[54]	DEVICE FOR THE EVERSION OF HOLLOW
	ORGANS AND VASCULAR STAPLING
	INSTRUMENT INCORPORATING SAME

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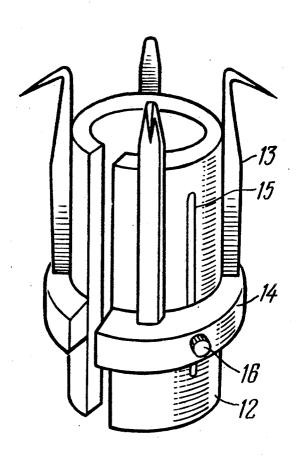
## [57] ABSTRACT

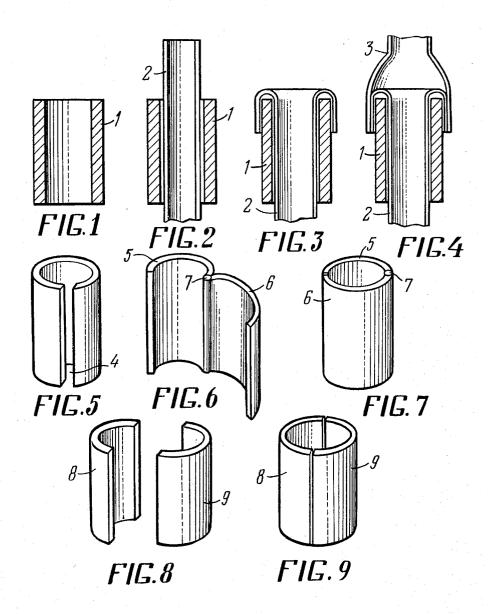
The present invention relates to the field of medicine, and more particularly to vascular surgery, with particular reference to a device for the eversion of hollow organs and a vascular stapling instrument.

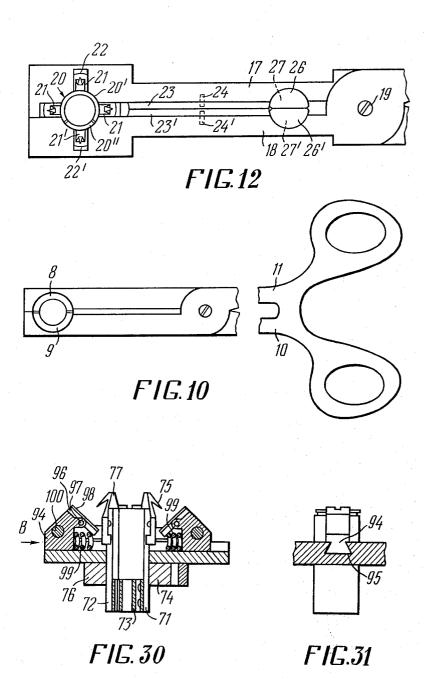
According to the invention, a device for the eversion of hollow organs, comprising a bush, whereinto the hollow organ end to be everted is introduce, is provided with spikes, whereon the edge of said hollow organ end is pinned, which spikes are arranged on their base along a contour conforming to the lateral guide surface of said bush, said base being mounted so as to move freely along said bush.

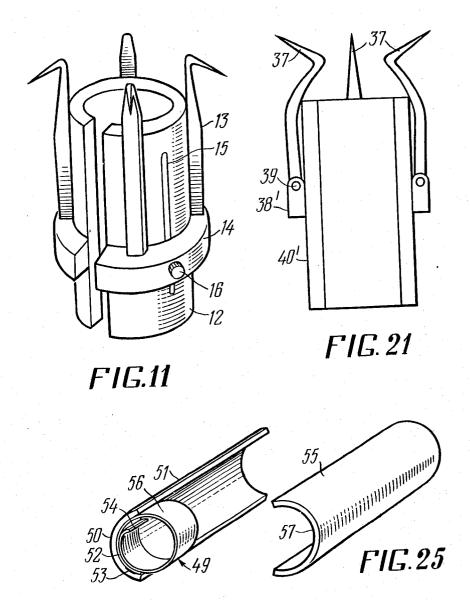
The disclosed device for the eversion of hollow organs is recommended for use in instruments for suturing of hollow organs and, inter alia, vascular stapling instruments.

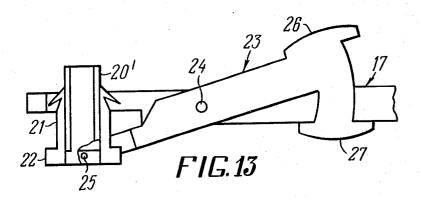
27 Claims, 31 Drawing Figures

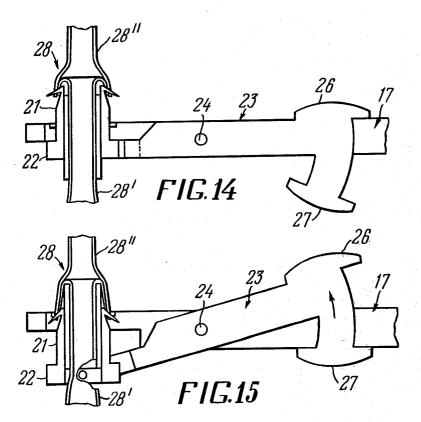


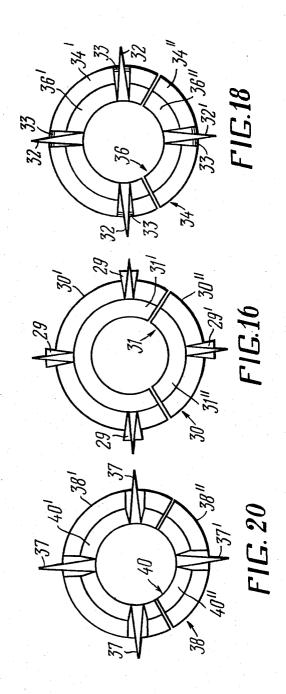


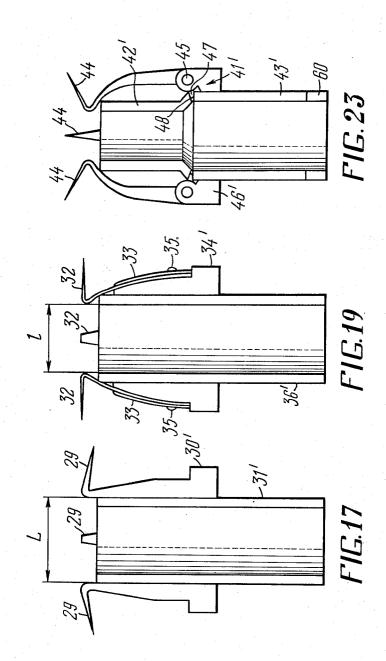


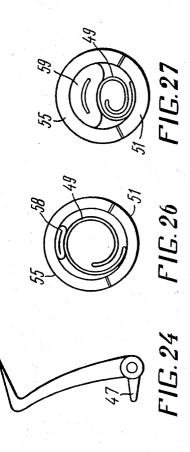


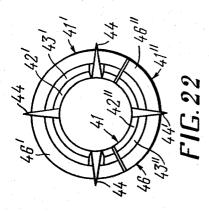


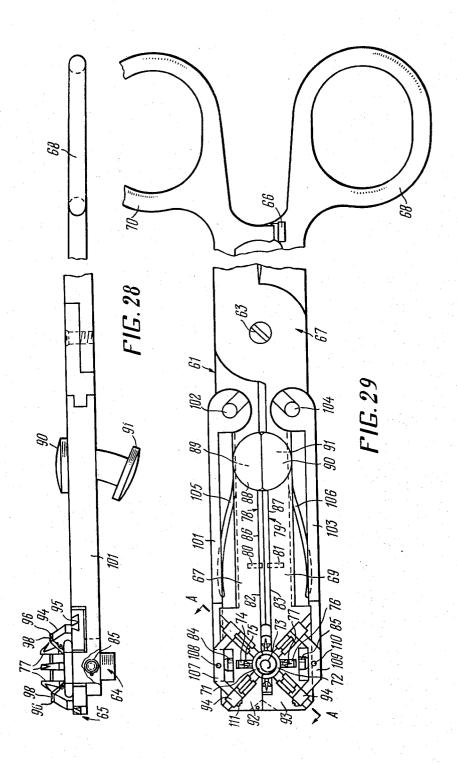












## DEVICE FOR THE EVERSION OF HOLLOW ORGANS AND VASCULAR STAPLING INSTRUMENT INCORPORATING SAME

The present invention relates generally to the field of 5 medicine, more specifically to vascular surgery, and has particular reference to a device for the eversion of hollow organs and to a vascular stapling machine incorporating such a device.

Those skilled in the art are aware that whenever hollow organs are to be everted, for example in the case of end-to-end suturing of blood vessels, all the eversion operations are performed manually on a bush into which the hollow organ end to be everted is introduced and on which the entire eversion process is carried out as on a mandrel.

The bush on which the process of eversion is carried out is generally manufactured to be convenient for the introduction thereinto of the hollow organ end to be everted. Thus, for instance, the bush is made to be split along a plane passing through its longitudinal axis into two half-bushes.

Such a bush, which may be manufactured in a variety of designs and on which all the operations of eversion 25 are performed, is a known device for the eversion of hollow organs. Among the above-described designs of bushes on which the process of eversion is carried out and which consequently are known devices for the eversion of hollow organs, the most advanced is the split bush comprising two half-bushes and described hereinahove

The process of eversion employed, inter alia, in endto-end suturing of blood vessels is effected in this known device in the following manner.

The half-bushes are separated from each other and the end of the blood vessel to be everted is placed therebetween.

Then the bush is put together by joining the two half-bushes, the end of the blood vessel being securely clamped inside the bush so that the end of the vessel to be everted should be left outside of the bush in surmounting relation thereto. Then the loose end of the vessel is manually everted with pincers by turning it in-45 tima outwards and stretching it over said bush.

Finally, the end of the vessel thus everted is fixed on the bush by ligating it at the edge thereof or by clamping it with a cuff clamp.

Also known is a vascular stapling instrument which 50 incorporates a device for vessel eversion, formed as a split bush, comprising two half-bushes, one for each end of the vessel (cf. USSR Author's Certificate NO. 127361, Cl.30a, 81<sub>06</sub>, issued on Oct. 9, 1958). The vessel eversion procedure is performed in the abovedescribed sequence immediately prior to the stapling operation.

The above-described known device for the eversion of hollow organs suffers from a number of serious disadvantages which impose limitations upon its application for the eversion of hollow organs in general, and for the eversion of blood vessels in particular.

Thus, the process of eversion of hollow organs, and particularly blood vessels, is rather labour-consuming, requires a lot of time and puts a great strain on the operating surgeon, this disadvantage being especially manifest with regard to small vessel eversion.

Another disadvantage consists in that the known device is inapplicable for the eversion, and hence anastomosing, severely sclerosed vessels.

Obviously, the afore-mentioned disadvantages are inherent in the above-described vascular stapling instrument which incorporates such a device for the eversion of these vessels formed as a plurality of split bushes each comprising two half-bushes.

An object of the present invention, therefore, is to 10 provide a simple and reliable device for the eversion of hollow organs and inter alia, blood vessels of all kinds, even severaly sclerosed, which would required little time for the eversion procedure and would put no great strain on the operating surgeon.

It is another object of the invention to provide an instrument for end-to-end vessel stapling which would be built around the foregoing eversion device.

The invention contemplates the provision at a device for the eversion of hollow organs, wherein most manual operations involved in the eversion of a hollow organ on the bush would be ruled out through maximum mechanization of the entire process of hollow organ eversion. Furthermore, the contemplated design of a device for the eversion of hollow organs should provide for its easy incorporation in the corresponding instruments for anastomosing of hollow organs and, inter alia, in vascular stapling instruments.

It is further contemplated that such a device for the eversion of hollow organs shall be designed as an individual unit (eversion unit) forming part of said instrument for anastomosing of hollow organs, or else as a unit kinematically linked with other units of this instrument to provide for the required sequence of steps in a surgical operation to suture hollow organs.

Accordingly, there is provided a device for the eversion of hollow organs, comprising a bush, whereinto the hollow organ end to be everted is introduced, which, in accordance with the invention, is fitted with spikes, whereon the edge of said hollow organ end is to be fixed, and which are arranged on a base along a contour conforming to the lateral guide surface of said bush, said base being adapted to move a long said bush.

It is possible to make the spikes, whereon the edge of the hollow organ segment to be everted is to be fixed, rigidly connected to said base of the proposed device for the eversion of hollow organs.

The spikes, whereon the edge of the hollow organ end to be everted is to be fixed, should be preferably made spring-loaded relative to said base so that the diameter of the contour along which said spikes are arranged prior to the eversion process, should be less than the diameter of the corresponding contour at the end of the eversion process.

It is desirable that the spikes, whereon the edge of the hollow organ end to be everted is to be fixed, should be movably mounted on said base by means of hinges so that the spikes could be drawn together prior to the eversion process.

The device of this invention for the eversion of hollow organs should be preferably provided with spikes formed as S-shaped levers of the first order, each having its fulcrum in said hinge serving to movably mount said spike on said base, and the smaller arm of each lever is defined by a wedge-shaped projection which is disposed below and immediately adjacent the hinge, so as to face said bush, whereas the larger arm of each lever is disposed above the hinge and tapers to a sharp

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point, whereon the edge of the hollow organ end to be everted is pinned while being fixed on the spike, and the base, whereon the spikes are movably mounted, envelops the bottom part of the bush, wherealong said base is adapted to move, while the upper part of the bush is made replaceable and having an inner diameter roughly equal to the outer diameter of the hollow organ end to be everted, and the lower end of said replaceable part of the bush has a surface conforming in shape to the surface of the wedge-shaped projections of the spikes so that, with the spikes in the extreme upper position, the larger arms thereof should be forced against the upper edge of the replaceable part of the bush.

The proposed device for the eversion of hollow orogans should be preferably provided with a hand actuator having at least one lever, whereof the fulcrum should be fixed relative to said bush, said base with spikes being movably mounted on one arm of said lever, whereas the other arm thereof should be adapted to be manually actuated to transmit motion to said base when everting a hollow organ segment, whereof the edge is fixed on the spikes fitted on said base.

It is desirable that in the proposed device for the eversion of hollow organs, which incorporates a split bush comprising two half-bushes separated along a plane parallel to its longitudinal axis, the base, whereon said spikes are fixed, should be formed as two half-rings, each of which envelops one of the half-bushes and is connected by a hinge to the respective lever of 30 the hand actuator.

The proposed device for the eversion of blood vessels should be preferably provided with a haemostatic clamp positioned in said bush on the base thereof.

The said haemostatic clamp provided in the proposed device for the eversion of blood vessels may be formed as a flat spiral spring, whereof the outer end is attached to the bush while the inner end is left loose.

It is preferred that an instrument for end-to-end staple-suturing of blood vessels should be provided, comprising a base, a device for the eversion of the blood vessels being sutured mounted thereon and incorporating at least one bush with slots to accommodate said stapled, and a mechanism for feeding and directional bending of said stapled at the instant of stapling, which instrument should incorporate a device for the eversion of the blood vessels being sutured in accordance with the present invention.

The disclosed device for the eversion of hollow organs is simple in design and easy to handle.

It may be employed in any vessel-suturing instrument, since building the proposed device into the corresponding instrument involves no special design effort worth mentioning and offers no technological difficulties.

In the proposed device practically all the steps of hollow organ eversion are mechanized, which saves a considerable amount of time for the entire process of eversion, with the consequent time gain for the surgical procedure associated with the suturing of the corresponding ends of hollow organs.

The vessel-suturing instruments incorporating the disclosed device for the eversion of hollow organs, including vascular stapling instruments are reliable, easy to handle and applicable for the suturing of vessels of various diameters and in various states even severely sclerosed vessels.

The unique haemostatic clamp formed as a flat spiral and built into the bush of the disclosed device permits considerably extending the field of application of the corresponding vascular stapler, as it enables operations to be performed with the blood vessels being sutured having short ends.

The invention will be better understood from the following detailed description thereof, as well as some specific embodiments of the proposed device for the eversion of hollow organs and a vascular-stapling instruments incorporating same, taken in conjunction with the accompanying drawings, wherein:

FIG. 1 is a longitudinal section of a known bush serving as a mandrel for the hollow organ end to be everted;

FIG. 2 is the view of FIG. 1, with the hollow organ end to be everted introduced into the bush;

FIG. 3 is the view of FIG. 1 with an everted end of a hollow organ;

FIG. 4 is the view of FIG. 1, with an everted hollow organ end prepared for suturing and the other hollow organ end stretched over the former;

FIG. 5 is a longitudinally sectioned known bush;

FIG. 6 is a known split bush comprising two pivotally connected half-bushes, shown in axonometry (the half-bushes separated);

FIG. 7 is the view of FIG. 6, with the half bushed joined:

FIG. 8 is a known split bush comprising two halfbushes mechanically disengaged from each other (the half-bushes brought apart);

FIG. 9 is the view of FIG. 8, with the half-bushes joined;

amp positioned in said bush on the base thereof.

The said haemostatic clamp provided in the proposed 35 bushes according to FIG. 8 mounted on the working price for the eversion of blood vessels may be formed pieces thereof;

FIG. 11 is a device of this invention for the eversion of hollow organs, built around a bush with a longitudinal slot;

FIG. 12 is a plan view of the device of this invention for the eversion of hollow organs, comprising a split bush consisting of two half-bushes;

FIG. 13 is a side elevation of FIG. 12, with the elements on one of the branches;

FIG. 14 is a side elevation of FIG. 12, with the hollow organ ends being sutured, prior to the eversion process;

FIG. 15 is a view of FIG. 14, at the end of the eversion process;

FIG. 16 is a plan view of an alternative embodiment of a device for the eversion of hollow organs, with the spikes being rigidly fixed on the base;

FIG. 17 is a side elevation of FIG. 16, illustrating the elements of the larger half-bush;

FIG. 18 is a plan view of an alternative embodiment of a device for the eversion of hollow organs, with the spikes spring-loaded relative to the base;

FIG. 19 is a side elevation of FIG. 18, illustrating the elements of the larger half-bush;

FIG. 20 is a plan view of an alternative embodiment of a device for the eversion of hollow organs, with hanged spikes;

FIG. 21 is a side elevation of FIG. 20, illustrating the elements of the larger half-bush;

FIG. 22 is a plan view of a modification of the device of FIG. 20;

FIG. 23 is a side elevation of FIG. 22, illustrating the elements of the larger half-bush;

FIG. 24 is a hinged spike of a portion of the device for the eversion of hollow organs shown in FIG. 23;

FIG. 25 is a bush of the proposed device for the eversion of blood vessels with a haemostatic clamp, shown in axonometry;

FIG. 26 is a cross-section of the bush of FIG. 25, with a small-diameter blood vessel introduced into the bush;

FIG. 27 is the same view, but illustrating a largerdiameter blood vessel;

porating the device for the eversion of blood vessels of this invention:

FIG. 29 is a plan view of a vascular stapler incorporating the device of this invention for the eversion of blood vessels:

FIG. 30 is a section taken on the line XXIV—XXIV of FIG. 23, illustrating a vascular stapler incorporating the device of this invention for the eversion of blood vessels: and

illustrating a vascular stapler incorporating the device of this invention for the eversion of blood vessels.

In vascular surgery whenever hollow organs are to be sutured, one of the most important procedures is their eversion, that is to say turning the internal layer (the 25 is larger than the other. intima in case of blood vessels) outwards in the form of a cuff.

In a standard procedure, hollow organs are everted on a bush (FIG. 1) formed as a thin-walled hollow cylinder of inner diameter roughly equal to the diameter 30 of the hollow organ to be everted, so that the bush 1 serves as a mandrel on which the entire process of eversion is carried out.

End 2 (FIG. 2) of the hollow organ to be everted is introduced into the bush 1 so that its edge should ex- 35 tend above the said bush 1 by 5 to 6 mm.

Then this edge of the hollow organ end is everted and stretched over the bush 1 with its internal surface outwards as illustrated in FIG. 3, whereupon it is fixed on the bush by any known technique, for example, ligated.

This marks the end of the eversion procedure.

All further procedures are determined by the chosen method of anastomosing the hollow organ.

According to one of these methods, the two hollow organ ends are sutured by a circular suture at the point 45 where the everted ends of both hollow organ ends are bent over. Both ends of the hollow organ are pierced at the point of suture by staples whose ends are subsequently bent, the second segment of the hollow organ being everted on the second bush, as described hereinabove. Thus are hollow organs everted in all known instruments, including vascular staplers, as well as in the above-described known vascular stapler which embodies the USSR Author's Certificate No. 127361.

Under another procedure, the end edge of a second end 3 (FIG. 4) of the hollow organ is stretched over the same bush 1 on top of the everted edge of the first end 2 of the hollow organ, whereupon the edge of the second end 3 is likewise fixed.

As has already been noted, the eversion of hollow organs, particularly small vessels, on an elementary device, such as a bush, involves some difficulties, takes a lot of time and puts a considerable strain on the operat-

Consequently, surgical engineers have concentrated much of their effort on a search for an improved design of an eversion device, and above all, an improved design of the bush, which is only natural in the light of the foregoing discussion.

If the bush is provided with a longitudinal slot 4 (FIG. 5), the process of introducing thereinto the hollow organ end to be everted is simplified and, more serious still, the sutured segment may be withdrawn from the bush without being drawn theralong.

FIGS. 6 and 7 illustrate a split bush comprising two half-bushes 5 and 6 interconnected by a pivot 7. With FIG. 28 is a side elevation of a vascular stapler incor- 10 the half-bushes 5 and 6 separated, the hollow organ end to be everted may be introduced into the bush and securely fixed therein by bringing the two half-bushes together. Such a bush is obviously an improvement on the solid bush or the bush with a slot described above and 15 facilitates the procedure of hollow organ eversion.

> Yet, far more popular is a split bush comprising two half-bushes which are not mechanically interconnected by any pivot.

The latter bush may split into two half bushes along FIG. 31 is a view taken along the arrow A of FIG. 24, 20 a plane passing through the longitudinal axis of the bush, or else along a plane somewhat shifted relative to the longitudinal axis of the bush.

> In the former case the half-bushes have an identical cross-section, whereas in the latter case one half-bush

> Since the half-bushes 8 and 9 are not pivotally connected, it is difficult to handle them during the process of hollow organ eversion. For this reason these halfbushes may be fixed, for example, on the working pieces of branches 10 and 11 (FIG. 10).

> Separating the branches 10 and 11, the half-bushes 8 and 9 will also be separated, thereby permitting the hollow organ end to be everted and introduced into the bush between the half-bushes 8 and 9.

> All the above-described design principles aiming at the improvement in the device for the eversion of hollow organs by standard design modifications actually fall short of the objective, i.e. to substantially facilitate the process of hollow organ eversion as far as the operating surgeon is concerned. It is only the approach of the present invention based on a complete mechanization of the process of hollow organ eversion, that has proved really effective and met the objects described hereinabove.

> In one of the specific embodiments of the present invention, the device for the eversion of hollow organs comprises: a bush 12 (FIG. 11) having a longitudinal slot; spikes 13; a base 14 of the spikes 13, which base 14 envelops the bush 12 and has a longitudinal slot, whereof the width is equal to that of the longitudinal slot in the bush 12.

> The base 14 of the spikes 13 is so disposed on the bush 12 that its longitudinal slot should be opposite the corresponding slot in the bush 12. In order to prevent the base 14 from turning around the bush 12 and also to ensure that said base 14 can only move lengthwise said bush 12, the latter is provided with a longitudinal slot 15. The base 14 of the spikes 13 is provided with a set screw 16 which fixes said base 14 in its extreme upper and lower positions.

Besides, the end of the set screw 16 enters said longitudinal groove, thereby preventing the base 14 of the spikes 13 from turning around the bush 12.

The process of eversion in the above-described device proceeds as follows.

The hollow organ end to be everted is introduced into the bush 12 through the longitudinal slot therein.

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The base 14 with the spikes 13 is moved to its extreme upper position and fixed therein by the set screw 16.

The edge of said hollow organ end is pinned on the spikes 13 using pincers for the purpose. Then said base 14 with the spikes 13 is released from its extreme upper position, using the set screw 16, and moved to its extreme lower position, thereby causing the eversion of the edge of said hollow organ end.

Said base 14 with the spikes 13 is fixed by the set screw 16 in its extreme lower position, thereby securely 10 holding on the bush the everted hollow organ segment which may now be subjected to the further steps of the surgical procedure.

Another embodiment of the device for the eversion of hollow organs in accordance with the invention com- 15 prises: two branches 17 and 18 (FIGS. 12, 13) interconnected by an axle 19; a split bush 20 consisting of a larger half-bush 20' mounted on the working piece of the branch 17 and a smaller half-bush 20" mounted on the working piece of the branch 18; spikes 21 and 21'; 20 a base of the spikes 21 and 21', which base consists of a half-ring 22 enveloping the half-bush 20' and carrying the spikes 21 fixed thereon, and a half-ring 22' enveloping the half-bush 20" and carrying the spike 21' fixed thereon; a hand actuator formed as first-order le- 25 vers 23 and 23', the lever 23 being mounted by a pivot 24, serving as the fulcrum therefor, on the working piece of the branch 18. One arm of the first-order lever 23 is movably connected with the half-ring 22 by a hinge 25, while the similar arm of the first-order lever 30 23' is movably connected to the half-ring 22' by a hinge (not shown).

The other arms of the first-order levers 23 and 23' are provided at the free ends thereof with keys 26 and 26' (top) and 27 and 27' (bottom). The keys 27 and 27' (lower) in FIG. 12 are hidden from view by the keys 26 and 26' (upper), which is the reason why their location is indicated by dotted lines.

The eversion of hollow organs with the foregoing device is performed in the following sequence.

By depressing the upper keys 26 and 26', the levers 23 and 23' are turned clockwise, thereby causing the half-ring 22 with the spikes 21 and the half-ring 22' with the spike 21' to move the extreme upper position, wherein the spikes 21 and 21' will be positioned above the bush 20. The branches 17 and 18 are separated, thereby causing the half-bushes 20' and 20" of the bush 20 mounted on these branches to separate. One of the ends 28' (FIG. 14) of a hollow organ 28 is interposed between the half-bushes 20' and 20" so that its edge should extend upwards therefrom.

The branches 17 and 18 are brought together, thereby causing the half-bushes 20' and 20" of the bush 20 fixed on these branches, to be brought together and clamp the end 28' of the hollow organ 28. The edge of one segment 28' and then the edge of the other end 28" of the hollow organ 28 are pinned with pincers on the spikes 21 and 21' (FIGS. 12, 13). Then the levers 23 and 23' are turned counterclockwise by simultaneously depressing the lower keys 27 and 27'. As a result, the half-ring 22 with the spikes 21 and the half-ring 22' with the spike 21' will move to the extreme lower position.

The edge of one of the ends 28' (FIG. 16) of the hollow organ 28 is everted, whereupon the edge of the other end 28' of the hollow organ 28 is stretched over the everted edge of the end 28'.

The edges of the ends 28' and 28'' of the hollow organ 28 are securely held on the bush 20 by the spikes 21 and 21'.

This completed, the next step of surgery may be commenced, for example, the suturing of the ends 28' and 28'' of the hollow organ 28 by applying a circular suture to the juxtaposed edges of said ends 28' and 28''.

After the hollow organ 28 has been sutured, the levers 23 and 23' are turned clockwise by depressing the upper keys 26 and 26', which causes the half-ring 22 with the spikes 21 and the half-ring 22' with the spikes 21' to move to the extreme upper position. The spikes 21 and 21', carrying the edges of the joined ends 28' and 28'' of the hollow organ 28 pinned thereon, will be positioned above the bush 20. Then, using pincers, the hollow organ 28 is taken off the spikes 21 and 21', the branches 17 and 18 separated and the hollow organ 28 withdrawn out of the bush 20.

The description of the specific embodiments of the proposed device for the eversion of hollow organs fails to bring out in sufficient detail the design features of the spikes which, by and large, determine the efficiency of the entire device for the eversion of hollow organs.

The spikes may be mounted on their base rigidly, or they may be spring-loaded relative to the base, or else they may be made hinged.

These varieties of spikes are discussed below as mounted on a base made up of two half-rings which envelop the respective half-bushes of unequal size.

In one embodiment of the disclosed device for the eversion of hollow organs, wherein the spikes are rigidly mounted on the base, spikes 29 (FIGS. 16, 17) are integral with a half-ring 30' of a base 30, while a spike 29' is integral with a half-ring 30" of the base 30.

The spikes 29 and 29' are arranged along a circumference, whereof the diameter corresponds to the external diameter of a bush 31 made to split into two halfbushes 31' and 31". The distance L between the diametrically opposite spikes 29 is equal to the outer diameter of the bush 31 and remains constant throughout the process of eversion.

The above-described type of spikes rigid mounted on their base is easy to manufacture and reliable in operation. Nevertheless, in the process of eversion of hollow organs some difficulties arise in regard to the pinning on the spikes of said segments of hollow organs to be everted, particularly when dealing with small vessels.

In another embodiment of the proposed device for the eversion of hollow organs, wherein the spikes are spring-loaded relative to their base, each spike 32, 32' (FIGS. 18, 19) is made of an elastic steel ribbon (flat spring) which, together with another steel ribbon 33 forcing thereagainst, is anchored to a base 34 by a screw 35. The base 34 is formed as two half-rings, one half-ring 34' with the spikes 32 enveloping a half-bush 36' of a bush 36, while the other half-ring 34'' with the spike 32', envelops a half-bush 36'' of the bush 36.

Prior to the process of eversion, when the spikes 32 and 32' are disposed above the bush resting on its edge, the spikes are arranged along a circumference, whereof the diameter corresponds to the inner diameter of the bush. The distance 1 between the diametrically opposite spikes 32 and 32' is equal to the inner diameter of the bush 36, which facilitates the pinning of the hollow organ end to be everted on the spikes 32 and 32'.

In the course of eversion, the spikes 32 and 32' together with the base 34 move downwards and away

from each other, so that at the end of the eversion process the spikes 32 and 32' are arranged along a circumference, whereof the diameter corresponds to the outer diameter of the bush 36, thereby ensuring reliable fixation of the hollow organ segment pinned on the spikes 5 32 and 32'.

In an alternative embodiment of the disclosed device for the eversion of hollow organs, wherein the spikes are hinge-mounted on their base, hinged spikes 37 and 37' of the most elementary type (FIGS. 20, 21) are 10 part 42' of the half-bush 41'. mounted on their base on hinges 39.

The base 38 is formed as two half-rings, one half-ring 38' with the spikes 37 enveloping a half-bush 40' of a bush 40, while the other half-ring 38" with the spike 37' envelops a half-bush 40" of the bush 40.

Prior to the eversion process, the hinges spikes 37 and 37' extend outwards above the bush.

When the hollow organ end to be everted is pinned on the spikes 37 and 37', the spikes are brought as close to the centre as possible, thereby providing for 20 the simplicity and speed of this operation. More serious still, this feature reduces the probability of injuring the walls of the corresponding hollow organ end.

In the course of eversion, the spikes 37 and 37' move downwards and away from each other, and at the end 25 bush is made sloping at such an angle that, when the reof the operation the spikes are arranged along a circumference, whereof the diameter corresponds to the outer diameter of the bush 40, which ensures reliable fixation of the hollow organ ends pinned on the spikes 37 and 37'.

An improved modification of the latter embodiment of the disclosed device with hinged spikes is a device for the eversion of hollow organs comprising a split bush 41 (FIGS. 22 - 24) which consists of two halfbushes 41' and 41". The half-bushes 41' and 41" of 35 the bush 41 respectively have replaceable upper parts 42' and 42" and basic lower parts 43' and 43". Hinged spikes 44 and 44' are movably mounted on a base 46 by means of hinges 45. The base 46 is formed as two half-rings, one half-ring 46' with the spikes 44 enveloping one basic lower part 43' of the half-bush 41' of the bush 41, while the other half-ring 46" with the spike 44' envelops the other basic lower part 43" of the halfbush 41" of the bush 41.

Each spike 44 and 44' is formed as an S-shaped lever of the first order, whereof the fulcrum is the hinge 45 serving to movably mount said spike on the base 46.

A wedge-shaped projection 46 positioned immediately adjacent the hinge 46 with its tapered portion towards the bush 41, serves as the smaller arm of said S-shaped lever of the first order. The other, larger, arm of said S-shaped lever of the first order is positioned above the hinge 45 and ends in a sharp point, whereon the edge of the hollow organ end to be everted is pinned when being fixed on the spikes 44 and 44'. The wedge-shaped projection 47 of each spike 44 and 44' provides for an interaction with the replaceable parts 42' and 42" of the respective half-bushes 41' and 42" so that the spikes 44 and 44' are drawn together while 60 being moved to the initial (extreme upper) position thereof.

The device for the eversion of hollow organs illustrated in FIGS. 22 - 24 operates in the following man-

First, the replaceable parts 42' and 42" of the halfbushes 41' and 41", respectively are installed. These replaceable parts 42' and 42" of the half-bushes 41'

and 41" are so selected that their diameter should correspond to that of the hollow organ to be everted. Then the base 46 with the spikes 44 and 44' is raised to the initial (upper position thereof. This causes the spikes 44 and 44' to be drawn together as a result of interaction between the spikes 44 and 44', end the replaceable parts 42' and 42" of the half-bushes 41' and 41" so that the distance 1 between the opposite spikes 44 becomes equal to the inner diameter of the replaceable

The above-mentioned interaction of the spikes 44 and 44' with the replaceable parts 42' and 42" of the half-bushes 41' and 41" respectively occurs in the following sequence.

When the base 46 is in its lower position, the spikes 44 and 44' may occupy any random position whatever usually they are fully swung back, i.e. brought maximum apart. As the base 46 carrying the spikes 44 and 44' approaches its extreme upper position, the wedgeshaped projections 47 of the spikes 44 and 44' thrust against the end faces 48 of the replaceable parts 42' and 42" of the half-bushes 41' and 41" and begin turning round the hinges 46, drawing together.

The end face 48 of the replaceable part of each halfplaceable parts 42' and 42" of the half-bushes 41' and 41" are installed in the eversion device, the spikes 44 and 44' in their upper position will be so disposed that the distance between the diametrically opposite spikes 30 44 and 44' will become equal to the inner diameter of the replaceable part 42' of the half-bush 41'.

The device for the eversion of hollow organs (FIGS. 22 - 24) is simple in design, reliable in operation and, what with the replaceable parts in the bushes, may be employed for the eversion of a variety of hollow organs, inter alia, vessels of various diameters. Furthermore, with the foregoing embodiment of the disclosed device for the eversion of hollow organs, the entire eversion procedure is in fact mechanized, thereby substantially simplifying the process of eversion and the associated surgical procedure. for example vascular stapling. Hence, the said surgical procedure may be carried out with much less effort on the part of the operating surgeon.

Serious difficulties arise in the eversion of small vessels, particularly blood vessels.

No less than 20 mm of the vessel should be exposed, as otherwise the vessel end cannot be ligated, nor can a haemostatic cuff clamp be applied thereto.

Therefore, the device of this invention for the eversion of blood vessels is provided with a haemostatic clamp mounted in the bush at the base thereof.

FIG. 25 illustrates a unique haemostatic clamp formed as a flat spiral spring 49 mounted at a base 50 of a smaller half-bush 51. The outer end 52 of the flat spiral spring 49 is rigidly coupled, for example by welding (in FIG. 25 the point of welding is indicated at Ref. No. 53), to the smaller half-bush 51, the inner end 54 of the flat spiral spring 49 being left loose.

The blood vessel to be everted is placed between a larger half-bush 55 and the smaller half-bush 51. With the half-bushes approximated, the outer section 56 of the flat spiral spring 49 forces the blood vessel against the inner surface 57 of the larger half-bush 55. Such a design of the haemostatic clamp and its position the bush of the device for the eversion of blood vessels allow surgery with the exposure of short vessel ends (of

the order of 4 to 5 mm). In addition, the haemostatic clamp of this kind is highly elastic and, whatever the diameter of the blood vessel, it ensures haemostasis without injuring the walls of the blood vessel placed between the half-bushes 51 and 55.

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If a blood vessel 58 (FIG. 26) has a small diameter, the flat spiral spring 49 experiences a relatively small amount of deformation when the half-bushes 51 and 55 are brought together, and exerts a relatively small force on the blood vessel 58. This force, however, is quite 10 sufficient to ensure haemostasis.

If, on the other hand, a blood vessel 59 (FIG. 27) has a large diameter, then, on the union of the half-bushes 51 and 55, the flat spiral spring 45 experiences a comparatively large amount of deformation and accord- 15 and 85 with the half-rings 74 and 76. ingly exerts a comparatively large force on the blood vessel 59, thereby ensuring haemostasis in this case,

In the device for the eversion of blood vessels of the design illustrated in FIGS. 22 - 24, the haemostatic 20 FIG. 29 are hidden behind the upper keys 88 and 90 clamp is disposed at the bottom of the basic part of the bush 41, over an area 60 (FIG. 22).

The foregoing devices for the eversion of hollow organs and, inter alia, various vessels, for example blood vessels which are also classified as hollow organs, may 25 be manufactured as seft-contained devices independent of other surgical instruments.

These devices may be manufactured in a range of designs, based on the alternative embodiments of the proposed device described hereinabove.

However, the disclosed devices for the eversion of hollow organs are particularly important as constituent units of various instruments for anastomosis of hollow organs.

It should be noted that the proposed device for the 35 eversion of hollow organs may be incorporated in said instruments for anastomosis of hollow organs as a selfcontained unit (eversion unit), whereof the elements take no part in any operations not involved in the eversion of a hollow organ, or else it may form a unit kinematically connected to the other units of said anastomosing instruments, the latter design ensuring the required sequence of operations of all the elements of the instrument. In the latter case, individual elements of such an eversion unit way take part in operations not 45 involved in the eversion of a hollow organ.

End-to-end vascular stapling instruments built around the disclosed device for the eversion of hollow organs, hold particular promise.

An end-to-end vascular stapling instrument, according to the invention in one of its specific embodiments comprises: two branches 61 and 62 (FIGS. 28, 29) inter connected by an axle 63; a blood vessel eversion device 64; and a mechanism 65 for feeding and directional bending of the staples at the instant of blood vessel stapling.

The branches 61 and 62 are provided with a lock 66 which keeps the branches closed (as indicated in the drawing) and prevents them from spontaneous open-

The branch 61 consists of a working piece 67 and a handle 68. The branch 62 has a working piece 69 and a handle 70. The handles 68 and 70 of the respective branches 61 and 62 are formed as rings.

The eversion device 64, mounted at the ends of the working pieces of the branches, comprises a smaller half-bush 71, a larger half-bush 72, a haemostatic

clamp 73, a half ring 74 with a spike 75, a half-ring 76 with spikes 77 and small levers 78 and 79 which form a hand actuator of the described device for the eversion of blood vessels. The smaller half-bush 71 is mounted on the working piece 67 of the branch 61, while the larger half-bush 72 is mounted on the working piece 69 of the branch 62; the half-ring 74 envelops the smaller half-bush 71, while the half-ring 76 envelops the larger half-bush 72; the small lever 78 is mounted on a pivot 80 on the working piece 67 of the branch 61, whereas the small lever 79 is mounted on a pivot 81 on the working piece 69 of the branch 62.

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The ends of arms 82 and 83 of the small levers 78 and 79, respectively, are movably connected by pivot 84

The free end of the arm 86 of the small lever 78 ends in keys 88 (upper) and 89 (lower), wehreas the free end of the arm 87 of the small lever 79 ends in keys 90 (upper) and 91 (lower). The lower keys 89 and 91 in and their location is accordingly indicated by dotted

These keys have a shape very convenient for manual actuation of the small levers 78 and 79. It is easy to depress both upper keys 88 and 90 or both lower keys 89 and 91 with one finger, thereby causing the small levers 78 and 79 to turn simultaneously around their pivots 80 and 81 clockwise or counterclockwise, respectively. The mechanism 65 for feeding and directionaly bending of the staples is in the main disposed on upper surfaces 92 and 93 of the respective working pieces 67 and 69 of the branches 61 and 62. This mechanism incorporates sliders 94 (FIGS. 30, 31) adapted to move lengthwise their respective grooves 95, wherein they are mounted. The grooves 95 are formed in said upper surfaces 92 and 93 radially relative to the centre of the bush comprising the half-bushes 71 and 72. Each slider 94 has a plate 96 movably mounted thereon by a pivot

The plates 96 have longitudinal slots 98 intended to receive the staples whereby blood vessels are sutured (the staples are not shown in the drawings).

There are coil springs 99 disposed between the plates 96 and the respective sliders 94, said springs holding the plates 96 at a predetermined angle.

As staples are placed in the slot 98, the plate 96 aligns itself at the same angle at which the staple is bent, thereby making it possible to fix the staple relative to the bush (the drawings illustrate the half-bushes 71 and 71 making up the bush).

The lower parts of the sliders 94 are dovetail-shaped. The grooves 95, whreinto the respective sliders 94 fit with their lower parts, have a corresponding shape, which provides for just one degree of freedom of slider motion in the longitudinal direction, simultaneously minimizing the possibility of transverse (horizontal and vertical) motion (due to free play).

The free end of each slider 94 has a horizontal transverse hole 100. These holes provide for a movable connection of the sliders with the drive of the mechanism 65 (FIGS. 28, 29) for feeding and directional bending of the staples whereby blood vessels are sutured.

The actuator of the mechanism 65 for feeding and directional bending of the staples is manual and comprises: a lever 101 movably mounted by a pivot 102 on the working piece 67 of the branch 61; a lever 103 movably mounted by a pivot 104 on the working piece

69 of the branch 62; a flat spring 105 loading the lever 101; a flat spring 106 loading the lever 103; a fork 107 movably mounted by a pivot 108 on the free end of the lever 101; and a fork 109 movably mounted by pivot 110 on the free end of the lever 103. The ends of the brackets 107 and 109 enter the holes 100 (FIG. 30) in the sliders 94, thereby providing for the kinematic connection of these sliders with the hand actuator. There are screws 111 turned into the faces of the free ends of the forks 107 (FIG. 24) and 109. The screws 111 pro- 10 vided for the movement of the sliders 94 from the bush centre towards the periphery as the levers 101 and 103 are respectively urged by the springs 105 and 106 to return to their initial positions.

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provides for an interlock to attain a predetermined sequence of operation of its main component units: the mechanism to feed and directionally bend the staples cannot be actuated unless the blood vessels to be sutured is completely everted.

The interlock is ensured in a very simple and reliable way: the pivots 84 and 85 have elongated and bulging ends which thrust against the respective levers 101 and 103 in the course of eversion of the blood vessels to be sutured.

The instruments in question sutured blood vessels in the following manner.

The branches 61 and 62 are separated. As a result, the smaller half-bush 71 and the larger half-bush 72, respectively mounted on the working pieces 67 and 69 of the branches 61 and 62, are separated, the small levers 78 and 79 are turned counterclockwise, the halfrings 74 with the spike 75 and 76 with the spikes 77 are in the extreme lower position, and the mechanism 65 35 for feeding and directional bending of the staples is in the initial position (the levers 101 and 103 are drawn off by the springs and the sliders 94 are at a maximum distance from the bush centre). The staples are placed in the slots 98 of the plates 96.

By depressing the upper keys 88 and 90, the small levers 78 and 79 are turned clockwise, thereby causing the half-ring 74 with the spike 75 and the half-ring 76 with the spikes 77 to move to the extreme upper position. One end (usually the shorter) of the blood vessel 45 to be sutured is inserted into the larger half-bush 72. Actuating the handles 68 and 70, the branches 61 and 62 are brought together, thereby causing the smaller half-bush 71 and larger half-bush 72 to unite and envelop said end of the blood vessel. In this position the 50 branches 61 and 62 are fixed by the lock 66. The said end of the blood vessel enveloped by the half-bushes 71 and 72 is securely clamped by the haemostatic clamp 73. On the side of the adventitia the protruding edge of this end of the blood vessel is pinned at regular intervals on the spikes 75 and 77. Then the edge of the other end of the blood vessel is pinned on these same spikes 75 and 77. The ends of the blood vessel to be sutured are usually pinned on the spikes 75 and 77 with pincers - a simple enough matter for the operating surgeon.

Following this, the lower keys 89 and 91 are simultaneously depressed, causing the small levers 78 and 79 to turn counterclockwise and the half-rings 74 and 76with the ends of the blood vessels pinned on the spikes 75 and 77 are lowered to the extreme bottom position. In the course of this operation one end of the blood vessel to be sutured is everted (turned intima outwards)

and the other end of the blood vessel is stretched over this everted end of the blood vessel.

Since the half-rings 74 and 76 are lowered during the eversion of the blood vessels being sutured, so are the pivots 84 and 85, whereof the elongated and bulging ends release the mechanism 65 for feeding and directional bending of the staples. To actuate the mechanism 65 for feeding and directional bending of the staples, hence effecting the blood vessel suturing the levers 101 and 103 are to be depressed. Turning around their pivots 102 and 104, the levers 101 and 103 move up to the stop, thus drawing together and displacing the forks 107 and 109.

The sliders 94, kinematically connected via the forks The foregoing modification of a blood vessel stapled 15 107 and 109 with the levers 101 and 103, move along the grooves 95 toward the bush centre (the drawings illustrate the smaller half-bush 71 and the larger halfbush 72 of the bush).

> The plates 96 in whose slots 98 the stapled (not 20 shown) are arranged, turn and provide for the directional bending of the staples, thus ensuring the suturing of the blood vessels by these staples.

> After that the levers 101 and 103 are released and return, urged by the respective flat springs 105 and 106, 25 to their initial positions.

The sliders 94, kinematically connected via the forks 107 and 109 with the levers 101 and 103, respectively, move in the grooves 95 away from the centre of the bush (the drawing illustrates the smaller half-bush 71 and the larger half-bush 72 of the bush). By depressing the keys 89 and 90, the small levers 78 and 79 are turned clockwise, causing the half-ring 74 with the spike 75 and the half-ring 76 with the spikes 77 to move to the extreme upper position. Then, with pincers, the blood vessel is taken off the spikes 75 and 77, the branches 61 and 62 are separated and the stapled blood vessel released

The above-described instrument for vascular suturing is build around a device for the eversion of blood vessels having spikes rigidly mounted on a base composed of two half-rings.

Obviously, other modifications of vascular staplers may employ other embodiments of devices for the eversion of hollow organs (with spikes spring-loaded relative to the base and with hinged spikes), which embodiments have been described hereinabove with reference to the accompanying drawings.

Naturally, the above-described vascular stapler may be employed for suturing other vessels, too, for example lymphatics.

The disclosed device for the eversion of hollow organs, as well as the vascular stapler built there around, have been subjected to all-round experimental testing. The tests have revealed that the proposed device considerably facilitates and speeds up the process of eversion of hollow organs, including blood vessels, and, hence, considerably facilitates and speeds up surgical procedures connected with the need to suture hollow organs.

Thus, depending on the surgical situation, it takes 1 or 2 minutes for an average surgeon to suture a blood vessel (at one point), with not more than half a minute spent for the process of eversion, if use is made of a vascular stapler built around the proposed device for the eversion of hollow organs.

At the same time, with other vascular suturing instruments employing prior art devices for the eversion of

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hollow organs, a similar surgical procedure requires 3 to 5 minutes (depending on the surgical situation), of which 2.5 to 4.5 minutes are devoted to the process of eversion.

It has been shown experimentally that the proposed 5 device permits everting, and hence suturing, short vessel ends (of the order of 4 to 5 mm), whereas prior-art devices could only handle at least 20-mm long ends of the vessels to be everted and subsequently sutured. Experiments indicate that the proposed device is suitable 10 for the eversion of a great range of vessels, including the thinnest and severely sclerosed ones.

A vascular stapler employing the proposed device for the eversion of blood vessels has been proved in numerous trails carried out on dogs at the Organ Transplanta- 15 tion Laboratory of the Sklifossovsky Emergency Aid Institute (in Moscow).

The instrument was tested in the gravest surgical situations. Thus, it was used in such operations as homoa whole set of organs.

It was also employed for simple suturing of incised blood vessels, both arteries and veins. All in all, 40 suturings of blood vessels were performed at the first stage of experimentation. The sutures were invariably 25 of the highest quality with no thrombus formation on the suture line.

At the first stage, the follow-up period was up to two

Subsequently another series of god experiments was 30 run, in which a vascular stapled built around the proposed device for the eversion of hollow organs was employed in various blood vessel suturing operations.

Out of the 28 experiments (150 anastomoses) conducted with the use of this instrument 16 were carried 35 out at the Organ Transplantation Laboratory. Not in a single case, irrespective of the follow-up period (up to 18 months), was there a complication of any kind; not a single case of thrombosis or narrowing of the vascular lumen.

At present, the proposed device for the eversion of hollow organs and the instrument for staple-suturing of blood vessels build around the proposed device for the eversion of hollow organs undergo clinical trials.

What we claim is:

- 1. A device for the eversion of hollow organs, such as a blood vessel, comprising: a hollow bush member having a peripheral outer surface, the hollow organ end to be everted adapted to be introduced into said bush member; means within said bush member for clamping said hollow organ; spikes adapted to have the edge of said hollow organ end pinned thereto; a base movably secured around the outer surface of the bush member, said spikes arranged about said base along a contour conforming to the outer peripheral surface of said bush member; and means for moving said base, and thereby said spikes, axially along said bush member.
- 2. A device for the eversion of hollow organs as of claim 1, in which the spikes, whereon the edge of the 60 hollow organ end to be everted is fixed, are rigidly mounted on said base.
- 3. A device for the eversion of hollow organs as of claim 2, wherein said means for moving the base comprises at least one manually-operable lever with a fixed 65 fulcrum relative to said bush member, which lever carries on one arm thereby said movably mounted base with spikes, while the other arm of said lever is manu-

ally operable to transmit motion to said base in the course of eversion of a hollow organ end, whereof the edge is fixed on the spikes mounted on said base.

- 4. A device for the eversion of hollow organs as of claim 3 said bush member being a split bush consisting of two half-bushes separated along a plane parallel to the longitudinal axis of said bush, in which the base carrying the spikes is formed as two half-rings, each halfring enveloping one of the half-bushes and connected by a hinge with the respective arm of the lever of the hand actuator.
- 5. A device for the eversion of blood vessels as of claim 4, which incorporates means for clamping a hollow organ mounted in said bush at the base thereof.
- 6. A device for the eversion of blood vessels as of claim 5 with the clamping means formed as a flat spiral spring, whereof the outer end is attached to the bush while the inner end is left loose.
- 7. A device for the eversion of hollow organs as of transplantation of the head, the kidneys, the liver and 20 claim 1, in which the spikes, whereon the edge of the hollow organ end to be everted is fixed, are springloaded relative to said base so that the diameter of the contour along which the spikes are arranged prior to the process of eversion should be less than the diameter of the contour along which the spikes are arranged at the end of the eversion process.
  - 8. A device for the eversion of hollow organs as of claim 7, wherein the means for moving the base comprises at least one manually-operable lever with a fixed fulcrum relative to said bush member, which lever carries on one arm thereof said movably mounted base with spikes, while the other arm of said lever is manually operable to transmit motion to said base in the course of eversion of a hollow organ end, whereof the edge is fixed on the spikes mounted on said base.
  - 9. A device for the eversion of hollow organs as of claim 8 said such member being a split bush consisting of two half-bushes separated along a plane parallel to the longitudinal axis of said bush, in which the base carrying the spikes is formed as two half-rings, each halfring enveloping one of the half-bushes and connected by a hinge with the respective arm of the lever of the hand actuator.
  - 10. A device for the eversion of blood vessels as of claim 9, which incorporates means for clamping a hollow organ mounted in said bush at the base thereof.
    - 11. A device for the eversion of blood vessels as of claim 10 with the clamping means formed as a flat spiral spring, whereof the outer end is attached to the bush while the inner end is left loose.
    - 12. A device for the eversion of hollow organs as of claim 1, in which the spikes, whereon the edge of the hollow organ end to be everted is fixed, are movably mounted on said base by hinges so that said spikes could be drawn together prior to the eversion process.
  - 13. A device for the eversion of hollow organs as of claim 12, wherein the means for moving the base comprises at least one manually-operable lever, whereof the fulcrum is fixed relative to said bush member, which lever carries on one arm thereof said movably mounted based with spikes, while the other arm of said lever is manually operable to transmit motion to said base in the course of eversion of a hollow organ end, whereof the edge is fixed on the spikes mounted on said base.
  - 14. A device for the eversion of hollow organs as of claim 13 said bush member being a split bush consisting

of two half-bushes separated along a plane parallel to the longitudinal axis of said bush, in which the base carrying the spikes is formed as two half-rings, each halfring enveloping one of the half-bushes and connected by a hinge with the respective arm of the lever of the 5 hand actuator.

- 15. A device for the eversion of blood vessels as of claim 14, which incorporates means for clamping a hollow organ mounted in said bush at the base thereof.
- 16. A device for the eversion of blood vessels as of 10 claim 15 with the clamping means formed as a flat spiral spring, whereof the outer end is attached to the bush while the inner end is left loose.
- 17. A device for the eversion of hollow organs as of claim 1, which comprises a hand drive incorporating at 15 least one lever with a fixed fulcrum relative to said bush member, which lever carries on one arm thereof said movably mounted base with said spikes, while the other arm of said lever is made so that it could be manually actuated to transmit motion to said base in the course 20 of eversion of a hollow organ end, whereof the edge is fixed on the spikes mounted on said base.
- 18. A device for the eversion of hollow organs as of claim 17 said bush member being a split bush consisting of two half-bushes separated along a plane parallel to 25 the longitudinal axis of said bush, in which the base carrying the spikes is formed as two half-rings, each half-ring enveloping one of the half-bushes and connected by a hinge with the respective arm of the lever of the hand actuator.
- 19. A device for the eversion of blood vessels as of claim 18, which incorporates means for clamping a hollow organ mounted in said bush member at the base thereof.
- 20. A device for the eversion of blood vessels as of 35 claim 19 with the clamping means formed as a flat spiral spring, whereof the outer end is attached to the bush while the inner end is left loose.
- 21. A device for the eversion of hollow organs according to claim 1, wherein said spikes comprise S-40 shaped fulcrum levers, each having a fulcrum in the form of a hinge, one, smaller arm of said lever comprising a wedge-shaped projection disposed below immediately adjacent to the hinge and facing said bush member, the other, larger arm of said lever being disposed 45 above said hinge and tapering down to a point whereon said edge of the hollow organ to be everted is pinned,

the base to which said spikes are movably mounted embracing the lower part of the bush member, so as to be axially movable therealong, the upper part of the bush member being made replaceable with the inside diameter substantially equal to the outside diameter of the hollow organ to be everted, the surface of the lower end of said replaceable part of the bush member conforming to the surface of the wedge-shaped projections of the spikes so that with the spikes being in the uppermost position the larger arms thereof should be drawn together and thrust against the upper edge of the replaceable part of the bush member.

- 22. A device for the eversion of hollow organs as of claim 21, wherein the means for moving the base comprises at least one manually-operable lever, whereof the fulcrum is fixed relative to said bush member, which lever carried on one arm thereof said movably mounted base with spikes, while the other arm of said lever is manually operable to transmit motion to said base in the course of eversion of a hollow organ end, whereof the edge is fixed on the spikes mounted on said base.
- 23. A device for the eversion of hollow organs as of claim 22 said bush member being a split bush consisting of two half-bushes separated along a plane parallel to the longitudinal axis of said bush, in which the base carrying the spikes is formed as two half-rings, each half-ring enveloping one of the half-bushes and connected by a hinge with the respective arm of the lever of the hand actuator.
- 24. A device for the eversion of blood vessels as of claim 25, which incorporates means for clamping a hollow organ mounted in said bush at the base thereof.
- 25. A device for the eversion of blood vessels as of claim 24 with the clamping means formed as a flat spiral spring, whereof the outer end is attached to the bush while the inner end is left loose.
- 26. A device for the eversion of blood vessels as of claim 22, which incorporates means for clamping a hollow organ mounted in said bush member at the base thereof.
- 27. A device for the eversion of blood vessels as of claim 26 with the clamping means formed as a flat spiral spring, whereof the outer end is attached to the bush while the inner end is left loose.

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