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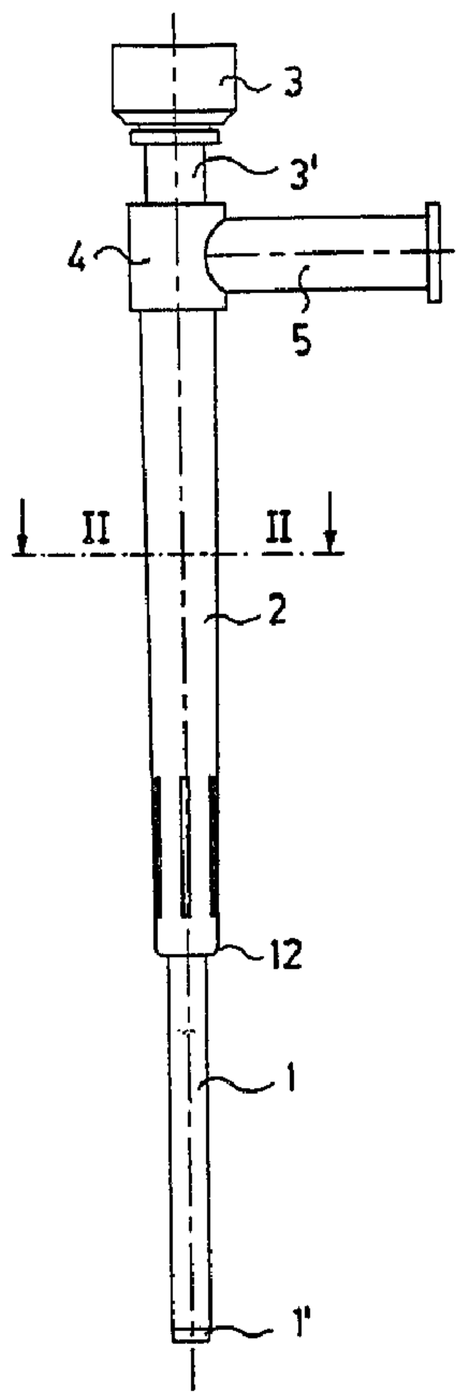
(54) Title: USE OF AND PROCESS FOR THE INTRODUCTION OF FIBRIN SEALANT INTO A PUNCTURE CHANNEL



(57) Abrégé/Abstract:
Following an intravascular operation, the puncture channel is sealed as near to the vessel as possible with a two-part fibrin sealant. This is done by means of a device which comprises a sealing cannula or the sealing cannula is fitted with a medical connector. The

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sealing cannula has a reinforced sleeve with a connecting stub in which the two fibrin sealant components are mixed and introduced into the axial gap between the working and sealing cannulas. The fibrin sealant is taken to the region of the vessel to be sealed via radial outlets.

ABSTRACT OF THE DISCLOSURE

Following an intravascular operation, the puncture channel is sealed as near to the vessel as possible with a two-part fibrin sealant. This is done by means of a device which comprises a sealing cannula or the sealing cannula is fitted with a medical connector. The sealing cannula has a reinforced sleeve with a connecting stub in which the two fibrin sealant components are mixed and introduced into the axial gap between the working and sealing cannulas. The fibrin sealant is taken to the region of the vessel to be sealed via radial outlets.

USE OF AND PROCESS FOR THE INTRODUCTION OF FIBRIN SEALANT INTO A PUNCTURE CHANNEL

The present invention relates to the use of endogenous blood coagulants obtained from plasma protein in the form of a two-component fibrin sealant, whose components are mixed at the instant they are delivered.

The invention also relates to a device for introducing the two-component fibrin sealant into a puncture channel in the vicinity of an arterial or venous puncture point.

Many operations in human or veterinary medicine require puncturing of vessels. With percutaneous transluminar coronary angioplasty (PTCA), heart operations and catheterizations of the heart in particular it is necessary to close the punctured vessels again with great care. In most cases this is performed by means of direct compression of up to one hour and a compression bandage which must be applied up to 24 hours and requires hospitalization of one to two days. Accordingly there is the desire to find a solution leading to a more rapid and secure closure of the puncture point.

A method by the name of Vasoseal was introduced during a meeting of the American Heart Association on 11. 17. 1992 in New Orleans. With this method respectively two collagen plugs made of bovine collagen were pushed into the puncture channel as far as the puncture point. It was noted during the said meeting that, besides the somewhat rare rejection reaction of the exogenous collagen, there are various other disadvantages or risks. It was noted that this system is ineffective in many cases and that there is a certain danger of emboli. In approximately 46% of all cases hematomas of an order of magnitude between 2 to 6 cm were formed. Weeks or months go by before the bovine collagen is completely resorbed. In addition, the method leads to increased scar

formation which makes an ultrasonic examination more difficult. Finally, although hospitalization did not become superfluous, it was reduced by at least 24 hours. However, one of the most essential problems lies in the handling, i.e. the introduction of the collagen plugs into the puncture channel. Since it is necessary to push two collagen plugs successively into the puncture channel, the user finds the penetration depth, for example, hard to determine. If the collagen plugs are pushed in too deeply it is possible that the collagen plug is pushed through the puncture point into the vessel, which would result in an obstruction or in the vessel itself being pushed closed.

Accordingly it was the object of the present invention to find a novel method to close such puncture points rapidly, dependably and without the above mentioned disadvantages.

It has been shown that when endogenous blood coagulants obtained from plasma protein in the form of a two-component fibrin sealant, whose components are mixed at the instant they are delivered, are used and this mixture is introduced into a puncture channel as close as possible to a vessel during or directly following an intravascular intervention, an optimal vessel seal is created. Histological tests have proven these facts.

It was a further object of the present invention to provide a device by means of which fibrin sealant can be introduced into a puncture channel in the vicinity of an arterial or venous puncture point.

This object is attained by a device comprising a sealing cannula through which a work cannula passes axially from top to bottom, wherein the work cannula which is used for the intravascular introduction of an instrument into a vessel is surrounded at a distance by the sealing cannula, so that the

fibrin sealant is conducted from a connector to at least one radially oriented outlet opening in the sealing cannula between the latter and the work cannula.

Further advantageous embodiments of the device ensue from the dependent claims and their meaning and advantages are explained in the subsequent description.

Two preferred exemplary embodiments of the device of the invention are represented in the drawings and explained by means of the description. Shown are in:

Fig. 1, a total view of a first embodiment of the device of the invention in a total view, and

Fig. 2, a cross section through the device of Fig. 1 along the line II - II on an enlarged scale.

Fig. 3, an axial longitudinal section through the embodiment of Fig. 1, and

Fig. 4, an enlarged section of the device in the area of the connector, and

Fig. 5, an enlarged section in the area of the exit of the working cannula from the sealing cannula.

Fig. 6 again shows a total view of a second embodiment of the device, and

Fig. 7, a cross section through this device along the line VII - VII of Fig. 6.

Fig. 8, represents an axial longitudinal section through the device of Fig. 6, and

Fig. 9, again an enlarged section of the drawing of Fig. 8 in the area of the connector, and

Fig. 10, in the area of the exit of the working cannula from the sealing cannula.

In what follows, first the two preferred embodiments of the device of the invention and then their manipulation and the general employment of fibrin sealant for sealing a puncture point in a vessel will be shown. The simpler embodiment of the device in accordance with Figs. 1 to 5 consists of only three elements which can be put together. The working cannula, also called worksheet in technical language, is identified by the reference numeral 1. The working cannula itself is simply a small cylindrical tube open at both ends, made of plastic. Its front end 1' is used for introducing the cannula through the puncture point into the opened blood vessel. The working cannula is relatively thin-walled and therefore has a certain amount of bending flexibility. In this embodiment the working cannula 1 is fixedly connected with a medical coupling 3 at the other end, the rear end. The actual medical coupling 3 can be a known Luer locking coupling, for example. An exactly fashioned muff 3' is formed in an interlocking and sealing manner on the actual medical coupling 3. The working cannula 1 axially extends in the longitudinal direction through a sealing cannula 2 and at the bottom projects for some distance out of the sealing cannula. The sealing cannula 2 itself is also again embodied in the shape of a small concentric tube, but its exterior diameter, and preferably also its interior diameter, decrease from the top to the bottom, i.e. the interior diameter is reduced from the side where the medical coupling 3 is inserted to the lower end where the working cannula emerges from the sealing cannula 2.

Thus a hollow space 7 remains between the working cannula and the sealing cannula over the entire length on which the working cannula 1 is concentrically enclosed by the sealing cannula 2. The sealing cannula 2 has a reinforced cuff 4 at the

upper end, which has a considerably greater wall thickness than the wall thickness of the sealing cannula 2. A connector 5 terminates in the sealing cannula 2 in the area of the reinforced cuff 4. A two-component fibrin sealant can be introduced into the hollow space between the working cannula and the sealing cannula through this connector 5. The fibrin sealant can exit from the hollow space 7 only through the outlet opening 6 in the lower area of the sealing cannula 2. So that fibrin sealant does not unintentionally enter the blood vessel, the outlet openings 6 are at least approximately radially oriented toward the outside. Of course, by radially not only the direction, interpreted in a strictly geometric sense, is meant. Instead this is only intended to express that the outflow direction is not axial. The functioning of the device is of course already assured by means of a single outlet opening, but preferably several outlet openings 6 distributed over the circumference will be provided. Also, in principle the form of the embodiment of the outlet openings 6 can be freely designed. However, for technical production reasons they will be formed in the shape of several linear slits distributed over the circumference.

To form an exact receptacle 15 for the medical coupling 3, the upper opening of the sealing cannula 2 must be provided with a snug fit.

For sealing the working cannula 1 against the sealing cannula 2 in the area of the through-opening 10, an annular sealing bead or sealing rib 11, which is oriented radially inward and sealingly rests on the outer surface of the working cannula 1, is disposed in the through-opening 10.

Although in a preferred manner the connector 5 is formed in one piece directly on the sealing cannula 2 in the area of the

reinforced cuff, it is of course also possible to manufacture the connector separately and to connect it later with the sealing cannula by means of a screw thread 17. In place of the screw connection 17, a welded or adhesive connection is of course also conceivable. Mixing elements are already available on the market for mixing the two components of the two-component fibrin sealant. Therefore, for reasons of cost the connector 5 would be sized in such a way that an already available mixing element 13 can be inserted into it.

As already mentioned, the wall thickness of the working cannula 1 is very little. Preferably it is only a few tenths of a millimeter. The hollow space 7 remaining concentrically around the working cannula 1 between its outer wall and the inner wall of the sealing cannula 2 is of extremely small dimensions. Since all of the surgical instruments must be inserted and removed though the working cannula 1, it is of advantage to provide means which cause this hollow space 7 to remain continuously open. Support ribs 9 which preferably extend axially are disposed on the inner wall of the sealing cannula 2 for this purpose.

The support ribs 9 also result in a stiffening of the also thin-walled sealing cannula 2. By means of this the danger is removed that a slight contraction of the muscular tissue through which the sealing cannula extends leads to a deformation of the sealing cannula 2 which could close the hollow space 7. In this way the required through-opening for the fibrin sealant is assured in any case. The second preferred embodiment of the device of the invention for introducing two-component fibrin sealant through a puncture channel into the vicinity of an arterial or venous puncture point is illustrated in Figs. 6 to 10. While with the first embodiment the working cannula 1 with the associated medical

coupling 3 must be exactly adapted to the sealing cannula for a sealing connection, with the second embodiment it is possible to use a commercially available working cannula with an arbitrary medical coupling 3. In this case a sealing connection between the medical coupling 3 and the sealing cannula 2 is omitted.

Hardly any difference can be seen in the exterior shape of the two devices. Accordingly, identical parts have been given the same reference numerals in both embodiments. Here, too, the working cannula 1 completely extends in the axial direction through the sealing cannula 2. However, the medical coupling 3 fixedly disposed on the working cannula 1 does not enter the sealing cannula 2, but is located shortly above it. The lower end of the working cannula 1' again is embodied to be conical.

The sealing cannula 2 again has a reinforced cuff 4 at its upper end. Here, too, a connector 5 terminates into the interior of the sealing cannula 2 in the area of the reinforced cuff 4. At is lower end, i.e. in the area shortly above the through-opening 10, it also has an outlet opening 6 directed approximately radially outward. Here, too, several outlet opening 6 are disposed evenly distributed over the circumference, which again are embodied slit-like. The essential difference between this embodiment and the previously described embodiment can be seen in particular in the sectional drawing of Fig. 8. In this case a support envelope 20 is maintained in the sealing cannula 2, which defines a free space 21 between itself and the inner wall of the sealing cannula 2. The working cannula 1 passing through the sealing cannula 2 now extends inside the support envelope 20. The fibrin sealant pressed in through the connector 5 now no longer flows directly between the outer wall of the working cannula 1 and the inner wall of the sealing cannula 2, but instead between the

outer wall of the support envelope 20 and the inner wall of the sealing envelope 2. In the area of the lower outlet opening 10, the sealing cannula 20 is provided with a thickened head area 12. This also applies to the first described embodiment. A concentric groove 23 has been cut into the inside of this thickened head area 12. This groove 23 narrows from top to bottom, so that the support envelope 20 is slightly widened when it is pushed on and comes to rest sealingly in the annular groove 23. The support envelope 23 is maintained at the top in a similar manner in a lead-in plug 18. The lead-in plug 18 has a centered through-bore 24.

The working cannula 1 enters the support envelope 20 through this bore. An annular sealing bead 25 results in a clamping and sealing support of the working cannula 1 in the support envelope 20. The lead-in plug 18 is provided with a collar 25 which, in the assembled state of the lead-in plug, fits completely into a recess in the reinforced cuff 4. The reinforced cuff 4 can be provided with an again reinforced outer diameter in the upper area to obtain a sufficient wall thickness. The lead-in plug 18 is also provided with an annular concentric groove 24, whose diameter widens from the bottom to the top, so that here, too, the slightly widened support envelope 20 is held clampingly and sealingly. As can be clearly seen from Fig. 9, the two-component fibrin sealant enters the free space 21 through the connector 5 in which the mixing element 13 is disposed.

Here, too, is the head area 12 abruptly thickened and rounded. The abrupt thickening is used so that the sealing cannula 2 is not pushed through the puncturing place in the blood vessel into the latter. On the other hand, the rounding is

intended to ease the introduction of the sealing cannula into the puncture channel.

The working cannula 1 is here also sealed against the sealing cannula 2. This is achieved by means of a sealing lip 22 at the end, which rests on the outer wall of the working cannula 1.

However, the function of the annular sealing lip 22 is not the same as that of the sealing bead 11 or the sealing ring, namely for sealing the hollow space of the sealing envelope 2 and therefore to prevent the exit of the fibrin sealant in the axial direction, but is used for preventing the entry of blood into the area between the working cannula 1 and the support envelope 20.

The employment of the device in accordance with the invention will be briefly described. In a first step in the course of catheterization a hollow needle is pushed through the skin and the various tissue layers underneath it up to the blood vessel to be punctured. A guide is pushed into the blood vessel through the hollow needle. Leaving the guide in the introduced position, the hollow needle is retracted over the guide and in place of it a dilator is pushed through the puncture channel into the blood vessel. Afterwards, the working cannula and the sealing cannula are then fed through the dilator, wherein the working cannula is inserted into the blood vessel, while the abruptly thickened head area of the sealing cannula is only pushed in as far as the puncture point. Thus the outlet openings 6 are located above the puncture point of the blood vessel, but inside the puncture channel. The physician now can insert the necessary instruments through the working cannula into the blood vessel. This can be a balloon catheter, a fiber-optical wave guide or the probe of a camera or also other means.

At the end of the operation or examination, first the instruments are pulled out of the vessel through the working cannula and then the two-component fibrin sealant is pressed through the connector 5, the free space 21 or the hollow space 7 and through the outlet openings 6 into the puncture channel. After only a few seconds the fibrin sealant results in coagulation into a fibrin clot of the in the area of the puncture channel or the puncture point, because of which bleeding is completely stopped. The formation of hematomas is entirely prevented. A risk of an embolus could no longer be noted. A one hundred percent effectiveness has been achieved in all tests performed to date. No rejection reactions to the human fibrin sealant were noted. Even with the use of an increased concentration of aprotinin, excellent sealing was obtained in animal tests (dog, minipig).

Hospitalization of the patient can therefore be omitted.

The use of the human two-component fibrin sealant, known for several years, for use in sealing a puncture point or a puncture channel to the puncture point is not known. This novel sealing method by means of the fibrin sealant is in no way obvious, since up to now it had always been assumed that the entry of fibrin sealant into the bloodstream could lead to complications. Only the present applicator permits a danger-free use of the fibrin sealant.

The application in accordance with the invention of the fibrin sealant can also take place without the device of the invention in that the fibrin sealant is directly applied in the puncture channel by means of an injection needle. However, since the exact location of the puncture channel by means of an injection needle is not quite simple, it would be better not to

employ this method. If the injection of the fibrin sealant takes place outside the area of the puncture channel, there will of course be no sealing of the blood vessel.

Surely other embodiments, besides the above described preferred embodiments of the device in accordance with the invention, are conceivable without departing from the basic concept of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A device for introducing a two-component fibrin sealant into a puncture channel in the vicinity of an arterial or venous puncture point, the device comprising a sealing cannula, through which a working cannula extends axially from top to bottom, which is used for intravascular introduction of instruments into a blood vessel, in which the working cannula is surrounded in spaced-apart manner by the sealing cannula, so that in use the fibrin sealant is conveyed from a connector to several slot-like, radially-directed outlet openings in the sealing cannula between the sealing cannula and the working cannula.

2. A device according to claim 1, in which the sealing cannula is provided with a one-piece shaped, reinforced cuff at an upper end.

3. A device according to claim 2, in which said working cannula is fixed to a medical coupling, which is held in the reinforced cuff of the sealing cannula in a frictionally and/or interlockingly sealing manner, extending axially with respect to the working cannula.

4. A device according to claim 3, in which, in the area of a lower passage of the working cannula through the sealing cannula, the sealing cannula has a radially inwardly-directed, annular sealing bead.

5. A device according to claim 2, in which the sealing cannula is closed at the top by a lead-in plug, in which is sealingly-held a tube-shaped support envelope, which itself

extends through the entire sealing cannula and is sealingly maintained in the sealing cannula at the opposite lower end, and in which the working cannula is guided in freely-movable manner in the support envelope, so that the fibrin sealant can flow in the radial free space between the support envelope and the sealing cannula from the connector to the outlet openings.

6. A device according to claim 5, in which said support envelope is provided with a plurality of radially-outwardly directed reinforcing ribs directed toward an inner wall of the sealing cannula.

7. A device according to any one of claims 2 to 6, in which said connector is laterally formed as one piece onto the reinforced cuff.

8. A device according to any one of claims 2 to 6, in which said connector is separately manufactured and is connectable to the reinforced cuff.

9. A device according to claim 7 or 8, in which a mixing element is insertably held in said connector.

10. A device according to any one of claims 1 to 9, in which the internal diameter of the sealing cannula decreases from the vicinity of the mouth of the connector to said outlet openings.

11. A device according to any one of claims 1 to 10, in which the sealing cannula has inwardly-directed support ribs, which ensure a cavity for guiding the fibrin sealant from the connector to the outlet openings.

12. A device according to claim 11, in which said support ribs are oriented at least approximately radially.

13. A device according to any one of claims 1 to 12, in which the sealing cannula has an abruptly widened, rounded head area at the lower end where the working cannula emerges therefrom.

14. A device according to claim 13, in which said head area has an axially-extending annular sealing lip seated on the working cannula.

15. A device for introducing a two-component fibrin sealant into a puncture channel in the vicinity of an arterial or venous puncture point, the device comprising a sealing cannula, through which a working cannula, having an open distal end and a proximal end with a fixedly-connected medical coupling, extends axially from an upper end through a lower end of the sealing cannula, the working cannula being movable within the sealing cannula and suitable for conveying intravascular instruments through the working cannula into a blood vessel, wherein: said working cannula is surrounded in a spaced-apart manner by said sealing cannula, whereby the fibrin sealant is conveyed from a connector connected to the upper end of said sealing cannula to at least one slit-shaped radially-directed outlet opening in the sealing cannula between the sealing cannula and the working cannula; and said sealing cannula comprises a reinforced cuff formed as one piece on an upper end of said sealing cannula, an inner diameter of said sealing cannula being reduced from an area of the termination of the connector to the at least one slit-shaped radially-directed outlet opening.

16. A device according to claim 15, wherein the connector is laterally integrally formed on the reinforced cuff.

17. A device according to claim 15, wherein the connector is a separate piece and is connected to the reinforced cuff.

18. A device according to claim 16 or 17, wherein a mixing element is insertably maintained in said connector.

19. A device according to any one of claims 15 to 18, wherein the sealing cannula comprises at least one inwardly-oriented support rib, thereby maintaining a hollow space for conducting the fibrin sealant from the connector to the at least one outlet opening.

20. A device according to claim 19, wherein the at least one support rib is arranged to extend at least approximately radially.

21. A device according to any one of claims 15 to 20, wherein the working cannula is fixedly connected to a medical coupling, and the medical coupling is maintained in the reinforced cuff of the sealing cannula in one of a frictionally and interlockingly sealing manner, extending axially with respect to the working cannula.

22. A device according to claim 21, wherein, in the area of a lower passage of the working cannula through the sealing cannula, the sealing cannula comprises a radially inwardly-directed annular sealing bead.

23. A device according to any one of claims 15 to 22, wherein the sealing cannula is closed at said upper end by a lead-in plug, a tube-shaped support envelope is sealingly-maintained within said lead-in plug, the tube-shaped support envelope extending through the sealing cannula and being sealingly maintained at the opposite lower end in the sealing cannula, and said working cannula is freely movable in the support envelope, whereby the fibrin sealant can flow in a radial free space formed between the supporting envelope and the sealing cannula from the connector to said at least one outlet opening.

24. A device according to claim 23, wherein the support envelope comprises a plurality of stiffening ribs directed radially-outward and toward an inner wall of the sealing cannula.

25. A device according to any one of claims 15 to 24, wherein the sealing cannula comprises an abruptly-widened rounded head area at the lower end where the working cannula emerges from the sealing cannula.

26. A device according to claim 25, wherein the head area comprises an axially-extending annular sealing lip seated on the working cannula.

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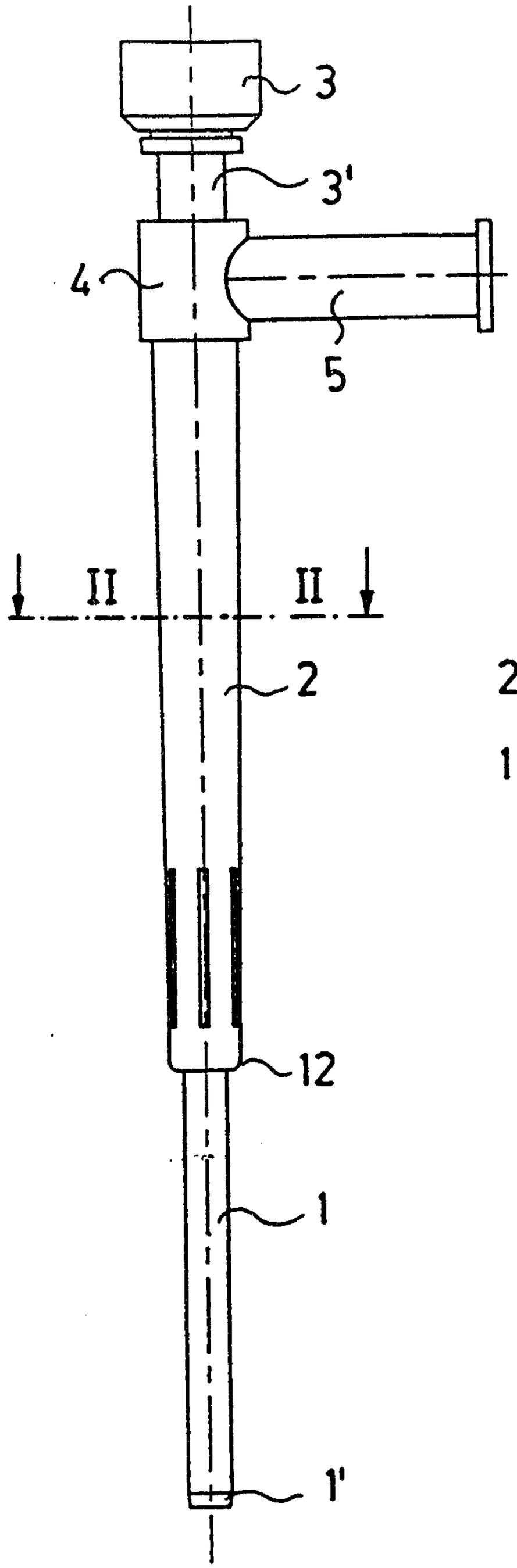

FIG. 1

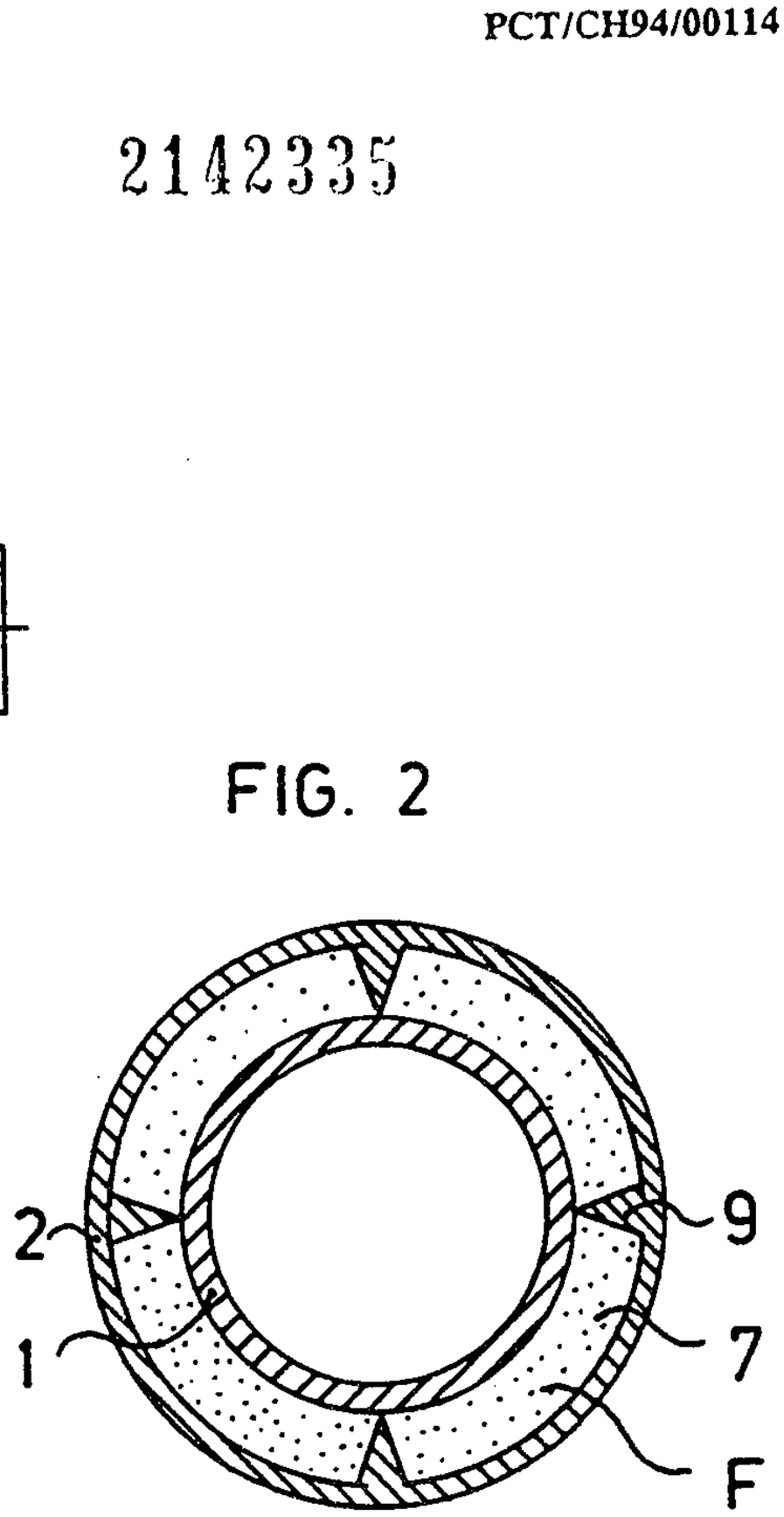

FIG. 2

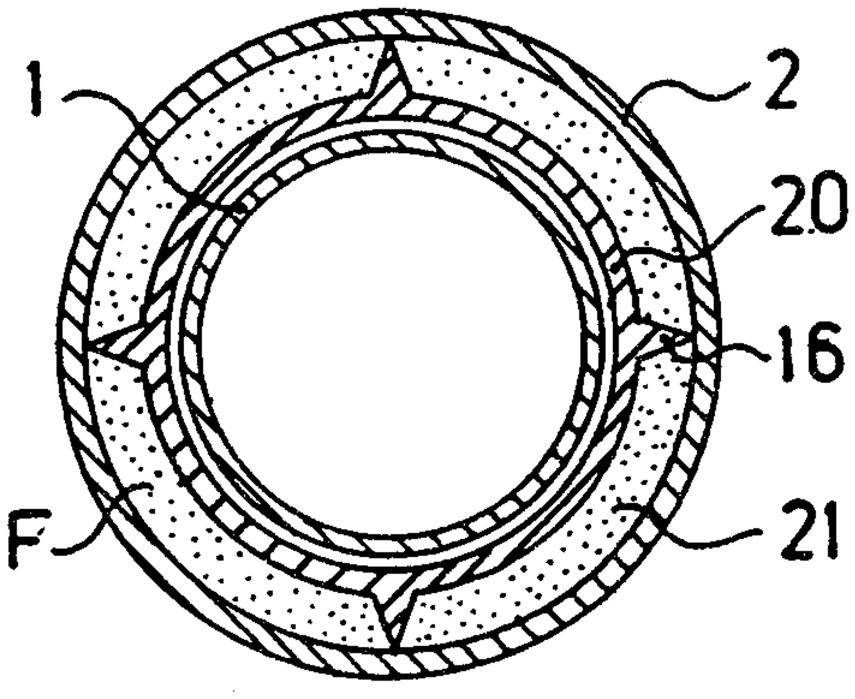

FIG. 7

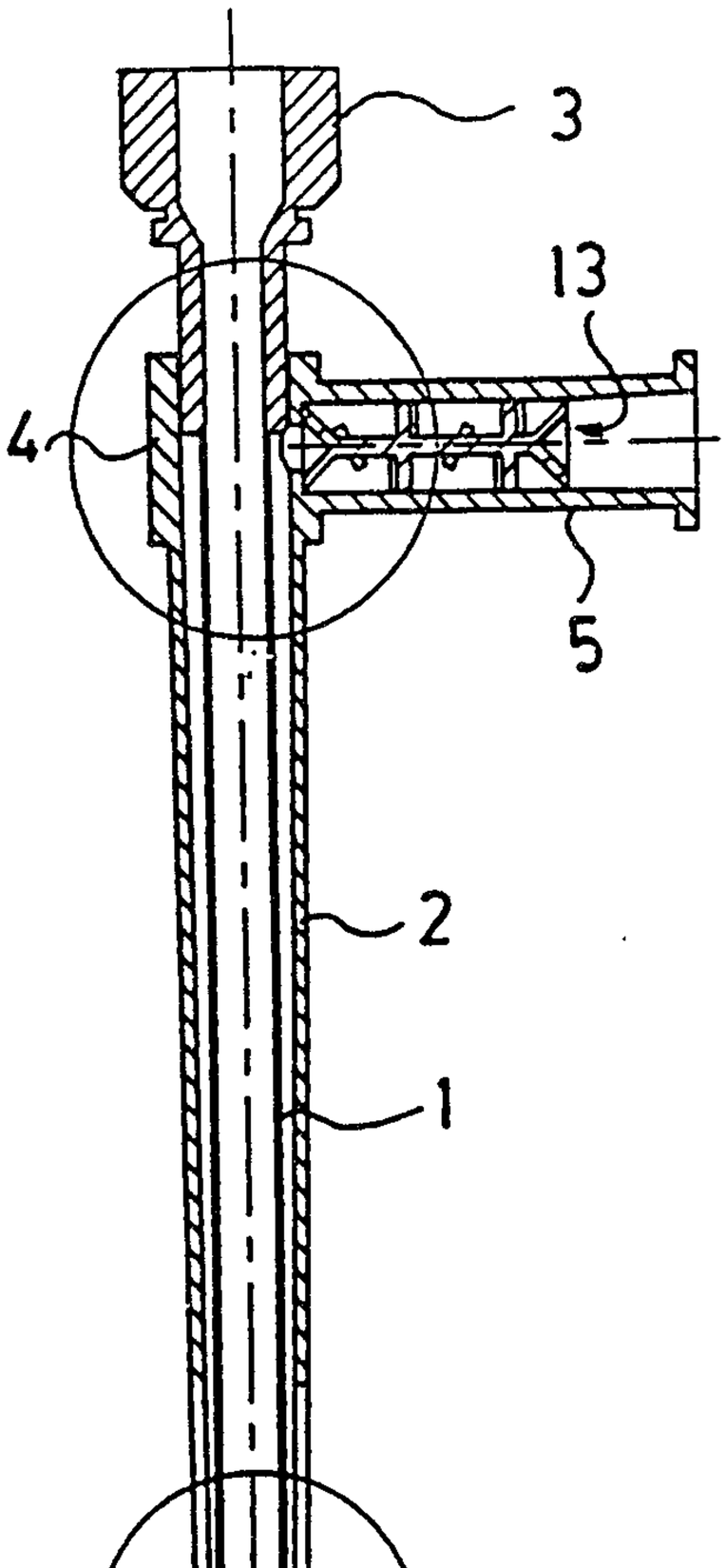

FIG. 3

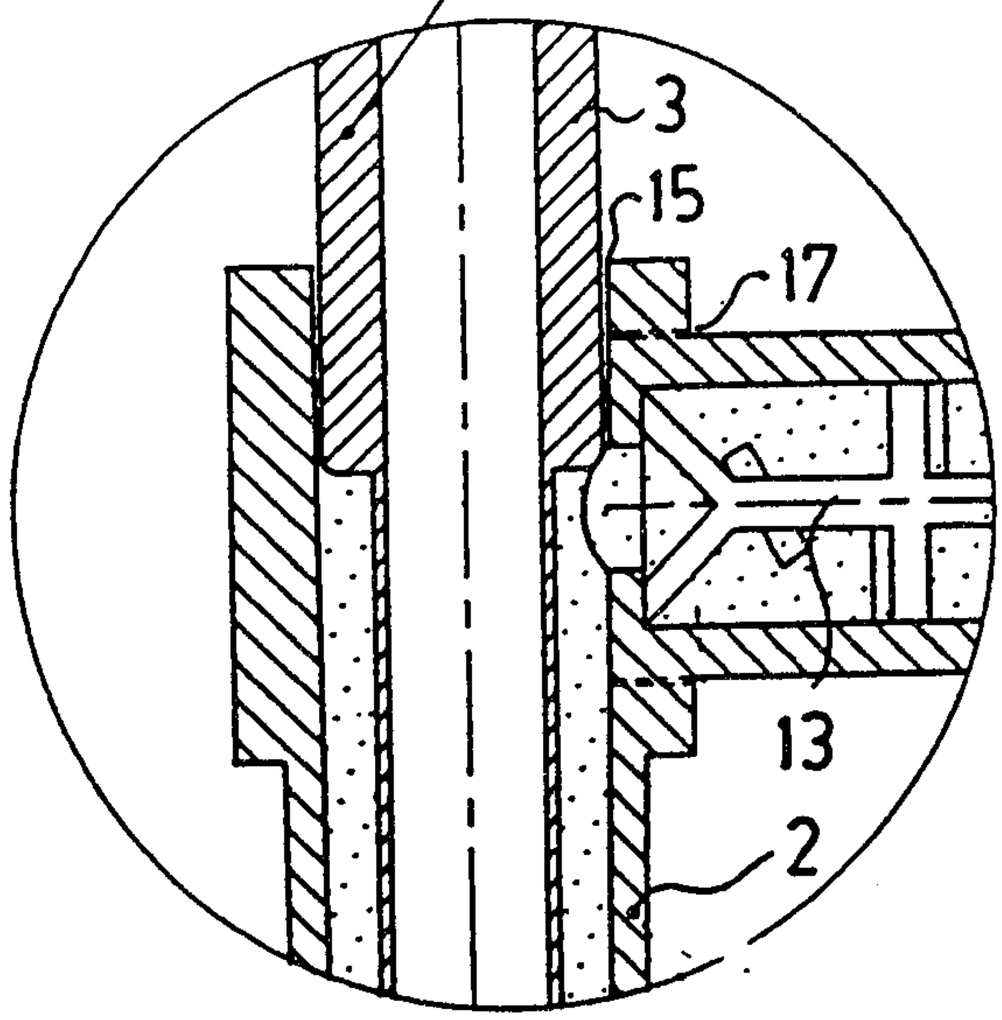

FIG. 4

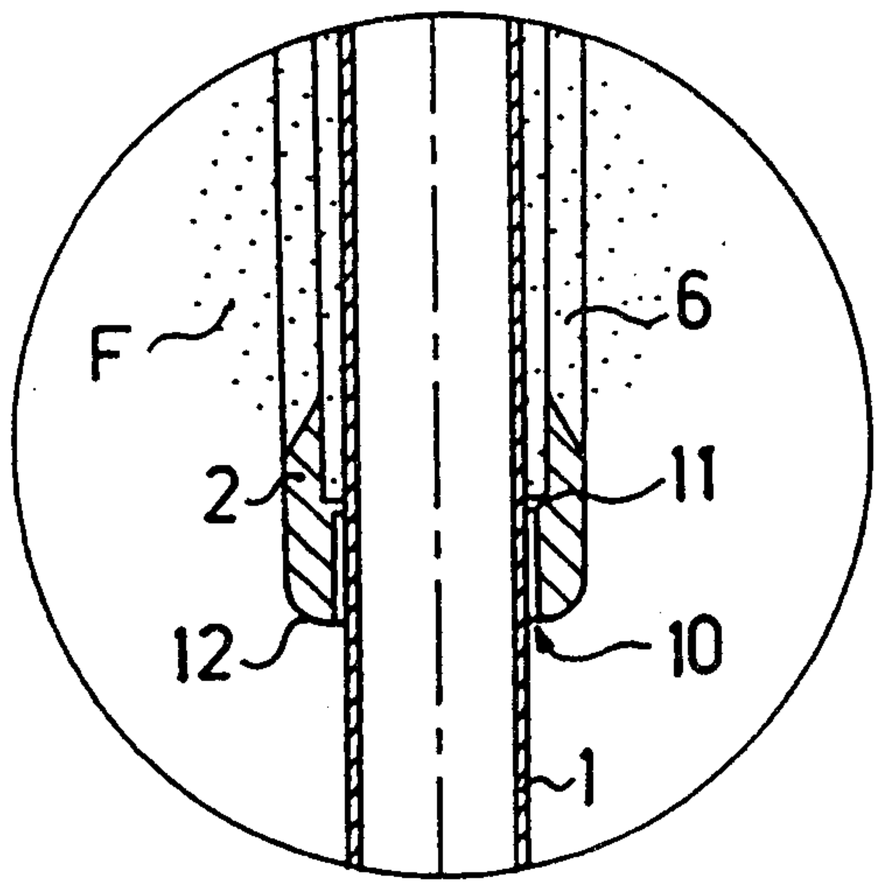

FIG. 5

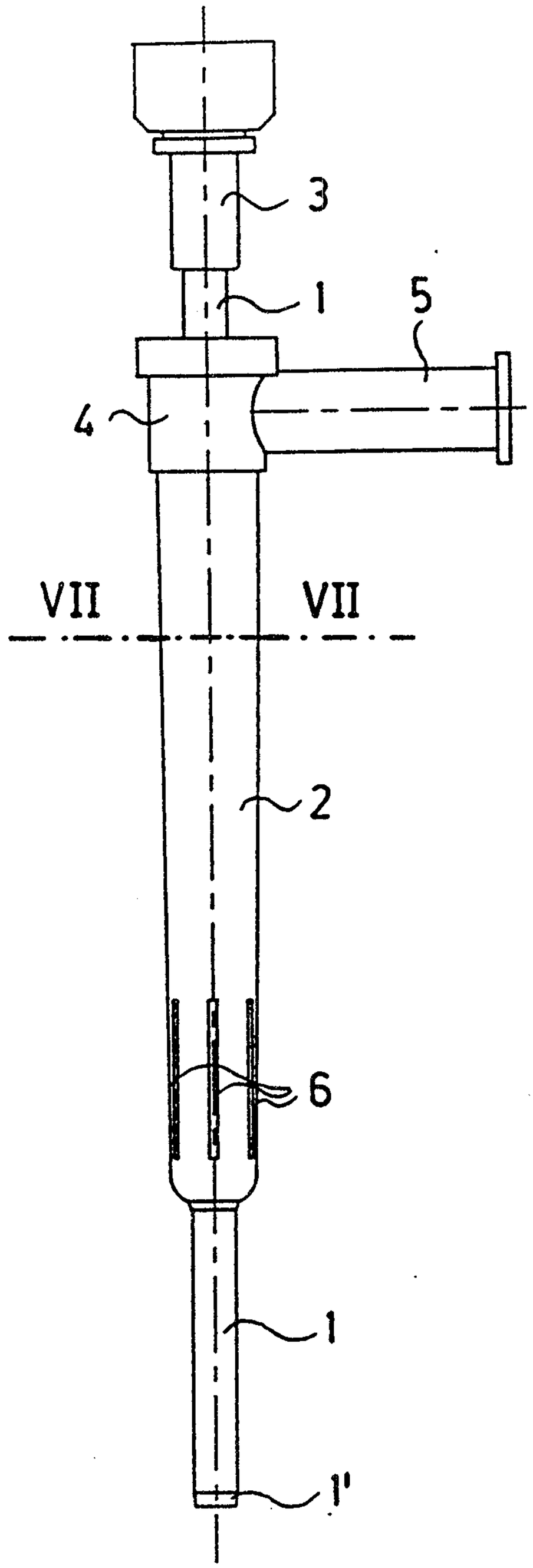

FIG. 6

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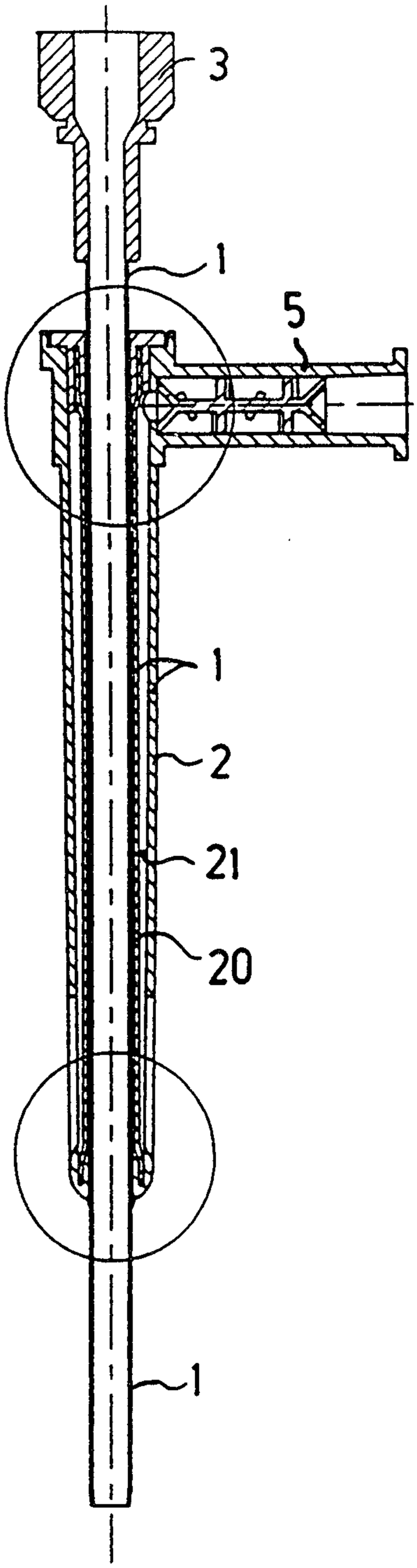


FIG. 8

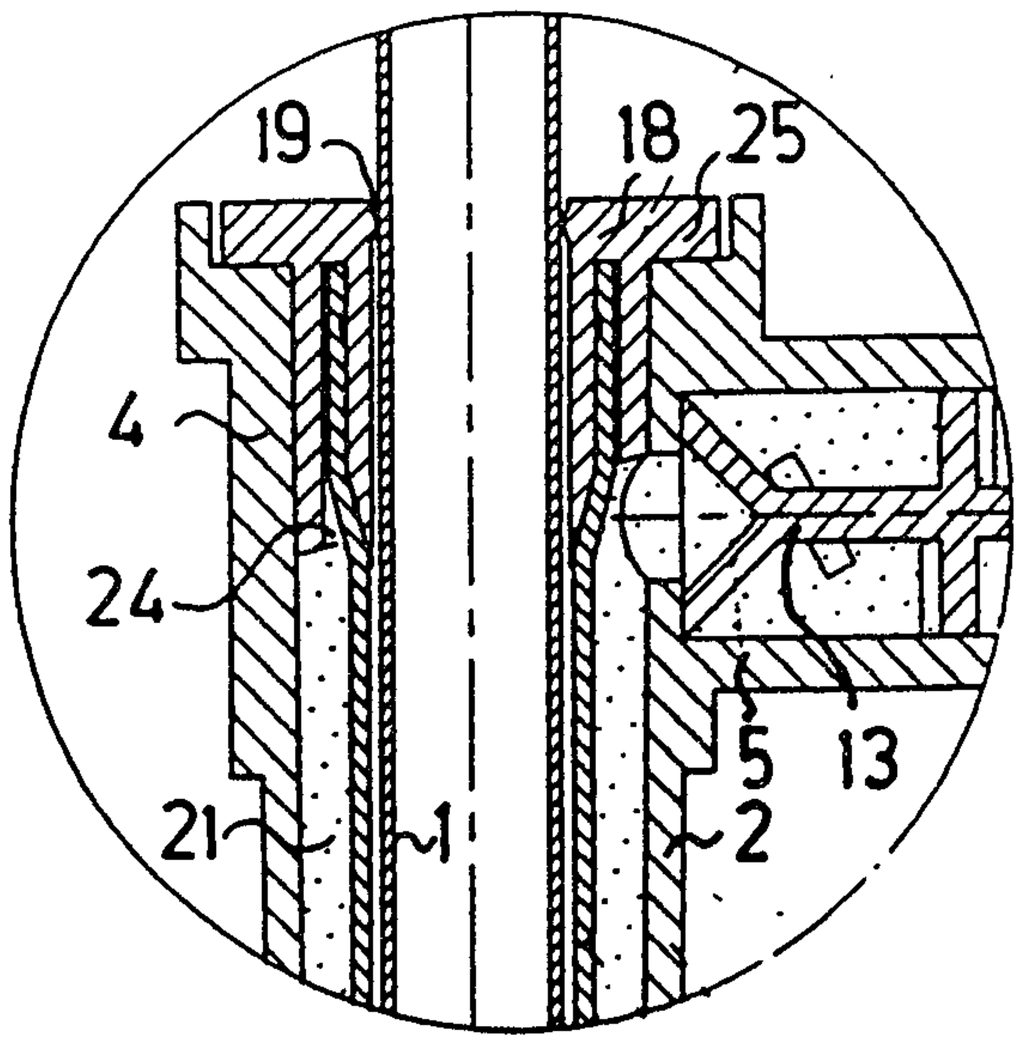


FIG. 9

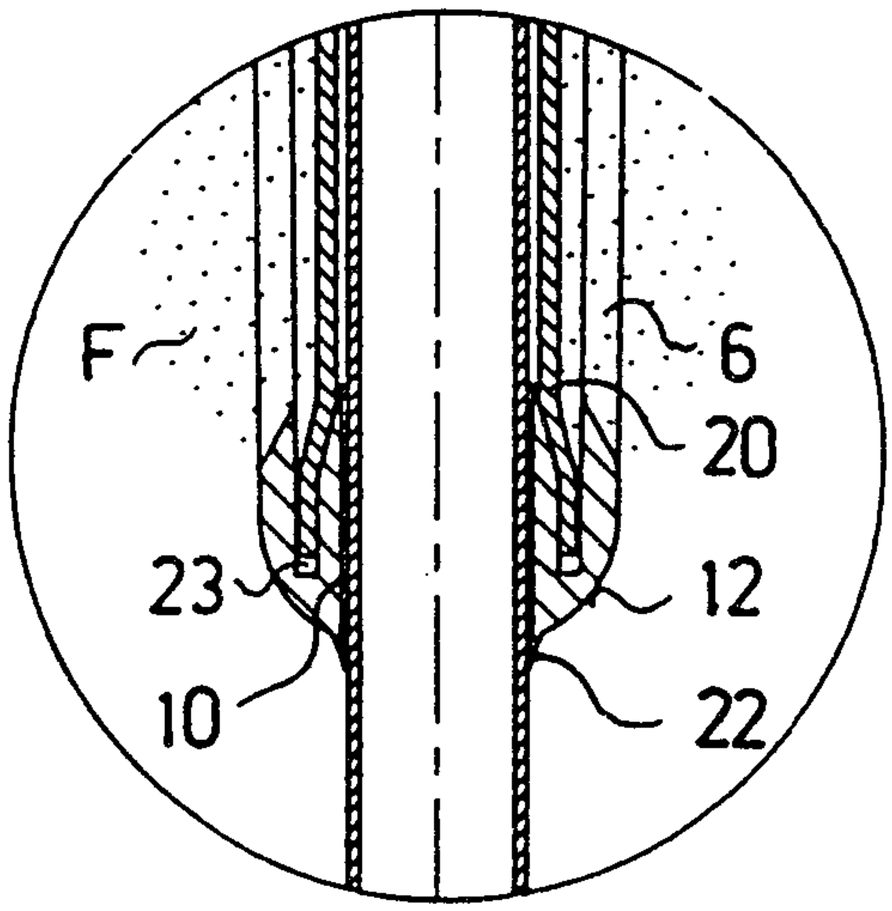
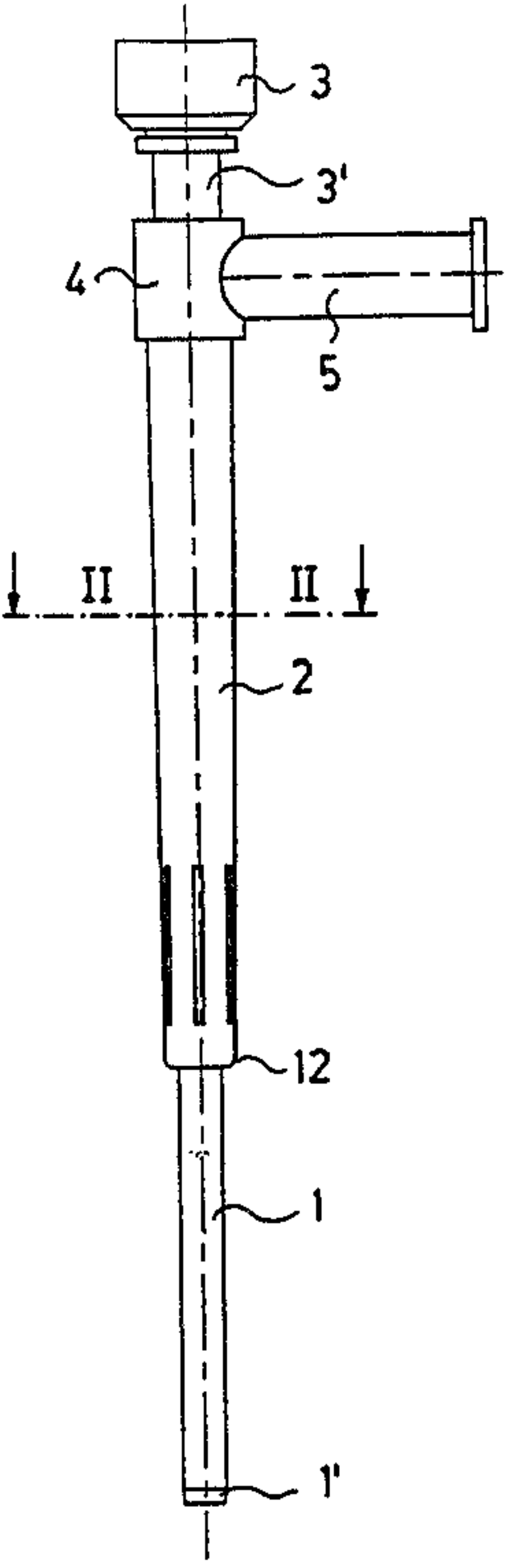


FIG. 10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