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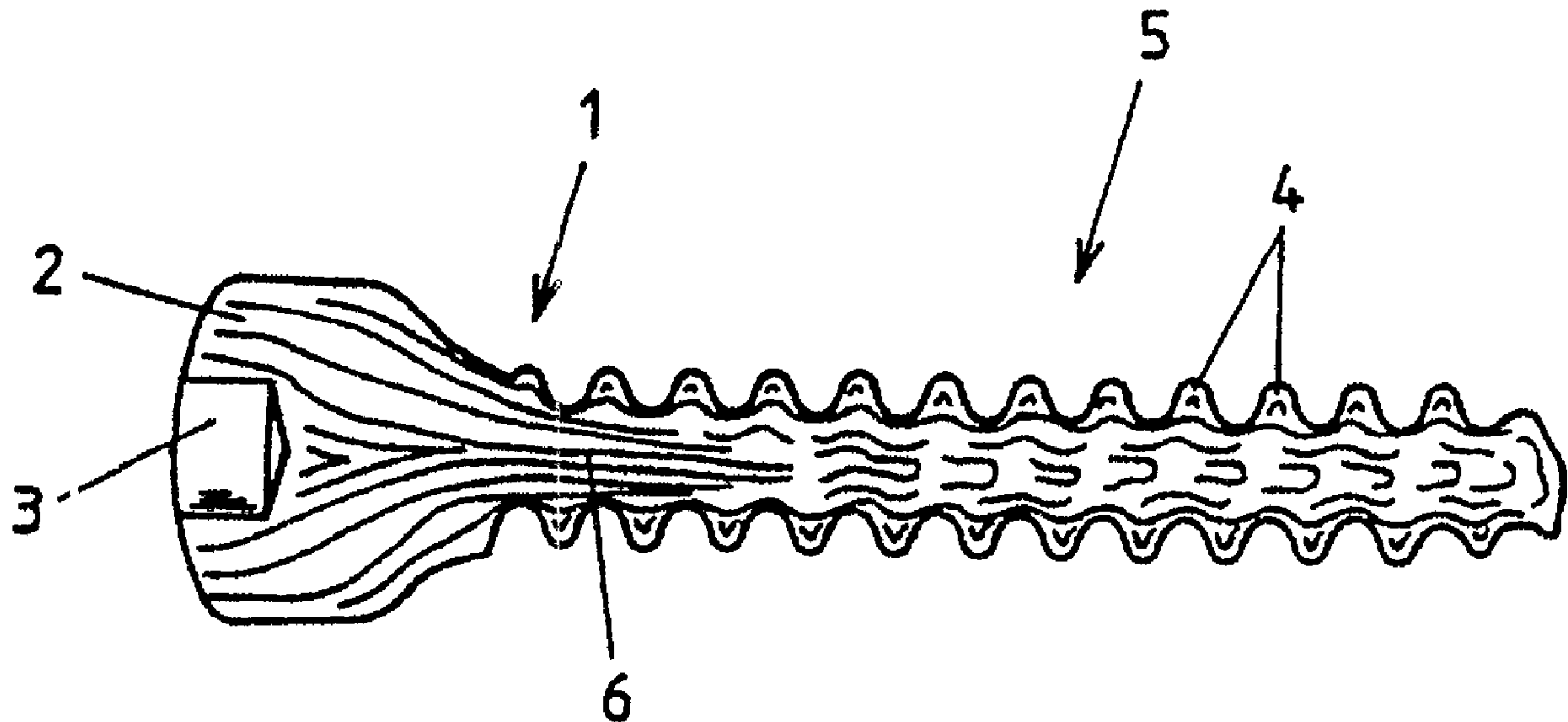
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(72) Inventeurs/Inventors:
 LOHER, URS, CH;
 MAYER, JORG, CH;
 TOGNINI, ROGER, DE;
 WEGENER, THOMAS, CH;
 WINTERMANTEL, ERICH, CH

(73) Propriétaire/Owner:
 SEPITEC FOUNDATION, LI

(74) Agent: ROBIC

(54) Titre : PROCÉDE DE FABRICATION DE COMPOSANTS EN MATIÈRES THERMOPLASTIQUES RENFORCÉES PAR DES FIBRES ET COMPOSANTS FABRIQUÉS SELON CE PROCÉDE
 (54) Title: PROCESS FOR MANUFACTURING COMPONENTS MADE OF FIBER-REINFORCED THERMOPLASTIC MATERIALS AND COMPONENTS MANUFACTURED BY THIS PROCESS



(57) Abrégé/Abstract:

An extruded component made of fibre-reinforced thermoplastic materials, in particular a screw (1) that contains a corresponding proportion of fibres. Carbon fibres shaped as endless fibres extend in an at least approximately parallel direction to the centre line of the screw (1) in the area of the head (2) of the screw (1) and in the three immediately adjacent thread turns of the shaft (5). At the surface of the remaining part of the threaded portion, the fibres follow the contour of the thread in the axial direction of the part. The fibres in the core of this section next to the end of the screw are distributed in an increasingly random manner towards the free end of the screw.



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(71) Anmelder (für alle Bestimmungsstaaten ausser US): AMSLER, Peter [CH/CH]; Höschstrasse 47, CH-8706 Meilen (CH).

(72) Erfinder; und

(75) Erfinder/Anmelder (nur für US): LOHER, Urs [CH/CH]; Glärnischstrasse 46, CH-9500 Wil (CH). MAYER, Jörg [DE/CH]; Tödistrasse 25, CH-8634 Hombrechtikon (CH). TOGNINI, Peter [CH/DE]; Im Rank 7, D-79771 Klettgau (DE). WEGENER, Thomas [CH/CH]; Sonnenbergstrasse 13, CH-9400 Rorschacherberg (CH). WINTERMANTEL, Erich [DE/CH]; Schulstrasse 3, CH-5442 Fislisbach (CH).

(74) Gemeinsamer Vertreter: AMSLER, Peter; Höschstrasse 47, CH-8706 Meilen (CH).

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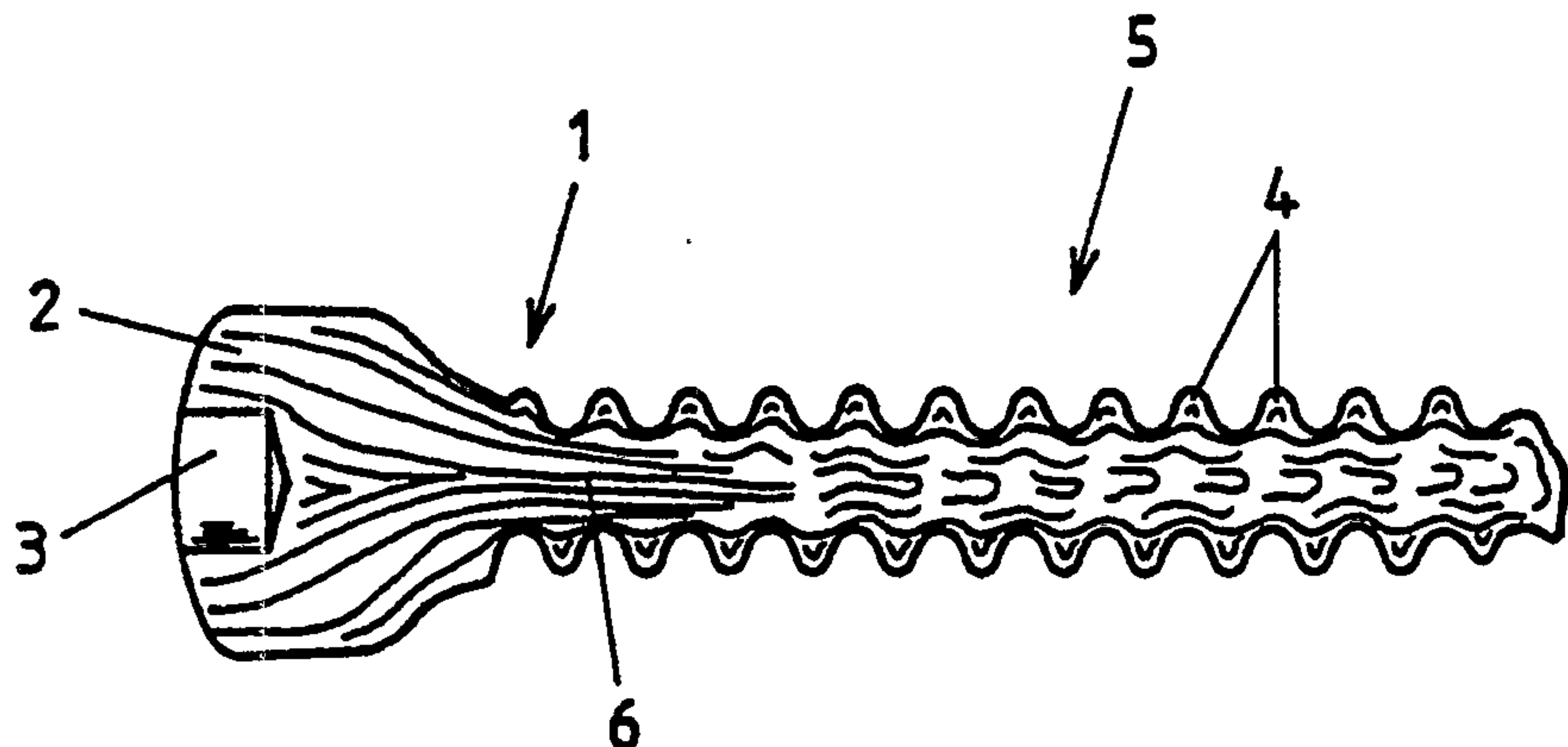
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(54) Bezeichnung: VERFAHREN ZUR HERSTELLUNG VON BAUTEILEN AUS FASERVERSTÄRKTEN THERMOPLASTEN SOWIE NACH DEM VERFAHREN HERGESTELLTER BAUTEIL

(57) Abstract

An extruded component made of fibre-reinforced thermoplastic materials, in particular a screw (1) that contains a corresponding proportion of fibres. Carbon fibres shaped as endless fibres extend in an at least approximately parallel direction to the centre line of the screw (1) in the area of the head (2) of the screw (1) and in the three immediately adjacent thread turns of the shaft (5). At the surface of the remaining part of the threaded portion, the fibres follow the contour of the thread in the axial direction of the part. The fibres in the core of this section next to the end of the screw are distributed in an increasingly random manner towards the free end of the screw.



(57) Zusammenfassung

Bei einem im Fließpreßverfahren hergestellten Bauteil aus faserverstärkten Thermoplasten geht es um eine Schraube (1), bei der ein entsprechender Faseranteil vorgesehen ist. Im Bereich des Kopfes (2) der Schraube (1) und über die drei unmittelbar daran anschließenden Gewindegänge des Schaftes (5) verlaufen Kohlenstofffasern in Form von Endlosfasern zumindest annähernd parallel zur Mittelachse der Schraube (1), wogegen die Fasern im restlichen Gewindeabschnitt oberflächennah der Gewindekontur in Achsrichtung des Bauteiles folgen. Im Kernbereich dieses dem Schraubenende zugewandten Abschnittes ist eine zum freien Ende hin zunehmend zufällig verteilte Faserorientierung vorgesehen.

Process for manufacturing components made of fiber reinforced thermoplastic materials and components manufactured by this process.

Field of the invention

This invention relates to a process for manufacturing components made of fiber reinforced thermoplastic materials, wherein initially a blank formed of short, long and/or continuous fibres and a thermoplastic material is prefabricated, and said blank is formed to the final shape of the component in a warm forming process under pressure in a female mold, to a process for manufacturing components made of fiber reinforced thermoplastic materials and subjected to tensional, bending and/or torsional loads, wherein initially a blank with a fiber content of more than 50% by volume and using at least predominantly continuous fibers and a thermoplastic material is prefabricated, and said blank is formed to the final shape of the component in a warm forming process under pressure in a femal mold, and to a component made of fiber reinforced thermoplastic materials, manufactured according to one of said processes.

Background

Components made of fiber reinforced thermoplastic materials are typically used as fasteners. Theses components are intended to be used as substitutes for metal screws, for example. It is particularly in medical engineering applications including, for example, bone screws, that screws made of fiber reinforced thermoplastic materials are significantly better suited than metal screws, because they are structure compatible with the bone, present no problems with corrosion resistance, can be made to weigh less than metal screws, and do not impair the conventional medical examination methods in contrast to the use of metal.

The art knows of screws and threaded studs made of fiber reinforced thermoplastic materials in which the screw blanks are produced either

by coextrusion or by a multi-component injection-molding process. In this known implementation (DE-A-40 16 427) circular solid bars produced by coextrusion are utilized as base material. For the core portion granular thermoplastic material with 5 to 10 mm long fibers is preformed in a first extruder, while for the peripheral region granular thermoplastic material with short fibers is performed in a second extruder. Thus a base material is obtained which comprises a coaxial arrangement of long fibers internally and short fibers externally. Using an extrusion process, the long fibers in the inner core portion have a predominantly axial orientation, while the short fibers in the outer area transfer shear forces in the turns of the thread. The turns of the thread are produced by a subsequent cold forming process, using, for example, thread rolling heads or thread rolling machines. While such cold forming is made possible through the use of short fibers, it is the very arrangement of such short fibers in the thread section that results in diminished strength values.

In a process according to DE-T2-68919466, a blank is placed in a split mold and formed therein. The blank is placed in a mold cavity in cold condition, is heated, expanded, and allowed to cool. With this process, deformation can be effected to a limited degree only and, in addition, it is practically impossible, or at least not possible to a predeterminable degree, to influence the orientation of the fibers.

In a process according to US-A-3 859 409, the slug is forced from a receiving chamber into the mold cavity which however has a larger diameter than the slug. Also in this known process the slug is deformed merely in its peripheral regions and in its end regions.

From EP-A-0 376 472 a thermoplastic composite plate material is known which has a quasi-isotropic lay-up and is readily adapted to be forced into a mold in order to produce a composite object of intricate shape, as, for example, a head of a golf club.

EP 0 373 294 A3 describes a process for, inter alia, the manufacture of threaded fiber reinforced fastening elements according to the introductory part of the present invention. In the process according to this

document, a final product is produced from a bar-shaped blank of fiber reinforced plastic material which is placed in a female mold, heated there and subsequently subjected to pressure to be conformed to the shape of the female mold. The process involved in this disclosure is one related to thread rolling or drop forging, because only a partial deformation of the blank takes place. The fibers of the blank made of fiber reinforced plastic material are continuous fibers which are varied only in the outer region of the blank in a radial direction along the female mold. In this process an axial fiber orientation takes place only on the outer periphery because there the fibers engage the female mold radially.

10 It is an object of the present invention to provide a process for the manufacture of a component made of fiber reinforced thermoplastic materials, which enables a component to be optimally adapted for its particular use. Still further it is an object of the invention to provide a component manufactured by this process, which enables in particular the application and distribution of force and the stiffness to be adapted to the characteristic of the body cooperating with the component.

Summary of the invention

20 The present invention comprises a process for manufacturing components made of fiber-reinforced thermoplastic materials, wherein a blank formed of a short, long and/or continuous fibers and a thermoplastic material is prefabricated and said blank is formed to the final shape of the component in a warm forming process under pressure in a female mold, characterized by the step of initially heating said blank to forming temperature in a heating section adjacent to and in fluid communication with the female mold and then pressing it into the female mold by an extrusion pressing operation.

30 The first process of the present invention accordingly comprises the steps of initially heating the blank to forming temperature in a heating section and then pressing it into the female mold by extrusion pressing. The subsequent extrusion pressing operation provides for orientation and distribution of the fibers, which are spread over the entire cross section of the blank, in a highly

selective and controllable manner. The fiber orientation and fiber distribution and hence the mechanical properties of a component manufactured according to this process can thus be especially characterized and related to the process parameters of the manufacturing process. In addition, extrusion pressing enables the fiber orientation to be controlled so that different strength values are obtainable also along the length of a component.

Advantageous embodiments of the present invention are defined hereafter.

In a preferred embodiment of this process and using more than
10 50% by volume of continuous fibers, the blank is initially heated to forming temperature in a heating section and then pressed into the female mold by extrusion pressing. It is precisely by the use of a high density of continuous fibers that stiffness and strength of a component to be manufactured are selectively controllable. In particular where intricately shaped components are involved, the precise precalculability of the optimum fiber orientation and optimum fiber density in a specified area affords advantages.

Another proposal comprises prefabricating the blank as a rod material and cutting it to the length necessary for the final component prior to the warm forming process. The sections of material required for the final component
20 are severed from the prefabricated rod material and subsequently fed to the warm forming process. Hence an approach similar to extrusion pressing of metal parts is provided.

Stiffness and strength can be enhanced still further by the use of continuous fibers of a length corresponding at least to the length of the blank for the final component.

Deforming a blank from longitudinally extending layers of different fiber orientation may also be contemplated. Hence, by way of advantageous embodiments of the processes of the invention, innumerable new fields of application can be covered, because the components can be manufactured to
30 an accurately predeterminable strength and stiffness to suit a particular application.

In this connection it is also possible for a blank to be deformed from more than one polymeric composite comprising, for example, several layers of different matrix material and different arrangement and/or different percentage by volume and/or different fiber material and/or different length of the fibers. Also with such approaches the final requirements of the component to be manufactured can be perfectly met.

In this connection it may also be advantageous for the blank to be deformed into the final component by a reciprocating extrusion pressing process. This involves deforming the blank severed from the rod material in a suitable extrusion mold. The process referred to as extrusion according to German Industrial Standard DIN 8583 is thus utilized. In the reciprocating extrusion pressing technique, the blank is deformed into the final component by multiple to-and-for movements in the female mold. This process has particularly advantageous effects in the manufacture of strip- or plate-shaped components.

In contrast to extrusion pressing or reciprocating extrusion pressing of metal parts, an essential distinguishing feature herein provided is that in extrusion pressing or reciprocating extrusion pressing the blank is heated to a forming temperature of, for instance, between 350 and 450°C in a heating section and then pressed into the female mold, a dwell pressure section being provided to effect cooling to a temperature below the glass transition temperature of the thermoplastic material of, for example, 143°C. For processing the fiber reinforced thermoplastic materials, the extrusion pressing technique known from metal parts is modified to the effect that the blank is deformed not at room temperature but at a temperature above the melting or softening temperature of the matrix material.

Still further, it is advantageous to use carbon or graphite as release agent in the warm forming process. It appears that such a release agent has not been used so far in the forming of thermoplastic materials. The particular added advantage afforded thereby is that graphite, for example, is biocompatible, in contrast to the otherwise typical coatings or mold release agents employed for plastics, so that the components are particularly well suited

for medical applications. According to another advantageous embodiment of the processes of the invention, provision is made for processing a blank from carbon fiber reinforced PEK (polyether ketone). Experience has shown that it is precisely through the use of such a material that the tensile strength of the component produced in this manner is on an average about 30% lower than the tensile strength of comparable steel components. For the field of application of such fiber reinforced thermoplastic components, this strength level is, however, more than sufficient, considering the materials with which such a component is required to cooperate. In medical engineering applications including, for example, bone screws or plate or splint components, a correspondingly high force at rupture is entirely sufficient, which on such components amounts already to almost three times the available force at fracture of a bone.

In another advantageous embodiment of the two processes of the present invention, provision is further made for at least a fraction of the fibers to extend parallel to the axis in the blank. It can also be considered that at least a fraction of the fibers has an orientation of between 0 and 90°C. Particularly in the manufacture of elongated components including, for example, a screw or a strip-shaped assembly part, special possibilities of adaptation to the requisite strength ranges are thereby afforded. The modulus of elasticity of screws made from blanks comprising fibers with an orientation parallel to the axis is correspondingly higher, such screws hence tending to be stiffer. Experience has shown that the use of an extrusion pressing technique enables a variation in the fiber orientation relative to the fiber orientation in the blank, so that additional adaptation parameters become possible due to the special fiber orientation in the blank.

In a further advantageous embodiment of the two processes of the invention, fibers of a length of more than 3 mm may be employed. In many known fiber reinforced thermoplastic materials for the manufacture of corresponding components, short or long fibers are typically employed. In combination with the warm forming process, the use of continuous fibers with the high fiber content of more than 50% by volume affords an optimum

possibility of controlling the strength property at any point of the component being manufactured, so that stiffness levels locally adjusted to a selected value are achievable.

In another advantageous embodiment of the two processes of the invention, during extrusion pressing the matrix material encloses the fibers, covering the complete surface. This eliminates the need for post-processing the final components produced by extrusion pressing, because the entire surface is practically completely sealed in the process.

10 In yet another advantageous embodiment of the two processes of the invention, it is also possible for the components to be provided with an additional surface seal during warm forming. Through the action of heat in the forming die or suitable additional devices, such as coatings or mold release agents, an additional surface seal on the finished components is accomplishable.

20 The processes of the present invention afford a variety of possibilities of controlling the manufacturing process. A component produced according to the processes of the invention is therefore characterized by zones of stiffness and strength values predetermined locally by a predetermined fiber orientation. Maximum tensile strengths have been attained, for example, with components manufactured at high forming speeds and high blank temperatures. By contrast, maximum torsional strength values are obtained in the presence of comparatively low forming temperatures and low forming speeds. Accordingly, it is in the very manufacture of components made of fiber reinforced thermoplastic materials that the processes of the invention afford possibilities of adapting a component for its special application, including the added possibility of having one operation cycle composed of two or more sections with different forming speeds, for example.

30 The present invention thus further relates to a component of fiber reinforced plastic, manufactured according to the new and inventive process, characterized by zones of stiffness and strength values predetermined locally by a predetermined fiber orientation, wherein said component is constructed as a

fastener element having an end for engagement with a tool and a threaded shank, and wherein the stiffness of said fastener element varies on account of different fiber orientation from the tool engaging end to the free end.

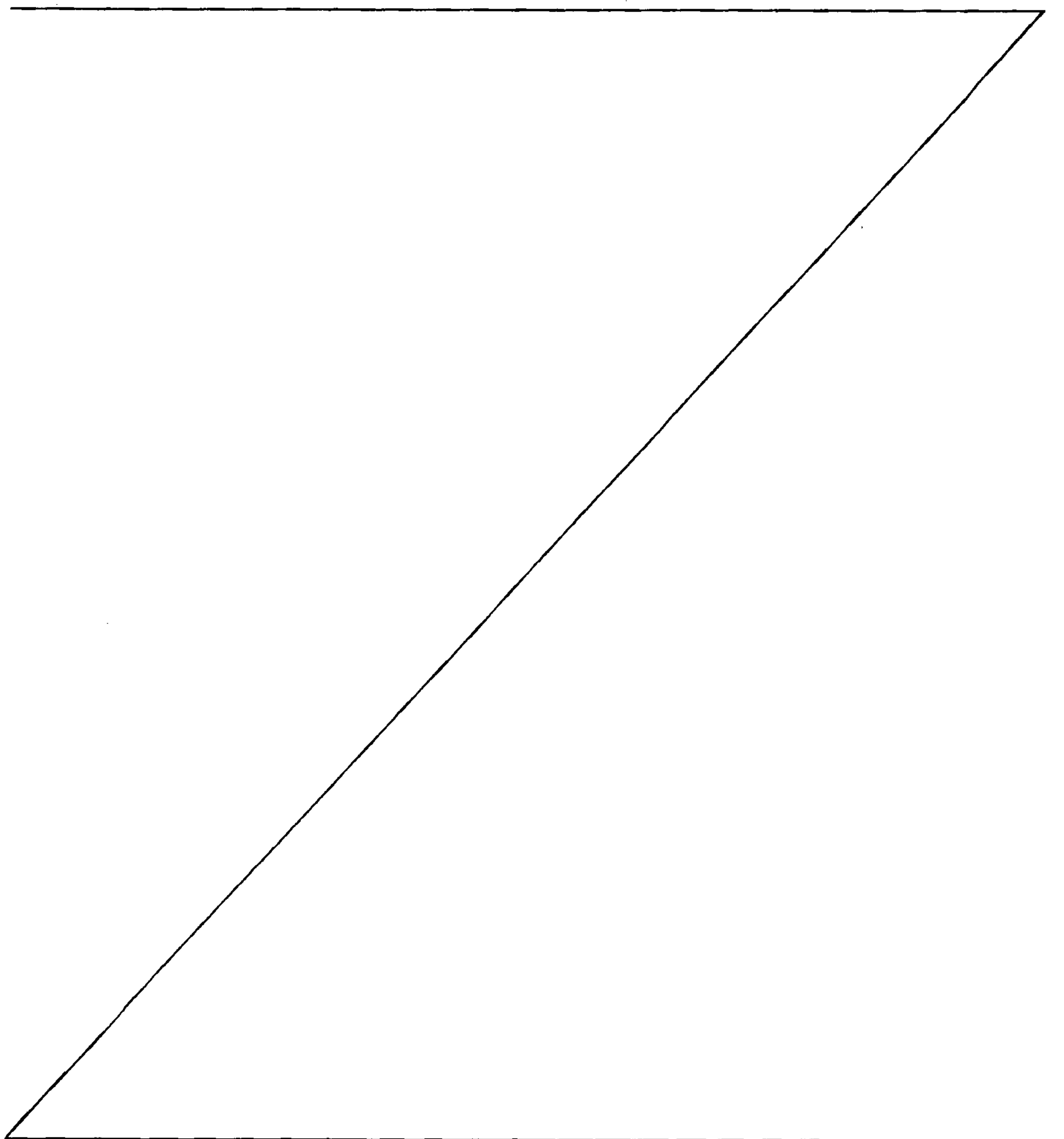
The invention also pertains to a component of fiber reinforced thermoplastic materials, manufactured according to a process as described hereinabove, characterized by zones of stiffness and strength values predetermined locally by a predetermined fiber orientation, wherein said component is constructed as a fastener element having a portion for engagement having a through opening, wherein the stiffness of said fastener
10 element varies on account of different fiber orientation in the region surrounding the through opening.

By way of adaptation to the mold and the particular field of application of the component, a predetermined orientation of the fibers in relation to the longitudinal direction, the diameter, the thickness, the shape of the component can be provided, or provision can be made in the component for zones with different fiber orientation in the region of apertures, recesses, indentations, or the like. Such a component is particularly well adaptable for a special application. With such a component, the application and distribution of force can be better adapted to the properties of the body cooperating with this
20 component. This applies in particular to the field of medical engineering including, for example, bone screws, or medical assembly parts and fastening strips, etc., but also to other mechanical, electrical, electronic or construction engineering applications.

This is also the reason why the component is advantageously constructed as a fastener element having an end for engagement with a tool and a threaded shank, wherein the stiffness of the fastener element varies on account of different fiber orientation from the tool engaging end to the free end. Particularly in components suitable for use in the bone region, an adaptation to the natural structure of a bone is possible, enabling a light weight, non magnetic,
30 X-ray transparent and biocompatible fastener element to be created. In contrast to customary metal screws, a genuinely effective component is obtainable thanks to the adaptation of the fiber structure and the fiber orientation.

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As another advantageous embodiment of the component of the present invention, it is proposed that the fibers extend at least approximately parallel to the component's center line from the tool engaging end up to and including the directly adjoining turns of the thread, whilst the fibers in the remaining threaded section, extending close to the surface, follow the thread contour in the component's axial direction, while, however, in the core zone of said section a fiber orientation is provided which is increasingly randomly



distributed towards the free end. Therefore, the strength is at its maximum level in the very area of the tool engaging end of the component formed as a screw and in the adjoining threaded section, whereas the threaded sections engaging within the bone's inner region have a lower tensile strength, because in this particular region tensile forces could not be taken up anyway.

In yet another embodiment of the component of the invention it is an advantage that, on account of different fiber orientation, the stiffness of the component decreases in steps or continuously as seen looking from the tool engaging end towards the free end. Therefore, the fiber orientation resulting from the manufacturing processes of the invention and, of course, also from the forming speed, permits achieving an exact adaptation to the particular field of application of the component.

Still another proposal comprises providing in the component at least one blind-end hole or one through opening, for example, for applying a rotary tool or for passing fasteners therethrough. With such an arrangement it is possible to apply corresponding torsional forces when such a screw-shaped component is turned in, in particular in cases when it should become necessary to turn it out. Where through openings or the like are provided, an advantageous construction is obtained also with flat components, because, for example, the area encompassing the opening can be reinforced with special fiber orientation. In this connection it is advantageous for the blind-end hole or the through opening to be integrally formed during the manufacture of the component. It is precisely in a warm forming process that special additional possibilities are afforded in order to provide, simultaneously with a forming process, suitable blind-end holes or through openings for rotary tools.

A special field of application for a component of the present invention results when the component is constructed as a cortex or cancellous bone screw structure-compatible for medical applications.

Another embodiment of a component provides for the component to be constructed as a strip- or plate-shaped assembly part having one or several through openings and/or sections projecting over the longitudinal and/or

lateral boundaries, with the stiffness and strength being predetermined over its full length and/or width and/or diameter. With the processes of the present invention it is hence possible to manufacture any type of component of special shape, including the possibility for an adaptation to the requisite strength and stiffness of selected sections, because it is the very fiber orientation and fiber density that can be predetermined.

In this connection, in an advantageous embodiment the component constructed as assembly part, owing to a denser arrangement of fibers in the area of through openings and/or projecting sections, exhibits in these customarily weakened zones the same strength and stiffness as in other zones of the component.

Each component may hence be designed to be devoid of weakened zones, so that also for very special applications the strength and stiffness required for all sections is attainable.

For strength and stiffness adaptable in this manner it is therefore just optimal when the component is constructed as an osteosynthesis plate to be used, for example, with a cortex or cancellous bone screw.

Description of the drawings

Embodiments of the present invention will be described in more detail in the following with reference to the embodiment illustrated in the accompanying drawings. In the drawings:

FIG. 1 is a partly cutaway view of a section of a rod-shaped blank, showing a 0° orientation of enclosed continuous fibers;

FIG. 2 is a view of a component in the form of a screw, showing in a schematic representation the fiber orientation distribution in the screw;

FIG. 3 is a diagram plotting stiffness against length of the component provided as a fastener element;

FIG. 4 is a schematic diagram of a possible extrusion die with temperature zones, for fabricating the component;

FIG. 5 is a schematic representation of an extrusion die illustrating another embodiment;

FIG. 6 is a schematic diagram illustrating the fabrication of a component using a reciprocating extrusion pressing process; and

FIG. 7 is a top view of a component fabricated by a reciprocating extrusion pressing process and especially suitable for use as an osteosynthesis plate.

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Description of preferred embodiments

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In the subsequent explanation of the processes of the present invention and the component manufactured thereby, it is assumed that the component (according to FIGS. 1 to 5) is a fastener element, in particular a screw, used specifically for medical engineering applications, that is, for example, as a cortex or cancellous bone screw, or that the component (according to FIGS. 6 and 7) is an assembly part, in particular an osteosynthesis plate for cooperation with an aforementioned fastener element. It will be understood, of course, that also other components are comprised, which are made of fiber reinforced thermoplastic materials and fabricated by the processes of the invention. The application of such components is not considered limited to medical engineering. The use of such components in other fields of application including, for example, mechanical, electrical, aerospace, construction engineering, etc., may also be contemplated. It is also not always necessary for the components to be manufactured in the form of fasteners (screws), but

rather, they may be used as components embodying entirely different constructions as, for example, splints or plates. Thus, for example, it is also envisaged that the fiber reinforced plastic components, which can be safely assumed to be not self-tapping screws, could be equipped with a suitable drill bit which may equally be fabricated from a biocompatible material or, alternatively, is readily removable subsequent to the drilling operation. Under circumstances, such removal is not necessary at all in a variety of application fields. The example is also explained with reference to a fiber reinforced thermoplastic material fabricated of continuous fibers with a fiber content of more than 50% by volume. With the processes of the invention, it is equally advantageously possible to process fiber reinforced thermoplastic materials containing only short fibers or only long fibers, or alternatively, combinations of short, long and/or continuous fibers. The processes of the invention can also be employed successfully with a fiber content of less than 50% by volume in the blank.

The fastener element in the form of a screw 1 as shown in the drawing is essentially comprised of a head 2, a tool engaging end 3 for the application of a force from a rotary tool, and a shank 5 having a thread 4. As becomes apparent particularly from FIG. 2 of the drawings, the orientation of the continuous fibers 6 in the screw 1 is of primary concern. The fibers being selectively locally oriented within the structure, the screw 1 exhibits selectively locally adjusted levels of stiffness. It is in the very use as a cortex screw that the stiffness is adaptable to the natural structure of a bone. By selecting a composite of thermoplastic materials and carbon fibers, a light weight, X-ray transparent and biocompatible fastener element can be obtained. The particular advantage of such a screw resides in that the stiffness levels and stiffness gradients are better adapted to the natural bone structure than is the case with conventional metal screws. The fiber structure ensures an improved force distribution, that is, it is not only the first three turns of the thread that carry the load. Furthermore, being non-magnetic and X-ray transparent, the fastener element does not adversely affect the usual medical examination methods. This being not the case with conventional metal implants including, among others,

fastener elements, they are at a great disadvantage in this regard. They are apt to render the examination results of modern diagnostic methods such as computer tomography or nuclear spin tomography, useless.

Owing to the adjusting action of the fastener element, its working loose is not to be expected until after a time of some length. When the fastener element is constructed as a cortex screw, the screw can be turned out again after an overtightening with the residual strength.

As set out previously the fastener element is suitable for utilization in general mechanical engineering in a corrosive environment and in particular
10 where high strengths and directionalized strengths at low weight are required. Here, too, the force application over more than three turns of the thread is of decisive importance.

A variety of further elements can be secured with the head 2 of the cortex screw shown in FIG.2 including, for example, an osteosynthesis plate. The tool engaging end 3 may be implemented as a hexagon socket, for example. The selection of other forms of application or engagement as, for example, a square opening, an internal star opening or a cross recess may equally well be contemplated.

A modification of the extrusion pressing process as known from
20 metal processing finds application in the manufacture of the cortex screw (for example, with a core diameter of 3 mm) from carbon fiber reinforced PEK (polyether ketone). A special variant provides for the use of carbon fiber reinforce PEEK (polyether ether ketone). The fiber orientation distribution and the mechanical properties of the screw are characterized and related to the process parameters of the manufacturing process.

The rupture load of the screws produced by extrusion pressing lies in the range of between 3,000 and 4,000 N, and the maximum torsional moment between 1 and 1.5 Nm, with the maximum torsion angle according to ISO 6475 amounting to up to 370°C. The screws possess a modulus of elasticity
30 diminishing from the head to the tip and are designated as homoelastic relative to the bone.

Nature uses in its structures frequently the principle of fiber reinforcement. For reasons of structure compatibility it is therefore advantageous to design medical implants equally as fiber composite parts. Particularly in the field of osteosynthesis engineering, developments are necessary to substitute less rigid implants of fiber composite materials for conventional osteosynthesis plates made from steel. It is precisely in connection with osteosynthesis plates that the construction of the invention is put to advantageous effect. Such an osteosynthesis system has numerous advantages over a conventional steel implant. For one thing, it is homoelastic relative to the bone, making an adapted load application to the bone possible, and for another thing it enables X-ray transparency and nuclear spin tomography. Moreover, the approaches of the invention result in a low-cost production using a warm forming process. What counts additionally is the fact that components constructed in this manner present no problems in cases where nickel allergies exist.

Research work in this field has revealed that only through the use of bone screws formed from carbon fiber reinforced thermoplastic materials and, in this connection, through the manufacturing processes of the invention has it been possible to create an optimal variant. On the basis of the extrusion pressing technique developed in the process, bone screws were made of carbon fiber reinforced PEK and characterized.

Extrusion pressing of metal parts generally involves forcing the work-piece into a die at room temperature by means of a punch. It is a process belonging to the group referred to as extrusion processes according to DIN 8583. For the processing of fiber reinforced thermoplastic materials, the process has been modified to the effect that the blank is not deformed at room temperature but at a temperature above the melting temperature of the matrix material.

Serving as blanks for manufacturing the screws are carbon fiber reinforced PEK round bars 7 (FIG. 1), M, with a fiber content of more than 50% by volume, advantageously 60% by volume, there being used two types of blank differing in their fiber orientation, one type including blanks with a fiber

orientation purely parallel to the axis, and the other type including blanks with a fiber orientation of between 0 and $\pm 90^\circ$.

A blank is heated to forming temperature (350 - 450°C, for example) in the heated extrusion die 8 (heating section), and it will be appreciated that it is also possible to heat the blank in consecutive heating sections 9 and 10 (FIG. 4). Accordingly, the blank 7 is placed in the first heating section 9, is preheated there, is further heated in section 10, and is then formed in the female mold in section 11. A punch 12 presses the blank 7 into the female mold (mold cavity) 13 to form it to its final shape. The extrusion speed may be in the range of between 2 and 80 mm/s. Various tests revealed an extrusion pressure of 120 MPa. During a subsequent dwell pressure section (during which the extrusion pressure is at 90 MPa, approximately), the die is allowed to cool by means of compressed air to a temperature below the glass transition temperature of PEK (143°C). After the extrusion die is opened, the finished cortex screw is ready for removal from the die.

A subsequent analysis of a screw fabricated by this process has revealed that optimum values are attainable in all respects. Contributing factors are the high fiber content, the use of continuous fibers and the very special warm forming process for producing the screw. As becomes apparent from FIG. 2, the fibers in the region of the head 2 of the screw 1 align themselves predominantly in the direction of the screw axis. In the region of the tip of the screw, the fibers follow the screw contour (that is, the thread contour) in the peripheral area, while a randomly distributed fiber orientation prevails in the core zone.

With regard to the mechanical properties it is noted that the mean value of the tensile strength of the cortex screws amounts to 460 N/mm², approximately. The highest tensile strengths were achieved with screws manufactured at high deformation speeds (80 mm/s, approximately) and high blank temperatures (400°C, approximately). The torsional strength of screws made from blanks with a fiber orientation parallel to the axis is on average 18% higher than that of screws made from blanks with a fiber orientation of between

0° and ±45°. The maximum values were measured on screws manufactured at comparatively low temperatures (380°C) and low deformation speeds (2 mm/s). The modulus of elasticity in the screw longitudinal direction is not constant, but rather, diminishes noticeably towards the tip. The moduli of elasticity vary between 5 and 23 GPa, with screws made from blanks with a 0° fiber orientation tending to be stiffer. This also becomes clearly apparent from the schematic diagram of FIG. 3. The stiffness represented by the line in the diagram increases in the direction of the screw head, the line exhibiting a kink in a specific area, as seen when looking along the length of the threaded shank 5. As FIG. 2 shows, it is in this very area where the fiber orientation parallel to the axis, as provided for in the core region, ends.

Taking a cortex screw as an example, it has shown that by way of extrusion pressing long fiber reinforced thermoplastic materials in a warm forming process, it is also possible to manufacture components with complex geometries. The fiber orientation distribution as the determining quantity for the mechanical properties is controllable within certain limits by suitably selecting the fiber orientation in the blank. The remaining examined process parameters (deformation speed and deformation temperature) have a lesser effect on the extruded product.

The tensile strength of extrusion pressed fiber reinforced PEK screws lies on average about 30% below that of comparable steel screws. For osteosynthesis applications an average force at rupture of 3,200 N is sufficient, considering that a corresponding screw is pulled out of the bone with a tensile force of as low as 800 – 1,300 N.

For steel screws of comparable dimensions, ISO 6475 specifies a minimum torque at rupture of 4.4 Nm and a torsion angle of at least 180°. Such specifications cannot be met with screws made of fiber reinforced thermoplastic materials (1.3 Nm, maximum). Tests have, however, revealed that an overtightening and hence a destruction of the screw as it is turned into the bone is precluded because the thread in the bone is already destroyed at a torque of 0.8 Nm, approximately. The slow decrease in residual strength upon a primary

failure would, after rupture, still enable the damaged screw to be turned out of the bone.

With a modulus of elasticity of between 5 and 23 GPa the extrusion pressed cortex screw resembles the bone in its elastic behaviour. The stiffness in longitudinal direction diminishes appreciably towards the tip (decreasing stiffness gradient). In screwed-in condition, the stiff part of the screw (head area) lies proximate the cortex and hence at the stiffest point of the bone being treated. With such a stiffness distribution a force application is attainable which is largely adapted to the bone structure.

10 The inventive processes herein described afford for the first time the possibility of manufacturing components made of fiber reinforced thermoplastic materials which have, for example, a special configuration of a thread, head, shape, etc., using a warm forming process, and to obtain a design compatible with the field of application by way of the material properties. In particular the exact orientation of fibers.

 The foregoing description is based on an extrusion pressing process which practically acts in only one direction. This process includes heating the blank to a suitable temperature (producing a dough- or honey-like consistency) and then forcibly urging it into the female mold 13. Particularly in
20 the manufacture of parts shaped in the manner of strips, splints or plates, but also including screw-type or other fastener elements and special shapes of parts or specific configurations of bolts, etc., a reciprocating extrusion pressing process may be employed. Using multiple pressing operations in alternate directions, that is, by reversing the direction of extrusion once or several times, it is then possible to obtain a desired fiber orientation and fiber distribution. Further details will be explained with reference to FIG. 6 and 7. The reciprocating extrusion pressing process may be of particular importance precisely when the component is to be provided, for example, with blind-end holes, through openings, indentations or special shapes. In these cases the special orientation
30 of the fibers can be influenced, and the component to be manufactured can be

particularly reinforced in the very region in which the particular reinforcement is necessary.

Provided as coating material in the use of the processes of the invention is carbon or graphite. In practice these coating materials or release agents have heretofore been utilized only for metal and not for plastic applications. Here added advantages are afforded because, unlike the conventional release agents for plastics, graphite is biocompatible.

In FIG. 2 provision is made for a relatively short recess, as seen looking in the axial direction, which serves for engagement 3 by a tool. The possibility also exists to make provision for a deeper blind-end bore or, alternatively, for an axially extending through opening for insertion of a corresponding rotary tool. In addition to the already existing values in respect of torsional strength, this would make it possible to overcome a higher turn-in torque, because a corresponding tool can be inserted in correspondingly longer receiving channels. Such a screw being manufactured by the extrusion pressing process of the invention, this additional design can be readily provided.

Where splints or plates are involved, it is likewise possible to make provision for through openings, indentations, blind-end holes, etc, which are then specially surrounded by the fibers.

The fiber orientation in the screw 1 of FIG. 2 or in another suitable component for another field of application has to be viewed with the particular application in mind. The very approaches of the inventive processes make it possible to obtain for each special application an optimal fiber orientation in the finished component. Particularly with a high fiber content of more than 50% by volume and in the use of continuous fibers, particularly effective variants result in many fields of engineering, in particular in the fastener and medical engineering fields.

FIG. 6 is a schematic showing illustrating a reciprocating extrusion pressing process comprising the consecutive process steps I to IV. Step I includes placing the blank 7 in a heating section (sections 9, 10) and heating it to forming temperature. In step II the blank is pressed into the female mold 13 in

the direction of arrow 16. In step III the blank 7, formed once, is pressed back into the opposite direction (direction of arrow 17). In step IV, the blank, formed twice or several times, is finally consolidated, allowed to cool, and removed from the mold, forming the final product.

Using pins 15 inserted into the female mold 13 or extending therethrough, it is possible to provide the components with through openings 14, the blank being forcibly urged past said pins 15 several times during the reciprocating extrusion pressing operation. From this results a very special orientation of the fibers 6, as becomes also apparent from FIG. 7. The effect
10 would be identical or similar if producing sections were provided on the longitudinal and/or lateral boundaries of the component designed as an assembly part 18. In the typically weakened zones A, a denser arrangement of the fibers 6 results, producing in these zones the same strength or stiffness as in the other regions B of such a component.

Such a component design is eminently suitable for osteosynthesis plates which can be utilized, for example, in conjunction with a screw manufactured according to the processes of the invention. The same advantages in terms of biocompatibility then apply, of course, equally to said plates, with the added effect that their strength and stiffness competes on equal
20 terms with that of the stainless steel plates hitherto mainly employed.

In reciprocating extrusion pressing various additional parameters are possible by means of which the predeterminability of the fiber orientation and hence the adaptation of strength and stiffness to the shape of the component can be still further improved. Accordingly, it is possible to set the number of strokes and reciprocating strokes, the stroke length, the stroke speed, the pressure and the reciprocating pressure. Steps II and III can be repeated as often as desired, with the possibility for the length of stroke to be selected again for each individual stroke and reciprocating stroke. It is not absolutely necessary to centrally locate the component in step IV. All parameters can be varied in step
30 II to IV as desired.

In such a process the continuous fibers are not subjected to excessive loads, preventing multiple breaks from occurring. The transition region between strictly oriented fibers and fibers with a homogeneous fiber distribution is continuous. Unlike a known laminating technique, the method also permits manufacturing components which are not shaped like metal parts. It enables geometries to be obtained which otherwise occur only in injection molding processes. The present invention even achieves substantially higher strength levels. Thus it has also become possible to produce components having holes, undercuts, etc. The fiber orientation can be optimized to a degree enabling full use to be made of the fiber capabilities in terms of for example, the mechanical properties. The method allows a composite processing which is on equal terms with continuous fiber reinforcement. Isotropic and anisotropic properties are found in one and the same component in side-by-side relation without an interface existing. Considering that interfaces are also critical areas, the present invention reduces, inter alia, also the component's susceptibility to fatigue.

In the reciprocating extrusion pressing process herein described, still further variants may be envisaged. It can be considered that provision is accordingly made for executing a stroke not only in one direction, but also using two or three main axes. Furthermore, it is also envisaged that the pins shown in FIG. 6 could be inserted at a stage subsequent to the homogenization of the blank, that is, subsequent to one or several of the steps II or III. The provision of a prior homogenized blank could also be contemplated, that is, a blank having been deformed once or several times in a preceding station.

Another possibility includes using blanks which are comprised of longitudinally extending layers of different fiber orientation. It is also envisaged that a blank (also by fabricating rod material of any cross section in a prior operation) comprised of more than one polymeric composite could be used. In such a case the blank could be comprised of several layers of different matrix material and different arrangement and/or different percentage by volume and/or different fiber material and/or different length of the fibers. In cases where continuous fibers are employed, these have typically a length corresponding at

least to the length of the blank 7 as severed from the rod material to match the finished component.

WHAT IS CLAIMED IS:

1. A process for manufacturing components made of fiber reinforced thermoplastic materials, wherein initially a blank (7) formed of short, long and/or continuous fibers (6) and a thermoplastic material is prefabricated and said blank (7) is formed to the final shape of the component in a warm forming process under pressure in a female mold, characterized by the step of initially heating said blank (7) to forming temperature in a heating section adjacent to and in fluid communication with the female mold and then pressing it into the female mold (13) by an extrusion pressing operation.
- 10 2. The process according to claim 1, wherein the fiber content exceeds 50% by volume and contains at least predominantly continuous fibers, and wherein the components are subjected to tension, bending and/or torsion loads.
3. The process according to claim 1 or 2, characterized by the step of prefabricating the blank (7) as a rod material and cutting it to the length necessary for the final component prior to the warm forming process.
4. The process according to claim 1 or 2, characterized using continuous fibers (6) of a length corresponding at least to the length of the blank for the final component.
- 20 5. The process according to any one of claims 1 to 4, characterized by the step of deforming the blank (7) from longitudinally extending layers of different fiber orientation.
6. The process according to any one of claims 1 to 4, characterized by the step of deforming the blank (7) from more than one polymeric composite comprising several layers of different matrix material and different arrangement, different percentage by volume, different fiber material or different fiber length.

7. The process according to any one of claims 1 to 6, characterized by the step of deforming the blank (7) into the final component using a reciprocating extrusion pressing technique.
8. The process according to any one of claims 1 to 7, characterized by the step of heating the blank (7) to a forming temperature of between 350 and 450°C in the heating section and then pressing it into the female mold (13), a dwell pressure section being provided to effect cooling to a temperature below the glass transition temperature of the thermoplastic material.
9. The process according to claim 8, wherein the glass transition
10 temperature of the thermoplastic material is 143°C.
10. The process according to any one of claims 1 to 9, characterized by using carbon or graphite as a release agent in the warm forming process.
11. The process according to any one of claims 1 to 10, characterized by processing the blank (7) from carbon fiber (6) reinforced PEK (polyether ketone).
12. The process according to any one of claims 1 to 11, characterized in that at least a fraction of the continuous fibers (6) extends parallel to the axis in the blank (7).
13. The process according to any one of claims 1 to 12, characterized in that
20 at least a fraction of the fibers (6) has an orientation of between 0 and 90° with respect to the axis in the blank (7).
14. The process according to any one of claims 1 to 13, characterized in that the fibers (6) have a length of more than 3 mm.
15. The process according to one of claims 1 to 14, characterized in that during extrusion pressing the matrix material encloses the fibers, covering the complete surface of the component.

16. The process according to any one of claims 1 to 15, characterized in that the press temperature and the press rate are adjusted as a variable to the variation of the position and orientation of the fibers in the finished component.
17. The process according to any one of claims 1 to 16, characterized by providing the components with an additional surface seal during the warm forming process.
18. A component of fiber reinforced thermoplastic materials, manufactured according to a process as claimed in any one of the claims 1 to 17, characterized by zones of stiffness and strength values predetermined locally by a predetermined fiber orientation, wherein said component is constructed as a fastener element having an end for engagement with a tool and a threaded shank (5), and wherein the stiffness of said fastener element varies on account of different fiber orientation from the tool engaging end to the free end.
- 10
19. A component according to claim 18, characterized in that the fibers (6) extend at least approximately parallel to the component's center line from the tool engaging end up to and including the directly adjoining turns of the thread (4), whilst the fibers (6) in the remaining threaded section, extending close to the surface, follow the thread contour in the component's axial direction, while, however, in the core zone of said section a fiber orientation is provided which is
- 20
- increasingly randomly distributed toward the free end.
20. The component according to claim 18 or 19, characterized in that, on account of different fiber orientation, the stiffness of said component decreases in steps or continuously as seen looking from the tool engaging end towards the free end.
21. The component according to any one of claims 18 to 20, characterized in that said component includes at least one blind-end hole or one through opening.

22. The component according to claim 21, characterized in that said blind-end hole or said through opening is integrally formed during the manufacture of said component.
23. The component according to any one of claims 18 to 22, characterized in that said component is constructed as a cortex or cancellous bone screw structure-compatible for medical applications.
24. The component according to claim 18, wherein, owing to a denser arrangement of fibers (6) in the area joining the end for engagement and the shank, the component constructed as assembly part (18) exhibits uniform strength and stiffness.
25. Use of the component as defined in claim 18, in a rotary tool.
26. A component of fiber reinforced thermoplastic materials, manufactured according to a process as claimed in any one of the claims 1 to 17, characterized by zones of stiffness and strength values predetermined locally by a predetermined fiber orientation, wherein said component is constructed as a fastener element having a portion for engagement having a through opening, wherein the stiffness of said fastener element varies on account of different fiber orientation in the region surrounding the through opening.
27. The component according to claim 26, characterized in that, owing to a denser arrangement of fibers (6) in the area of the through opening (14), the component constructed as assembly part (18) exhibits uniform strength and stiffness.
28. The component according to claim 26 or 27, characterized in that the component is constructed as an osteosynthesis plate.

26

29. Use of the component as defined in claim 26, for passing fastener elements therethrough.

30. Use of the component as defined in claim 28, with a cortex or cancellous bone screw.

Fig. 1

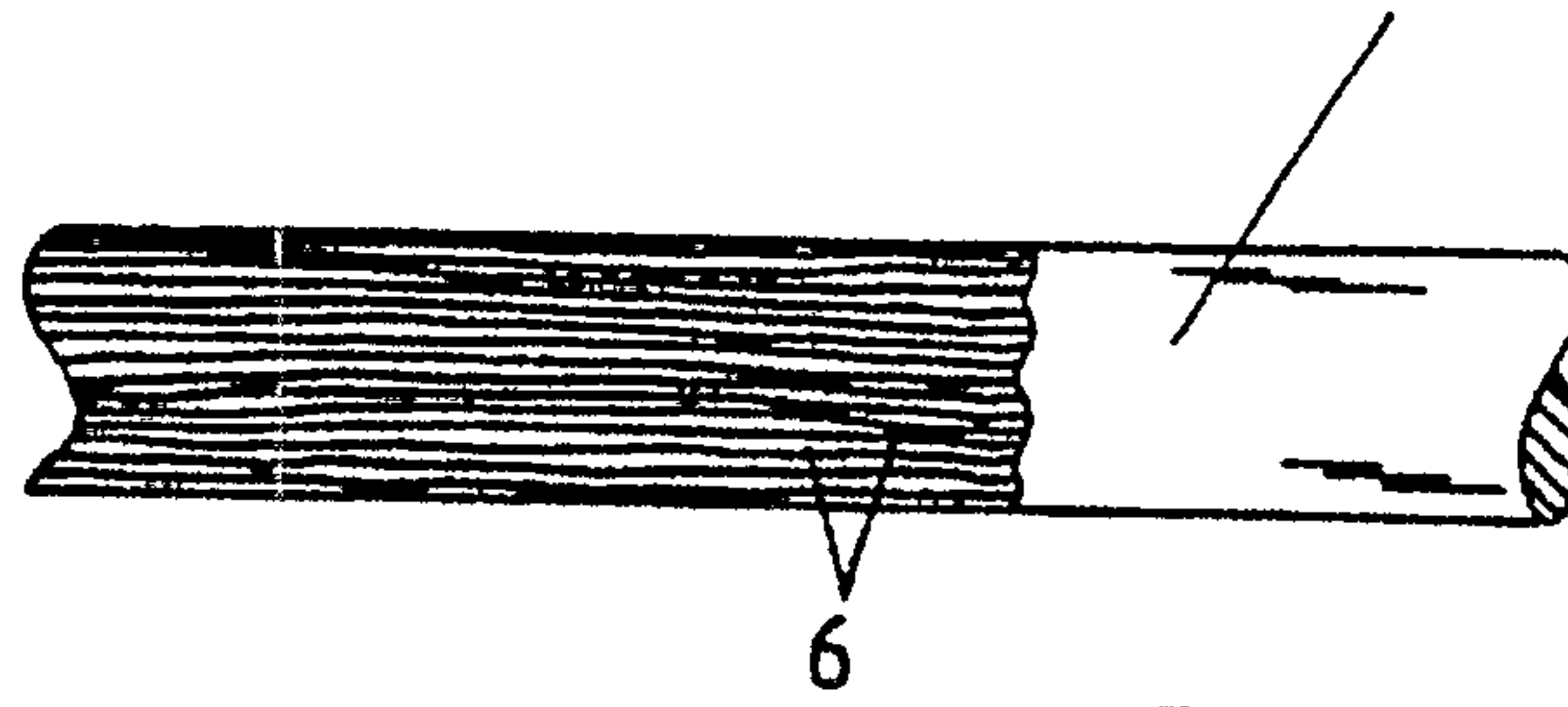


Fig. 2

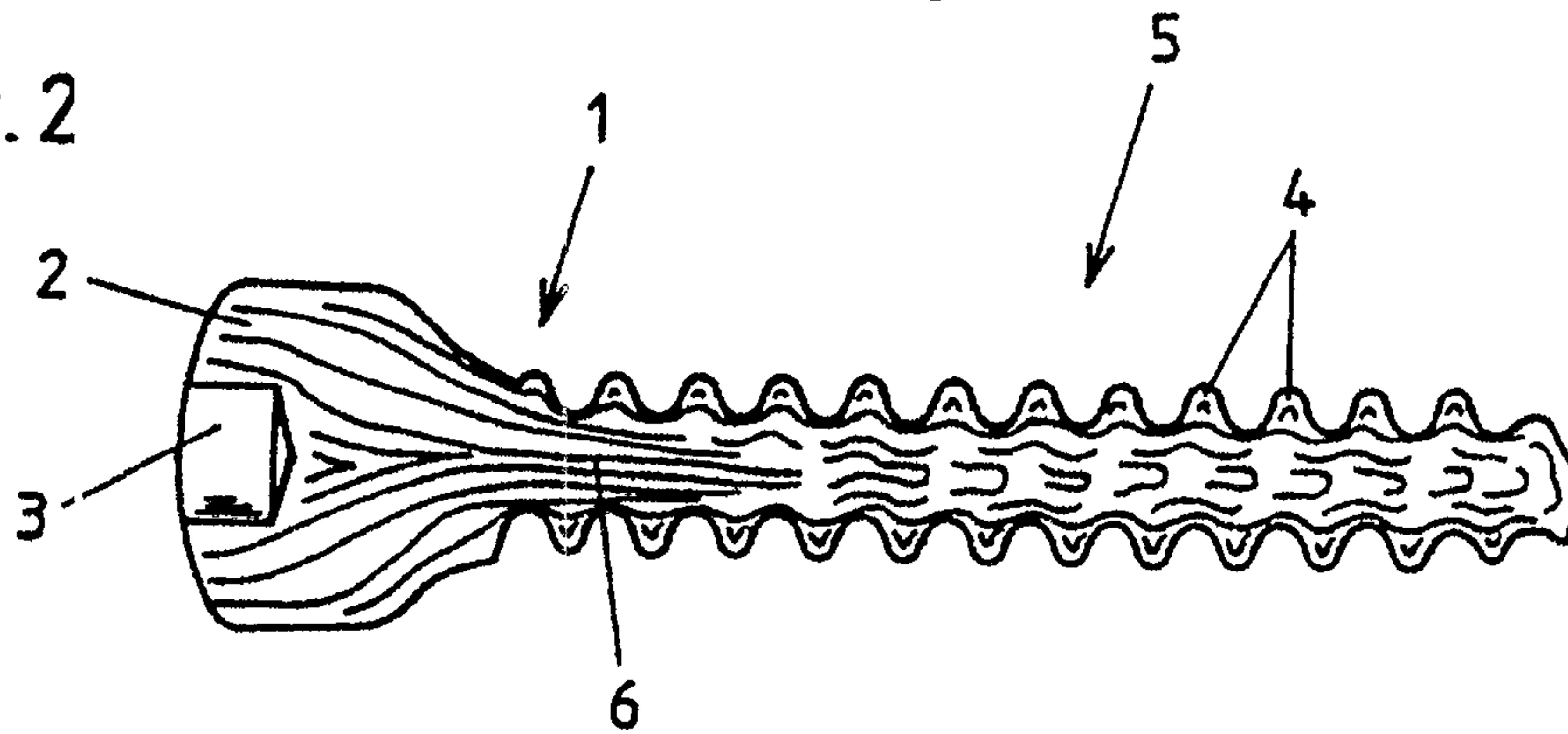


Fig. 3

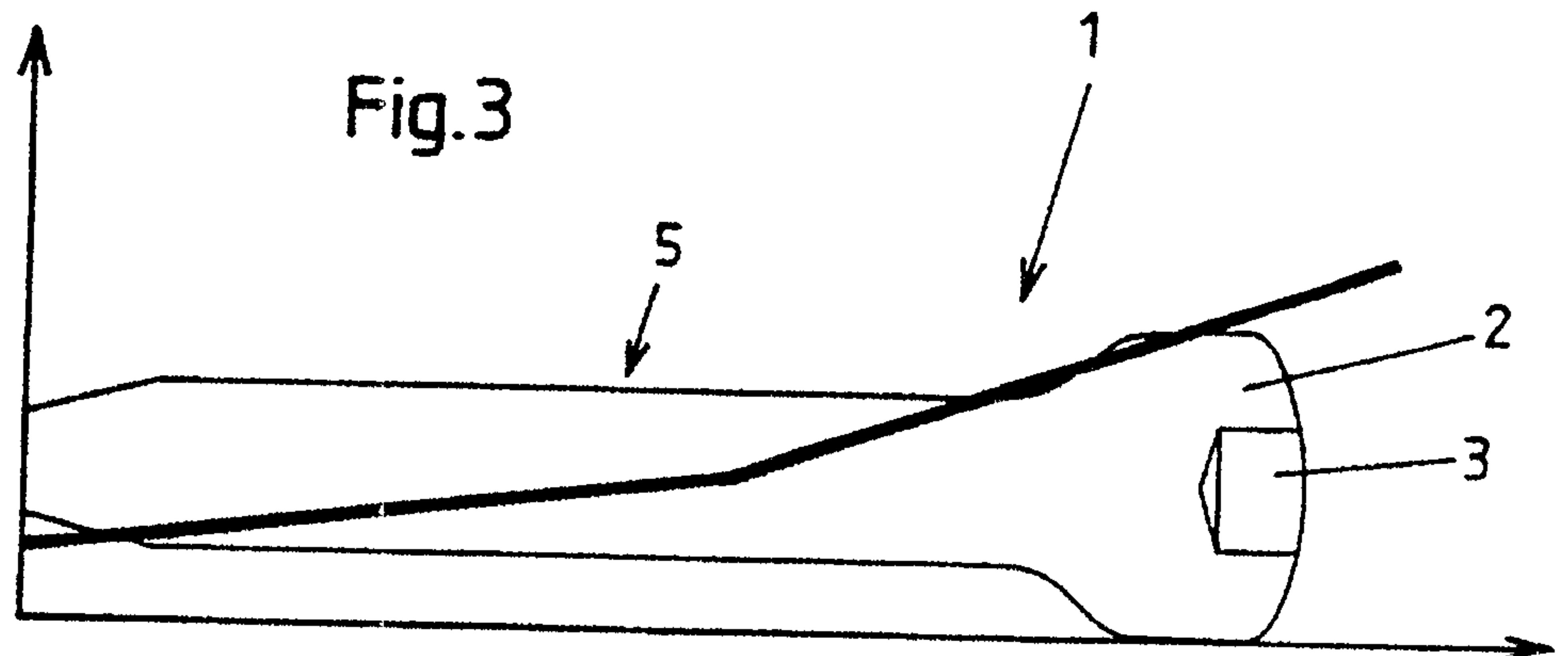


Fig. 4

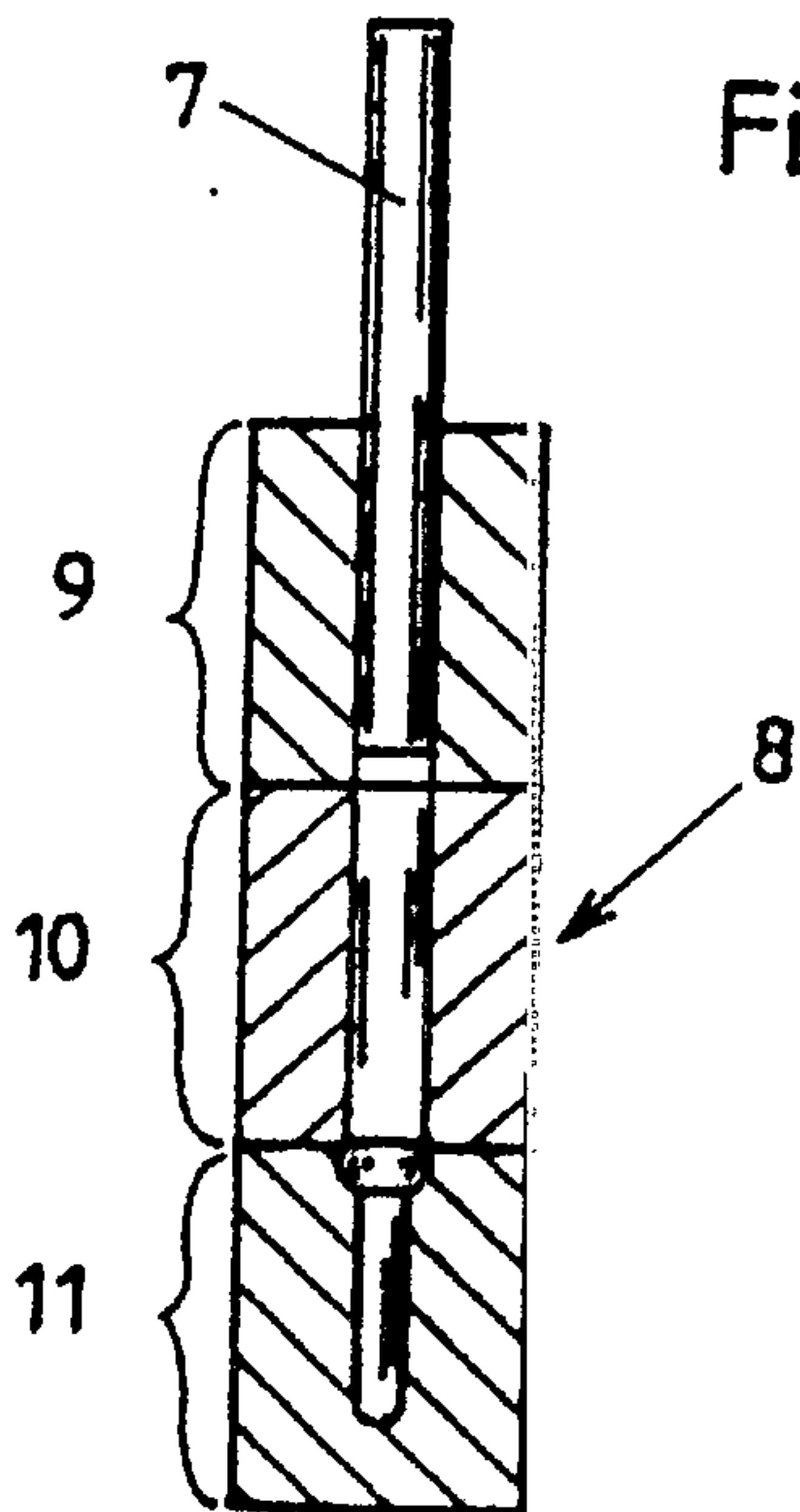


Fig. 5

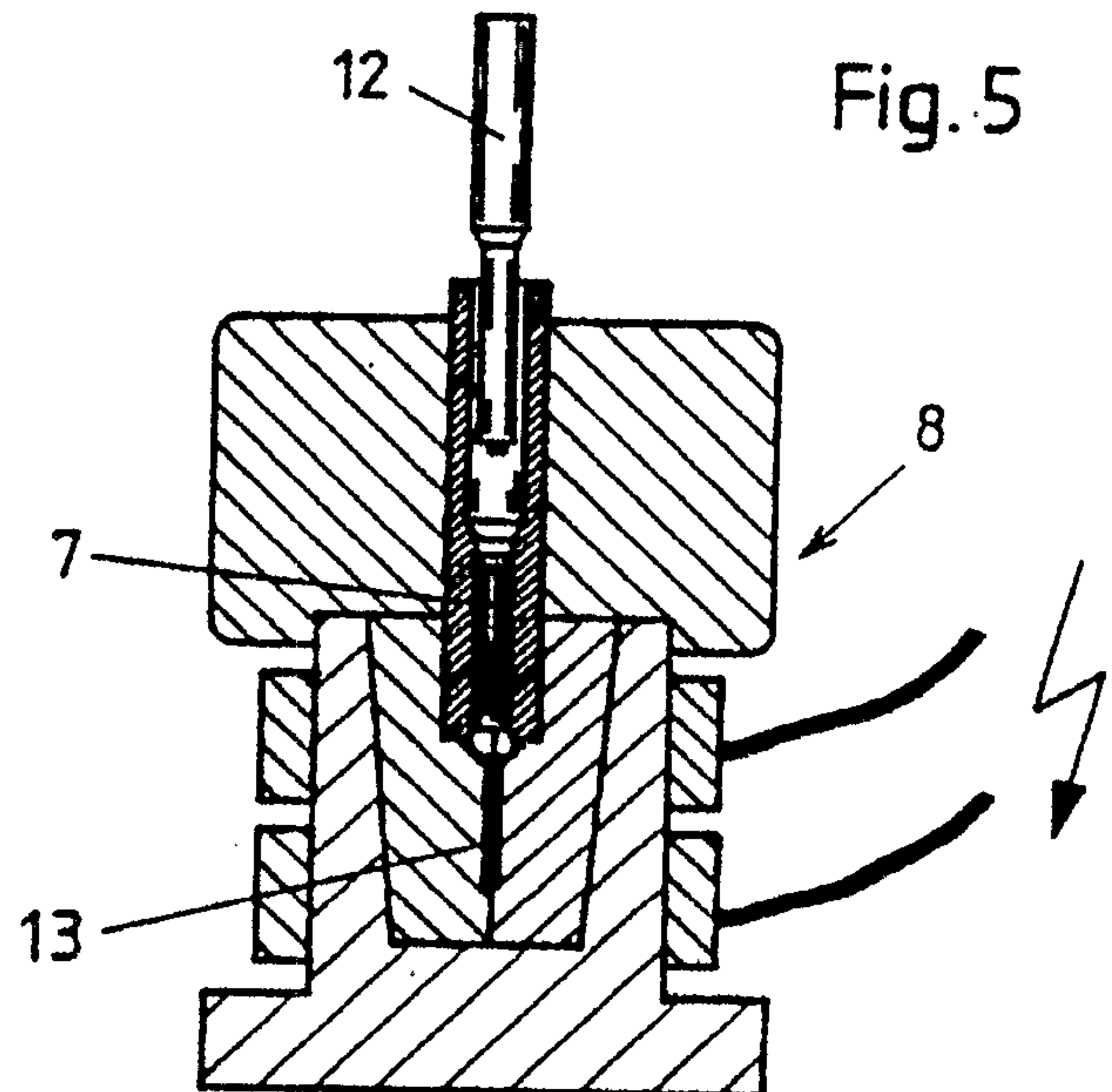


Fig. 6

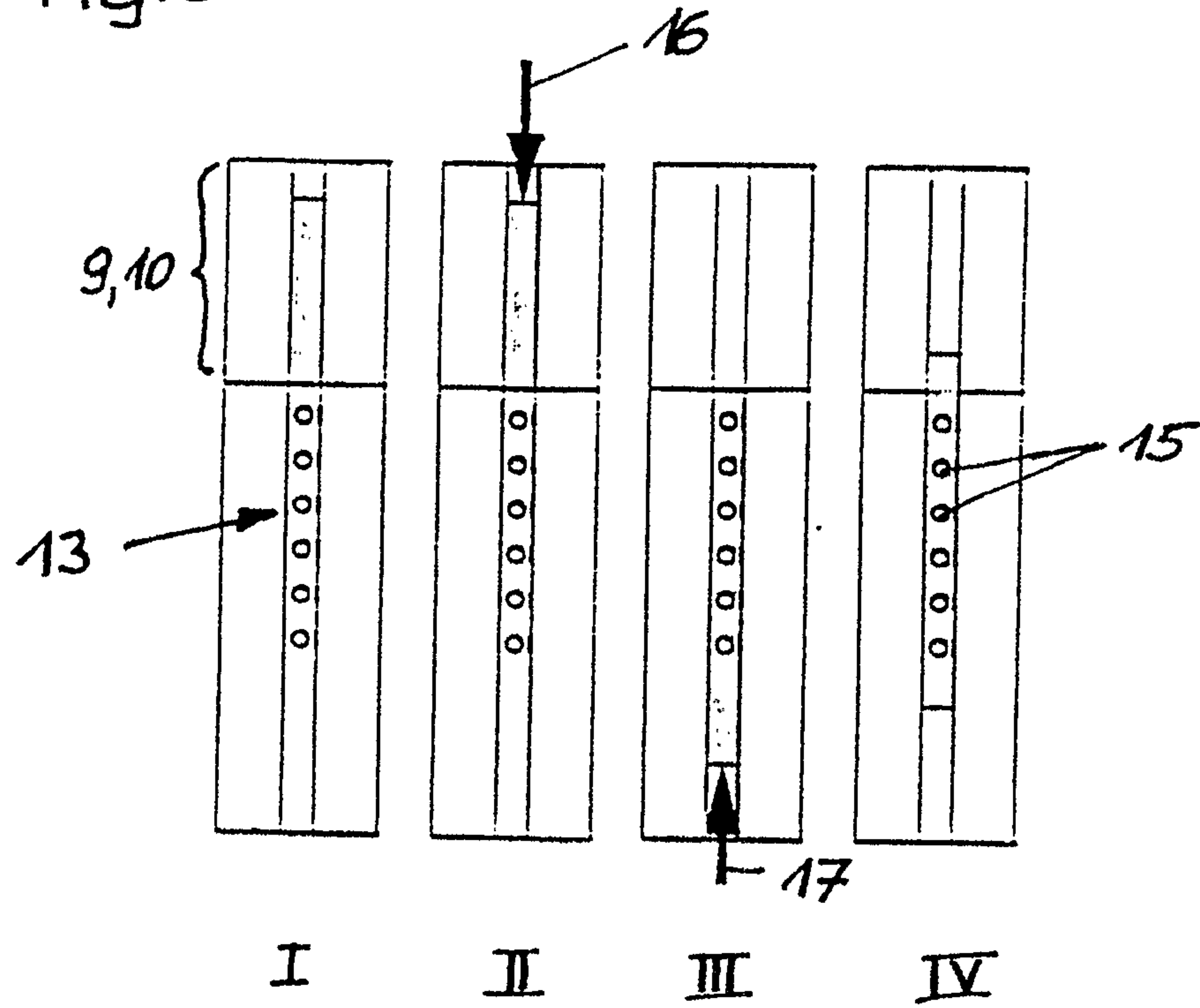


Fig. 7

