

United States Patent

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[73]	Assignee	New Research and Development Laboratories, Inc.
Continuation-in-part of application Ser. No. 473,055, July 19, 1965, now Patent No. 3,446,212.		

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[54] HEMOSTATIC CLIP
6 Claims, 17 Drawing Figs.

[52] **U.S. Cl.**..... **128/325,**
24/255, 128/346

[51] **Int. Cl.**..... A61b 17/08,
A61b 17/12

[50] **Field of Search**..... 128/325,
334, 335, 337, 346; 24/255

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ABSTRACT: A hemostatic clip is in the form of a tubular body member having a longitudinal slit extending completely across the body for receiving a wound flap when the body is distended from its original shape. A pair of projections are on the body member joined to the body member along a longitudinal line disposed about 90° from the slit to act as convenient means for distending the body from its original shape when external force is applied to the projections.

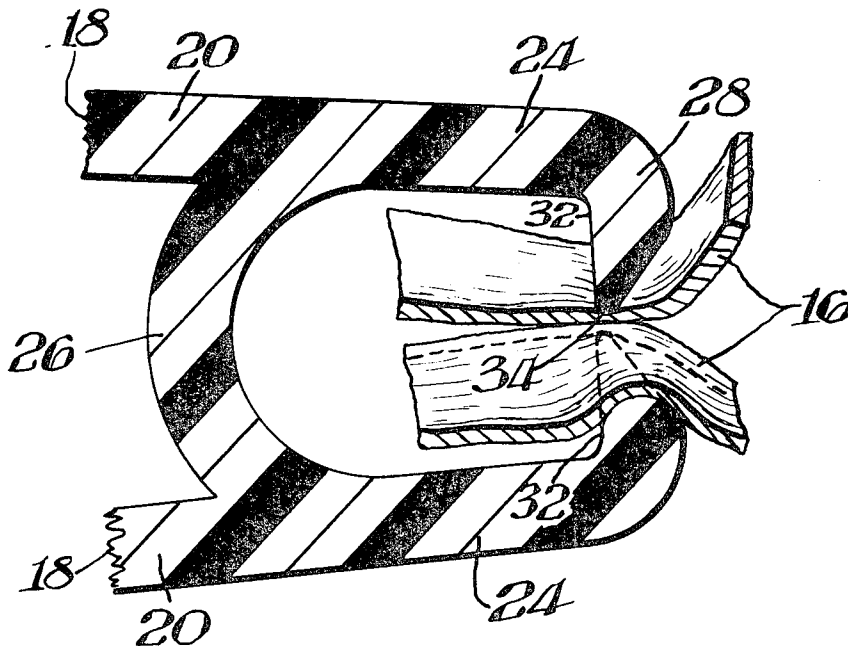


Fig. 1.

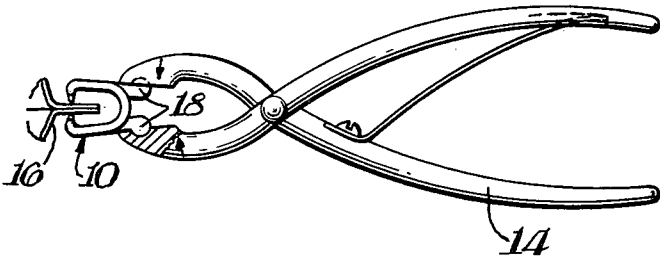


Fig. 2.

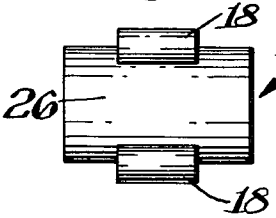


Fig. 3.

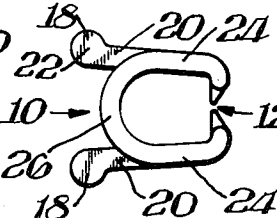


Fig. 4.

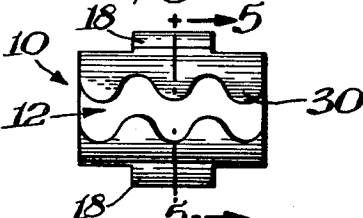
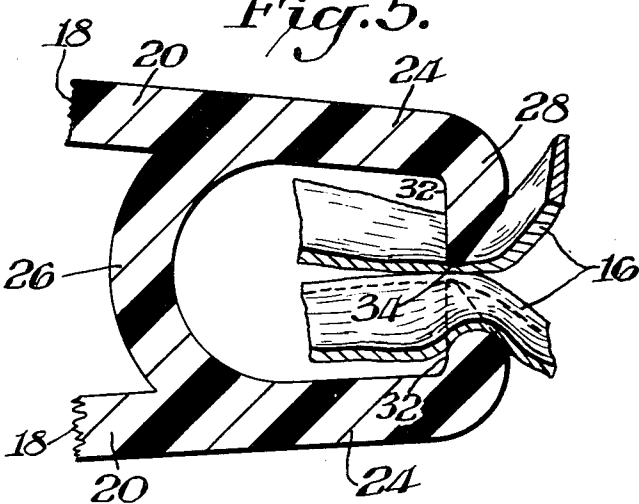
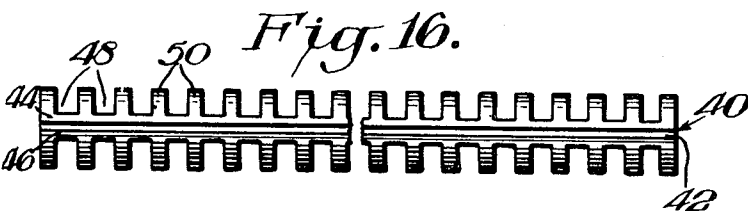
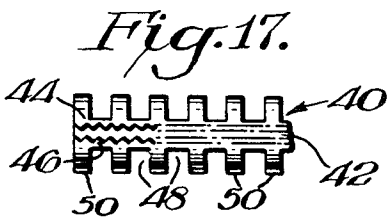
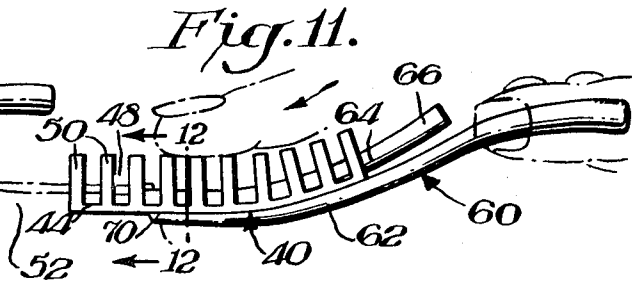
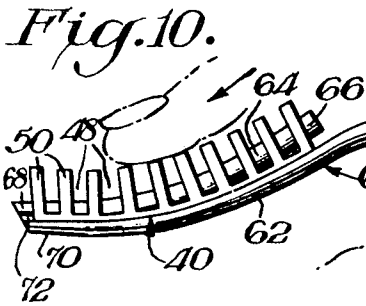
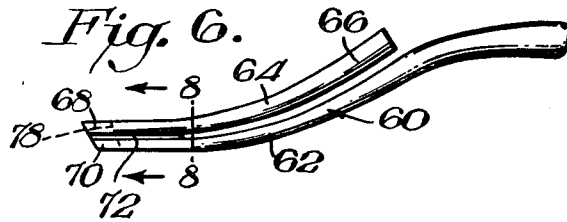
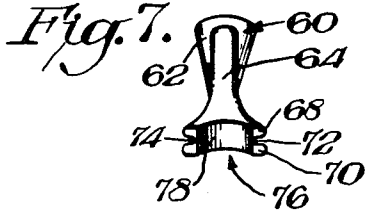


Fig. 5.





HEMOSTATIC CLIP

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of copending application Ser. No. 473,055, filed July 19, 1965, now U.S. Pat. No. 3,446,212 issued May 27, 1969.

BACKGROUND OF INVENTION

This invention relates to hemostatic clips for use in clamping wound flaps to prevent the flow of blood from severed arteries, capillaries and the like.

Applicant's patent previously referred to describes and claims a highly successful hemostatic clip which is inexpensive, easily sterilized so that it can be prepackaged, disposable, adapted to be made in a variety of dimensions and can be easily applied and removed by a relatively unskilled worker. The clip disclosed in that application is essentially a tubular member having a slit completely across its body so that it can be distended from its original shape to receive the wound flap therein. As particularly disclosed in the parent application the tubular body can be distended from its original shape because of the provision of a pair of parallel slots which are disposed about 90° from the longitudinal slit whereby a plierslike applying tool can be inserted into the slots and upon application of force thereto the longitudinal slit will be spread apart to receive the wound flap.

SUMMARY OF INVENTION

An object of this invention is to provide a modified form of the above-type clip which still retains all of its advantages.

In accordance with this invention a pair of projections are disposed on the body instead of the parallel slots. The projections are connected to the body along longitudinal lines which are similarly disposed about 90° from the wound flap receiving slit. When force is applied to the projections they act as levers to spread the longitudinal slit and facilitate the insertion of the wound flap therein.

Advantageously, each projection includes a stem portion connected to the clip body and an enlarged head portion on the stem. The body may be horseshoe shaped to accommodate a greater portion of the wound flap. Furthermore the body may terminate in flanges which are perpendicular to the leg sections of the horseshoe and which have parallel undulations to provide greater traction of the wound flap while minimizing tissue damage and pain.

In another form of this invention the body is provided with a plurality of parallel peripheral slots which terminate adjacent the wound flap receiving slit whereby a longitudinal margin is formed on each side of the slit to provide stability and to control flexibility of the body. Such a clip has the advantages of greater visibility, ventilation and drainage of the wound flap and can be utilized for clamping relatively long wound flaps.

THE DRAWINGS

FIG. 1 is a side view in elevation and partly in section showing a clip applied to a wound flap in accordance with one aspect of this invention;

FIG. 2 is a top plan view of the clip shown in FIG. 1;

FIG. 3 is a side view of the clip shown in FIGS. 1-2;

FIG. 4 is a bottom plan view of the clip shown in FIGS. 1-3;

FIG. 5 is an enlarged view taken through FIG. 4 along the line 5-5 and showing the clip clamping against a wound flap;

FIG. 6 is a side view of an applicator in accordance with another embodiment of this invention;

FIG. 7 is a front view of the applicator shown in FIG. 6;

FIG. 8 is a cross-sectional view taken through FIG. 6 along the line 8-8;

FIG. 9 is a plan view of a portion of the applicator shown in FIGS. 6-8;

FIGS. 10-11 are side views of the applicator and its clip in different phases of operation;

FIG. 12 is a cross-sectional view taken through FIG. 11 along the line 12-12;

FIGS. 13-15 are front, top and side views, respectively, of the clip shown in FIGS. 10-12; and

FIGS. 16-17 are side views of modified clips in accordance with this invention.

DETAILED DESCRIPTION

FIGS. 1-5 show a clip in accordance with one embodiment of this invention. As indicated therein clip 10 is generally of tubular form in that it is in the shape of a hollow body open at both ends. The clip can be constructed from any material possessing the required elastic modulus and physical properties. Nylon tubing for example as well as Delrin, Teflon polyethylene, polypropylene and other suitable polymers and/or plastics are particularly adapted for this invention. Additionally, thin metal tubes or other alloys are also suitable. The tubular body can be formed into a circular, rectangular, triangular, square, elliptical or other adaptable cross section having the appropriate physical properties and being clinically acceptable. As illustrated in the drawings, however, the tubular body is advantageously of generally horseshoe shape to increase its wound-flap-receiving capability.

Clip 10 may be of any desired length required by the specific purpose to which it is to be used. Some advantageous lengths for example are one-fourth, one-half, and 1 inch, with the longer length being suitable for large wound flaps.

Clip 10 includes a longitudinal slit 12 across its entire length so that it can be distended by for example any suitable applicator 14. Upon being distended the slit 12 is spread apart whereby the wound flap 16 can easily be inserted therein. Upon release of force from the applicator the slit edges are then applied to the two sides of wound flap 16 or other tissue to prevent the flow of blood from severed arteries, capillaries or the like. At approximately 90° to the longitudinal slit 12 are two parallel projections 18, 18 which are longitudinally centered on the clip body. Each projection includes a stem portion 20 which, as best shown in FIG. 5, is integral with the clip body and is tangential thereto. Stem 20 actually forms an extension of the leg sections 24 of the horseshoe-shaped clip body. Stem 20 terminates in an enlarged arcuate head 22 to facilitate the reception of applicator tool 14 thereon. Projections 18 extend at least one-third of the length of the clip body to provide a sufficient area for the reception of applicator 14.

As best shown in FIG. 5 the clip body is horseshoe shaped having an arcuate bridging section 26 between projections 18 with the straight leg sections 24 connected to the bridging section. Leg sections 24 terminate in substantially perpendicular flanges 28 which are spaced from each other to form the slit 12. The flanges 28, as shown in FIG. 4, terminate in parallel undulations 30 disposed generally parallel to the longitudinal axis of the clip body with the sinusoidal teeth being generally parallel and having gently merging hills and valleys. As shown in FIG. 5 the undulations taper in a converging direction toward the slit with the inner surfaces 32 of the flanges 28 being coplanar and with the flanges terminating in blunt or rounded ends 34. This particular configuration of slit 12 is particularly effective in providing sufficient traction to the wound flap while minimizing any pain thereto or undue damage to the tissue.

Clip 10 can be easily and rapidly removed either with applicator 14 or by hand. Manual removal is accomplished by squeezing projections 18 toward each other so that the projections act as levers to spread flanges 28 away from each other. The clip 10 can then be merely slipped off the wound flap 16 without noticeable damage to the tissue. Additionally, no special training is necessary for the scrub nurse, assistant, or surgeon in applying or removing clips 10.

Other advantages of clip 10 are that it can be sterilized by either the flash or routine method employing high pressure and high temperature. Clip 10 can also be sufficiently inexpensive to be disposable and thus packaged in presterile units.

When desired or necessary, however, clips 10 can be reused. Even if the clips are unduly abused by, for example, being dropped, the clips show no structural fatigue or cracks and maintain their elastic state to a high degree.

Correspondingly, the operative maintenance of applicator 14 is minimal. Applicator 14 may for example be made of a metal which can be autoclaved and handled without any unusual difficulty.

Advantageously, clip 10 may incorporate an X-ray or radiopaque material such as barium sulfate. Accordingly, the clip can be easily located if it should be "lost" within the operative site. Additionally, a bacteriostatic material may be used for clip 10. Accordingly, items such as iodinated compounds and an alpha or a low energy beta emitter may be added.

As indicated above clip 10 has proven to be exceptionally effective. For example, its ease of application, the lack of tissue irritability, the ease of adjustment, and the rapid removal enable the surgeon to move more quickly on entering the operative field. Clip 10 is particularly effective with scalp and back wounds, and can also be advantageously used on abdominal or long flap wounds as may be necessary in extremity work. Moreover, the gentleness with which the blood vessels are compressed and the lack of tissue irritability are especially notable.

FIGS. 6-17 illustrate another clip 40 formed in accordance with this invention. Clip 40 is for example made of a disposable plastic material or materials previously enumerated with respect to clip 10. Clip 40 is of extended or continuous length, being at least 10 inches long, so that it can be cut to the desired size for individual application. Additionally, clip 40 is specifically designed to provide maximum ventilation and drainage of the wound as well as increased visibility thereof.

As indicated most clearly in FIGS. 13-15, clip 40 is of tubular form having a suitable wall thickness and a continuous elongated longitudinal slit 42. Clip 40 may be of any length such as the medium-size clip as indicated in FIGS. 14-15 or the extra-long clip shown in FIG. 16. The border or margin on each side of slit 42 forms a pair of elongated longitudinal backbones 44 and 46. Additionally, clip 40 includes a plurality of parallel-spaced peripheral slots 48 which are separated by ribs 50 spanning backbones 44 and 46. The provision of these perforations or slots 48 not only provides visibility, ventilation, and drainage of the wound flap 52 (FIG. 11), but also permits the delicate adjustment of a balance between the clamping strength and ease of application of clip 40. The thickness of backbones 44 and 46 determines the flexibility of clip 40 and its ability to conform to any wound configurations. Thus clip 40 can be applied in a bent or curved manner, as well as in a relatively straight line.

Although slots 48 are an exceptionally effective manner of forming perforations in clip 40 it is also possible to form the perforations in other ways, as long as the perforations permit flexibility, adequate clamping force, and visibility of the wound.

One modification of clip 40 is shown in FIG. 17 in which backbones 44 and 46 are serrated along slit 42 to provide more positive traction on the wound flap.

FIGS. 6-12 illustrate the applicator 60 which is particularly adapted for clips 40. As indicated therein, applicator 60 is made of two parts. One part 62 is a relatively long support rod, one end of which may be conveniently held and used as a handle as shown in FIG. 15. The second member or part is guide rod 64. Guide rod 64 includes a feed end 66 and a discharge end 68. Discharge end 68 is secured to the remote end 70 of support rod 62 to form the dispensing end 76 of applicator 60. Members 62 and 64 are made, for example, in the form of flattened tubular elements as best shown in FIG. 16. Accordingly, a pair of grooves 72 and 74 are formed at the juncture of discharge end 68 and remote end 70. As shown in FIGS. 7 and 9 dispensing end 76 of applicator 60 tapers or widens outwardly. Thus the distance between grooves 72 and 74 also increases.

In use the tubular clip 40 is inserted around feed end 66 of guide member 64 as shown in FIG. 10. Since feed end 66 is spaced from support rod 62, clip 40 can easily be loaded around guide rod 64. Applicator 60 is then brought into the vicinity of wound flap 52. Advantageously, dispensing end 76 of applicator 60 is concave and tapered to act as a registry means for wound flap 52 so that wound flap can be inserted in the concave portion 78 and maintained in position for the application of clip 40 as most clearly shown in FIG. 15. Additionally, this registry is facilitated by the tapered end of applicator 60 in which guide member 64 projects slightly beyond support member 62.

After wound flap 52 has been brought into registry in tapered concave portion 78 clip 40 is slid down guide member 64. The end of clip 40 is open or distended by the outwardly tapering dispensing end 76 of applicator 60. Accordingly, clip 40 is simply progressively slid off applicator 60 in an open position onto flap 52.

Applicator 60 which is made of a clinically acceptable material such as steel or other metal or plastic, and can easily be held in either hand with the clip 40 being advanced by the thumb of the other hand. When the required length of clip 40 has been applied to wound flap 52, the excess clip can be cut off by, for example, a scissors. Clip 40 can thereby be easily applied in a simple sweeping fashion. Thus for example for the first time a large area can be clamped by employing two large continuous hemostatic clips 40 by using only two maneuvers, in contrast to the multiple repeated maneuvers which have been required with conventional small clamps. In addition to the above noted advantages of ease of application and removal of clip 40, the clip also renders the operative area free of clutter.

For removal, clip 40 can be fractionally withdrawn from wound flap 52 to allow for surgical closure by interrupted sutures for controlling hemostasis and approximation of tissue planes. This can be done manually, without requiring an instrument, as is ordinarily necessary for conventional clips. Alternatively, the clip 40 can be removed in one sweeping motion, if necessary, rather than fractionally or with the conventional multiple actions.

I claim:

1. A hemostatic clip comprising a body in the form of an elongated tubular element, said tubular element having an ellipsoidal cross section, wound-flap-engaging means on said body, said wound-flap-engaging means being an elongated longitudinal slit extended completely across said body whereby said body may be distended from its original shape, a pair of outwardly extending projections connected to said body remote from said slit for accommodating a force-applying tool, said body being resiliently urged to maintain its original tubular shape whereby the original tubular shape of said body may be distended upon application of force to said projections to cause said slit to widen and permit the insertion of a wound flap therein and said body will return toward its original undistended tubular shape upon cessation of the application of force for firmly engaging the wound flap, said slit being defined by a pair of longitudinal edges, and said edges being shaped as sinusoidal teeth having gently merging hills and valleys and wherein said teeth taper outwardly away from said edges, said teeth being defined in cross section by an inner wall disposed toward the interior of said tubular body, said inner walls of said teeth being generally aligned, and each outer wall being inclined from its edge where it merges with its inner wall outwardly away from its inner wall.

2. A clip as set forth in claim 1 wherein said body is made of a polymer material.

3. A clip as set forth in claim 2 wherein the sinusoidal curvatures of said teeth are generally parallel.

4. A clip as set forth in claim 3 wherein each of said projections is joined to said body along a longitudinal line disposed about 90° from said longitudinal slit, each of said projections comprising a stem portion connected to said body and a head portion connected to said stem portion, said stem portion and

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said head portion being of different cross-sectional widths with respect to a section line taken perpendicular to the longitudinal axis of said body to facilitate the reception of a force-applying tool thereon, and said head portion being of generally circular cross section and being solid with a greater width than said stem portion.

5. A hemostatic clip comprising a body in the form of an elongated tubular element, wound-flap-engaging means on said body, said wound-flap-engaging means being an elongated slit extending completely across said body whereby said

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body may be distended from its original shape, a plurality of parallel peripheral slots being in said body and terminating adjacent said longitudinal slit with a longitudinal margin on each side of said slit forming a thin backbone to provide stability and to control the flexibility of said body, and said body being at least 10 inches long and being axially bendable for clamping a relatively long wound flap.

6. A clip as set forth in claim 5 wherein the edges of said slit are serrated to provide positive traction on the wound flap.

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