and pressure of the cuff about the vessel.

A further variation in cuff design is shown in FIG. 9 wherein a convoluted and tapering body portion 34 permits a total encirclement of a vessel without the need for additional means to secure the ends 36 and 38 of the cuff together. The natural characteristics of the silicon rubber can be used in this embodiment by heat treatment to maintain the cuff in a vessel-encircling configuration.

One additional design variation is shown in FIG. 10 wherein a cuff having substantially flat portions 40 and terminal vessel-encircling portion 42 has been particularly fabricated for use along longitudinal vascular sutures. In many instances, vascular surgery is required to remove clots or other foreign bodies, and the most convenient incision in those instances is one made parallel to the axis of the vessel. This cuff design is very well suited to control hemorrhage and reinforce the vessel wall along the suture line of such incisions.

Other areas of application for this invention include reinforcing the walls of diseased or damaged vessels with appropriate cuff designs, fabricating the cuffs from radio opaque materials to permit X-rays to be made, and premedicating the cuffs with antibiotics, anticoagulants or other medications which expedite the healing process.

Because of the importance of the present invention in preventing continued bleeding from vascular suture lines, laboratory results have indicated that it is acceptable for long-term implantation and perhaps permanent securement about the damaged vessel. A spongy sheet of tissue forms around the cuff, and no deleterious effects have been observed from long-term implantation experiments.

Several embodiments of a hemostatic vascular cuff have been described in detail, and it is obvious that the many designs of suitable cuffs could be built of varying sizes depending upon the requirements of a particular application. Materials having varying degrees of resiliency and texture can be used interchangeably in the present inventive concept, and sheets or tubes of suitable material could be provided at the time of surgery so that a cuff of sufficient size and shape would be available when needed. Such changes in design and materials in the construction of the cuffs disclosed are contemplated and are considered to be within the claimed inventive concept.

We claim:

1. A hemostatic vascular cuff for reinforcing the sutured junction line of the two free abutting ends of a severed blood vessel and controlling hemorrhage to induce coactive tissue healing therealong comprising: an annulus having an annularly shaped substantially flat core of semi rigid material, and a body portion of softer, resilient material enveloping said core, said body portion adapted to contiguously and at least partially encircle the sutured junction line of the two vessel abutting ends and said core also having resilient properties which permit expansion and contraction of said core and said enveloping body portion while exerting constant and uniform pressure along the junction line as the vessel pulsates without damage to the vessel wall; and means integrally associated with the vessel contacting portion of said annulus body portion to resist slippage thereof along the exterior surface of the sutured vessel abutting ends, said annulus body portion having a substantially uniform and linear width sufficient to cover completely the width of the encircled sutured junction line and thereby discouraging hemorrhaging therealong.

2. The hemostatic vascular cuff as claimed in claim 1 wherein said core and said body portion are movable relative each to the other so that said body portion and said core completely encircle the sutured junction line.

3. The hemostatic vascular cuff as claimed in claim 1 wherein said core is formed of nylon and said body portion is formed of silicone rubber.

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