May 27, 1969 P. L. LE ROY 3,446,212

HEMOSTATIC CLIP AND APPLICATOR THEREFOR

Filed July 19, 1965 Sheet 1 of 2

Fig. 2.

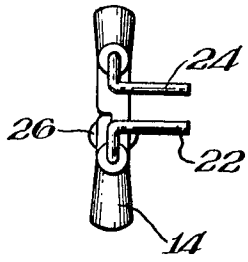


Fig. 1.

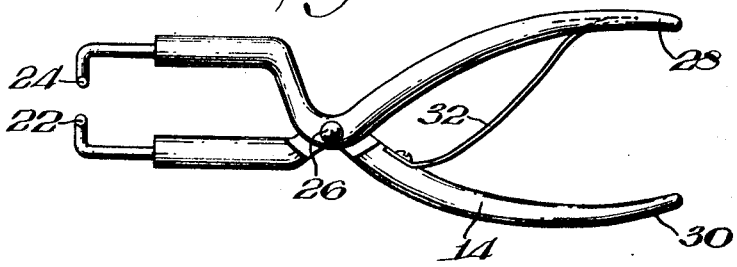


Fig. 4.

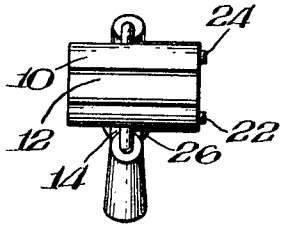


Fig. 3.

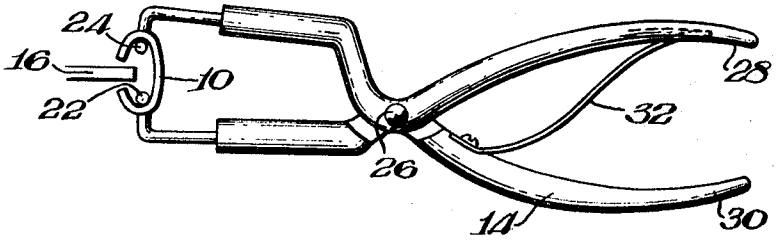


Fig. 9.

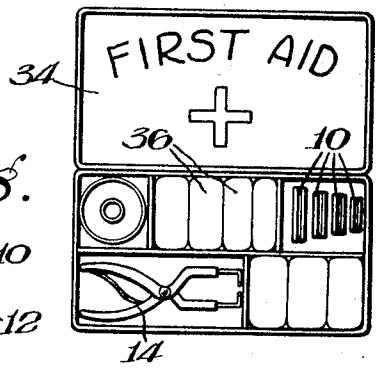


Fig. 7.

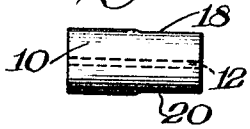


Fig. 5.



Fig. 8.

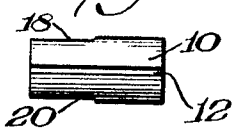
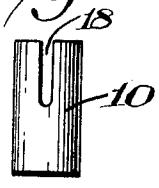


Fig. 6.



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HEMOSTATIC CLIP AND APPLICATOR THEREFOR

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Fig. 11.

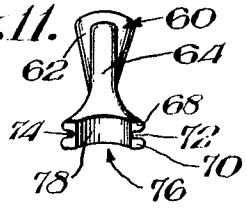


Fig. 10.

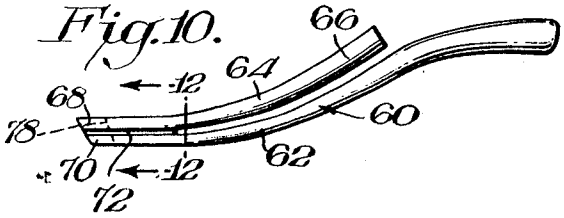


Fig. 12.

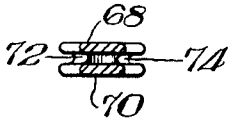


Fig. 13.

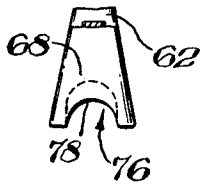


Fig. 16.

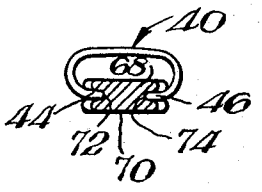


Fig. 14.

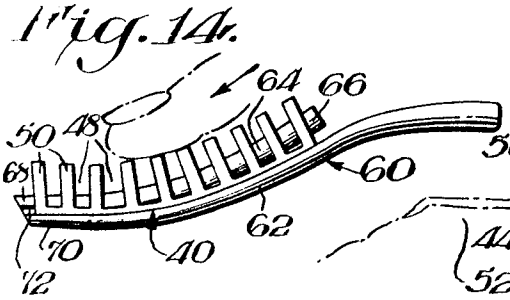


Fig. 15.

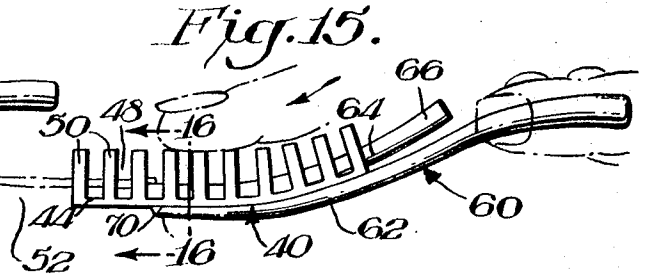


Fig. 21.

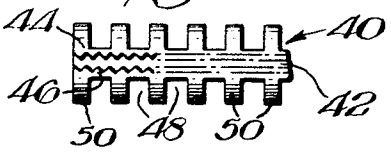


Fig. 18.



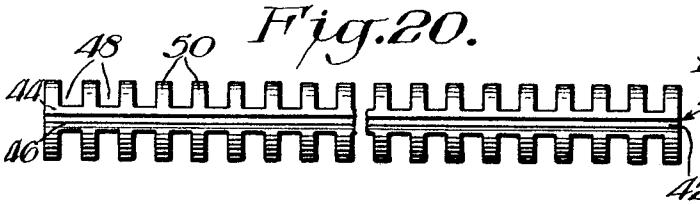
Fig. 17.



Fig. 19.



Fig. 20.



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3,446,212

HEMOSTATIC CLIP AND APPLICATOR THEREFOR

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Int. Cl. A61b 17/12
U.S. Cl. 128—325 7 Claims

ABSTRACT OF THE DISCLOSURE

A hemostatic clip includes a tubular body having an elongated slit extending completely thereacross with a pair of diametrically opposed slots extending from the end of the body inwardly, substantially halfway across the body. The slots are also disposed approximately 90 degrees from the longitudinal slit. A pivoting forceps type applicator is also provided for operatively placing the clip onto body wounds.

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

One of the most important considerations in an operation is the element of time. With conventional hemostatic clips the operative time is frequently prolonged because of the tedious procedures involved in applying and removing these clips. It is therefore very desirable to minimize the time of clip application and removal. This consideration is even more important during long operations such as the closing of a scalp wound, or in wartime when it is essential to free technical personnel to maximize their efficiency.

An object of this invention is to provide a hemostatic clip which is inexpensive, easily sterilized so that it can possibly be pre-packaged, disposable, adaptable to be made in a variety of dimensions to accommodate a wide range of applications, and can be easily applied and removed by a relatively unskilled worker.

A further object is to provide such a clip which is of the continuous type whereby it may be cut to any desired length.

A still further object is to provide such a clip which is provided with means for visibility, ventilation and drainage of the wound flap.

An additional object is to provide applicators for the above type clips.

In accordance with this invention the hemostatic clip is in the from of an elongated tube having a longitudinal slit so that the tube may be distended from its original shape to permit a wound flap to be inserted into the slit.

In one form of this invention, the clip has a pair of parallel slots extending partially across its tubular body and disposed approximately 90° from the longitudinal slit. The applicator for this clip is advantageously a pliers or reverse acting forceps type device in which its tip portions are parallel to each other and normally spaced from each other a distance equal to the diameter of the clip. Accordingly, the tips of the applicator may be conveniently inserted in the pair of clip slots and the clip may be distended or spread by manipulating the applicator to spread its tips apart.

In another advantageous form of this invention the clip is of the continuous type which is particularly adapted for disposability, as well as visibility, ventilation and drainage of the wound. In this form of the invention, the longitudinal margin of the tubular body on each side of its longitudinal slit forms a pair of elongated backbones. The remainder of the body is peripherally slotted with parallel spaced ribs spanning the backbones. Accordingly,

the peripheral slots provide the beneficial visibility, ventilation and drainage of the wound.

The applicator for the continuous type clip is in the form of a support rod having a guide member secured at one end thereto. The continuous hemostatic clip is slid on the free or feed end of the guide member toward its discharge end. A pair of grooves at the junction of the discharge end of the guide member and the support rod provides a convenient track for the clip. The distance between the grooves increases toward the dispensing end of the applicator. Accordingly, as the clip is slid off the dispensing end, its longitudinal slot is spread apart. Advantageously, the dispensing end of the applicator may be concave and tapered for receiving the wound flap and registering it with the clip so that the clip is accurately slid on the wound flap. When the desired length is applied to the wound flap, the clip is cut to that length and the remainder of the clip may be used in another location.

The above type clips may advantageously be made of a disposable platic material, and both the clips and the applicators can for example be packaged in a first-aid kit. The clips may also incorporate an X-ray or radiopaque material to easily locate the clips should they be "lost" within the operative site.

Novel features and advantages of the present invention will become apparent to one skilled in the art from a reading of the following description in conjunction with the accompanying drawings wherein similar reference characters refer to similar parts and in which:

FIG. 1 is a side view in elevation of an applicator in accordance with one embodiment of this invention;

FIG. 2 is a front view of the applicator shown in FIG. 1;

FIGS. 3–4 are a side view and a front view, respectively, of the applicator shown in FIGS. 1–2 in one phase of operation;

FIG. 5 is a front view of the clip shown in FIGS. 3–4;

FIG. 6 is a top view of the clip shown in FIG. 5;

FIGS. 7–8 are side views of the clip shown in FIGS. 5–6;

FIG. 9 is a plan view of a first-aid kit incorporating the applicator and clip shown in FIGS. 1–8;

FIG. 10 is a side view of an applicator is accordance with another embodiment of this invention;

FIG. 11 is a front view of the applicator shown in FIG. 10;

FIG. 12 is a cross sectional view taken through FIG. 10 along the line **12—12**;

FIG. 13 is a plan view of a portion of the applicator shown in FIGS. 10–12;

FIGS. 14–15 are side views of the applicator and its clip in different phases of operation;

FIG. 16 is a cross sectional view taken through FIG. 15 along the line **16—16**;

FIGS. 17–19 are front, top and side views, respectively, of the clip shown in FIGS. 14–16; and

FIGS. 20–21 are side views of modified clips in accordance with this invention.

FIGS. 1–8 show an applicator and clip in accordance with one embodiment of this invention. As most clearly shown in FIGS. 5–8 clip **10** is tubular in 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 steel tubes or other metal alloys are also suitable. The tubular body can for example be formed into a circular cross section (as shown in the drawings) or may have rectangular, triangular, square,

elliptical, or other adaptable cross section having the appropriate physical properties and being clinically acceptable.

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

As shown in FIGS. 5–8 clip **10** has a longitudinal slit **12** across its entire length so that it can be distended by for example applicator **14** as shown in FIGS. 1–4 to form a C. The slit edges are then applied to the two sides of a wound flap **16** (FIG. 3) or other tissue to prevent the flow of blood from severed arteries or capillaries or the like. At approximately 90° to the longitudinal slit **12** are two parallel and opposed slots **18**, **20** which are cut approximately half way along the length of the clip. Slots **18**, **20** are of sufficient width to accommodate the tips **22**, **24** of applicator **14**. Advantageously, the slots **18**, **20** are actually somewhat wider than tool tips **22** and **24** to permit easy withdrawal of tool **14** when the clip **10** is in the open C position, because of a pinching effect. In addition to the loading of the clips **10** on the applicator **14**, slots **18** and **20** also serve to properly orient clip **10** for attachment to the tissue.

It, of course, is also possible to form some other types of openings in clip **10** to accommodate applicators other than preferred applicator **14**. For example the clip can be modified to permit feeding and application by means of a magazine, or an applicator operating on a different principle than applicator **14**.

FIGS. 1–4 show the details of applicator **14**. This applicator is a pliers type or reverse acting forceps which is pivoted at its central portion **26**. As is apparent from the drawings, compression of handles **28**, **30** opens applicator **14** to spread the clips (FIGS. 3–4) prior to attachment to the wound or tissue flap **16**. Spring **32** is provided between handles **28** and **30** to maintain the applicator in the rest position shown in FIGS. 1–2. In this position the distance between tips **22** and **24** is substantially equal to the diameter of clip **10** so that the tips can be inserted into slots **18** and **20** and disposed under the unslotted portion of clip **10**. The handles **28**, **30** are of a length which is selected to provide a proper leverage ratio with respect to the applicator tips **22** and **24**, commensurate with the force required to open the resilient hemostatis clips **10**. The applicator tips **22** and **24** are of a compound right angle design being in a plane perpendicular to the lane of the remainder of applicator **14** as clearly shown in FIGS. 1–2. This design permits convenient fitting into the clip positioning slots **18** and **20**. After placing the clip over the tissue flap **16** as shown in FIG. 3, the applicator is relaxed and returned by spring **30** to its normal position with the clip being firmly secured on flap **16**. Applicator **14** is then readily withdrawn from clip **10** by reversing the charging or loading procedure.

Clip **10** has been clinically found to be very effective in a varying range of applications. For example, clip **10** has been successfully applied to wound flaps measuring ⅛ to ⅜ inch thick. The ease of application is quite notable. Additionally, when necessary, application of tool **14** is conveniently done while clip **10** is still in place bridging the wound, thus permitting adjustment of clip **10** to other positions without undue damage to either the clip or tissue. Moreover use of clip **10** on a wound has ranged for example from 1 to 4 hours and, except for the pressure imprint in the skin, clips **10** have caused no tissue irritation either on removal of the clip or on subsequent postoperative course. Furthermore there have been no allergic response to the patients on whom the clips **10** have been applied.

Clip **10** is more easily and rapidly removed either with applicator **14** or by hand than other previous conventional hemostatic clips. Manual removal is accomplished by simply grasping the greater diameter of clip **10** with the thumb and forefinger, and merely slipping the clip off the wound flap without noticeable damage to the tissue involved. 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 iodonated 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 extermity work. Morover, the gentleness with which the blood vessels are compressed and the lack of tissue irritability are especially notable.

The ease of application of clip **10** enables it to be used for example in a first-aid kit **34** as indicated in FIG. 9. Kit **34** thus includes the ordinary first-aid equipment **36** as well as applicator **14** and a set of clips **10**. Clips **10** may be all of the same size or, as indicated in FIG. 9, may vary in length. Thus a wounded person could easily self-apply clip **10** without undue difficulty or previous experience on vessels or wounds which are bleeding profusely.

FIGS. 10–21 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. 17–19, 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. 18–19 or the extra long clip shown in FIG. 20. 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 spacer 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. 15), 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. 21 in which backbones **44** and **46** are serrated along slit **42** to provide more positive traction on the wound flap.

FIGS. 10–16 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. 11 and 13 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. 14. 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 applicator 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, 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.

Obviously, many modifications and variations of the present invention are possible in the light of the above teachings. It is therefore to be understood that within the scope of the appended claims the invention may be practiced otherwise as specifically described.

What is claimed is:

1. 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 longitudinal slit extending completely across said body whereby said body may be distended from its original shape, a plurality of slots being formed in said body, said slots being a pair of diametrically opposed parallel slots extending from one end of said body to a point approximately halfway across said body, said slots being disposed approximately 90 degrees from said longitudinal slit, and 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 thereto to permit the insertion of a wound flap in said longitudinal slit and said body will return toward its original undistended tubular shape upon cessation of the application of force for firmly engaging the wound flap.

2. A clip as set forth in claim **1** wherein said body is of solid closed construction between said pair of slots.

3. A clip as set forth in claim **2** wherein said body is X-ray opaque.

4. A clip as set forth in claim **2** wherein said body is made of a disposable plastic material.

5. A clip as set forth in claim **2** wherein said body is from ¼ inch to 1 inch long.

6. A clip as set forth in claim **2** wherein the opposed edges of said longitudinal slit are serrated to provide a positive traction on the wound flap.

7. An applicator for applying a hemostatic clip to a wound flap comprising a pair of elongated arms, each of said arms having a handle portion and a tip portion separated by an intermediate portion, pivot means connecting the intermediate portions of said arms, resilient means urging said arms into a rest position with the tip portions of said arms spaced from each other, the tip portions of said arms being parallel to each other in a plane normal to the plane of the remaining portions of said arms, in combination with a hemostatic clip, said clip comprising an elongated tubular body, a longitudinal slit extending completely across said body whereby the original tubular shape of said body may be distorted upon application of force thereto, a pair of opposed parallel slits extending partly across said body approximately 90° from said longitudinal slit, the distance between said slots being approximately equal to the spacing between said applicator tip portions, said slots being at least slightly wider than said tip portions, and said tip portions being inserted into said slots disposed under the unslotted portion of said body whereby actuation of said applicator handle portions causes said longitudinal slit to spread for receiving a wound flap therein.

References Cited

UNITED STATES PATENTS

622,610	4/1899	Dudley	24—259
2,319,316	5/1943	Gerendas	24—259
2,536,145	1/1951	Tapke	128—346
2,890,519	6/1959	Storz	29—225
2,973,761	3/1961	Kohl	128—346
3,040,420	6/1962	Kulp	29—229
3,056,408	10/1962	Brown	128—325

FOREIGN PATENTS

143,841	10/1951	Australia.
164,940	6/1921	Great Britain.
464,802	7/1951	Italy.

DALTON L. TRULUCK, *Primary Examiner.*

U.S. Cl. X.R.

24—255; 29—229; 128—337, 346