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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number: WO 90/04982
A61L 27/00, A61F 2/02	A1	(43) International Publication Date: 17 May 1990 (17.05.90)

(21) International Application Number: PCT/FI89/00204

(22) International Filing Date: 7 November 1989 (07.11.89)

(30) Priority data:
885164 10 November 1988 (10.11.88) FI

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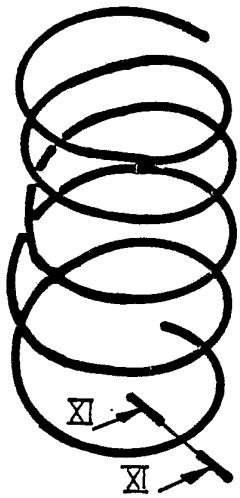
(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.

Published
With international search report.
In English translation (filed in Finnish).

(54) Title: BIODEGRADABLE SURGICAL IMPLANTS AND DEVICES



(57) Abstract

The invention relates to a surgical implant, a device or a part thereof made of a material which is at least partially biodegradable. It is intended for supporting and/or joining and/or separating tissues and/or operated and/or damaged tissues or parts thereof and/or for keeping open a tissue cavity. The implant, device or a part thereof consists at least partially of at least one, at least partially biodegradable elongated piece which is at least partially wound at least once around a winding centre into a helical configuration. The implant is at least partially reinforced with biodegradable reinforcement elements.

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Biodegradable surgical implants and devices

The present invention relates to a surgical implant and/or device determined in more detail in the preamble of claim 1.

In surgery, it is prior known to employ at least partially biodegradable, elongated (typically tubular) surgical implants for supporting, connecting or separating elongated organs, tissues or parts thereof, such as canals, ducts, tubes, intestines, blodd vessels, nerves etc. In this context, the biodegradable (absorbable, resorbable) material refers to a material whose decomposition and/or dissolution products leave the system through metabolic ducts, kidneys, lungs, intestines and/or skin by secretion.

US Patent No. 3 108 357, Liebig, discloses a tubular device to be implanted in animals and humans, comprising a resilient woven tube which contains biologically absorbable oxidized cellulose.

US Patent No. 3 155 095, Brown, discloses hollow cylindrical anastomosis joints which are made of an absorbable material.

US Patent No. 3 272 204, Artandi and Bechtol, discloses collagen-made flexible tubes which can be externally reinforced with a plastic coil or plastic rings.

US Patent No. 3 463 158, Schmitt and Polistina, discloses fibre-made tubular surgical devices which are at least partially made of absorbable polyglycolic acid (PGA).

US Patent No. 3 620 218, Schmitt and Polistina, discloses PGA-made surgical devices, such as tubes.

WO 84/03035, Barrows, discloses longitudinally openable, porous, coarse-surfaced biodegradable tubes used as a remedy for the nerves.

The publication Plast. Rec. Surg. 74 (1984) 329, Daniel and Olding, discloses an absorbable anastomosis device which comprises cylindrical, tubular, complementary parts.

However, the prior known tubular, at least partially biodegradable surgical implants and devices involve several drawbacks and limitations. As for the implants including biostable parts, such as polymeric and like fibres, plastic or metallic coils or rings or the like, such biostable parts or components remain in the system even after a tissue or an organ has healed and such components can be later harmful to a patient by causing infections, inflammatory reactions and like foreign matter reactions and/or they might release particles, corrosion products or the like which can wander in the system and/or cause harmful cellular level reactions.

The prior known tubular biodegradable implants manufactured by melt working technique or a like method are often massive and stiff creating in resilient tissues (such as ducts, tubes, blood vessels etc.) an undesirable stiff, non-physiological bracing effect which can lead to harmful alterations in the properties of a tissue to be braced. In addition, the massive, tubular implants create a heavy local foreign matter loading on the system at the installation site thereof and such loading can also contribute to harmful alterations in an operated tissue, such as canal, tube, duct, blood vessel or the like.

On the other hand, the tubular structures constructed from biodegradable fibres by braiding, knitting, weaving or some other similar technique do not possess

the structural rigidity and/or resilience often required of a support implant to be fitted inside or outside a tubular tissue.

It has been surprisingly discovered in this invention that the deficiencies and drawbacks of the prior known, at least partially biodegradable surgical implants and devices used for supporting, connecting or separating organs, tissues or parts thereof can be substantially eliminated with an implant, device or a part thereof which is mainly characterized by comprising an at least partially biodegradable elongated member which is at least partially wound at least once around a centre of rotation into a helical configuration and which is at least partially reinforced with biodegradable reinforcing elements.

An implant, an device or a part thereof (hereinbelow "device") can be conceived having been formed in a manner that around a certain centre point is wound some elongated member at a distance of a certain winding radius from the centre point. If the winding centre is stationary and the winding radius increases as the winding angle increases, the configuration of an obtained device is a spiral configuration, especially if the winding radius remains in the same plane. Provided that the winding radius is constant and the winding centre travels during the turning of an elongated member along a certain, e.g. linear path, the device obtained has a circle-cylindrical screw-threaded configuration (helix). On the other hand, if the winding radius changes while the winding centre travels along a certain path, there will be produced a spiral configuration whose external surface is in conical shape. It is obvious that the implantt, device or a part thereof can include the above shapes and configurations as a combination and e.g. a

combination of a spiral and a cylindrical screw-threaded configuration. The implant, device or a part thereof can also be provided with otherwise shaped members in addition to a screw-threaded configuration, such as plates, sleeves etc.

The invention relates also to a method for manufacturing an implant, an device or a part thereof ("device"). The essentially characterizing features of the method are set forth in the characterizing clause of the independent claim directed to a method.

The invention relates also to the use of an implant, an device and a part thereof.

The invention is described in more detail in the following specification with reference made to the accompanying drawings. In the drawings

fig. 1 shows the formation of a material micro-structure in an device of the invention in a perspective view schematically, an array of lamellae turning into a fibrillated structure,

fig. 2 shows an intra- and inter-fibrillary molecular structure,

fig. 3 shows schematically the micro-structure of a fibrillated polymer,

fig. 4 shows schematically the molecular structure of fibrillated devices of the invention,

figs. 5 and 6 are schematical perspective views of spiral-shaped embodiments of the device,

figs. 7a, b - 9a, b are schematical perspective views of conical embodiments of the device,

figs. 10a and 10b are schematic perspective views of a cylindrical embodiment of the device,

figs. 10c and 10d show some further embodiments of a cylindrical device,

figs. 11a - 11l illustrate some preferred cross-sectional shapes and surface patterns for the elongated member (blank) of devices shown in figs. 5-10,

figs. 12 and 13 illustrate one special embodiment of the invention schematically in a perspective view,

fig. 14 shows schematically a test arrangement described in example 1,

fig. 15 illustrates a surgical operation described in example 3,

fig. 16 illustrates a surgical operation described in example 4,

fig. 17 shows schematically an device described in example 5, and

fig. 18 shows one embodiment for an device of the invention.

In this context, the biodegradable reinforcing elements refer to the following:

(a) orientated (aligned) structural units included in the micro-structure (molecular structure) of a material, such as orientated parts of molecules, bundles of molecules or parts thereof or microfibrils, fibrils or the like orientated structural units formed thereby,

(b) biodegradable organic filaments, fibres, membrane fibres or the like or structures constructed thereof, such as bands, braids, yarns, fabrics, non-woven structures or the like, or

(c) biodegradable inorganic (ceramic) filaments, fibres, membrane fibres or the like or structures constructed thereof.

A particularly preferred embodiment of the invention is such an implant or an device which is structurally self-reinforced. A self-reinforced biodegradable structure is defined in the invention US Patent No. 4 743 257, Tormala, et al. In a self-reinforced structure, a biodegradable polymer matrix is reinforced with biodegradable reinforcement elements (units) having the same proportional elemental composition as the matrix. The reinforcement elements are typically orientated molecules or parts thereof or the like obtained by orientation or fibrils, microfibrils, fibres, filaments or the like structures constructed thereof.

Reinforcement elements inside the microstructure of a self-reinforced polymer material are produced e.g. by orientating the molecular structure of a material either in melt state or in solid state in such conditions the structure-reinforcing orientation remains at least partially permanently in material either as a result of the rapid cooling and/or solid state of the melt and/or as a result of the prevention of molecular movements (relaxation) of the melt. The self-reinforcement based on draw orientation is described in the invention PCT/FI87/00177, Törmälä et al., as follows:

A partially crystalline, non-oriented piece of polymer typically consists of crystal units i.e. spherulites and amorphous areas thereinside and/or therebetween.

The orientation and fibrillation of a polymer system possessing a spherulitic crystalline structure is a process that has been extensively studied in connection with the production of thermoplastic fibres. For example, the invention US Patent 3 161 709 discloses a three-step drawing process for transforming a melt-worked polypropene filament into a fibre having a high tensile strength.

The mechanism of orientation and fibrillation is basically as follows (C.L. Choy et al. Polym. Eng. Sci. 23, 1983, p. 910). As a partially crystalline polymer is being drawn, the molecule chains of crystal lamellae quickly begin to parallel themselves (orientate) in the drawing direction. Simultaneously the spherulites extend in length and finally break. Crystal blocks detach from lamellae and join together as queues by means of tight tie-molecules which are formed through the partial release of polymer chains from crystal lamellae. The alternating amorphous and

crystalline zones, together with tight tie-molecules, form long, thin (appr. 100 Å wide) microfibrils which are paralleled in the drawing direction. Since the intrafibrillar tie-molecules form in the phase boundaries between crystal blocks, they will be mainly located on the external surface of microfibrils. Those tie-molecules, which link various lamellae in an isotropic material prior to drawing, serve in a fibrillated material to link various microfibrils together i.e. become interfibrillar tie-molecules which are located in boundary layers between adjacent microfibrils.

Fig. 1 illustrates schematically the transformation of an array of lamellae into a fibrillar structure (a fibril consisting of a bunch of microfibrils) due to the action of water and fig. 2 shows some of the molecular structure inside and between microfibrils. Fig. 3 illustrates schematically some of the structure of a fibrillated polymer. The figure shows several fibrils (one being dyed grey for the sake of clarity) which consist of a plurality of microfibrils having a length of several microns.

Orientation is initiated right at the start of drawing and also a fibrillated structure is formed at rather low drawing ratios λ (wherein λ = length of piece after drawing/length of piece prior to drawing). For example, HD-polyethene is clearly fibrillated at λ value 8 and polyacetal (POM) at λ value 3.

As the drawing of a fibrillated structure is continued further (this stage of the process is often referred to as ultra-orientation), the structure is further deformed with microfibrils sliding relative to each other to further increase the proportional volume of straightened interfibrillar tie-molecules. If drawing is effected at a sufficiently high temperature, the

oriented tie-molecules crystallize and build axial crystalline bridges which link together crystalline blocks.

The excellent strength and modulus of elasticity properties of a fibrillated structure are based on the vigorous orientation of polymer molecules and polymer segments in the direction of drawing (in the direction of the longitudinal axis of microfibrils) characteristic of the structure.

The fibrillation of macroscopic polymeric blanks, such as rods or tubes, is prior known in the cases of biostable polyacetal and polyethene (see e.g. K. Nakagawa and T. Konaka, Polymer 27, 1986, p. 1553 and references included therein). What has not been prior known, however, is the orientation and fibrillation of at least partially helical and/or spiral or similarly shaped members or pieces manufactured from biodegradable polymers.

The at least partial orientation and/or fibrillation of a biodegradable helical and/or spiral or similar piece can be effected e.g. by rapidly chilling a flowing state (e.g. in an injection mould) polymer melt into a solid state in a manner that the orientation of molecules existing in the flowing melt in flowing direction is not allowed to discharge through molecular movements either entirely or partially into a state of random orientation.

A more vigorous orientation and fibrillation and thus also improved mechanical qualities are generally provided for a polymer piece by mechanically working the material (orientation), generally drawing or hydrostatic extrusion or die-drawing in such a physical condition (usually in solid state), wherein it is

possible for the material to undergo dramatic structural deformations in its crystalline structures and amorphous areas occurring at molecular level for creating orientation and fibrillation. As a result of fibrillation, e.g. a resorbable polymer material produced by injection moulding or extrusion and initially possessing mainly a spherolitic crystalline structure transforms into a fibrillated structure which is vigorously oriented in the direction of drawing and comprises e.g. elongated crystalline microfibrils as well as tie-molecules linking them as well as oriented amorphous areas. In a partially fibrillated structure, the amorphous areas between microfibrils make up a more substantial portion of the material than in an ultra-oriented material which, in the most preferred case, only includes amorphousness as crystal defects. As a result of orientation, fibrillation and ultra-orientation the values of strength and modulus of elasticity of a material are multiplied compared to a non-fibrillated structure.

Orientation and the resulting fibrillation can be used for treating biodegradable polymers, copolymers and polymer compositions so as to form self-reinforced composites in which nearly the entire material stock is oriented in a desired fashion and the portion of amorphous matrix is small, these being the reasons why such materials have extremely high quality strength properties in orientation direction: bending strength e.g. up to 400-1500 MPa and modulus of elasticity 20-50 GPa and thus the orientation and fibrillation can be used to provide helixes or spirals or the like devices with multiple strength values compared to those of normal melt-processed biodegradable materials, which are typically in the order of 30-80 MPa.

The same way as in the fibrillated structure of polymer fibres, also in the structure of fibrillated devices

there can be found e.g. the following structural units which are schematically shown in fig. 4: crystalline blocks, the stock therebetween comprising an amorphous material (e.g. loose polymer chains, chain ends and molecular folds), tie-molecules which link the crystalline blocks together (the number and tightness of these increases as drawing ratio λ increases) as well as possible crystalline bridges between crystalline blocks. Bridges can form during the drawing as tie-molecules orientate and group themselves as bridges (C. L. Choy et al. J. Polym. Sci., Polym. Phys. Ed., 19, 1981, p. 335).

The oriented fibrillated structure shown in figs. 1-4 is already developed by using so-called "natural" drawing ratios 3-8. As drawing is then continued as ultra-orientation, the portion of crystalline bridges can increase to be quite considerable whereby, in the extreme case, the bridges and crystal blocks provide a continuous crystalline structure. However, the effects of tie-molecules and bridges are often similar and, thus, the exact distinction thereof from each other is not always possible.

Orientation and fibrillation can be experimentally characterized by the application of several different methods. Orientation function fc, which can be determined by X-ray diffraction measurements, characterizes orientation of the molecule chains of a crystalline phase. Generally, fc already reaches a maximum value of 1 by natural drawing ratios ($\lambda < 6$). For polymer materials having a spherolitic structure $fc << 1$.

Double-refraction (Δ) measured with a polarization microscope is also a quantity which represents the orientation of molecule chains. It generally increases at natural drawing ratios ($\lambda < 6$) vigorously and

thereafter in ultra-orientation more slowly, which indicates that the molecule chains of a crystalline phase orientate vigorously in the drawing direction at natural drawing ratios and orientation of the molecules of an amorphous phase continues further at higher drawing ratios (C.L. Choy et al. Polym Eng. Sci., 23, 1983, p. 910).

The formation of a fibrillous structure can also be demonstrated visually by studying the fibrillated material by means of optical and/or electronic microscopy (see e.g. T. Konaka et al. Polymer, 26, 1985, p. 462). Even the individual fibrils consisting of microfibrils can be clearly distinguished in scanning electron microscope images of a fibrillated structure.

An oriented and/or fibrillated and/or ultra-oriented piece (blank) is then rotated at least once around a centre of rotation into a helical configuration to form "an device" of the invention by shaping it at least partially by means of an external force or pressure and/or external heat and/or by means of heat induceable in the piece (e.g. by radiowave radiation). In practice, the rotation of winding of the device is effected in a manner that an elongated blank is wound around a suitable, if necessary heated mould (e.g. a mould of cylindrical shape). Such a mould is typically round in cross-sectionso as to produce helical shapes having a circular cross-section. The cross-sectional shape of a mould can also be elliptical, oval, angular etc. to produce helical shapes having various cross-sections. Orientation, fibrillation or ultra-orientation can also be effected in a continuous action and/or simultaneously with winding in a manner that an elongated blank is being drawn and the drawn section is simultaneously wound around a cylindrical mould.

At least partially oriented and/or fibrillated and particularly yltra-oriented biodegradable devices are an example of an oriented, self-reinforced biodegradable (US Patent 4 743 257, Törmälä et al.) composite material, wherein the oriented reinforcement elements (such as fibrils, microfibrils, crystal blocks, tie-molecules or crystallized bridges) are formed and/or grouped during a mechanical working and a phase binding those elements consists e.g. of the following structural elements: amorphous phase, interfaces between crystal blocks as well as interfaces between bridges and microfibrils, a typical feature of which is also a vigorous orientation in drawing direction.

Another method for using biodegradable reinforcement elements in devices of the invention is the reinforcement thereof with fibres manufactured from polymer, copolymer or a polymer composition, with film fibres, filaments or structures constructed threof, such as braids, threads, ribbons, non-woven structures, fabrics, knittings or the like, by combining ready-made fibres with a suitable polydmer matrix. Such fibres can be manufactured e.g. from biodegradable polymers set forth in table 1. The fibres can also be biodegradable ceramic fibres, such as calcium phosphate fibres (see e.g. S. Vainionpää et al., Progr. Polym. Sci., in printing).

Various plastic technological methods can be applied to manufacture devices of the invention reinforced with biodegradable organic and/or inorganic fibres or with structures constructed threof, said manufacturing being carried out by binding the reinforcement structures at least partially to each other with biodegradable polymer, copolymer or a polymer composition (matrix) in such conditions which serve to produce a sufficiently equal quality composite from the matrix and reinforcement elements, said matrix being usually in

solution or melt state. Methods for combining reinforcement fibres or the like and a matrix as well as for processing them into semi-finished products and/or devices include e.g. injection moulding, extrusion, pultrusion, winding, compression moulding etc.

The at least partially spirally shaped, at least partially biodegradable device of the invention can be used in a versatile manner for supporting, expanding, joining or separating organs, tissues or parts threof. An device of the invention offers a plurality of benefits over the prior art implants and devices or devices. When using an device of the invention, the amount of foreign matter remains smaller than with traditional implant tubes. Devices of the invention are more flexible and resilient than the rigid prior art tubes and, on the other hand, devices of the invention are stronger under compression and retain their shape better than fibre-constructed tubular devices, whereby devices of the invention are capable of being used for retaining open or even expanding the medullary cavity of tubular tissues.

Devices of the invention can be manufactured from biodegradable polymers, copolymers and polymer compositions. Table 1 shows a number of prior known biodegradable polymers, which or mixtures of which can be used as raw materials for devices of the invention both as a matrix (or binder polymers) and/or reinforcement elements.

Table 1. Biodegradable polymers

1. Polyglycolide (PGA)

Copolymers of glycolide

2. Glycolide/lactide copolymers (PGA/PLA)
3. Glycolide/trimethylene carbonate copolymers (PGA/TMC)

Polylactides (PLA)

Stereoisomers and copolymers of PLA

4. Poly-L-lactide (PLLA)
5. Poly-D-lactide (PDLA)
6. Poly-DL-lactide (PDLLA)
7. L-lactide/DL-lactide copolymers
L-lactide/D-lactide copolymers

Copolymers of PLA

8. Lactide/tetramethylene glycolide copolymers
9. Lactide/trimethylene carbonate copolymers
10. Lactide/δ-valerolactone copolymers
11. Lactide/ϵ-caprolactone copolymers
12. Polydepsipeptides (glycine-DL-lactide copolymer)
13. PLA/ethylene oxide copolymers
14. Asymmetrically 3,6-substituted poly-1,4-dioxane-2,5-diones
15. Poly-β-hydroxybutyrate (PHBA)
16. PHBA/β-hydroxyvalerate copolymers (PHBA/PHVA)
17. Poly-β-hydroxypropionate (PHPA)
18. Poly-β-dioxanone (PDS)
19. Poly-δ-valerolactone
20. Poly-ϵ-caprolactone
21. Methylmethacrylate-N-vinylpyrrolidone copolymers
22. Polyesteramides
23. Polyesters of oxalic acid
24. Polydihydropyranes
25. Polyalkyl-2-cyanoacrylates
26. Polyuretanes (PU)
27. Polyvinyl alcohol (PVA)
28. Polypeptides
29. Poly-β-maleic acid (PMLA)
30. Poly-β-alkanoic acids
31. Polyethylene oxide (PEO)
32. Chitin polymers

Reference: S. Vainionpää, P. Rokkanen and P. Törmälä, Progr. Polym. Sci., in printing

It is obvious that other biodegradable polymers than those set forth in table 1 can also be used as raw materials for implants, devices or parts thereof. For example, the biodegradable (absorbable) polymers described in the following publications can be used for the above purposes: US Patent No. 4 700 704 (Jamiolkows and Shalaby), US Patent No. 4 655 497 (Bezwada, Shalaby and Newman), US Patent No. 4 649 921 (Koelmel, Jamiolkows and Bezwada), US Patent No. 4 559 945 (Koelmel and Shalaby), US Patent No. 4 532 928 (Rezada, Shalaby and Jamiolkows), US Patent No. 4 605 730 (Shalaby and Jamiolkows), US Patent No. 4 441 496 (Shalaby and Koelmel), US Patent No. 4 435 590 (Shalaby and Jamiolkows), US Patent No. 4 559 945 (Koelmel and Shalaby).

It is also natural that devices of the invention may contain various additives and adjuvants for facilitating the processability of the material (e.g. stabilizers, antioxidants or plasticizers) or for modifying the properties thereof (e.g. plasticizers or powdered ceramic materials or biostable fibres, such as carbon fibres) or for facilitating the manipulation thereof (e.g. colourants).

According to one preferred embodiment, devices of the invention contain some bioactive agent or agents, such as antibiotics, chemotherapeutic agents, wound-healing agents, growth hormone, contraceptive agent, anticoagulant (such as heparin) etc. Such bioactive devices or devices are particularly preferred in clinical application since, in addition to mechanical effect, they have biochemical, medical and the like effects in various tissues.

Devices of the invention can also be advantageously combined with other types of biodegradable implants and devices. For example, by inserting a helical device

as shown in figs. 7-10 into a tube woven or knitted from biodegradable and/or biostable thread there is obtained a firm and resilient tube which has a variety of applications in surgery for replacing or supporting tissues and/or for keeping open the cavities within or between tissues.

A device of the invention can also be fitted with long biodegradable rods which extend parallel to the longitudinal axis of e.g. a helical-shaped device. Thus, if necessary, the device can be braced to form a tubular structure.

The device can also be fitted with various other accessories, such as flat perforated plates at the ends of a device for securing the ends of a device firmly to the surrounding tissues by means of surgical stitches.

Devices of the invention can have various geometrical configurations. Fig. 5 illustrates a flat or planar (in imaginary plane 1) spiral 2 that can be used as a resilient separating material between tissues. The helixes of spiral 2 can also be connected with each other by means of biodegradable radial wires, rods 3 or the like as shown in fig. 6, the spiral having a high strength in the direction of plane 1 but being resilient in the direction perpendicular to that plane.

A device of the invention can also vary in its dimensions in various sections threof. For example, figs. 7a-10a and 7b-10b illustrate chematically a few such devices. These can be used for providing external and/or internal support for organs or their parts of various shapes (such as liver, spleen, kidneys, intestines etc.).

A device shown in fig. 7a is wound into a conical body. The conical body can have a side face outline which is either straight or arched or a combination thereof according to intended application. Devices shown in figs. 8a and 9a include two conical bodies joined to each other either at the base of conical bodies (fig. 8a) or at the apex threof (fig. 9a). Fig. 10a illustrates a device having its outer face wound into a cylindrical configuration.

Figs. 7b, 8b, 9b and 10b illustrate device configurations matching those of figs. 7a, 8a, 9a and 10a and fitted with rods 3 connecting the turns of a helical body.

Furthermore, fig. 10c shows an embodiment in which the device is comprised of two nested device elements VO1 and VO2 wound into a helical configuration preferably in opposite directions. Each has cylindrical helical configuration. Fig. 10d shows an embodiment of a device, wherein a number of device elements wound into a helical configuration have been twined together. The device elements are adapted to run alternately over and under each other to form a tubular structure.

Figs. 11a-11l illustrate some types of cross-section for a blank. A blank for manufacturing devices of the invention can have a cross-section which is e.g. circular (11a), elliptical (11b, 11c), flat (11d, 11e), angular (11f, 11g, 11h), asteroid (11i) etc. By varying the cross-section of a blank it is possible to effect e.g. on the mechanical properties of a device, the growth of tissues on the surface of a blank and the growth of tissues through the device. The thickness of a blank can also vary in different sections of a blank or it can be provided with holes

R (11j) or similar structures, such as recesses L (11k) or slots (111) for facilitating the fastening or securing threof to tissues.

According to one preferred embodiment, a device of the invention is manufactured by winding or rolling a flat blank having a cross-section shown in fig. 12 into a tube as shown in fig. 13. Since the longitudinal edges of a blank (see figs. 12a and 13a) are provided with folded or otherwise designed gripping means T which engage each other, during the winding there will be formed a flexible tube that can be used in the treatment of e.g. a windpipe or the like flexible tissue channels as a temporary prothesis.

According to one preferred embodiment, devices of the invention can be used join together tissues, organs or parts thereof, such as muscular tissue or the like soft tissues. Such embodiment is illustrated in fig. 18. Fig. 18a shows a cross-section of a tissue K1 and a tissue K2 which should be joined with each other. The joining can be effected by using a sharp-pointed spiral S which is driven the same way as a corkscrew through the tissues (fig. 18b). By locking the top portion of a spiral in position after the turning (e.g. by stitching the spiral firmly to surrounding tissues by means of surgical stitches disssolving through the holes made in the spiral blank) said spiral serves to secure tissues K1 and K2 to each other preventing the separation or sliding thereof relative to each other.

The invention and its applicability is described in more detail by means of the following examples.

EXAMPLE 1.

Some polymers set forth in table 1 were used to prepare helical devices of the invention, such as that shown

in fig. 10 (blank thickness 1 mm, outer diameter of helix 6 mm, inner diameter 4 mm, pitch angle 15 degrees and length of device 20-50 mm), by subjecting the polymeric melt to injection moulding to produce blanks having a diameter (Ø) of 1.5 - 2.0 mm by drawing (orientation and self-reinforcement) them at a temperature of Tm > T > Tg (wherein Tg is polymer glazing temperature and Tm is polymer (possibly) melting temperature) to the Ø reading of 1 mm and by winding them in hot state around a metal pipe (diameter 4 mm) as well as by cooling the device and by removing the finished device from the surface of the metal pipe.

Reference materials were made by using similar polymers to prepare tubular pieces (tube length 10 mm, outer diameter 6 mm and inner diameter 4 mm) by injection moulding polydmer melt into a cooled tubular mould. The compression strength of the devices and that of the corresponding tubes were compared to each other by squeezing a device (fig. 14b) or a tube (fig. 14a) placed between two steel plates with an external force in the direction orthogonal to its longitudinal axis. The bending of a device in lateral direction was prevented by prepressing the device into a compact bundle between two vertical plates (fig. 14b).

The compression load strengths of a tube (fig. 14a) and a device (fig. 14b) made of the same polymer and having equal weights were compared to each other. This was followed by the determination of the relative compression load strength (SP) of the device = a force required to fracture the device/a force required to fracture the tube. Devices and tubes were manufactured by using the following biodegradable polydmers, copolymers and polymer compositions: polyglycolide (Mw 60 000), glycolide/lactide copolymer (Mw 40 000),

glycolide/trimethylenecarbonate copolymer (Mw 60000), PLLA (Mw 260 000), PDLLA (Mw 100 000), lactide/δ-valerolactone copolymer (Mw 60 000), lactide/ϵ-caprolactone copolymer (Mw 60 000), PHBA (Mw 700 000), PHPA (Mw 50 000) and PDS (Mw 40 000). Resulting values for SP were ranging between 1.8 - 12.

EXAMPLE 2.

Devices of the invention such as that shown in fig. 10 were prepared by using a biodegradable polymer matrix as well as biodegradable reinforcing fibres included threin as reinforcements by compression moulding a bundle of parallel fibres and fine particulate polymer powder (particle size 1-10 µm) mixed therein (thermoplastic polymers) in a rod-shaped mould (length 8 cm, Ø 1.5 mm) above the melting point (partially crystalline polymers) or glazing point (amorphous polymers) of the matrix polymer. The amount of reinforcing fibres was 40-60 % by volume. The rod blanks were wound in a heated condition helically around a hot cylindrical mould (outer diameter of helix 8 mm) and the mould was cooled. When using a reaction polymer (n-butylcyano acrylate) as a matrix, the bundle of reinforcing fibres was rapidly impregnated with cyanoacrylate and the uncured wetted bundle of threads was wound helically around a teflon-coated steel pipe followed by wetting and removing the device. A corresponding device was made by using just cyanoacrylate.

Impregnation technique was also applied when using a matrix containing segmented polyurethane (S. Gogolewski and A. Pennings, Makromol. Chem. Rapid Comm. 4, 1983, p. 213) which was dissolved in N,N"-dimethylformamide-/tetrahydrofurane solution (weight ratio 3/2). Then, the bundle of fibres helically wound on the surface of a teflon-coated pipe was impregnated at 80 degrees

with a polyurethane solution and the pipe was immersed in a mixture of ethanol/distilled water (1:1). This process was repeated several times for preparing the device. A corresponding device was made by using just polyurethane.

Devices corresponding to such reinforced devices were also manufactured from mere thermoplastic matrix polymers by the application of melt working technique.

Table 2 illustrates the matrix polymers and fibrous reinforcements for the devices prepared.

Table 2. Structural components for fibre-reinforced biodegradable devices.

Matrix polymer	Fibre reinforcement
PDS	PGA
-"-	PGA/TMC
-"-	PGA/PLLA
-"-	PLLA
-"-	PHBA
-"-	PHBA/HVA
-"-	Chitin fibre
-"-	PDS
PDLLA	PGA
-"-	PGA/TMC
-"-	PGA/PLLA
-"-	PLLA
-"-	PHBA
-"-	PHBA/HVA
-"-	PDS
-"-	PDLLA
PLLA	PGA
-"-	PGA/TMC
-"-	PLLA
PVA	PGA
-"-	PGA/TMC
-"-	PGA/PLLA
-"-	PLLA
-"-	PHBA
-"-	PHBA/HVA
-"-	PDS
-"-	Chitin fibres
PGA/TMC	PGA
-"-	PGA/TMC
PHBA	PGA
-"-	PGA/TMC
-"-	PHBA
Poly-ϵ-caprolactone	PGA
-"-	PGA/TMC
-"-	PHBA
Methylmetacrylate-N-vinylpyrrolidone	PGA
Polyurethane	PGA
	Collagen (catgut)
PEO	PGA
-"-	PGA/TMC
-"-	PGA/PLA
-"-	PLLA
n-Butylcyano-acrylate	Collagen (catgut)
	PGA

The devices were secured by their ends to a tension apparatus and were drawn until broken in the direction of the longitudinal axis of the device (winding axis of the blank). This was followed by the determination of the relative tensile load-bearing strength (SV) of a reinforced device = a force required to fracture a reinforced device/a force required to fracture a corresponding non-reinforced device. The SV values were ranging between 1.5 - 8.

EXAMPLE 3.

Preparation of a self-reinforced polylactide device as shown in fig. 10 (hereinbelow "helix" (KR) (raw material poly-L-lactide/poly-DL-lactide copolymer (PLLA/PDLLA molar ratio 80/20), Mw = 60 000). Helix (KR) was manufactured from a thick, extrusion-made PLLA/PDLLA rod which was drawn to a drawing ratio of $\lambda = 7$ at a temperature of 90 degrees for self-reinforcing the material. A thus prepared self-reinforced rod having a thickness of 1 mm was then wound to form "a helix" as described in example 1. The helix was cut into lengths of 12 mm for the following examination.

The gastric cavity of a dog was opened in general anaesthesia, the intestines were set aside and the bile duct (ST) was exposed by preparation (see fig. 15). A roughly 6 mm long incision (AK1) was made threin. As shown in fig. 15a, a distance of 5 mm of this incision was provided with non-resorbable stitches (KO) (which pucker up the duct and narrow it permanently together with a cicatrical tissue formed on incision (AK1). This was followed by closing the gastric cavity, stitching the skin and, after waking up from anaesthesia, the dog was allowed to move freely in its cage. After one month the dog was re-anesthetized,

the gastric cavity was incised and the blocked bile duct was prepared to re-expose it. The duct was opened with a longitudinal incision (AK2) at the region of cicatricial pucker, a helix having an inner diameter of 2 mm and an outer diameter of 3 mm was inserted in the bile duct in a manner that both of its ends were located in healthy bile duct and its central portion within the incised pucker region. The bile duct was closed with a stitch (O), whereby its walls extended around the spiral. The situation is schematically illustrated in the cross-sectional figure 15c. After the operation, the bile duct was normal in volume. The gastric cavity and skin were closed the same way as in the first operation. The dog was put away after 14 months by which time the helix had nearly disappeared and the bile duct had a normal extent and volume and the pucker was no longer macroscopically observable.

EXAMPLE 4.

The femoral vein (RL in fig. 16a) of a dog was cut in general anaesthesia in the right hind leg. The base portion of the more distal vein was threaded into the interior of a biodegradable, reinforced device ("helix") having an inner diameter of 8 mm and an outer diameter of 9 mm and a length of 2 cm, said device being like the one shown in fig. 10 (reinforcing fibres: Ca/P-fibres; matrix polymer PLLA, Mw = 100 000; fibre/polymer weight ratio = 30/70 (w/w) and vein (LO) was stitched with end-to-end technique by using a resorbable 6-0 yarn to make a tight seam with no bleeding. After the operation, due to the flabbiness of the walls, the vein tended to collapse within the region of the stitched seam and this leads to a poorer circulation in the vein resulting easily in the development of a coagulation or a clot formed by blood particles within the region of the seam and

thus the vein will be blocked. The situation is illustrated in the schematic view of fig. 16a from the side of stitched seam and in fig. 16b from above a stitched seam. Therefore, a biodegradable helix (KR) was pulled over the seam portion with the stitched seam remaining at the half-way point of helix (KR). The wall of a vein was attached at the stitched seam over its entire circumference to the helix by means of non-resorbable support stitches (TO) (fig. 16c). This way the vein was tensioned to its normal extent with the help of a support provided by the device. After the seam had healed, especially after the inner surface of a blood vessel or endothelium had healed, there is no longer a risk of developing a clot and the helix can resorb away with no harm done. After 6 months the dog was put away and the femoral vein had healed without a pucker or a clot.

EXAMPLE 5.

The test animals were male rabbits weighing 3 kg. The animals were anesthetized for the operation with im. ketamin and iv. pentobarbital preparations. A poly-lactide blank (Ø 1 mm) was used to prepare a helix having an outer diameter of 8 mm and a length of 15 mm and an extension formed by a thin tubular neck section, 10 mm, followed by two helical coils (fig. 17).

The anesthetized test animals were subjected to a surgical incision of the urinary bladder through abdominal covers. Through the opened bladder the prothesis was threaded into position with the narrow neck section remaining within the region of closure muscle and the helical coil ends on the side of the urinary bladder.

The prothesis was fitted in 15 test animals which were under observation for 3 months. The study verified that an implant of the invention can be used for preventing a lower urethra obstruction caused by the enlargement of forebland.

EXAMPLE 6.

The test animals were male rabbits weighing appr. 3 kg. The animals were anesthetized for the operation with im. ketamin and iv. pentobarbital preparations.

The implants employed were PLLA helixes as described in example 1 (cross-section of blank circular, thickness of blank 1 mm, outer diameter of helix 6 mm and length 15 mm).

On the anesthetized test animals was performed scission of the blind urethra to the extent sufficient for a prothesis. The prothesis was placed on the distal side of closure muscle. In connection with the operation an antibiotic as a single dose: ampicillin 100 mg/kg.

The prothesis was fitted in 15 animals which were put away with iv overdose of anesthetic 2 weeks, 3 months, 6 months, 1 year and 2 years after the implantation. The urethra was dissected and tissue samples were taken for histological and electron microscopic analysis.

Histological studies indicatedd that PLLA had caused only slight foreign matter reaction in tissues. 2 years after the implantation the helix hadnearly completely biodegraded and the urethra was almost normal in its dimensions.

EXAMPLE 7.

Cloggings in the ureters leading from kidney to bladder will become more common as a result of the increased observation surgery of upper urethras. The ureter has a good regeneration ability when subjected longitudinal incision but its healing requires an internal support. Transverse incision or short deficiency always leads to the development of a clogging.

The purpose of this example was to examine the applicability of a helix made of a biodegradable material both to the healing of a longitudinal dissection of the urethra and to the healing of a transverse deficiency.

The test animals were female rabbits weighing appr. 3 kg. The animals were anesthetized. Incision of the abdominal cavity was performed on the flank without opening, however, the actual abdominal cavity.

a) the urethra having a diameter of ca. 4 mm was dissected lengthwise over a distance of ca. 2 cm followed by threading a self-reinforced PGA-helix (blank thickness 1 mm) inside the urethra, said helix having an outer diameter of 4 mm and a length of 20 mm. The region of dissection was covered with fat.

b) a length of ca. 1 cm was cut off the urethra, the remaining ends were dissected over a distance of 0.5 cm and the above-described prothesis was threaded in, so that the remaining defect zone of the tissue was 1 cm. The defect zone was covered with surrounding fat. After 1 month, 3 months and 1 year from the operation a tracer imaging of the kidneys

was performed for observing the healing of urethra. The operated urethras had healed to almost normal condition over the period of 1 year (on the basis of tracer imaging).

Claims

1. A surgical implant or device or a part thereof made of a material at least partially biogradable for supporting and/or joining or separating tissues or operated and/or damaged tissues or parts thereof and/or for keeping open a tissue cavity, **characterized** in that the implant, device or a part thereof at least partially consists of at least one, at least partially biodegradable elongated piece which is at least partially wound at least once around a winding centre into a helical configuration and which is at least partially reinforced with biodegradable reinforcement elements.

2. An implant, device or a part thereof as set forth in claim 1, **characterized** in that the elongated piece is at least partially wound into a spiral configuration (figs. 5 and 6).

3. An implant, device or a part thereof as set forth in claim 2, **characterized** in that the elongated piece is at least partially wound into a screw-threaded configuration.

4. An implant, device or a part thereof as set forth in claim 2 or 3, **characterized** in that at least some of the spirals or screw threads are connected with each other by means of biodegradable radial wires, rods or the like (fig. 6).

5. An implant, device or a part thereof as set forth in claim 4, **characterized** in that the helically shaped body is cylindrical.

6. An implant, device or a part thereof as set forth in claim 4, **characterized** in that the helically shaped body is conical.

7. An implant, device or a part thereof as set forth in claim 1, **characterized** in that the reinforcement elements consist of oriented structures formed at least partially by polymer molecules or parts thereof.

8. An implant, device or a part thereof as set forth in claim 1 and 7, **characterized** in that the reinforcement elements comprise at least partially micro-fibrils, fibrils or structures formed thereby.

9. An implant, device or a part thereof as set forth in any of claims 1, 7 and 8, **characterized** in that the reinforcement elements are at least partially fibres, film fibres, wires, braids, ribbons, staples, non-woven constructions, fabrics, knittings or corresponding structures constructed of fibres.

10. An implant, device or a part thereof as set forth in any of claims 1 and 7-9, **characterized** in that the reinforcement elements are at least partially biodegradable ceramic fibres.

11. An implant, device or a part thereof as set forth in any of claims 1 and 7-10, **characterized** in that the reinforcement elements further comprise biostable fibres, such as polymeric fibres and/or ceramic fibres.

12. An implant, device or a part thereof as set forth in any of claims 1 and 7-11, **characterized** in that the reinforcement elements are at least partially biodegradable ceramic fibres.

13. An implant, device or a part thereof as sett forth in any of claims 1 and 7-12, **characterized** in that it is structurally at least partially self-reinforced.

14. An implant, device or a part thereof as set forth in any of claims 1 and 7-13, **characterized** by comprising at least two, at least partially helical device sections (VO1, VO2) joined to each other in a manner that the helixes preferably turn in opposite directions, said device sections being at least partially nested within each other (fig. 10c).

15. An implant, device or a part thereof as set forth in claim 14, **characterized** by comprising at least two device sections which are twined together to form a substantially tubular structure (fig. 10d).

16. A method for manufacturing an implant or a device as set forth in claims 1-15, **characterized** in that an elongated blank formed by a biodegradable polymer matrix and biodegradable reinforcement elements is wound at least partially at least once around a winding centre into a helical configuration.

17. A method as set forth in claim 16, **characterized** by (a) orienting and/or fibrillating and/or ultra-orienting an elongated piece made of an at least partially biodegradable polymer, copolymer or polymer composition by means of mechanical draw and/or rapid cooling of a flowing melt, followed by (b) winding it at least partially into a helical configuration by working it by the application of an external force or pressure and/or heat.

18. A method as set forth in claims 16 and 17, **characterized** in that a plurality of blanks are wound simultaneously around a common winding centre.

19. A method as set forth in claim 18, characterized in that during the winding said blanks are driven over and under each other for producing a tubular braid.

20. The application of an implant, device or a part thereof as set forth in claims 1-15 as an anti-pucker or anti-blocking and/or expanding device for a channel, a duct, a tube or a blood vessel and/or as an anastomosis device.

21. The application of an implant, device or a part thereof as set forth in claims 1-15 as devices for joining together tissues, organs or parts thereof.

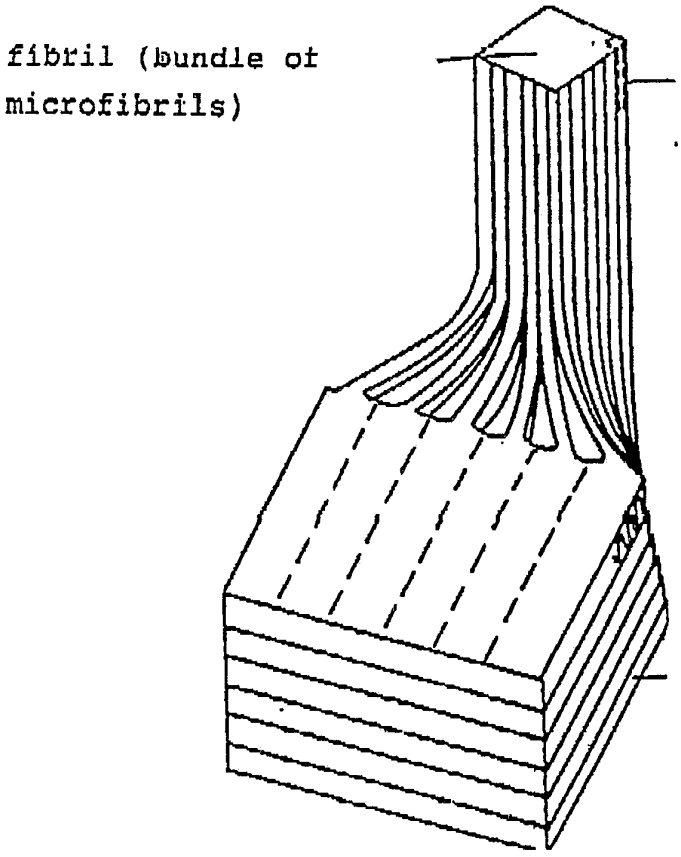


FIG 1

Transformation of lamellarstructure to fibrillar structure

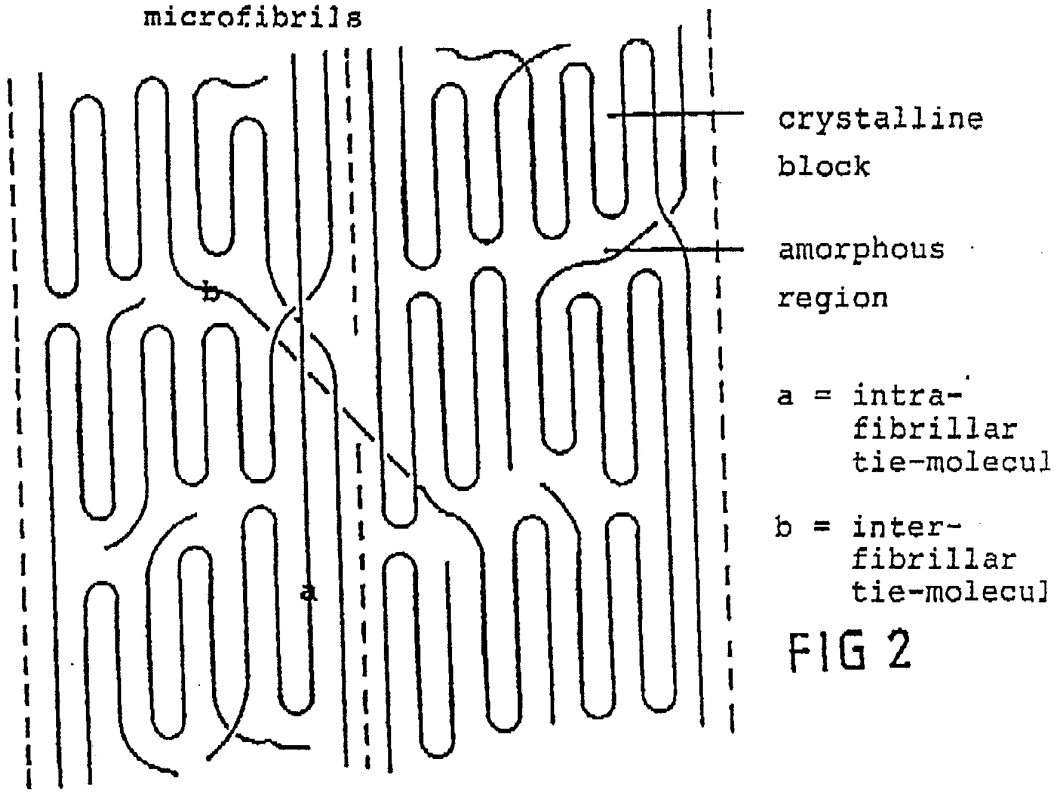


FIG 2

Microfibrillar structure

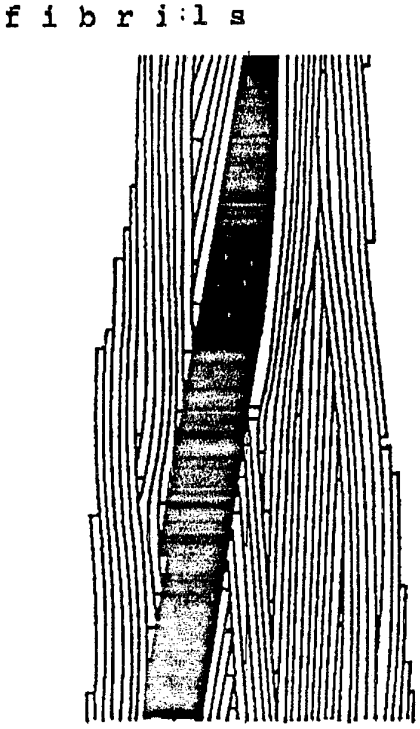

f i b r i l s
1 µ

FIG 3

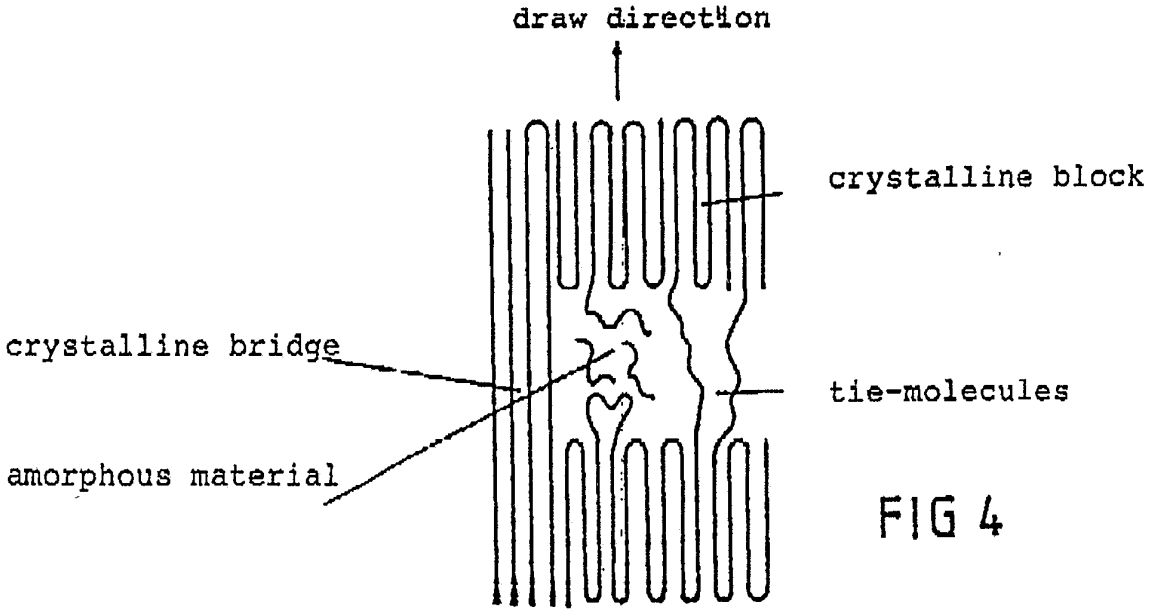

draw direction
crystalline block
crystalline bridge
tie-molecules
amorphous material

FIG 4

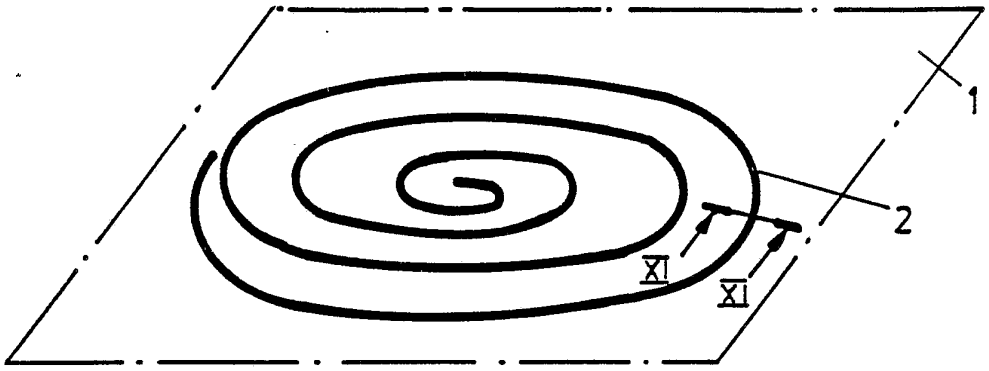


FIG 5

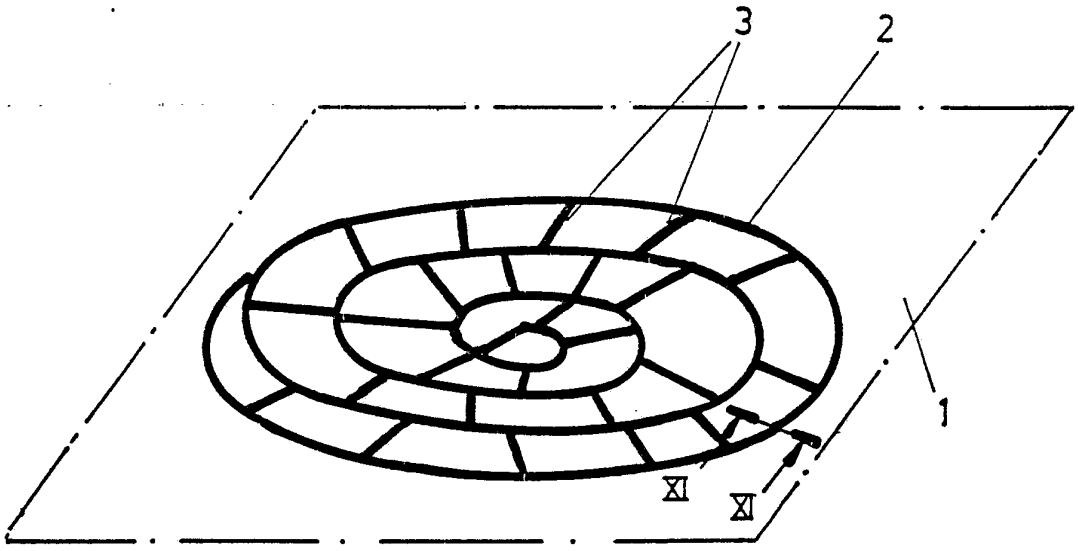


FIG 6

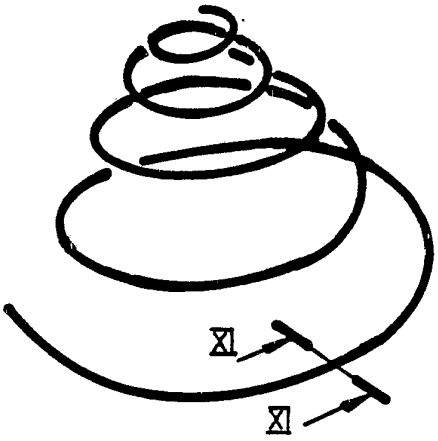


FIG 7a

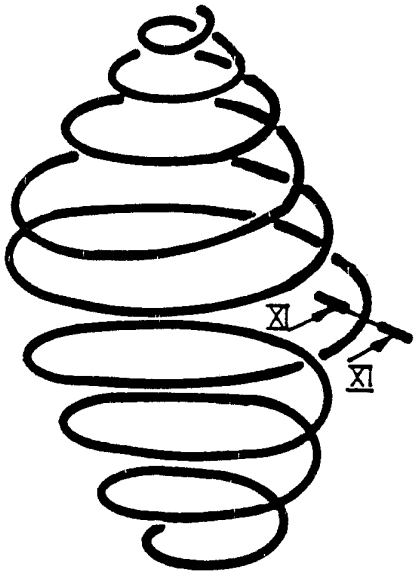


FIG 8a

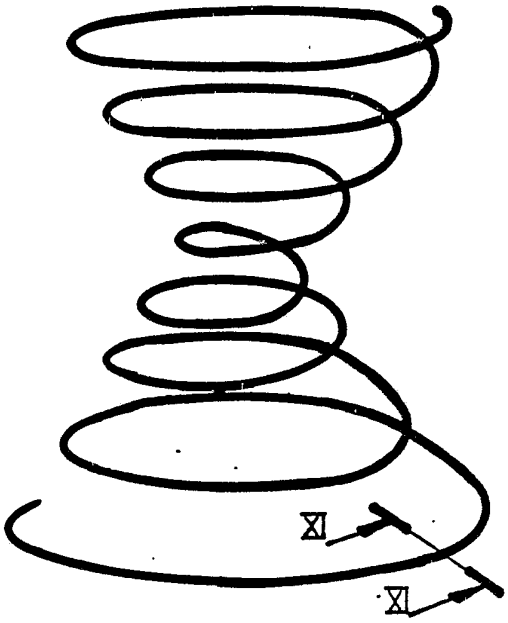


FIG 9a

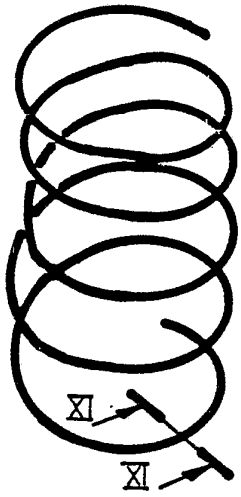


FIG 10a

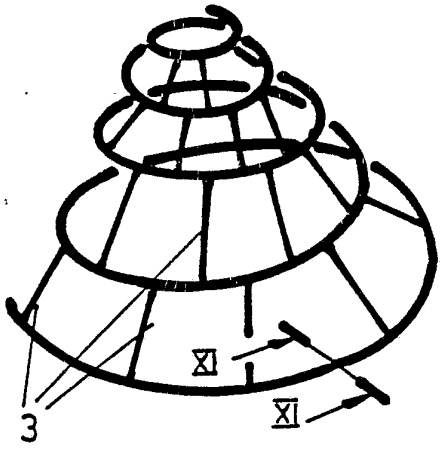


FIG 7b

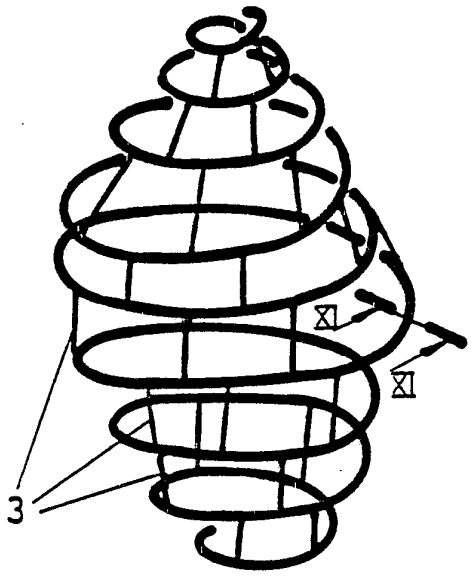


FIG 8b

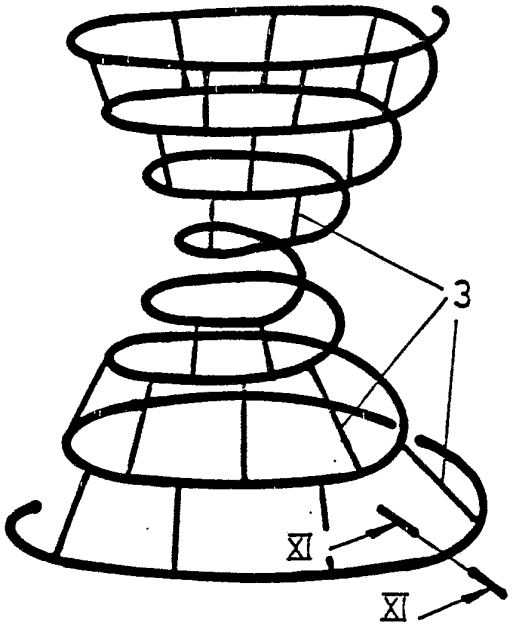


FIG 9b

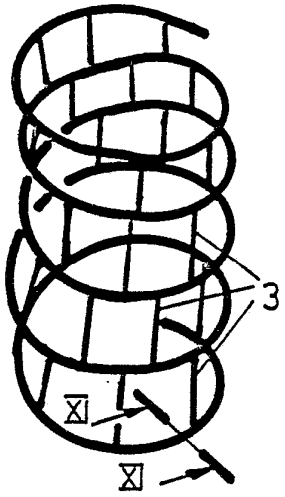


FIG 10b

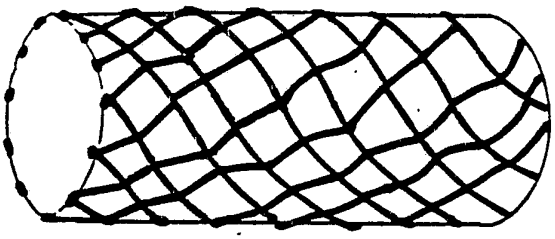


FIG 10d

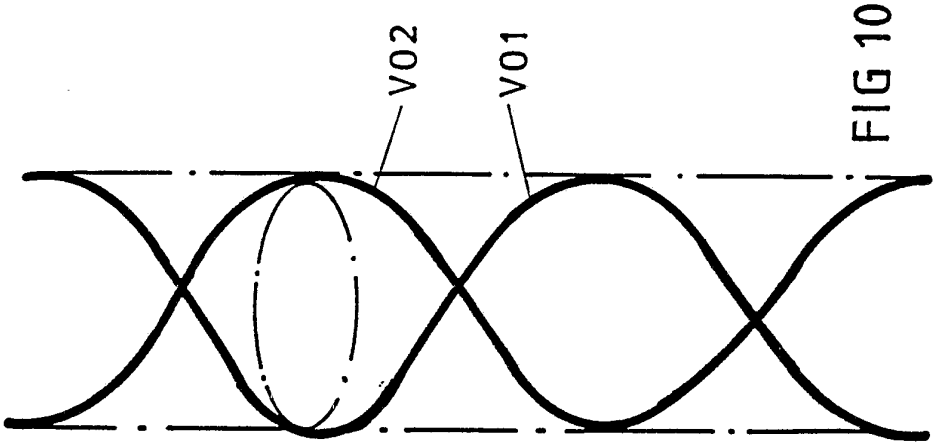


FIG 10c

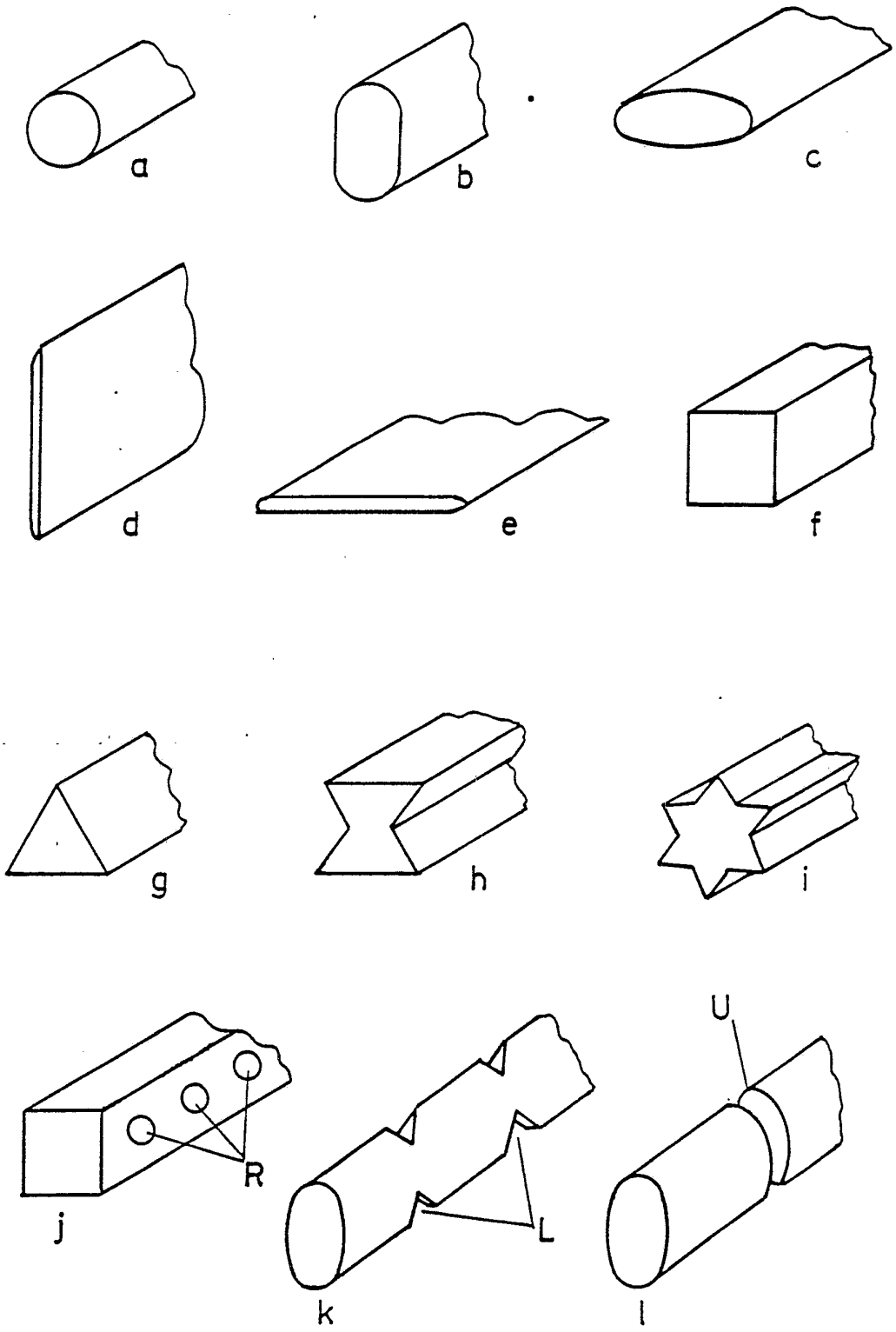


FIG 11

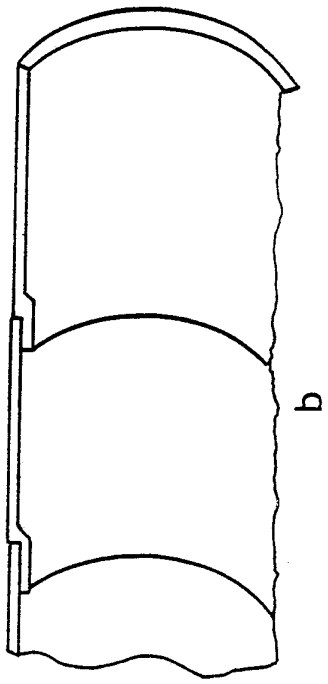
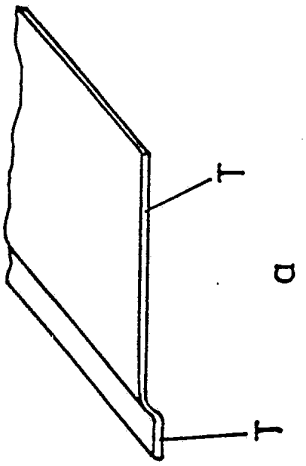


FIG 12



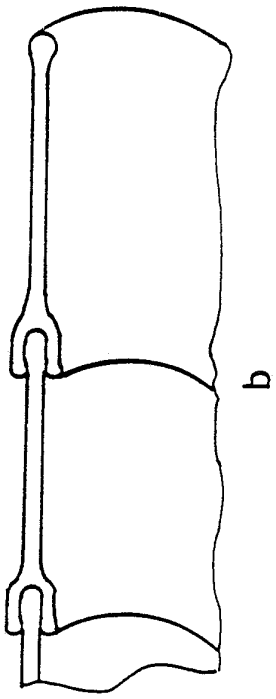
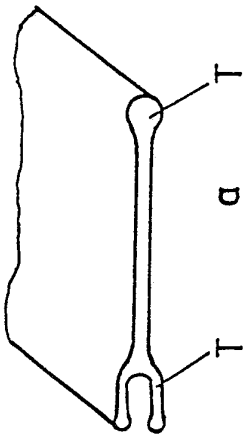


FIG 13



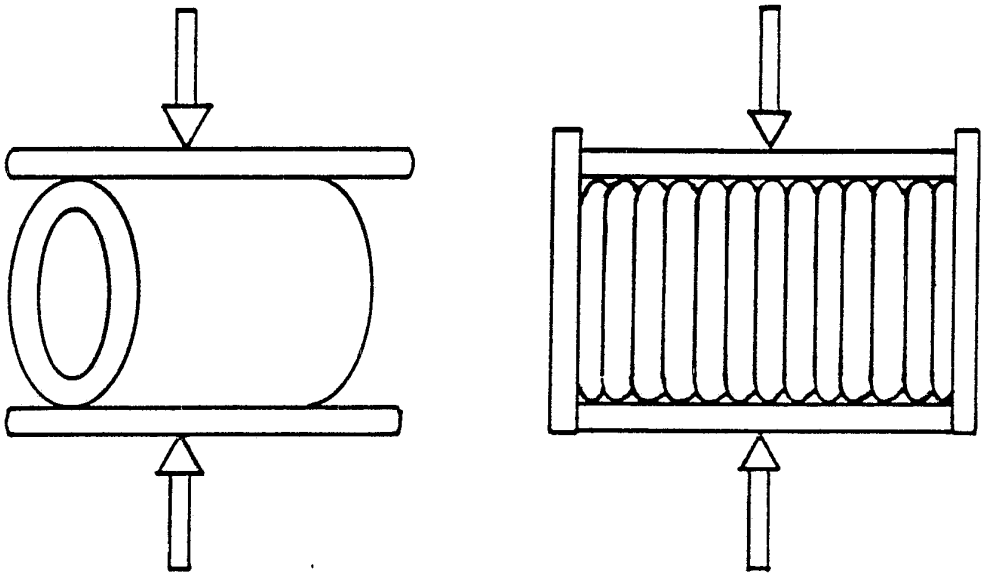


FIG 14

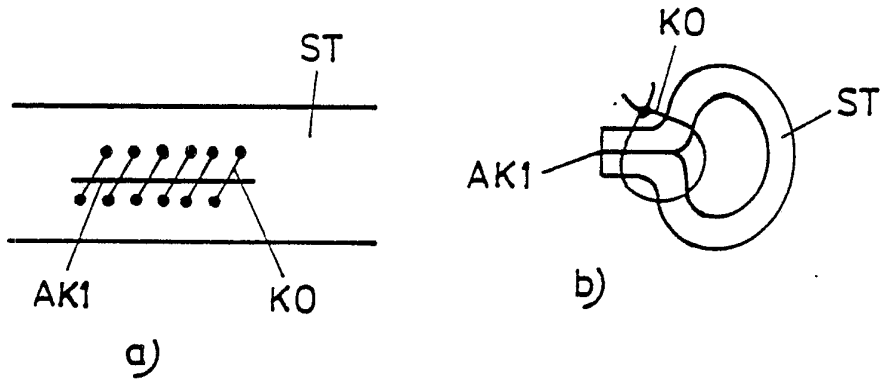


FIG 15

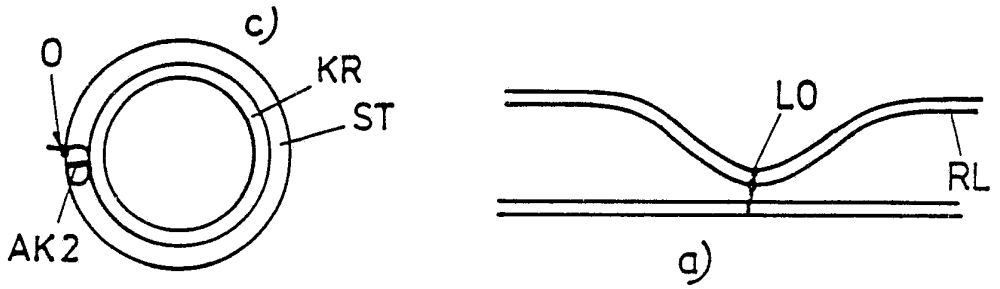
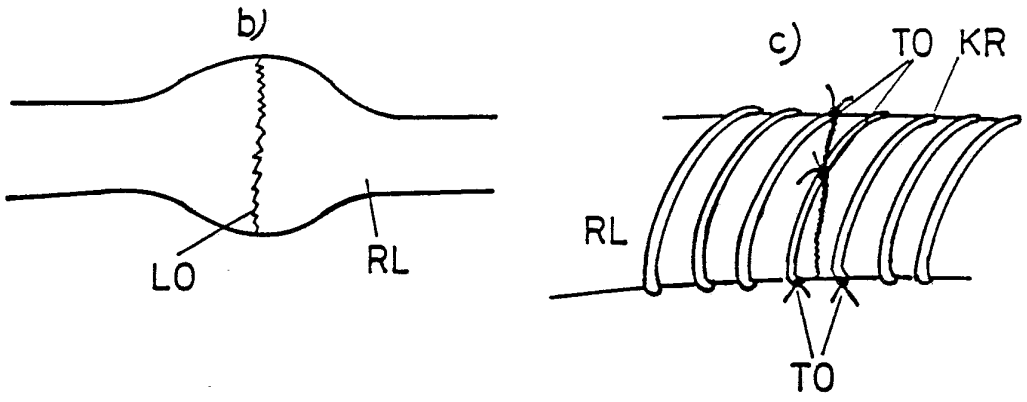


FIG 16



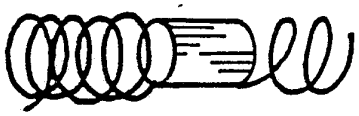
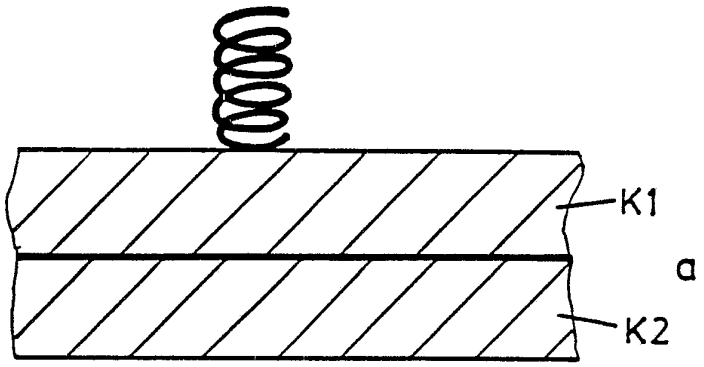


FIG 17



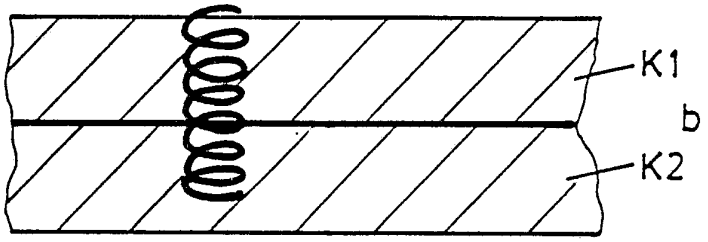


FIG 18

INTERNATIONAL SEARCH REPORT

International Application No PCT/FI 89/00204

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 L 27/00, A 61 F 2/02

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC5	A 61 L; A 61 F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

SE,DK,FI,NO classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	WO, A1, 88/05312 (MATERIALS CONSULTANTS OY) 28 July 1988, see the whole document --	1-19
X	WO, A1, 88/06872 (ASTRA MEDITEC AB) 22 September 1988, see abstract; figures 2,3,9,10; claims 1-13 --	1-7,14-19
X	EP, A1, 0122744 (HOWMEDICA INC.) 24 October 1984, see page 5, line 6 - line 11; page 10, line 16; abstract; figure 2; claims 1-10 --	1-19
X	EP, A1, 0121362 (ETHICON INC.) 10 October 1984, see page 7, line 20 - line 21; abstract; figures 1-3,6 --	1-3

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
14th February 1990	1990 -02- 16
International Searching Authority	**Signature of Authorized Officer**
SWEDISH PATENT OFFICE	Sofia Nikolopoulou Sofia Nikolopoulou

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
X	EP, A2, 0202444 (AMERICAN CYANAMID COMPANY) 26 November 1986, see page 5, line 9 - line 16; abstract; claims 1-10 --	1-5,9
Y	WO, A1, 83/03752 (WALLSTEN, HANS, IVAR) 10 November 1983, see abstract; figure 1a; claims 1-11 --	1-3,9
Y	US, A, 4792336 (HLAVACEK ET AL) 20 December 1988, see abstract; figures 1-4; claim 1 --	1-3,9

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 20-21, because they relate to subject matter not required to be searched by this Authority, namely:

See PCT Rule 39.1 (iv): Methods for treatment of the human or animal body by surgery or therapy

2. [ ] Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

[ ] The additional search fees were accompanied by applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. PCT/FI 89/00204

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 08/11/89
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A1- 88/05312	28/07/88	AU-D-	10842/88	10/08/88
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		JP-T-	1501847	29/06/89
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