

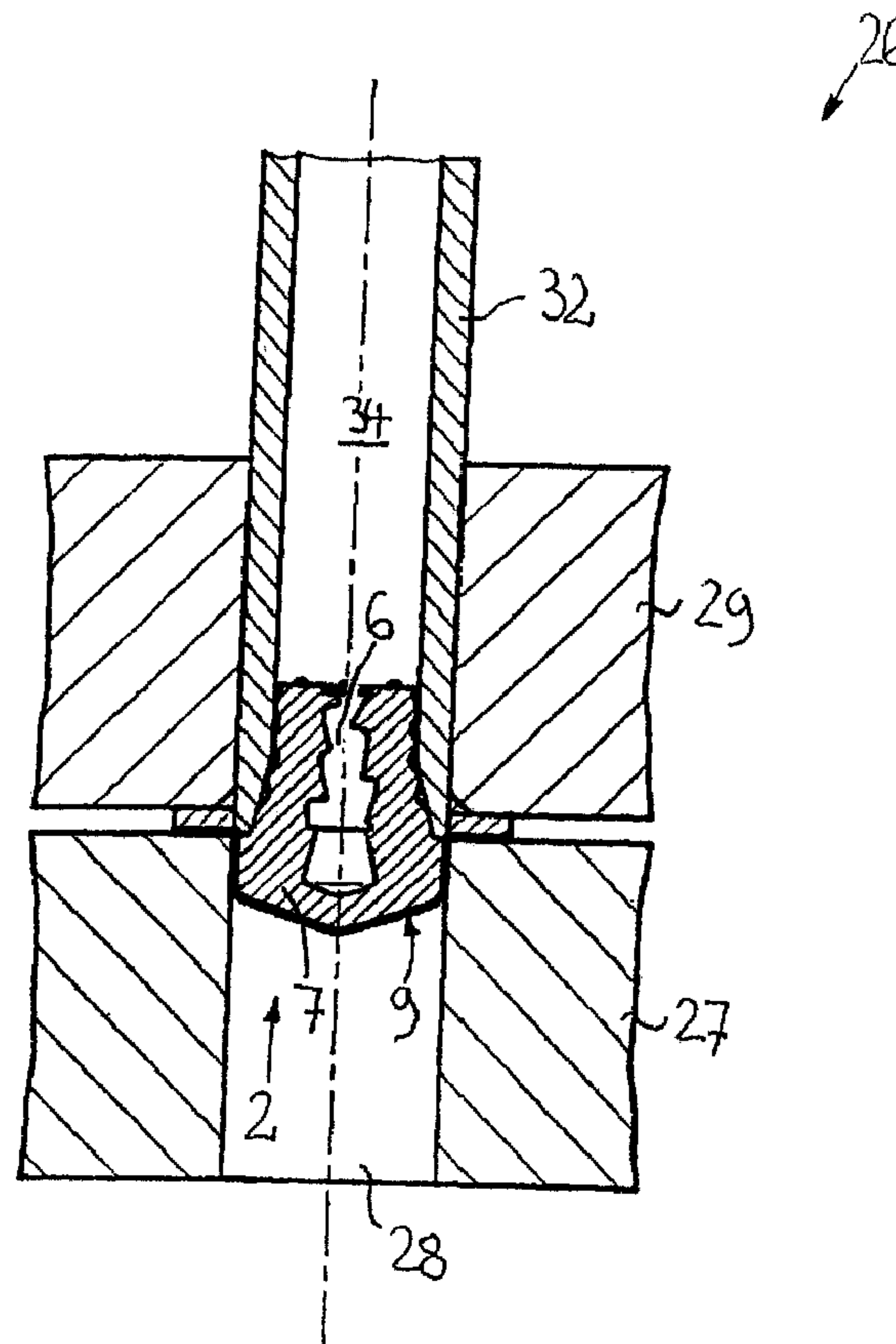


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(54) Titre : PISTON DE SERINGUE PHARMACEUTIQUE ET PROCEDE ET DISPOSITIF DE FABRICATION DE CELUI-
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(54) Title: PHARMACEUTICAL SYRINGE PISTON AND METHOD AND DEVICE THEREFOR



(57) Abrégé/Abstract:

The invention relates to a piston stopper (2) which is substantially made of rubber, comprising a piston section (8) which is enclosed in cap-like manner by an inert film (9') facing the contents of a syringe or carpule cylinder (1) and whose inert film (9') is



(57) Abrégé(suite)/Abstract(continued):

located adjacent to the syringe or carpule cylinder (1). Adjacent to said piston section (8), the piston stopper (2) has a non-coated tight section (10). The invention also relates to a device and a method for the production of one such piston stopper (2). A non-vulcanized rubber sheet (7) is inserted into a form tool, together with an inert film (9). Under the effect of pressure and heat, an entire piston stopper contour is formed from said layered arrangement, extending as far as a flange (16) which protrudes laterally above the piston stopper (Z) in the region of the separating plane of the form tool. A receiving cavity (6) for a piston rod is created in the piston section (8) which is enclosed by in a cap-like manner by the inert film (9). The wall area of the tight section (10) surrounding the receiving cavity (6) is forced into the receiving cavity (6). The piston stopper (2) is subsequently separated from the flange (16) in a stamping process, whereby a peripheral tight area (13), directly adjacent to the edge of the inert film (9') enclosing the piston section (8), is formed in the tight section (10)..

Abstract

The invention relates to a piston stopper (2) which is substantially made of rubber, comprising a piston section (8) which is enclosed in cap-like manner by an inert film (9') facing the contents of a syringe or carpule cylinder (1) and whose inert film (9') is located adjacent to the syringe or carpule cylinder (1). Adjacent to said piston section (8), the piston stopper (2) has a non-coated tight section (10). The invention also relates to a device and a method for the production of one such piston stopper (2). A non-vulcanized rubber sheet (7) is inserted into a form tool, together with an inert film (9). Under the effect of pressure and heat, an entire piston stopper contour is formed from said layered arrangement, extending as far as a flange (16) which protrudes laterally above the piston stopper (2) in the region of the separating plane of the form tool. A receiving cavity (6) for a piston rod is created in the piston section (8) which is enclosed by in a cap-like manner by the inert film (9). The wall area of the tight section (10) surrounding the receiving cavity (6) is forced into the receiving cavity (6). The piston stopper (2) is subsequently separated from the flange (16) in a stamping process, whereby a peripheral tight area (13), directly adjacent to the edge of the inert film (9') enclosing the piston section (8), is formed in the tight section (10)..

Pharmaceutical syringe piston and method and device therefor

The invention concerns a method to produce a pharmaceutical piston stopper made essentially from rubber or a similar elastomer, that has a receiving cavity
5 for connecting with a piston rod or a similar displacement transferring element and a piston section enclosed in a cap-like manner by a fluorinated polymer film or similar inert film, said piston section in the working position facing the contents of a syringe or carpule cylinder and abutting on the outside circumference with its inert film against the syringe or carpule cylinder, said piston stopper having an
10 uncoated sealing section adjacent to this piston section that in the working position abuts against the syringe or carpule cylinder, while in a forming operation a layered arrangement comprising a non-vulcanised rubber sheet and a fluorinated polymer film or a similar inert film is placed into a forming tool and is formed into a piston stopper under the influence of pressure and heat, whereby
15 the rubber sheet is vulcanised and joined with the inert film in an undetachable manner.

In addition the invention concerns a device to produce pharmaceutical piston stoppers made basically from rubber or a similar elastomer, that have a receiving
20 cavity for connecting with a piston rod or a similar displacement transferring element and a piston section that in the working position faces the contents of a syringe or carpule cylinder and is enveloped in a cap-like manner by a fluorinated polymer film or a similar inert film, said piston section abutting on the outside circumference with its inert film against the syringe or carpule cylinder, said piston
25 stopper having adjacent to this piston section an uncoated sealing section that abuts in the working position against the syringe or carpule cylinder, with a forming tool to form the piston stopper from a layered arrangement comprising a non-vulcanised rubber sheet and a fluorinated polymer film or a similar inert film, wherein the forming tool has at least one first die plate and a second die plate
30 interacting with the former, which can be displaced relative to one another into a closed and open position, as well as with a blanking device to separate the piston stoppers from a layered arrangement flange laterally projecting past the piston stoppers and remaining in the region of the partition plane of the forming tool.

The invention further concerns a pharmaceutical piston stopper, that has a base body from rubber or a similar elastomer, a receiving cavity for connecting a piston rod or a similar displacement transferring element and a piston section enveloped by a fluorinated polymer film or similar inert film, the piston section in the working position facing the contents of a syringe or carpule cylinder and abutting with its inert film on the outside circumference against the syringe or carpule cylinder, while the piston stopper has an uncoated sealing section adjacent to this piston section, the uncoated sealing section abutting in the working position against the syringe or carpule cylinder, having at least one continuous sealing lip on its outside circumference.

When storing medications or pharmaceutical preparations, as a rule in liquid or powdery form, in the pre-filled syringe or carpule cylinders, varying requirements are placed on the piston stoppers to be used. Thus a chemical or biological compatibility with the contents of the syringe or carpule cylinder is required, what on the one hand means that the substances contained in the material of the piston stopper must not leach into the medication situated in the syringe or carpule cylinder and contaminate it or alter its therapeutical effect. On the other hand, however, no active substances of the medication must penetrate into the piston stopper, because with the increasing storage period the concentration of the active substance in the medication would decrease. Finally, substances that penetrate from the medication into the piston stopper may also alter the functional properties of the piston stopper. Moreover, the piston stopper has to seal the interior of the syringe or carpule cylinder against gas, liquid and germs.

From EP 0 148 426 A1 a piston stopper made basically from rubber is already known, that has a piston section which in the working position faces the contents of the syringe cylinder and is enveloped in a cap-like manner by an inert film and on its outside circumference has a continuous sealing lip coated with the inert film and abutting against the syringe cylinder. By doing so, the inert film should prevent a direct contact between the contents of the syringe cylinder and the rubber material that is incompatible with that. For the purpose of improving the sealing of the piston stopper against the syringe cylinder, adjacent to the coated piston section the piston stopper has a non-coated sealing section that on its

outside circumference has two parallel continuous sealing lips. In the working position these non-coated sealing lips abut against the syringe cylinder. Between the two sealing lips of the sealing section and between the uncoated piston section and the sealing lip of the sealing section adjacent to it a recess each is
5 provided, by which the sealing lips are distanced from one another.

However, for pre-filled syringe systems, wherein the medication is stored in the syringe for a longer period, the piston stoppers are only conditionally suitable. The first sealing lip coated with the inert film seals namely only relatively poorly
10 against the syringe cylinder. Due to this it is possible that a portion of the medication in the syringe cylinder could leach through between the first sealing lip and the wall of the syringe cylinder into the recess situated between the first and the second sealing lip. During the administration of the medication this portion of the medication remains unused between the lamellae, as a result of which a
15 syringe pre-filled with a specific quantity of a medication the quantity of medication applied is correspondingly reduced. Moreover, the portion of the medication penetrated between the sealing lips of the piston stopper comes also into contact with the non-coated rubber material of the piston stopper, due to which the storage life of the medicinal contents of the syringe may be reduced.

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The production of the known piston stopper is carried out in several operations. In the first operation for the forming of a first piston stopper portion with a piston section enveloped in a cap-like manner by the inert film first a non-vulcanised rubber sheet together with an inert film is pressed into a first hollow form of a
25 calliper plate of a forming tool. By doing so, the rubber sheet is vulcanised under the influence of pressure and heat and is undetachably joined with the inert film. In a further operation the piston stopper portion formed thus is removed from the forming tool and blanked out from the coated rubber sheet. By doing so the blanked out edge of the completed piston stopper forms the recess between the
30 first sealing lip coated with the inert film and the second sealing lip adjacent to it. In a further operation the first piston stopper portion produced in this manner is placed into a hollow form of a second forming tool. Into this second forming tool a second non-vulcanised rubber sheet is placed, from which under the influence of pressure and heat a second piston stopper portion is formed, that is joined with

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the first piston stopper portion to provide the essentially complete piston stopper. During the forming in the second forming tool a receiving cavity for connecting with the piston rod of a syringe is formed on that face of the piston stopper which is opposite to the inert film terminating at a distance from the first piston stopper portion. Afterwards the piston stopper is blanked out from the second rubber sheet.

The known method has the disadvantage that two forming operations and two blanking operations are necessary for the production of the piston stopper. Therefore the method is relatively expensive. The method is also only conditionally suitable for a mass production. Although a plurality of the first piston stopper portions can be simultaneously formed in the first forming tool, they are, however, after their removal from the forming tool blanked out from the rubber sheet and then separated. The placing of the single piston stopper portions into a second forming tool, that has a number of forming cavities corresponding with the number of the piston stopper portions produced by the first forming tool, is therefore relatively complicated.

Therefore an object of some embodiments is to produce a piston stopper of the type mentioned in the introduction that can be simply and cost-effectively produced, that makes a better sealing of a syringe or carpule cylinder possible and whereby an interaction between the material of the piston and the contents in the syringe or carpule cylinder is reliably prevented. There is the additional objective method and a device of the type mentioned in the introduction that makes a simple and cost-effective production of such a piston stopper possible.

In some embodiments, the objective with regard to the method is achieved by that during the forming operation the complete contour of the piston stopper is formed from the layered arrangement up to the layered arrangement flange laterally protruding past the piston stopper and remaining in the region of the partition plane, that during the forming operation the receiving cavity is produced in the rubber sheet past the layered arrangement flange in the piston section enveloped in a cap-like manner by the inert film, that in a separating operation at least the wall region of the sealing section bordering the receiving cavity and protruding past the layered

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arrangement flange is displaced into the receiving cavity and the piston stopper is then separated from the layered arrangement flange by a blanking operation, so that in the sealing section an annular continuous sealing zone is formed that directly joins the edge of the inert film that envelopes the piston section in a cap-like manner, the sealing zone abutting in the working position against the syringe or carpule cylinder.

According to one aspect of the present invention, there is provided a method to produce a pharmaceutical piston stopper made essentially from rubber or a similar elastomer, that has a receiving cavity for connecting with a piston rod or a similar displacement transferring element and a piston section enclosed in a cap-like manner by a fluorinated polymer film or similar inert film, said piston section in a working position facing contents of a syringe or carpule cylinder and abutting on an outside circumference with its inert film against the syringe or carpule cylinder, said piston stopper having an uncoated sealing section adjacent to this piston section that in the working position abuts against the syringe or carpule cylinder, while in a forming operation a layered arrangement comprising a non-vulcanised rubber sheet and a fluorinated polymer film or a similar inert film is placed into a forming tool and is formed into a piston stopper under the influence of pressure and heat, whereby the rubber sheet is vulcanised and joined with the inert film in an undetachable manner, wherein during the forming operation the complete contour of the piston stopper is formed from a layered arrangement up to a layered arrangement flange laterally protruding past the piston stopper and remaining in a region of a partition plane, that during the forming operation the receiving cavity is produced in the rubber sheet past the layered arrangement flange in the piston section enveloped in a cap-like manner by the inert film, that in a separating operation at least a wall region of the sealing section bordering the receiving cavity and protruding past the layered arrangement flange is displaced into the receiving cavity and the piston stopper is then separated from the layered arrangement flange by a blanking operation, so that in the sealing section an annular continuous sealing zone is formed that directly joins an edge of the inert film that envelopes the piston section in a cap-like manner, the sealing zone abutting in the working position against the syringe or carpule cylinder.

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According to another aspect of the present invention, there is provided a device to produce a pharmaceutical piston stopper made basically from rubber or a similar elastomer, that have a receiving cavity for connecting with a piston rod or a similar displacement transferring element and a piston section that in a working position

5 faces the contents of a syringe or carpule cylinder and is enveloped in a cap-like manner by a fluorinated polymer film or a similar inert film, said piston section abutting on an outside circumference with its inert film against the syringe or carpule cylinder, said piston stopper having adjacent to this piston section an uncoated sealing section that abuts in the working position against the syringe or

10 carpule cylinder, to carry out the method as described above, with a forming tool to form the piston stopper from a layered arrangement comprising a non-vulcanised rubber sheet and a fluorinated polymer film or a similar inert film, wherein the forming tool has at least one first die plate and a second die plate interacting with the former, which can be displaced relative to one another into a

15 closed and open position, as well as with a blanking device to separate the piston stopper from a layered arrangement flange laterally projecting past the piston stoppers and remaining in a region of a partition plane of the forming tool, wherein the forming tool is constructed for a forming of a complete contour of at least one piston stopper up to the layered arrangement flange remaining in the region of the

20 partition plane of the forming tool and laterally protruding past the piston stopper and that for this purpose the at least one first die plate has at least one first cavity fitting a form of the piston section of the piston stopper to be produced enveloped in a cap-like manner by the inert film and the second die plate has at least one second cavity fitting a form of the uncoated sealing section of the piston stopper,

25 that in the at least one second cavity a form core is provided to form a receiving cavity of the piston stopper that can be joined with the piston rod or a similar displacement transferring element, said form core engaging with its free end the opposite situated at least one first cavity in the closed position of the forming tool, that the blanking device has a cutting die with at least one orifice for a central

30 placement of the piston section enveloped in a cap-like manner by the inert film, that a sleeve-shaped cutting punch having a cutting edge on its outer circumference is allocated to the cutting die to separate the layered arrangement flange from the piston stopper, said cutting punch being able to move axially

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towards and away from the orifice of the at least one cutting die, and that an inside cavity of the cutting punch is constructed to accommodate an inward deformed sealing section of the piston stopper.

According to still another aspect of the present invention, there is provided a
5 pharmaceutical piston stopper, that has a base body from rubber or a similar elastomer, a receiving cavity for connecting a piston rod or a similar displacement transferring element and a piston section enveloped in a cap-like manner by a fluorinated polymer film or similar inert film, the piston section in a working position facing the contents of a syringe or carpule cylinder and abutting with its inert film
10 on an outside circumference against the syringe or carpule cylinder, while the piston stopper has an uncoated sealing section adjacent to the piston section, the uncoated sealing section abutting in the working position against the syringe or carpule cylinder, having at least one continuous sealing lip on its outside circumference, wherein the base body is made from one piece, that the receiving
15 cavity extends up into the piston section that is enveloped in a cap-like manner by the inert film, and that on its outside circumference the sealing section has an annular continuous sealing zone that is directly adjacent to the edge of the inert film enveloping the piston section in a cap-like manner, said sealing section in the working position abutting flat against the syringe or carpule cylinder.

20 In some embodiments, this is possible by producing the piston stopper in only one forming operation and only one blanking or separating operation. In the forming operation the essentially complete contour of the piston stopper is formed from the layered arrangement, comprising the rubber sheet and the inert film. On the same occasion the receiving cavity is produced in the rubber sheet at that end of the
25 piston stopper which is opposite the inert film in the piston section enveloped in a cap-like manner by the inert film past the surface plane coated with the inert film of the layered arrangement flange protruding past the piston stopper. Therefore the wall region of the sealing section that borders the receiving cavity can be displaced into the receiving cavity by the blanking or cutting tool during the
30 blanking of the layered arrangement flange from the piston stopper. By virtue of this it is possible to separate the layered arrangement flange from the piston stopper in such a manner, that in the sealing section of the piston stopper an

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annular continuous sealing zone is formed that is directly adjacent to the edge of the inert film enveloping in a cap-like manner the piston section, said sealing section being aligned with the edge region of the inert film or slightly protruding past it with the inert film abutting in the working position against the syringe or

5 carpule cylinder. Thus in the working position the piston stopper is sealed against the wall of the syringe or carpule cylinder by the sealing zone directly joined to the inert film, due to which a contact of the contents of the syringe or carpule cylinder with the uncoated regions of the piston stopper, situated behind the sealing zone, is reliably prevented.

10 In the case of an embodiment of the invention during the forming operation at least one annular continuous sealing lip is formed on the outside circumference of the sealing section. In this case the piston stopper produced in accordance with the method seals in the working position even better against the

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wall of the syringe and carpule cylinder. Due to this particularly the penetration of gases and/or germs into the contents of the syringe or carpule cylinder is made basically more difficult. In addition, the sealing lip makes an easy sliding of the piston stopper in the syringe or carpule cylinder possible. By virtue of the sealing zone formed during the separating operation it will be impossible for the contents of the syringe or carpule cylinder reach the intermediate space between the sealing lip and the piston section enveloped cap-like by the inert film and for an interaction to occur therein with the elastomeric piston material.

10 Some embodiments of the invention provide that in the separating operation the at least one piston section enveloped in a cap-like manner by the inert film is placed centred into an opening of a cutting die and the layered arrangement flange bordering the piston stopper is clamped between this cutting die and a clamping plate, while that portion of the sealing section which projects
15 past the layered arrangement flange engages a passing-through opening provided in the clamping plate, and that afterwards the wall region of the sealing section bordering the receiving cavity of the piston stopper is displaced by a cutting punch into the receiving cavity and the layered arrangement flange is blanked off the piston stopper. The piston stopper is then placed into the opening
20 of the cutting die with its piston section centred relative to the longitudinal axis of the cutting tool and during the blanking operation it is fixed in the centred position via the layered arrangement flange clamped between the cutting die and the blanking plate. The portion of the sealing section that engages the passing-through opening of the blanking plate and abuts against its wall is additionally
25 centred in the passing-through opening relative to the cutting tool. The wall region of the sealing section bordering the receiving cavity can be easier displaced then into the receiving cavity by the cutting tool during its blanking forward movement.

It is particularly advantageous when the cutting punch to separate the piston
30 stopper from the layered arrangement flange is moved in the direction from the free end of the sealing section towards the layered arrangement flange. In this case the wall region of the piston stopper bordering the receiving cavity can be even better displaced into the receiving cavity.

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Some embodiments of the invention provide that the rubber sheet is continuously sealed on its outside edge against at least one die plate of the forming tool resting on it and that during and/or after the opening of the forming tool to release the vulcanised layered arrangement from the die plate a gas is injected between this die plate and the layered arrangement. The vulcanised layered arrangement is then evenly acted upon by the pressure of the injected gas prior to the removal from the die plate, making a gentle removal of the layered arrangement possible. An excess stretching of the vulcanised rubber and/or of the inert film is prevented by this. Consequently, the piston stoppers produced in accordance with the method keep their dimensions very well, making the placing of the vulcanised layered arrangement into the cutting die particularly possible.

It is advantageous when for the sealing of the vulcanised layered arrangement against the die plate during the forming operation a seal, tightly abutting against the die plate and continuous around the layered arrangement, is formed on the outside edge of the layered arrangement. Therefore the seal necessary for the sealing of the rubber sheet is produced together with the piston stopper(s) in one operation. Consequently the method can be carried out even simpler.

In some embodiments, the objective mentioned above with regard to the device is achieved by that the forming tool is constructed for the forming of the complete contour of at least one piston stopper up to the layered arrangement flange remaining in the region of the partition plane of the forming tool and laterally protruding past the piston stoppers and that for this purpose the first die plate has at least one first cavity fitting the form of the piston section of the piston stopper to be produced enveloped in a cap-like manner by the inert film and the second die plate has at least one second cavity fitting the form of the uncoated sealing section of the piston stopper, that in the second cavity a form core is provided to form a receiving cavity of the piston stopper that can be joined with the piston rod or a similar displacement transferring element, said form core engaging with its free end the opposite situated first cavity in the closed position of the forming tool, that the blanking device has a cutting die with at least one orifice for the central placement of the piston section enveloped in a cap-like manner by the inert film,

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that a sleeve-shaped cutting punch having a cutting edge on its outer circumference is allocated to the cutting die to separate the layered arrangement flange 16 from the piston stopper, said cutting punch being able to move axially towards and away from the orifice of the cutting die, and that the inside cavity of the cutting punch is constructed to accommodate the inward deformed sealing section of the piston stopper.

In some embodiments the device makes the production of the piston stoppers possible in a single forming operation and a single punching operation.

10 Because the form core protruding in the cavity of the second die that in the working position abuts against the rubber sheet to form the receiving cavity of the piston stopper that can be joined with a piston rod or a similar displacement transferring element in the closed position of the forming tool engages with its free end the opposite situated cavity of the first die plate that in the working

15 position abuts against the inert film, the receiving cavity is formed during the forming of the piston stopper in the forming tool up into the piston section enveloped in a cap-like manner by the inert film. The vulcanised layered arrangement, comprising the rubber sheet and the inert film, after the removal from the forming tool is placed centred with the piston section enveloped in a cap-

20 like manner by the inert film into the opening of the cutting die. During the forward movement of the sleeve-shaped cutting punch that can be axially displaced relative to this opening, the wall region of the piston laterally bordering the receiving cavity is inward deflected transversely to the feed movement and is placed into the inside cavity of the cutting punch. For this reason it is possible to

25 push the cutting punch onto the free end of the sealing section of the piston stopper without damaging it. In a further progression of the blanking forward movement of the cutting punch the cutting punch pierces the layered arrangement flange laterally protruding past the piston stopper and separates it from the piston stopper. On this occasion an annular sealing zone, continuous

30 around the sealing section, is formed that in the working position abuts against the syringe or carpule cylinder. The dimensions of the outside cross-section of the cutting punch, that has a cutting edge on its outside circumference, correspond the cross-sectional dimensions of the orifice of the cutting die or are somewhat smaller than those. The cross-sectional dimensions of the cavity of the

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- first die plate to form the piston section enveloped in a cap-like manner and consequently the cross-sectional dimensions of this piston section correspond approximately those of the orifice of the cutting die. Therefore in the case of the complete piston stopper the sealing zone, directly adjacent to the inert film and
- 5 continuous around the sealing section, is aligned with the edge region of the inert film that in the working position abuts against the syringe or carpule cylinder or radially protrudes slightly past it, as a result of which the sealing section reliably seals against the syringe or carpule cylinder.
- 10 For the simultaneous forming of a plurality of piston stoppers, the die plates of the forming tool can have a number of cavities that corresponds to the number of piston stoppers to be formed. In that case the cutting die of the blanking device can have a number of orifices that corresponds to the number of cavities of a die plate with a cutting punch each provided above them, while the arrangement of
- 15 the orifices corresponds to that of the cavities of the die plate, so that the vulcanised layered arrangement can be placed into the cutting die for the simultaneous blanking of all piston stoppers provided on it with the piston sections enveloped in a cap-like manner.
- 20 Some embodiments of the device, according to the invention provide that the stamping device has a clamping plate with at least one passing-through orifice that is aligned with one of the at least one opening of the cutting die to accommodate the sealing section, that for the purpose of clamping the layered arrangement flange between the clamping plate and the cutting die the clamping
- 25 plate is axially displaceable towards the opening of the cutting die relative to the cutting die, and that the cutting punch is axially displaceably guided in the passing-through orifice of the clamping plate.

- In some embodiments of the invention the circumferential
- 30 wall of the at least one cavity of the second die plate has at least one annular continuous recess to form an annular continuous sealing lip on the outside circumference of the piston stopper's sealing section. The piston stoppers produced with the forming tool then seal even better against the syringe or carpule cylinder.

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In a useful manner at its free end facing the cutting die the cutting punch has on its inside an entry slope. The wall of the piston stopper, bordering the receiving cavity, can then be easier displaced during the blanking movement of the sleeve-shaped cutting punch into the inside cavity of the cutting punch.

5

Some embodiments of the invention provide that the outside edge of the vulcanised layered arrangement can be sealed against at least one die plate by means of a continuous seal around the layered arrangement, and that a gas supply channel opens into the region of this die plate bordered by the seal, the gas supply channel being connected to a source of pressurised gas for the detaching of the layered arrangement from the die plate. The vulcanised layered arrangement with the syringe piston(s) formed on it can be then simply removed from the second die plate by the gas pressure. At the same time the gas pressure makes an even and gentle detaching of the layered arrangement from the die plate possible. This is of particular advantage when the cavity (cavities) of the die plate has (have) recesses that engage the layered arrangement.

It is advantageous when at least one die plate for the formation of the seal sealing the outside edge of the layered arrangement against the die plate has inside its form cavity an annular groove bordering the cavity (cavities) of this die plate at a distance. In this case the seal is formed on the edge of the layered arrangement preferably on the rubber sheet during the forming of the piston stopper(s).

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In a useful manner a valve is provided in the entry region of the gas supply channel, preferably a disc valve. The gas supply channel is then sealed by the valve during the forming of the piston stopper, so that the elastomer and/or the inert film cannot penetrate into the gas supply channel.

30

The above mentioned objective with regard to the pharmaceutical piston stopper is achieved by that the base body is made from one piece, that the receiving cavity extends up into the piston section that is enveloped in a cap-like manner by the inert film, and that on its outside circumference the sealing section has an

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annular continuous sealing zone that is directly adjacent to the edge of the inert film enveloping the piston section in a cap-like manner, said sealing section in the working position abutting flat against the syringe or carpule cylinder.

- 5 Accordingly, in the working position the piston stopper is sealed by the sealing zone against the wall of the syringe or carpule cylinder directly where the inert film joins it, due to which a contact of the contents of the syringe or carpule cylinder with the uncoated regions of the piston stopper situated behind the sealing zone is reliably prevented. Because the base body is made from one
10 piece, the piston stopper can be produced simply and cost-effectively from a single rubber sheet coated with an inert film.

It is advantageous when the sealing zone is provided as a straight extension to the outside circumferential section of the inert film that in the working position
15 abuts against the syringe or carpule cylinder or slightly projects past this outside circumferential section. In this case in the working position the sealing zone seals against the wall of the syringe or carpule cylinder directly joining the inert film.

In the case of a useful embodiment of the invention a section of the inside wall of
20 the piston stopper bordering the receiving cavity has an internal thread to connect with the thread of the piston rod or a similar displacement transferring element, while this section of the internal thread terminates at a distance from the bottom of the receiving cavity. In this case the piston stopper can be joined or screwed together with the piston rod or the displacement transferring element in a form-
25 locking manner. The piston stopper then can be produced in a forming tool from a layered arrangement, comprising a non-vulcanised rubber sheet and a fluorinated polymer film or a similar inert film, and can be easily removed afterwards from the forming tool.

30 Some embodiments of the invention provide that the section of the piston stopper with the internal thread terminates at the piston section enveloped in a cap-like manner or at a distance from it, and that preferably a cylindrical or tapered receiving cavity joins the section with the internal thread, the receiving cavity extending into the piston section enveloped in a cap-like manner. In this

case it is even easier to remove the piston stopper during the production from the forming tool.

Another embodiment of the invention provides that the cross-section of the receiving cavity commencing from the bottom tapers out towards the opening of the receiving cavity. This piston stopper, intended to be connected with the piston rod of a carpule, is also easier to remove during its production from the forming tool.

In the following embodiments of the invention are explained in detail based on the drawing. They show in:

Fig.1 - a cross-section through a forming tool in the open position, into which a rubber sheet, coated with an inert film on one side, is placed,

Fig.2 - an illustration similar to that of Fig.1, but with the forming tool closed,

Fig.3 - a cross-section through the forming tool during the air-assisted removal of the layered arrangement comprising the vulcanised rubber sheet and the inert film,

Fig.4 - a cross-section through the forming tool during the removal of the vulcanised layered arrangement,

Figs.5-8 - a partial cross-section through a blanking device to separate an only partially illustrated layered arrangement flange that projects laterally past a piston stopper from the piston stopper, wherein the clamping plate and the punch of the blanking device are illustrated in various working positions,

Figs.9 and 11 - a side view of a pharmaceutical piston stopper, partially sectioned,

Fig.10 - a side view of a syringe, partially sectioned, and

Fig.11 - a side view of a carpule, partially sectioned.

A pharmaceutical syringe or carpule has a syringe or a carpule cylinder 1 with a piston stopper 2 that can be axially displaced therein. The syringe or carpule cylinder 1 has at one end a discharge orifice for a liquid pharmaceutical preparation situated in the cylindrical cavity 4 of the syringe or carpule cylinder 1, the discharge orifice being tightly closed off by a removable cover 3. The syringe or carpule cylinder 1 has a passing-through opening at that end which is situated opposite the discharge orifice for a piston rod 5 joined with the piston stopper 2, the piston rod engaging a receiving cavity 6 of the piston stopper 2 with its end facing the receiving cavity.

As it can be particularly well seen in Figs.9 and 11, the piston stopper 2 has a single-piece base body 7' from rubber or a similar elastomer, that is enveloped in a cap-like manner by a fluorinated polymer film or a similar inert film 9' on a section 8 of the piston which faces the contents of the syringe or carpule cylinder 1. A non-coated sealing section 10 of the piston stopper 2 is adjacent to this piston section 8. It can be seen in Figs.10 and 12 that on its outside circumference the piston stopper 2 abuts against the inside wall of the carpule cylinder 1 with both the edge region of the inert film 9' and the sealing section 10.

On its outside circumference the sealing section 10 has a plurality of continuous sealing lips 11, that are spaced from one another by continuous recesses 12 situated between them on the outside circumference of the sealing section 10. A recess 12 is also provided between the sealing lip 11 adjacent to the inert film 9' and the inert film 9'. Between this recess 12 and the inert film 9' the sealing section 10 has on its outside surface an annular continuous sealing zone 13, that joins directly the edge of the inert film 9' enveloping in a cap-like manner the piston section 8. The sealing zone 13 is aligned with the surface of the edge region of the inert film 9' abutting against the inside wall of the syringe or carpule cylinder 1 or projects slightly radially past this surface. In the working position the piston stopper 2 abuts with the sealing zone 13 fully against the syringe or carpule cylinder 1. Due to this the recesses 12 are reliably sealed against the liquid pharmaceutical preparation situated in the cylindrical cavity 4, so that the

preparation cannot interact there with the elastomer. Consequently, the sealing zone 13 prevents the penetration of the pharmaceutical preparation between the inert film 9' with a poorer sealing than that of the non-coated elastomer and the inside wall of the syringe or carpule cylinder 1 into the adjacent recess 12.

- 5 Moreover, the sealing zone 13 also seals the pharmaceutical preparation against the penetration of moisture, gases and/or germs. In addition, the cylindrical cavity 4 is sealed by the sealing lips 11 that are in a series with the sealing zone 13.

10 As it can be seen from Figs.9 and 11, the receiving cavity 6 extends from the receiving cavity situated at that end region of the piston stopper 2 that is remote from the inert film 9' up into the piston section 8 enveloped in a cap-like manner by the inert film 9' and terminates there at a distance from the inert film 9'.

15 In the embodiment according to Fig.9 a section 6a of the receiving cavity has an internal thread, that can be screwed together with a matching external thread of the piston rod 5. The section 6a of the piston stopper 2 with the internal thread extends within the region of the piston limited by the non-coated sealing section 10 and terminates at a distance from the piston section 8 in a cap-like manner. Section 6a with the internal thread is joined by an approximately cylindrical
20 receiving cavity section 6c, that extends up into the piston section 8 enveloped in a cap-like manner. However, other form-locking connections between the piston stopper 2 and the piston rod 5 or similar displacement transferring element are also conceivable. In the embodiment according to Fig.11 the receiving cavity has, in the form of an example, a tapered shape and it tapers commencing from its
25 receiving orifice towards the deepest position of the receiving cavity 6.

For the production of the piston plug 2 first an non-vulcanised rubber sheet 7, together with a fluorinated polymer film or a similar inert film 9 is placed between the die plates 14, 15 of a forming tool. The die plates 14, 15 can be displaced
30 relative one another and can be brought to a closed position (Fig.2) and an open position (Fig.1). As this is shown in Fig.1, the foil-like inert film 9, that is initially flat, can be firmly joined with the rubber sheet 9. However, the inert film 9 and the rubber sheet 9 may be introduced between the die plates 14, 15 independently from another and placed loosely on top of one another.

- The forming tool is constructed to form the complete contour of the piston stopper 2 up to the layered arrangement flange 16 remaining in the region of the partition plane of the forming tool and laterally projecting past the piston stopper 2. It can be seen in Fig.1, that for this purpose the first die plate 14 facing the inert film 9 has a plurality of first cavities 17, the form of which corresponds to the negative form of the piston section 8 enveloped in a cap-like manner by the inert film of the syringe piston 2 to be produced. The second die plate 15 facing the rubber sheet 7 has a plurality of second cavities 18, the number of which corresponds to the number of the first cavities 17, the form of which corresponds to the negative form of that portion of the syringe piston sealing section 10 which adjoins the sealing zone. The first and second cavities 17, 18 are aligned with one another, so that in the closed position of the forming tool they essentially define the outside contour of the syringe piston 2 to be produced. In the closed position of the forming tool the first and second cavities 17, 18 are distanced from one another by a separation gap 19, that extends in the partition plane over all cavities 17, 18 of the forming tool and joins these with one another. During the forming of the layered arrangement comprising the rubber sheet 7 and the inert film 9 the layered arrangement flange 16 is formed in the partition plane 19.
- As it can be particularly well seen in Fig.2, the second cavities limit a form core 20 each to form the receiving cavity 6 of the piston stopper 2 that can be connected with the piston rod 5. In the closed position of the forming tool this form core 20 engages with its free end the opposite situated first cavity 17, so that during the forming of the piston stopper 2 the receiving orifice 6 is brought up into the piston section 8 of the piston stopper 2 enveloped in a cap-like manner by the inert film 9. The circumferential walls of the second cavities 18 have annular continuous depressions 21 to form the annular continuous sealing lips 11 on the outside surface of the piston stopper sealing section 10.
- When the forming tool is closed, the rubber sheet 7 is vulcanised under the influence of pressure and heat and is undetachably joined with the inert film 9. On the same occasion the sections of the inert film 9 abutting against the walls of the first cavities 17 assume the form of the first cavity 17 and the sections of the

rubber sheet 7, abutting against the walls of the second cavity 18, the form of the second cavities.

For the formation of a seal 22 that seals the outer edge of the vulcanised layered arrangement against the die plate 14, the second die plate has inside its forming cavity a continuous groove 23 that borders the cavities 18 of this die plate 14 at a distance. During the closing of the forming tool the elastomer situated on the edge of the rubber sheet 7 is displaced into this annular groove 23, while it assumes the form of the annular groove 23.

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The second die plate 14 has a gas supply channel 24, that opens into the form cavity formed between the die plates 14, 15 within the region bordered by the annular groove 23. After the completion of the forming process compressed air is blown through this gas supply channel 24, the compressed air lifting the layered arrangement comprising the vulcanised rubber sheet 7 and the inert film 9 off the second die plate 15. It can be seen in Fig.3 that during the removal of the layered arrangement, assisted by the compressed air, from the second die plate the sealing initially remains engaged with the annular groove 23, so that between the rubber sheet 7 and the second die plate 15 an air cushion can be formed. At the same time the forming tool is opened, so that the layered arrangement during the opening remains with its inert film 9 initially adheres to the first die plate 14, as this can be recognised from Fig.3. However, another course of action is also possible, whereby first the forming tool is opened and the first die plate 14 is removed off the layered arrangement and afterwards the compressed air is blown between the layered arrangement and the second die plate. After detaching the layered arrangement from the second die plate 15, the layered arrangement is removed from forming tool. On this occasion the inert film 9 detaches itself from the first die plate 14 (Fig.4).

30 As it can be particularly well perceived from Fig.3, in the entry region of the gas supply channel 24 a valve 25 is provided, that with its valve head faces the first die plate 14. It can be clearly seen that the valve is provided outside the cavities 18 and is at a lateral distance from them. The valve plate of the valve 25 is held in the closed position by a helical spring and can be lifted off its valve seat against

the restoring force of the helical spring by the pressure of the compressed air that can be conveyed through the gas supply channel 24.

After its removal from the forming tool the layered arrangement is placed on a
5 blanking device 26 to separate the piston plug 2 from the layered arrangement
flange 16 surrounding it. The blanking device 26 has a cutting die 27, that is
constructed as a plate with a number of orifices 28 that corresponds to the
number of the first cavities 14. The diameter of these orifices 28 corresponds
approximately to the diameter of the first cavities 14. The relative position of the
10 orifices 28 also corresponds to the relative position of the cavities 14 to one
another. The layered arrangement is so arranged on the blanking die 27, that the
individual piston sections 8 of the layered arrangement, enveloped in a cap-like
manner by the inert film 9, engage centrally the orifice 28 associated with them
and the layered arrangement flange 16 will lie on the cutting die 27.

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Parallel to the plane of the cutting die 27 there is a clamping plate provided, that
has a number of passing-through openings 30 corresponding to the number of
orifices 28 of the cutting die 27, the passing-through openings having the same
diameter as the orifices 28 of the cutting die 27 and are aligned in a straight
20 extension with the orifices 28. After placing the layered arrangement into the
blanking die 27, the clamping plate 29 is moved towards the blanking die 27 until
the layered arrangement flange is clamped between the clamping plate 29 and
the blanking die 27 and the piston stoppers 2 provided on it are thus fixed on the
blanking die 27 (Fig.6).

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From Fig.5 it can be seen that at that end of the passing through orifices 30 which
face the blanking die 27 an entry slope 31 formed by a chamfer is provided for
the sealing section 10 of the piston stopper 2 to be introduced into the passing-
through opening 30. The sealing section 10 of the piston stopper 2 is centred by
30 this entry slope 31 when the clamping plate 29 is moved towards the punching
die 26.

In each passing-through opening 30 a sleeve-shaped cutting punch 32 is axially
displaceably guided, that has a cutting edge on its circumference. It can be seen

from Figs.6 to 8, that to separate the layered arrangement flange 16 from the piston stoppers positioned on the cutting punch 32 the cutting punches 32 move towards the cutting die 27, and after the separation of the layered arrangement flange 16 they are pulled back to their initial position.

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At their free ends facing the cutting die 27 the cutting punches 32 have on their inside an entry slope 33. It can be seen from Fig.7, that during the cutting forward movement of the cutting punch 32 the wall of the piston stopper 2 bordering the receiving cavity 6 is displaced by its entry slopes 33 into the internal cavity 34 of the cutting punch 32. At the same time the cross-section of the receiving cavity 6 is correspondingly reduced.

It can be seen from Fig.8, that the diameter of the cutting punch 32 corresponds approximately to the diameter of the orifice 28 of the cutting die 27, so that the layered arrangement flange 16 is separated from the piston stopper 2 by the cutting punch 32 flush with that portion of the inert film 9 that in the working position abuts against the syringe cylinder 1. This forms the sealing zone 13.

Therefore the invention concerns a piston stopper 2 made basically from rubber, that has a piston section 8 enveloped in a cap-like manner by an inert film 9' and in the working position facing the contents of a syringe or carpule cylinder 1 and abutting with its inert film 9' against the syringe or carpule cylinder 1. Adjacent to this piston section 8 the piston stopper 2 has an uncoated sealing section 10. Furthermore, the invention concerns a device and a method for the production of such a piston stopper 2. A non-vulcanised rubber sheet 7, together with an inert film 9, is placed into a forming tool and under the influence of pressure and heat the complete piston stopper contour up to a flange 16 laterally projecting past the piston stopper 2 in the region of the separation plane is formed from this layered arrangement. A receiving cavity 6 for a piston rod is formed up into the piston section 8 enveloped in a cap-like manner by the inert film 9. The wall region of the sealing section 10 bordering the receiving cavity 6 is displaced into the receiving cavity 6. Afterwards the piston stopper 2 is separated from the flange by a blanking operation, whereby in the sealing section 10 a continuous sealing

zone 13 that is directly adjacent to the edge of the inert film 9' enveloping the piston section 8.

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CLAIMS:

1. A method to produce a pharmaceutical piston stopper made essentially from rubber or a similar elastomer, that has a receiving cavity for connecting with a piston rod or a similar displacement transferring element and a
5 piston section enclosed in a cap-like manner by a fluorinated polymer film or similar inert film, said piston section in a working position facing contents of a syringe or carpule cylinder and abutting on an outside circumference with its inert film against the syringe or carpule cylinder, said piston stopper having an uncoated sealing section adjacent to this piston section that in the working
10 position abuts against the syringe or carpule cylinder, while in a forming operation a layered arrangement comprising a non-vulcanised rubber sheet and a fluorinated polymer film or a similar inert film is placed into a forming tool and is formed into a piston stopper under the influence of pressure and heat, whereby the rubber sheet is vulcanised and joined with the inert film in an undetachable
15 manner, wherein during the forming operation the complete contour of the piston stopper is formed from a layered arrangement up to a layered arrangement flange laterally protruding past the piston stopper and remaining in a region of a partition plane, that during the forming operation the receiving cavity is produced in the rubber sheet past the layered arrangement flange in the piston section enveloped
20 in a cap-like manner by the inert film, that in a separating operation at least a wall region of the sealing section bordering the receiving cavity and protruding past the layered arrangement flange is displaced into the receiving cavity and the piston stopper is then separated from the layered arrangement flange by a blanking operation, so that in the sealing section an annular continuous sealing zone is
25 formed that directly joins an edge of the inert film that envelopes the piston section in a cap-like manner, the sealing zone abutting in the working position against the syringe or carpule cylinder.

2. A method according to claim 1, wherein during the forming operation at least one annular continuous sealing lip is formed on an outside circumference
30 of the sealing section, and that the sealing lip is displaced during the separating operation towards the receiving cavity.

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3. A method according to claim 1 or 2, wherein in the separating operation the at least one piston section enveloped in a cap-like manner by the inert film is placed centred into an opening of a cutting die and the layered arrangement flange bordering the piston stopper is clamped between this cutting
5 die and a clamping plate, while that portion of the sealing section which projects past the layered arrangement flange engages a passing-through opening provided in the clamping plate, and that afterwards the wall region of the sealing section bordering the receiving cavity of the piston stopper is displaced by a cutting punch
10 into the receiving cavity and the layered arrangement flange is blanked off the piston stopper.

4. A method according to claim 3, wherein the cutting punch to separate the piston stopper from the layered arrangement flange is moved in the direction from a free end of the sealing section towards the layered arrangement flange.

15 5. A method according to any one of claims 1 to 4, wherein the rubber sheet is continuously sealed on its outside edge against at least one die plate of the forming tool resting on it and that during and/or after an opening of the forming tool to release the vulcanised layered arrangement from the die plate a gas is injected between the at least one die plate and the layered arrangement.

20 6. A method according to any one of claims 1 to 4, wherein for the sealing of the vulcanised layered arrangement against a die plate during the forming operation a seal, tightly abutting against the die plate and continuous around the layered arrangement, is formed on an outside edge of the layered arrangement.

25 7. A method according to claim 5, wherein for the sealing of the vulcanised layered arrangement against the at least one die plate during the forming operation a seal, tightly abutting against the at least one die plate and continuous around the layered arrangement, is formed on an outside edge of the layered arrangement.

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8. A device to produce a pharmaceutical piston stopper made basically from rubber or a similar elastomer, that have a receiving cavity for connecting with a piston rod or a similar displacement transferring element and a piston section that in a working position faces the contents of a syringe or carpule cylinder and is enveloped in a cap-like manner by a fluorinated polymer film or a similar inert film, said piston section abutting on an outside circumference with its inert film against the syringe or carpule cylinder, said piston stopper having adjacent to this piston section an uncoated sealing section that abuts in the working position against the syringe or carpule cylinder, to carry out the method according to any one of claims 1 to 7, with a forming tool to form the piston stopper from a layered arrangement comprising a non-vulcanised rubber sheet and a fluorinated polymer film or a similar inert film, wherein the forming tool has at least one first die plate and a second die plate interacting with the former, which can be displaced relative to one another into a closed and open position, as well as with a blanking device to separate the piston stopper from a layered arrangement flange laterally projecting past the piston stopper and remaining in a region of a partition plane of the forming tool, wherein the forming tool is constructed for a forming of a complete contour of at least one piston stopper up to the layered arrangement flange remaining in the region of the partition plane of the forming tool and laterally protruding past the piston stopper and that for this purpose the at least one first die plate has at least one first cavity fitting a form of the piston section of the piston stopper to be produced enveloped in a cap-like manner by the inert film and the second die plate has at least one second cavity fitting a form of the uncoated sealing section of the piston stopper, that in the at least one second cavity a form core is provided to form a receiving cavity of the piston stopper that can be joined with the piston rod or a similar displacement transferring element, said form core engaging with its free end the opposite situated at least one first cavity in the closed position of the forming tool, that the blanking device has a cutting die with at least one orifice for a central placement of the piston section enveloped in a cap-like manner by the inert film, that a sleeve-shaped cutting punch having a cutting edge on its outer circumference is allocated to the cutting die to separate the layered arrangement flange from the piston stopper, said cutting punch being able to move axially towards and away from the orifice of the at least one cutting

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die, and that an inside cavity of the cutting punch is constructed to accommodate an inward deformed sealing section of the piston stopper.

9. A device according to claim 8, wherein the blanking device has a clamping plate with at least one passing-through orifice that is aligned with one of the at least one orifice of the cutting die to accommodate the sealing section, that for a purpose of clamping the layered arrangement flange between the clamping plate and the cutting die the clamping plate is axially displaceable towards the orifice of the cutting die relative to the cutting die, and that the cutting punch is axially displaceably guided in the passing-through orifice of the clamping plate.
10. A device according to claim 8 or 9, wherein the circumferential wall of the at least one second cavity of the second die plate has at least one annular continuous recess to form an annular continuous sealing lip on an outside circumference of the piston stopper's sealing section.
11. A device according to any one of claims 8 to 10, wherein at a free end facing the cutting die, the cutting punch has on its inside an entry slope.
12. A device according to any one of claims 8 to 11, wherein an outside edge of the vulcanised layered arrangement is sealed against at least one die plate by means of a continuous seal around the layered arrangement, and that a gas supply channel opens into a region of the at least one die plate bordered by the seal, the gas supply channel being connected to a source of pressurised gas for detaching the layered arrangement from the at least one die plate.
13. A device according to claim 12, wherein the at least one die plate for the formation of the seal sealing the outside edge of the layered arrangement against the at least one die plate has inside its form cavity an annular groove bordering the cavity of the at least one die plate at a distance.
14. A device according to any one of claims 8 to 13, wherein a valve is provided in the entry region of the gas supply channel.
15. A device according to claim 14, wherein the valve is a disc valve.

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16. A pharmaceutical piston stopper, that has a base body from rubber or a similar elastomer, a receiving cavity for connecting a piston rod or a similar displacement transferring element and a piston section enveloped in a cap-like manner by a fluorinated polymer film or similar inert film, the piston section in a working position facing the contents of a syringe or carpule cylinder and abutting with its inert film on an outside circumference against the syringe or carpule cylinder, while the piston stopper has an uncoated sealing section adjacent to the piston section, the uncoated sealing section abutting in the working position against the syringe or carpule cylinder, having at least one continuous sealing lip on its outside circumference, wherein the base body is made from one piece, that the receiving cavity extends up into the piston section that is enveloped in a cap-like manner by the inert film, and that on its outside circumference the sealing section has an annular continuous sealing zone that is directly adjacent to the edge of the inert film enveloping the piston section in a cap-like manner, said sealing section in the working position abutting flat against the syringe or carpule cylinder.

17. A pharmaceutical piston stopper according to claim 16, wherein the sealing zone is provided as a straight extension to an outside circumferential section of the inert film that in the working position abuts against the syringe or carpule cylinder or slightly projects past the outside circumferential section.

18. A pharmaceutical piston stopper according to claim 16 or 17, wherein a section of an inside wall of the piston stopper bordering the receiving cavity has an internal thread to connect with a thread of the piston rod or a similar displacement transferring element, and that the section of the internal thread terminates at a distance from a bottom of the receiving cavity.

19. A pharmaceutical piston stopper according to claim 18, wherein the section of the piston stopper with the internal thread terminates at the piston section enveloped in a cap-like manner or at a distance from it, and that preferably a cylindrical or tapered receiving cavity joins the section with the internal thread, the receiving cavity extending into the piston section enveloped in a cap-like manner.

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20. A pharmaceutical piston stopper according to claim 18 or 19, wherein a cross-section of the receiving cavity commencing from the bottom tapers out towards an opening of the receiving cavity.

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PATENT AGENTS

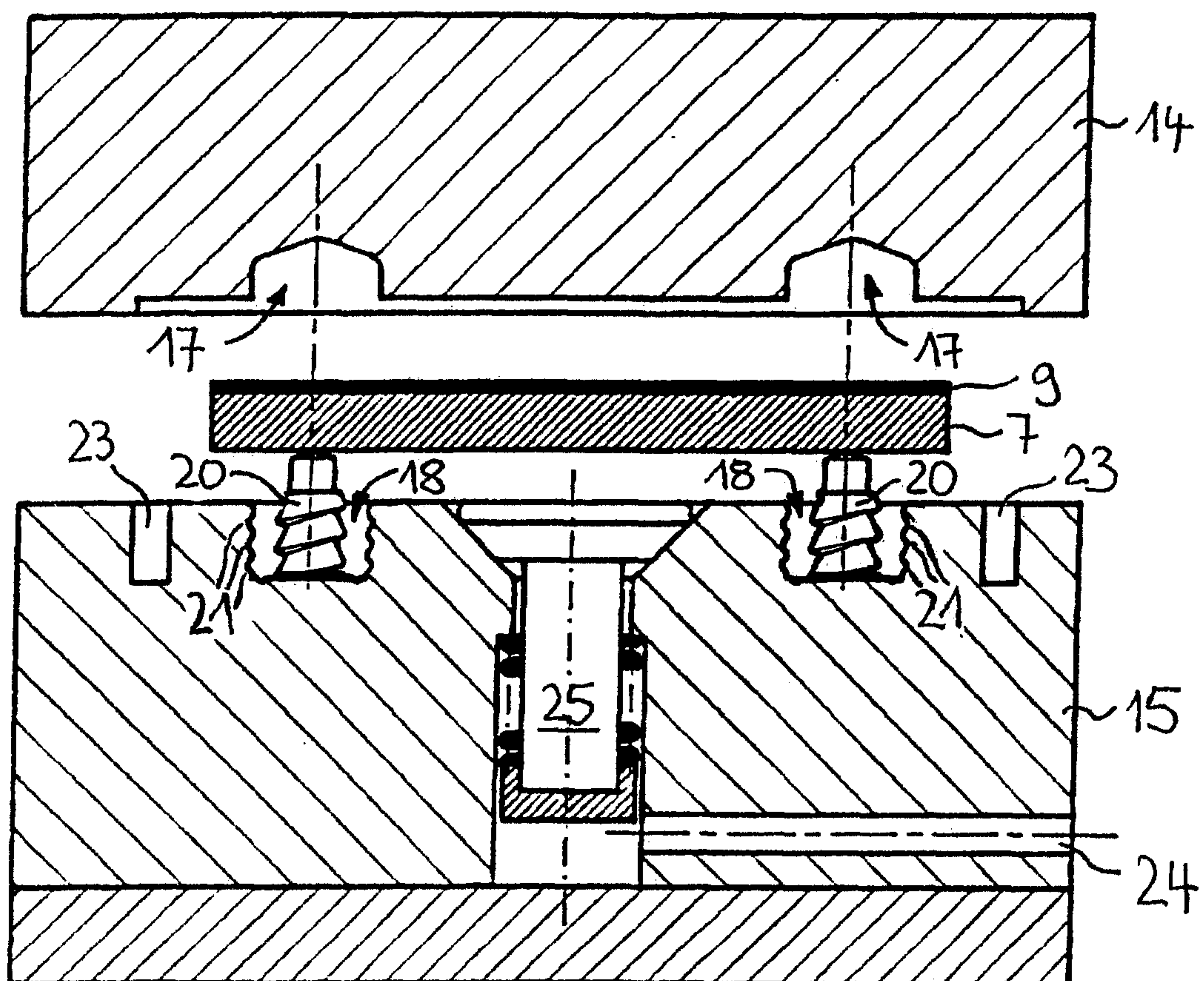


Fig. 1

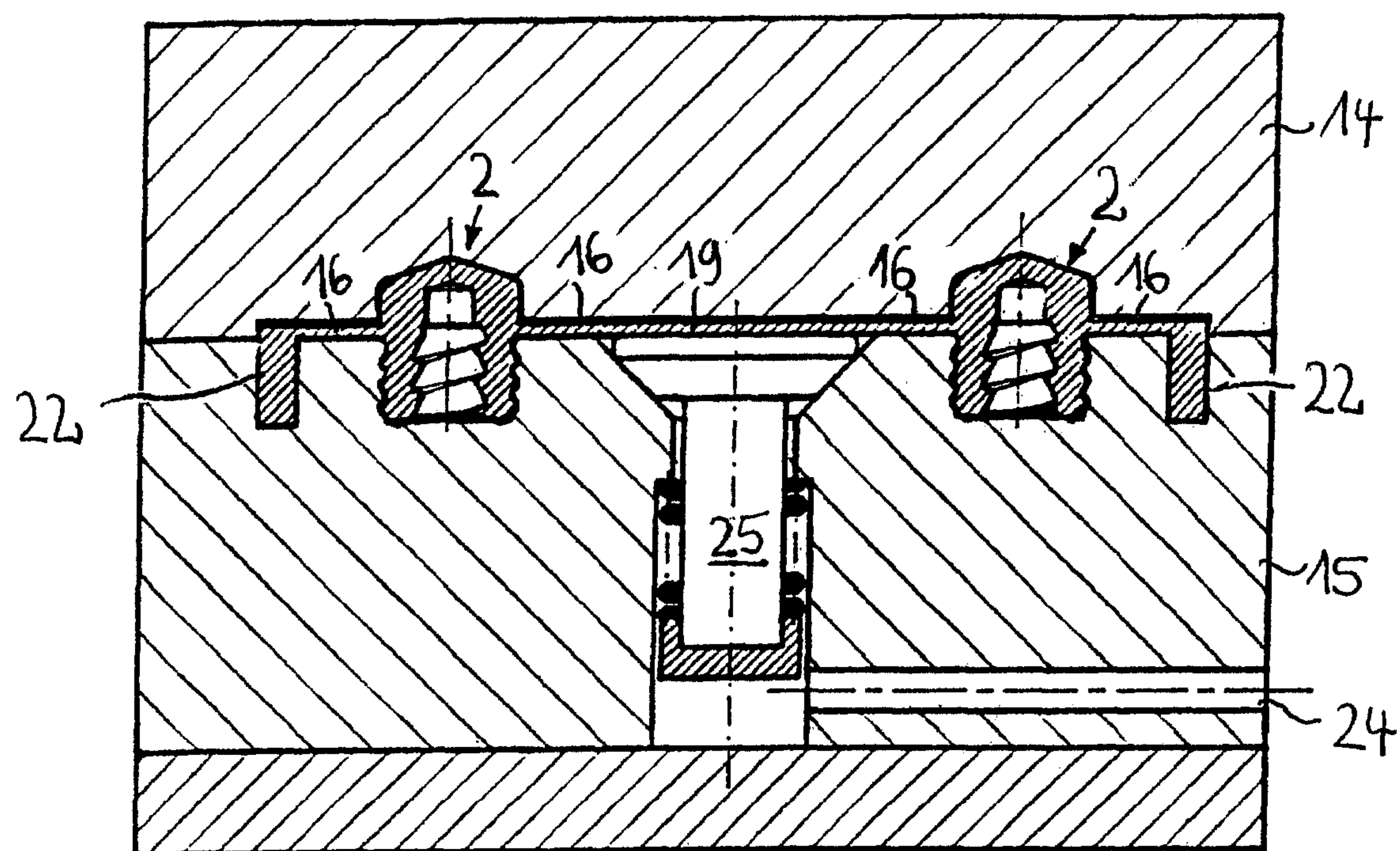


Fig. 2

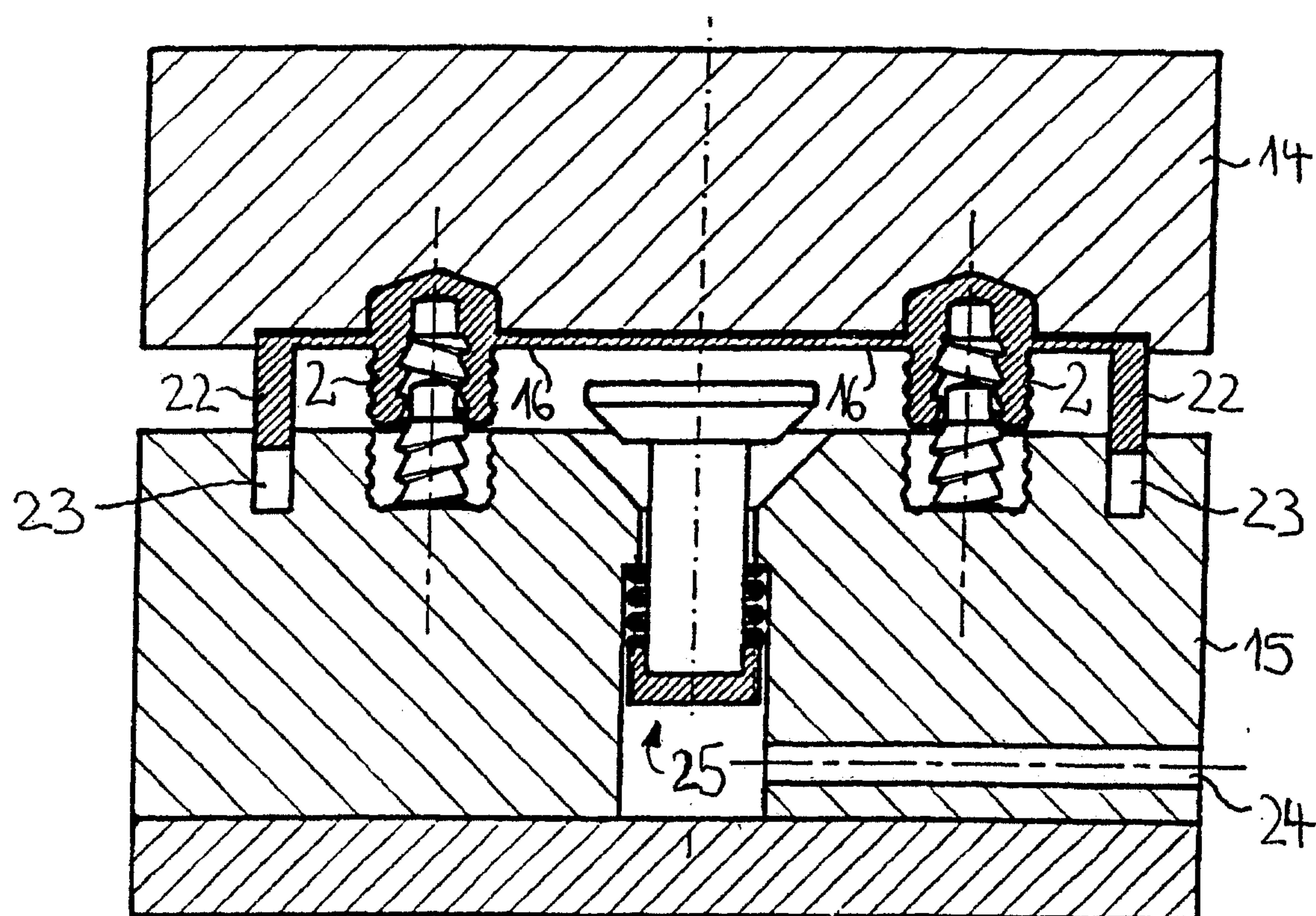


Fig. 3

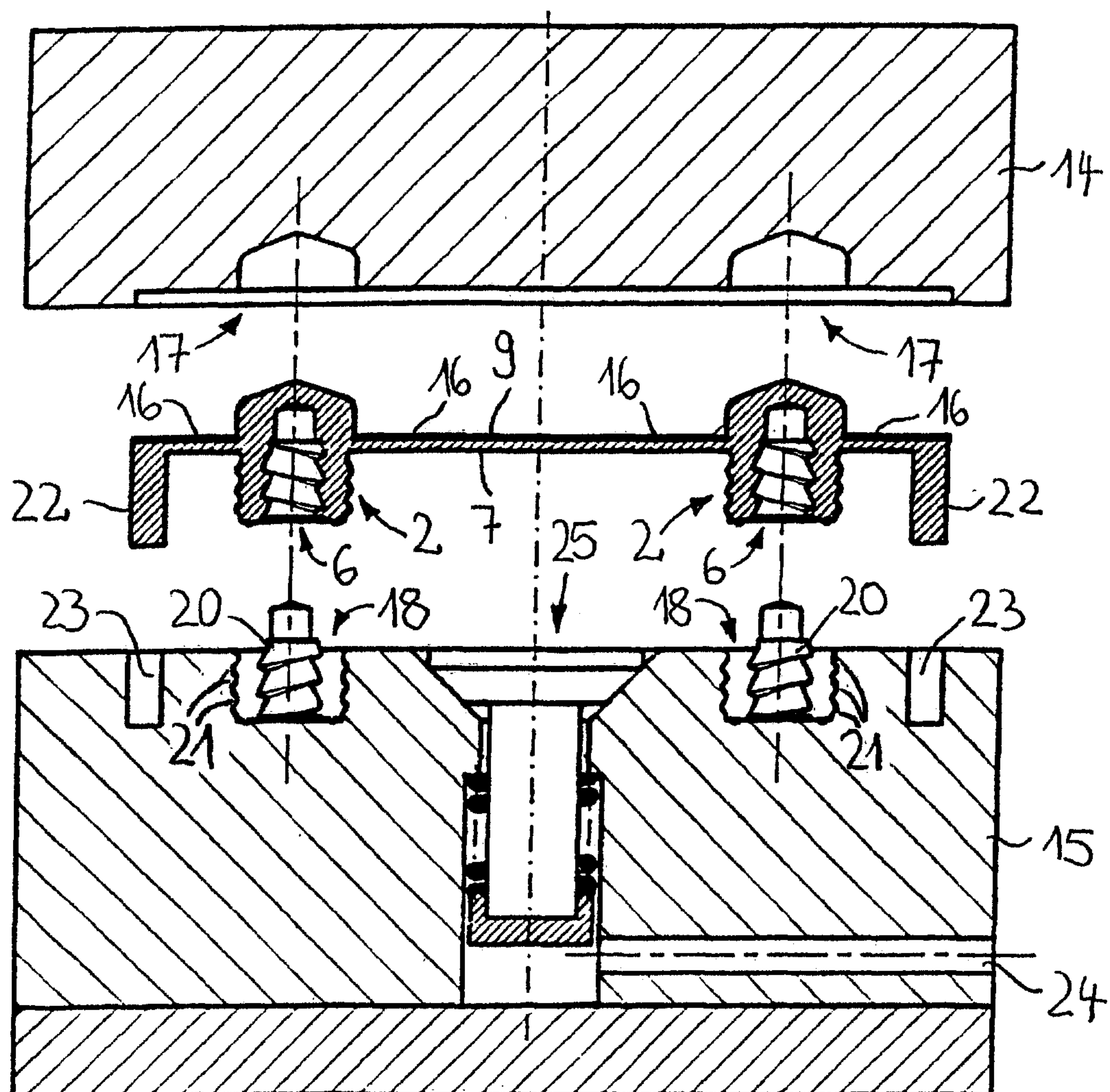


Fig. 4

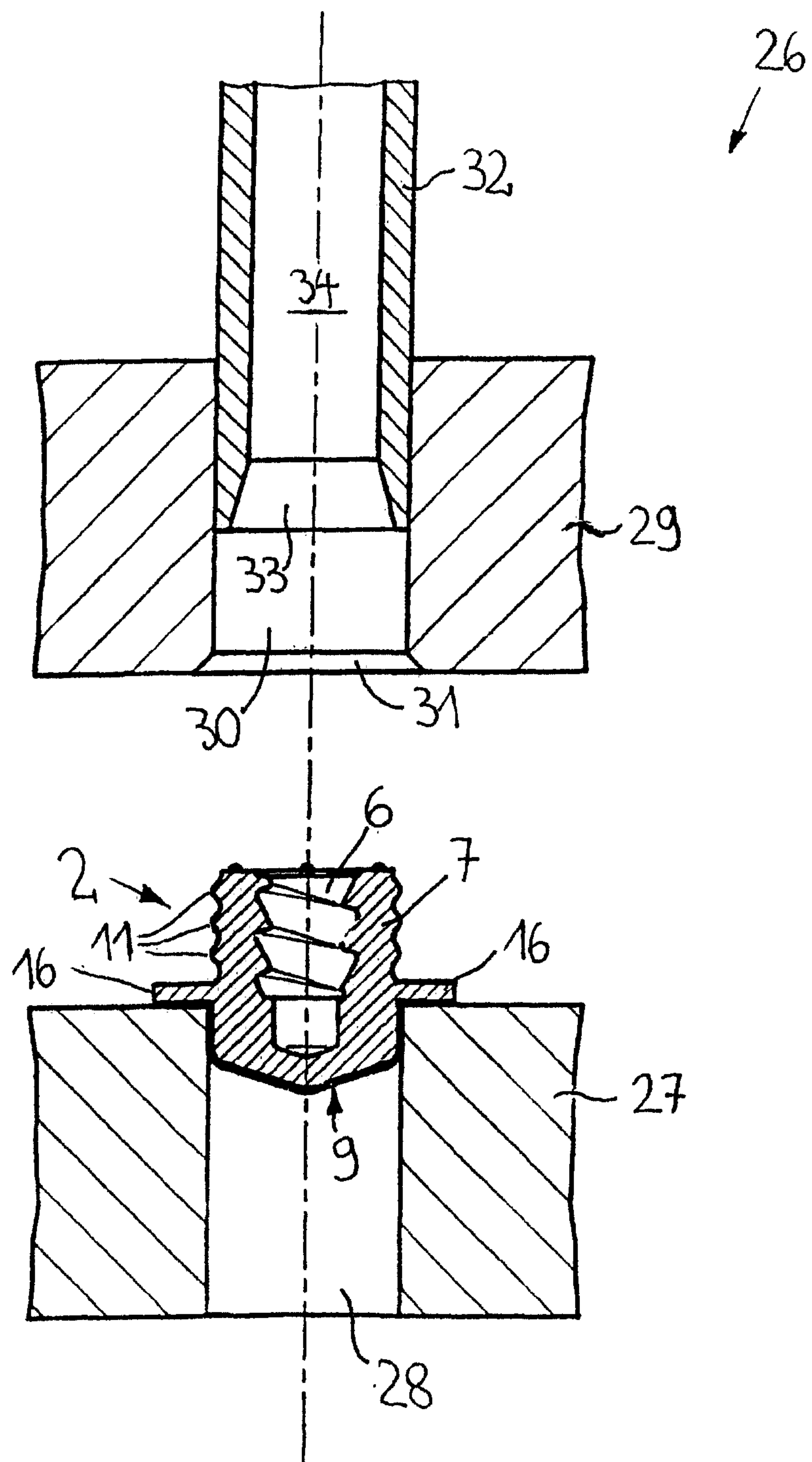


Fig. 5

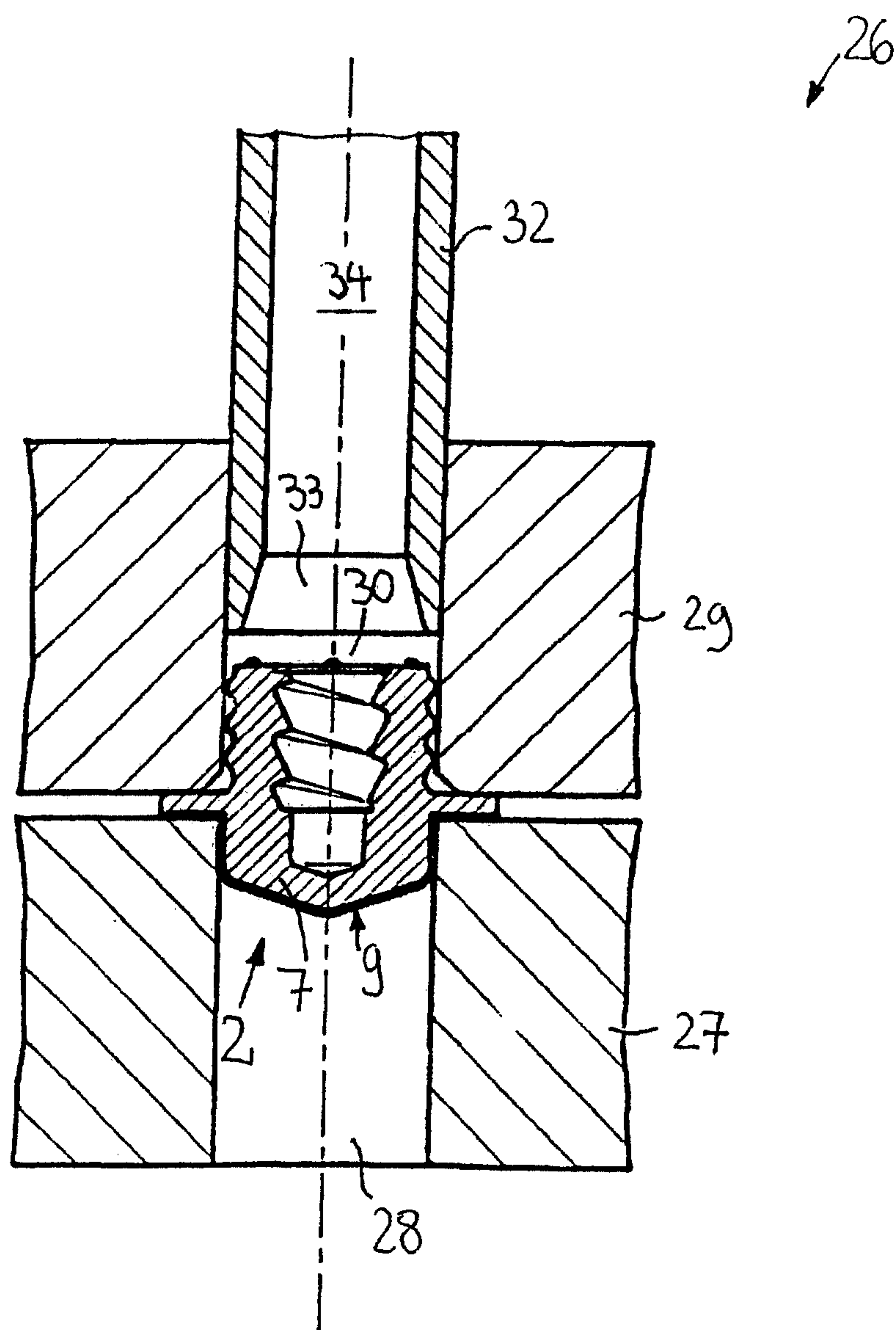


Fig. 6

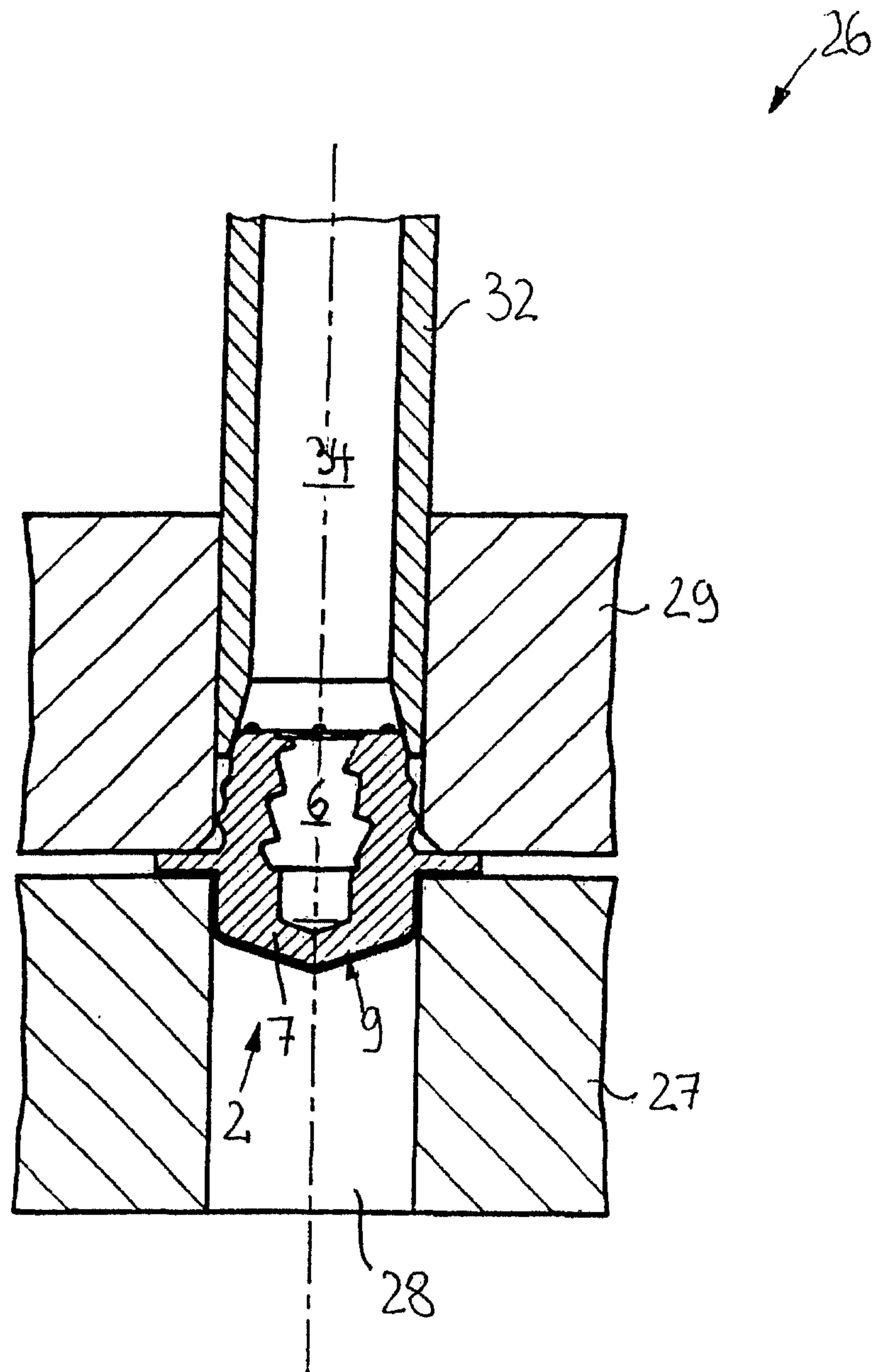


Fig. 7

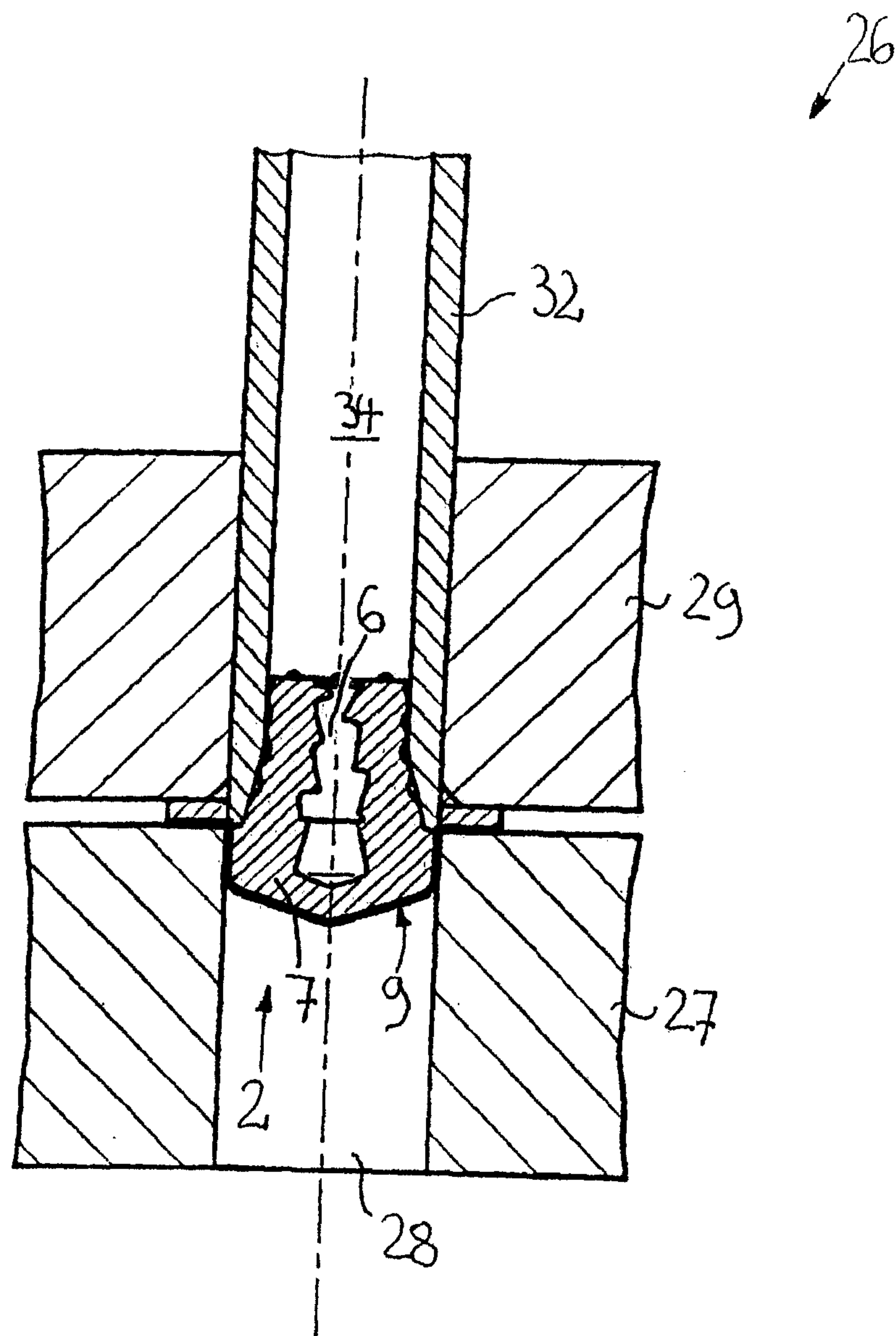


Fig. 8

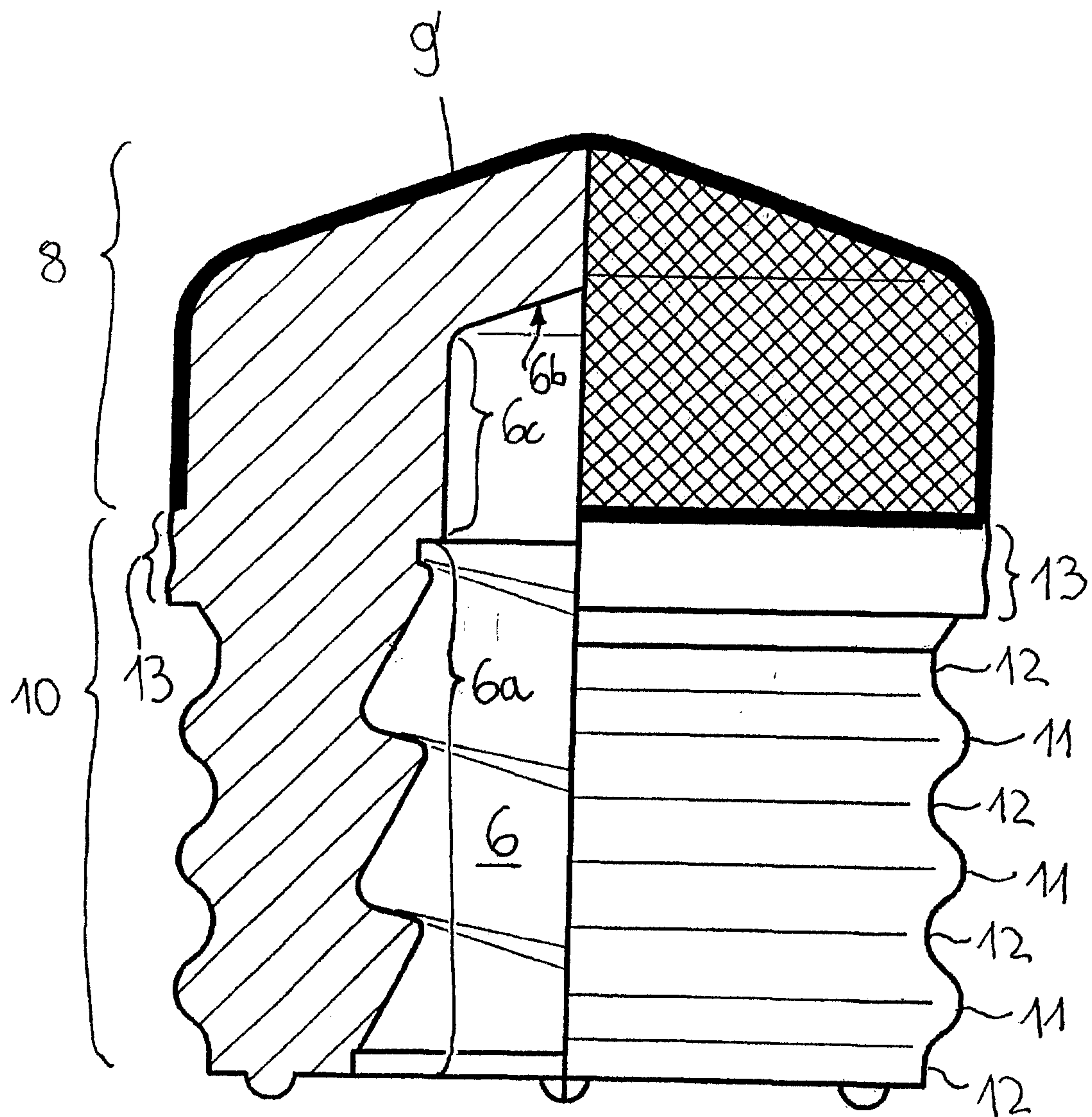


Fig. 9



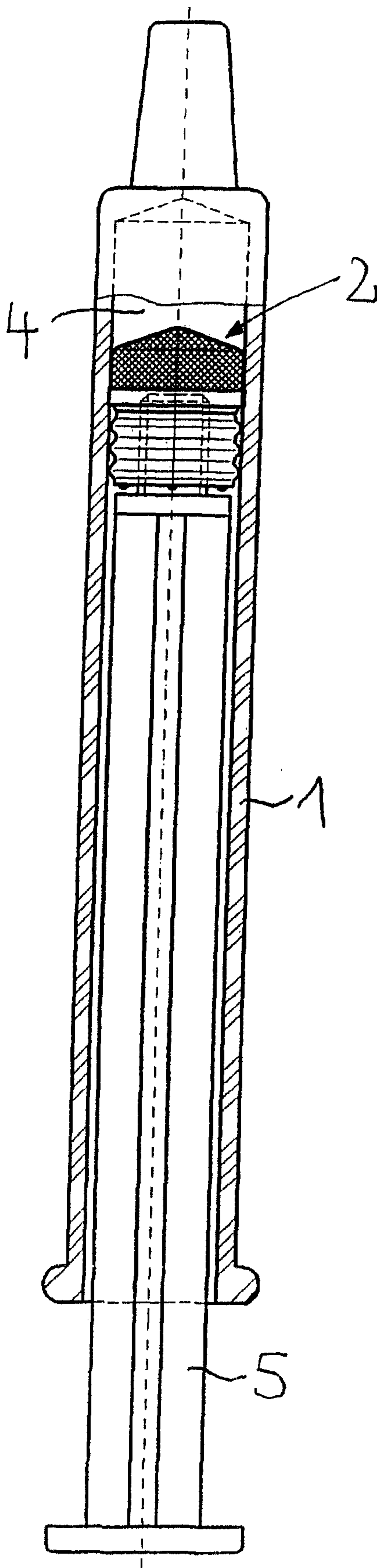


Fig. 10

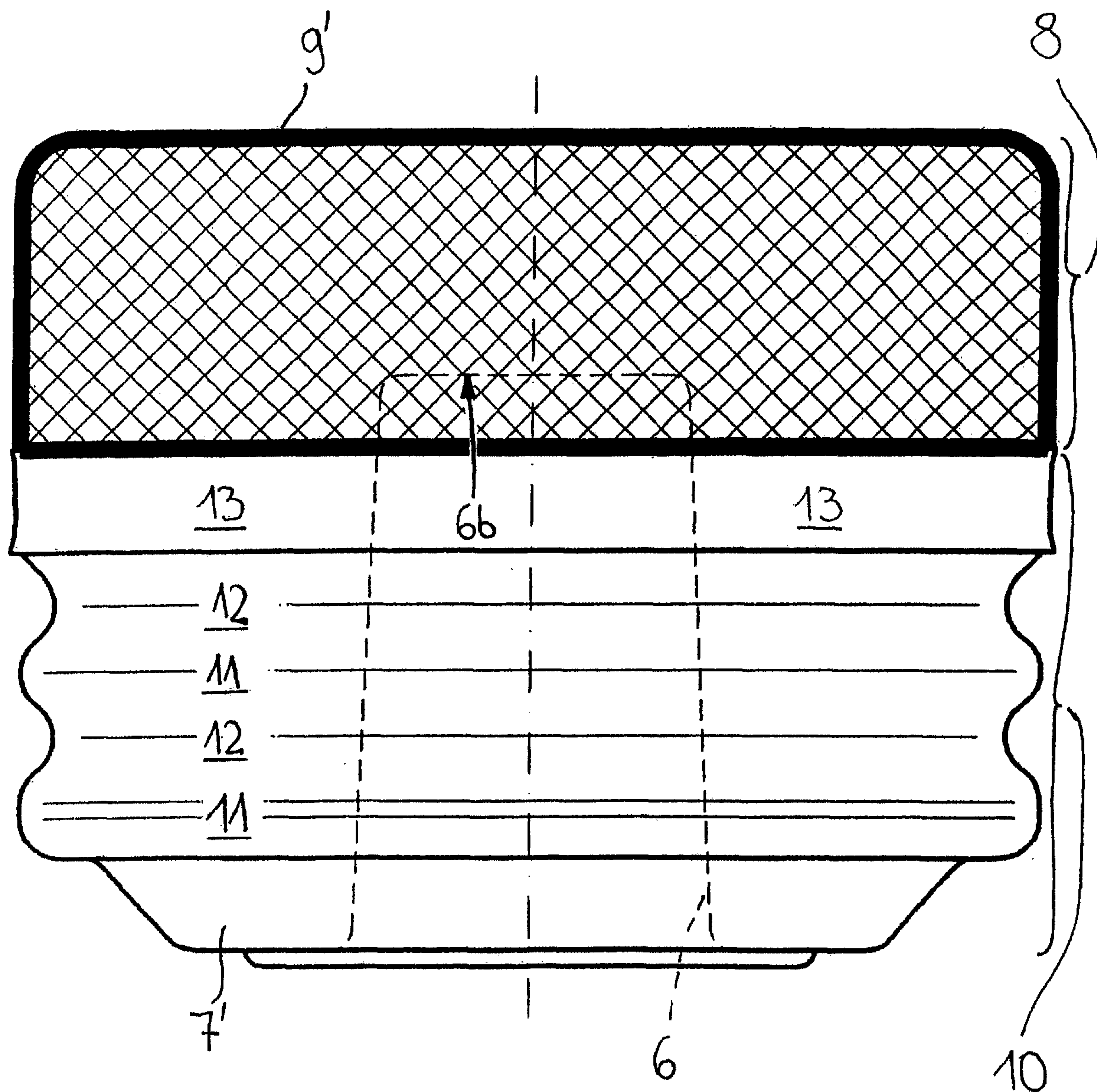


Fig. 11

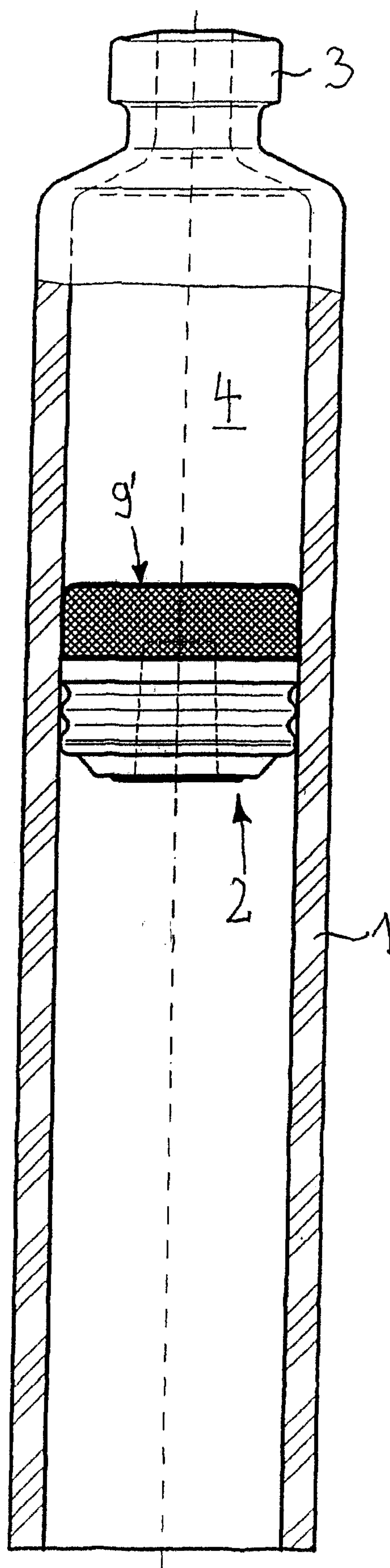


Fig. 12

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