

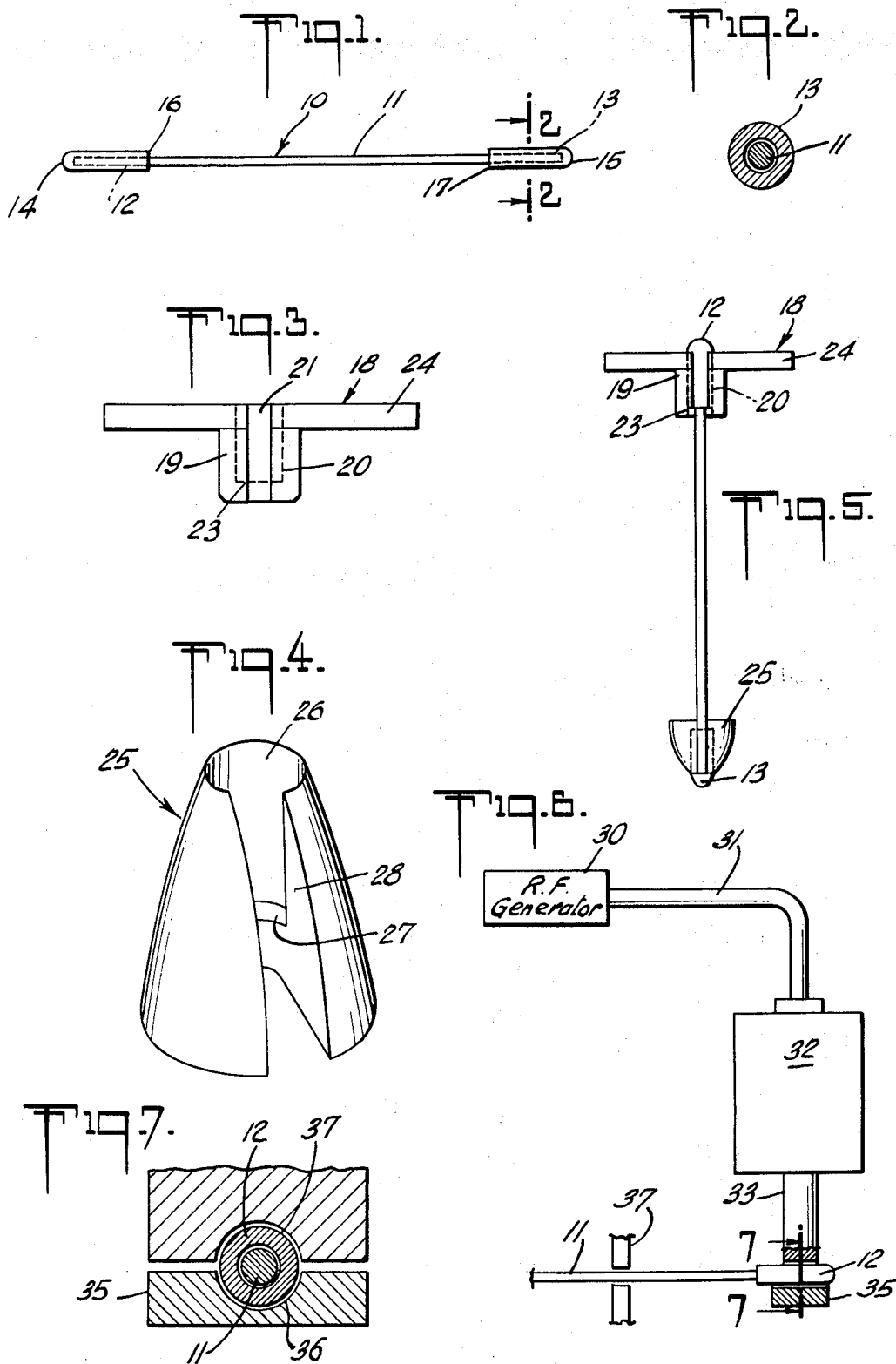
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VEIN STRIPPING INSTRUMENT

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VEIN STRIPPING INSTRUMENT

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ABSTRACT OF THE DISCLOSURE

A surgical vein stripping instrument is made by providing a length of cable formed from a monofilament of axially oriented synthetic thermoplastic material and ultrasonically welding a tubular plastic cap to each end of the cable. Each cap is smoothly rounded on its end to permit free passage of the cable through a vein and each cap is adapted to be secured to both an auxiliary bullet-shaped tip and a handle for aiding the doctor in the removal of the vein.

BACKGROUND OF THE INVENTION

This is a division of application Ser. No. 12,795, filed Feb. 19, 1970, now U.S. Pat. 3,659,606.

This invention relates to surgical instruments and, more particularly, to a disposable surgical vein stripping instrument of synthetic plastic material for performing phlebectomies, and to a method for making the instrument.

The surgical treatment of varicose veins (phlebectomy) is disclosed and illustrated in the "Atlas of General Surgery" by Joseph R. Wilder, 2d edition, 1964, published by C. V. Mosby Company (pages 240 et seq.) and in several United States patents, such as, U.S. Pat. Nos. 2,788,787 and 2,863,458. The procedure has been performed for many years and is well known to the medical profession.

Many attempts have been made to improve upon the vein stripping instrument, as exemplified by the above-cited patents, but, until recently, these efforts have been devoted to the improvement of conventional metal vein strippers.

U.S. Pat. No. 3,508,553 discusses in detail the inherent shortcomings associated with the manufacture and use of conventional metal vein strippers and discloses an improved vein stripping instrument which is made from a single molded rod of synthetic thermoplastic material. A vein stripper comprising a cable formed of a monofilament of synthetic thermoplastic material which is monoaxially oriented and a bullet-shaped guider tip integral with each end thereof is provided by clamping the ends of the relatively short molded rod and axially stretching the rod. The clamped end portions of the rod remain in the original unoriented condition and the diameter of the ends remains substantially unchanged. However, the cable portion of the vein stripper intermediate the ends becomes greatly reduced in diameter and the molecular structure becomes axially oriented to produce a high tensile pulling member. For the reasons stated in the patent application, this instrument has been found to be superior to the previously known metallic vein strippers.

Although the above-described plastic vein stripper affords numerous advantages over the prior art devices, difficulties have been encountered in providing a uniform, smooth cable portion and in obtaining a tip portion that is small enough to permit free passage through exceptionally small or constricted veins.

The cross sectional uniformity of the cable is difficult to control because the stretching of the heated rod often results in irregular reduction in the cable diameter as the

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cable increases in length. These uncontrollable reductions in diameter may result in premature failure. The cable has also been observed to fray and become rough to the touch as a result of the stretching operation. This is an undesirable characteristic since a phlebectomy is an extremely painful operation and it is desirable to provide as frictionless a surface as possible on the vein stripper. This, of course applies equally well to the guider tips, since the size of the tips can often affect the ease with which the vein stripper may be threaded through a vein. Unfortunately, in the above-described device the diameter of the guider tips is determined by the original diameter of the molded rod which must be sufficiently large to permit the formation of the entire vein stripper.

It is, therefore, an object of this invention to provide an improved plastic vein stripper that incorporates the advantages that the above-described instrument possesses over the prior art devices without the inherent disadvantages set forth above.

SUMMARY OF THE INVENTION

The present invention provides a surgical vein stripping instrument that comprises an elongated high tensile cable formed of a uniformly extruded axially oriented monofilament of synthetic plastic material, such as, nylon. A tubular plastic cap is welded over each end of the cable to provide enlarged tips that may be attached to either an auxiliary bullet-shaped stripping member or to a handle for assisting the surgeon in pulling the stripper through a vein. The caps are smoothly rounded on their ends and are only slightly larger in outside diameter than the diameter of the cable in order that the stripper may be freely passed through a vein.

The unique vein stripper of this invention is manufactured by providing an appropriate length of the plastic cable material and ultrasonically welding the pair of tubular plastic caps over the ends thereof. The energy from the ultrasonic weld is controlled so that only a very thin outer layer of the circumferential surface of the cable ends is melted to thereby preserve the major portion of the cable material in the original axially oriented condition.

The resulting vein stripper is extremely uniform in external dimensions since the entire outer surface is unaltered during the assembly operation. Also, the diameter of the caps may be closely controlled and may conform to any desired specification. The bond created by the ultrasonic welding operation is exceptionally strong and the bond is rapidly accomplished without the use of deleterious external heat.

For a better understanding of the invention, as well as other objects and further features thereof, reference is made to the following detailed description to be read in conjunction with the accompanying drawing, wherein:

FIG. 1 is a plan view of the plastic vein stripper of the present invention;

FIG. 2 is a cross sectional view taken along line 2—2 in FIG. 1;

FIG. 3 is a side elevational view showing the construction of the preferred handle of the present invention;

FIG. 4 is a perspective view of the bullet-shaped tip of the present invention;

FIG. 5 is a plan view illustrating the vein stripper of the present invention completely assembled with the handle and tip of FIGS. 3 and 4, respectively;

FIG. 6 is a side elevational view schematically illustrating the process for manufacturing the vein stripper shown in FIG. 1; and

FIG. 7 is a cross sectional view taken along line 7—7 in FIG. 6.

The preferred embodiment of the vein stripper of the present invention is illustrated at 10 in FIG. 1, wherein

an elongated cable 11 is shown with two tubular plastic caps 12 and 13 secured to the ends thereof. Cable 11 is formed from a uniformly extruded axially oriented monofilament of synthetic plastic material. The material is stretch oriented during the extrusion operation so that the molecules are aligned axially within the monofilament. This axial orientation greatly increases the tensile strength of the cable and provides an exceptionally strong pulling member for the vein stripper.

Caps 12 and 13 are ultrasonically welded to the ends of cable 11 in a manner to be later described and the ends of the caps 14 and 15, respectively, are smoothly rounded so that the vein stripper may freely pass through the vein without presenting any sharp edges. In the preferred embodiment, caps 12 and 13 are molded from a material similar to that used in the formation of cable 11 and the caps are molded so that the ends 14 and 15 are completely closed during the molding operation. It will be appreciated, however, that the tubular caps may be open at both ends and subsequently closed by a fusing operation after the caps have been welded to cable 11. The innermost ends 16 and 17, respectively, of caps 12 and 13 are preferably formed approximately 90° to the longitudinal axis of the caps and form square shoulders.

Referring to FIG. 3, a handle shown generally at 18 is provided to aid the surgeon in pulling the vein stripper after the stripper has been firmly secured to the vein. Handle 18 is constructed with a generally cylindrically shaped main body portion 19 which has a bore 20 extending partially therethrough. An axially directed slot 21 extends inwardly through one wall of body portion 19 to permit passage of cable 11 into the central bore 20. Bore 20 does not extend completely through body portion 19 and, therefore, a shoulder or a shelf 23 is formed in the lower portion thereof. A cross member 24 is secured to the top of body portion 19 which acts as a gripping member for the hand of the surgeon.

Referring to FIG. 4, a generally bullet-shaped stripping tip is shown generally at 25, which tip is constructed in a manner very similar to that of body portion 19 of handle 18. Tip 25 has a central bore 26 that extends partially therethrough and terminates in a shoulder 27 near the bottom thereof. A slot 28 extends through one wall of tip 25 and provides a passage for the cable 11 into the central bore 26. Both handle 18 and tip 25 may be molded from a material similar or identical to that from which caps 12 and 13 are molded.

When in use, the vein stripper, as shown in FIG. 1, may be threaded through the entire length of a vein by the surgeon. Since caps 12 and 13 are substantially identical, either end of the vein stripper may be utilized as the forward, threading end. After the stripper 10 has been completely threaded through a vein, the forward tip or cap is then secured to tip 25 by passing cable 11 through slot 28 until it is within the central bore 26. The cable is then pulled downwardly and, as illustrated, cap 13 is forced into bore 26 until shoulder 17 is resting firmly against shoulder 27. The same procedure may then be followed with respect to the opposite cap handle 18, wherein cable 11 may be passed through slot 21 until it is centered within bore 20 and pulled downward until shoulder 16 of cap 12 is seated firmly against shoulder 23 within handle 18. The surgeon may then pull firmly on handle 18 and the vein will be completely stripped from the patient by tip 25.

The preferred method for manufacturing the vein stripper of this invention will now be described in detail. Referring to FIG. 6, the procedure for welding caps 12 and 13 to cable 11 is schematically illustrated. In order to avoid the necessity of utilizing additional materials, such as, adhesives, and in order to eliminate the deleterious effects of the application of heat to obtain the necessary bond between caps 12 and 13 and cable 11, an ultrasonic welding device has been adopted. This device is specifically described in U.S. Pat. No. 3,440,117 and com-

prises a radio frequency generator 30, a conductor 31 for transmitting alternating current energy at about 20 kilocycles per second from the generator 30 to a sonic converter unit 32. Sonic converter 32 is fitted with a horn 33 for transferring sonic energy to the caps 12 and 13. The sonic converter 32, generally, is a device which converts electrical energy to mechanical vibration and, to this end, includes one or more piezoelectric disks which vibrate under the influence of alternating current electrical energy. The vibrations are amplified and appear as longitudinal vibrations at the tip of horn 33.

In order to assemble cap 12 onto the end of cable 11, the molded tubular cap is placed onto an end of the cable and placed into the ultrasonic welding apparatus. The cap is placed into a support member 35 (see FIG. 7) having a substantially semi-circular notch 36 conforming to the contour of the cap. Horn 33 which also has a downwardly extending substantially semi-circular notch 37 is then brought into contact with the upper surface of cap 12 and the device is actuated to perfect the welding between cap 12 and cable 11. It should be noted that the parts 33 and 35 are so dimensioned that they do not come completely into contact during the welding operation. The construction is such that the cap 12 is substantially encapsulated by horn 33 and support member 35 so that a uniform welding takes place completely around the internal periphery thereof.

It should be noted at this time that the exact theory of operation of the ultrasonic welding device is not completely understood, however, it is generally believed that the vibration of horn 33 creates an extreme amount of friction between the outer surface of the end of cable 11 and the inner surface of cap 12 so that the surfaces melt and form a strong bond therebetween. It is extremely important in this invention that the amount of energy supplied to the welding horn 33 and, therefore, the degree of vibration of cap 12, be closely controlled in order that the melting of the outer circumferential surface of the end of cable 11 be limited to only the extreme outer layer. This is a critical aspect of this invention since the melting of a thermoplastic material such as those contemplated for use with this invention destroys the axial orientation of the molecules and, thus, greatly decreases the tensile strength of the cable. Thus, it is important that the major portion of the cross section of the ends of cable 11 remain in the axially oriented condition after the ultrasonic welding operation. It has been found to be helpful during the ultrasonic welding operation, to clamp cable 11 proximate to the welding station to prevent axial dislocation of the end of the cable as a result of the vibration of cap 12. This can be done by any suitable clamping device such as that illustrated at 37 in FIG. 6.

The thermoplastic materials usable with this invention are not critical, however, it has been found that an axially oriented monofilament of nylon provides an extremely strong tensile member for cable 11 and molded nylon has also been found to be very suitable for tips 12 and 13, handle 18 and tip 25. An additional requirement for the thermoplastic materials usable for the cable 11 and caps 12 and 13 is that these materials have approximately equal melting temperatures. If this requirement is not satisfied, a strong bond will not result from the ultrasonic welding operation. For example, if the thermoplastic material utilized for cable 11 has a lower melting temperature than the thermoplastic material utilized for cap 12, the material of cable 11 will melt before that of cap 12 and destroy the axial orientation of a substantial portion of the cable. This would yield an inferior product, since the cable would probably fail at the end portions when an excess amount of tension was applied thereto.

It will be apparent from the foregoing that the present invention provides a uniquely designed plastic vein stripper that may be produced with precise and uniform dimen-

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sions. The molded tubular caps may be provided with any desired length and diameter without any restrictions on their size. The uniformity of the plastic cable may be precisely controlled as to cross section and smoothness so that a superior surgical instrument is provided. The ultrasonic welding operation eliminates the need for additional material, such as, adhesives and, if controlled, will not appreciably affect the axial orientation of the thermoplastic material from which the cable is made. In addition, the ultrasonic welding is extremely fast and, thus, provides a fast and economical means for producing a highly uniform product.

What is claimed is:

1. A method of making a vein stripper comprising the steps of:

- (1) providing a length of cable formed from a monofilament of axially oriented synthetic thermoplastic material, said cable having a substantially uniform cross section throughout its entire length;
- (2) placing a tubular plastic cap over at least one end of said cable;
- (3) welding the outer circumferential surface of said end of said cable to the inner surface of said cap.

2. The method of claim 1 wherein said cable and cap are welded by bringing an ultrasonic welding horn into contact with said cap.

3. The method of claim 2 further comprising the step of ultrasonically welding a second plastic cap to the other end of said cable.

4. A method of making a vein stripper comprising the steps of:

- (1) providing a length of cable formed from a monofilament of axially oriented synthetic thermoplastic material, said cable having a substantially uniform cross section throughout its entire length;
- (2) placing a tubular plastic cap over an end of said cable;
- (3) bringing an ultrasonic welding horn into contact with said cap; and

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(4) welding said cable and said cap together by melting the outer circumferential surface of said end of said cable and the inner surface of said cap.

5. The method of claim 4 wherein the melting of said outer circumferential surface of said cable is limited to the extreme outer layer, whereby, the major portion of said cable remains in the original axially oriented condition.

6. The method of claim 5 further comprising the step of placing said cap on a support member having a substantially semi-circular notch conforming to the contour of said cap prior to contacting said cap with said horn.

7. The method of claim 6 wherein said horn also has a substantially semi-circular notch for contacting said cap so that said cap is substantially encapsulated during the welding operation.

8. The method of claim 7 further comprising the step of clamping said cable proximate said cap to prevent axial dislocation of the end of said cable from said cap during the welding operation.

9. The method of claim 5 wherein said thermoplastic material is nylon.

10. The method of claim 9 wherein said tubular plastic has a melting point approximately equal to the melting point of said nylon.

11. The method of claim 10 wherein said tubular plastic is nylon.

References Cited

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