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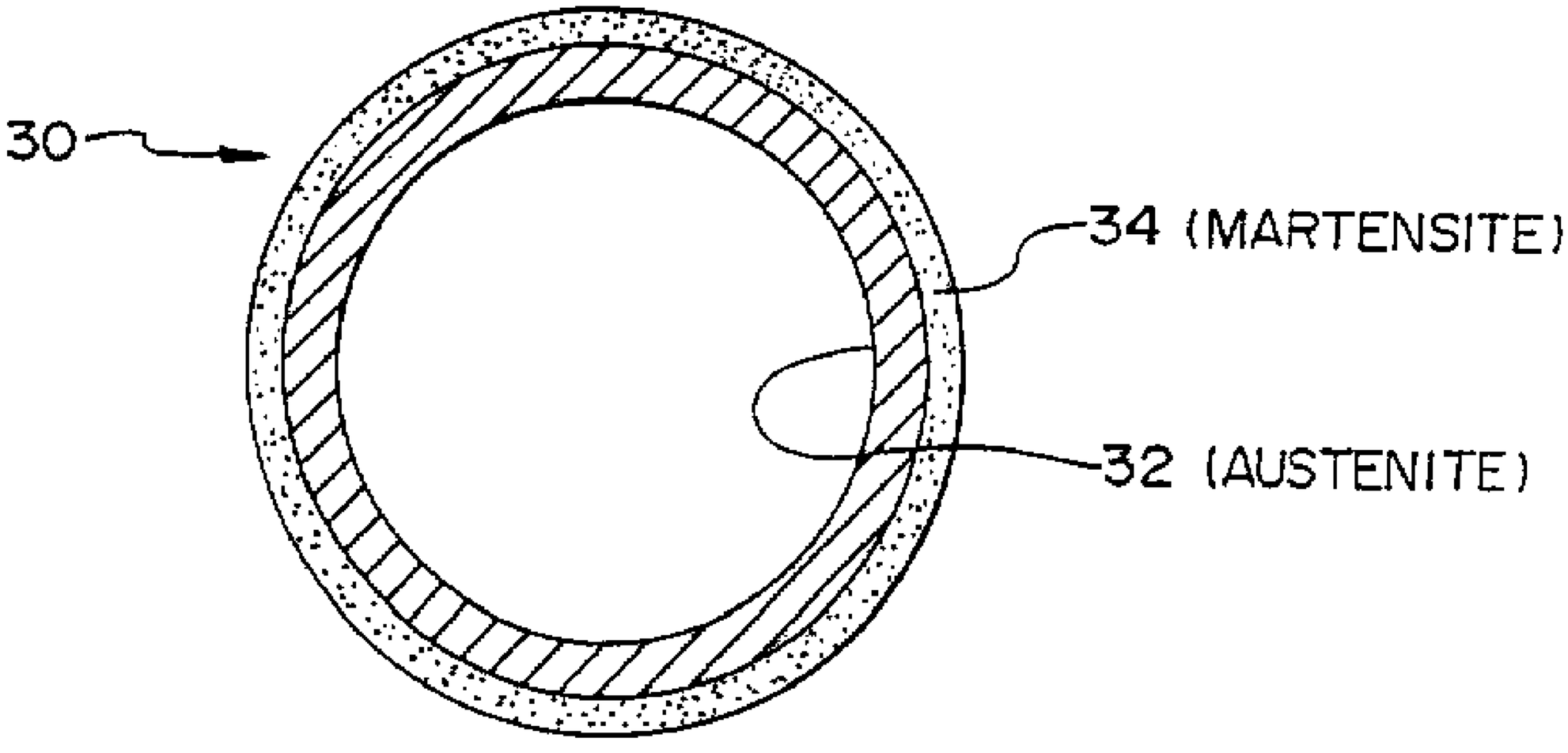
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(72) Inventeurs/Inventors:
BURMEISTER, PAUL H., US;
EUTENEUER, CHARLES L., US;
BROWN, BRIAN J., US;
FORDENBACHER, PAUL J., US;
VRBA, ANTHONY C., US

(73) Propriétaire/Owner:
SCIMED LIFE SYSTEMS, INC., US

(74) Agent: NENNIGER, JAMES T.

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A new multiple component stent (10) which allows for initial self-expansion and subsequent deformation to a final enlarged size. In one embodiment, stent (10) comprises a first resilient element (12) and a second deformable element (14). In another embodiment, stent (30) is made of a first austenite component (32) and a second martensite component (34).

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(71) Applicant *(for all designated States except US)*: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: BURMEISTER, Paul, H. [US/US]; 8554 Quarles Road North, Maple Grove, MN 55311 (US). EUTENEUER, Charles, L. [US/US]; 1951 Lander Avenue N.E., St. Michael, MN 55376 (US). BROWN, Brian, J. [US/US]; 178 Jandel Avenue N.E., Hanover, MN 55341 (US). FORDENBAUCHER, Paul, J. [US/US]; 3015 James Avenue South, Minneapolis, MN 55408 (US). VRBA, Anthony, C. [US/US]; 1266 88th Place North, Maple Grove, MN 55369 (US).

(74) Agents: ARRETT, Oliver, F. et al.; Vidas, Arrett & Steinkraus, Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402 (US).

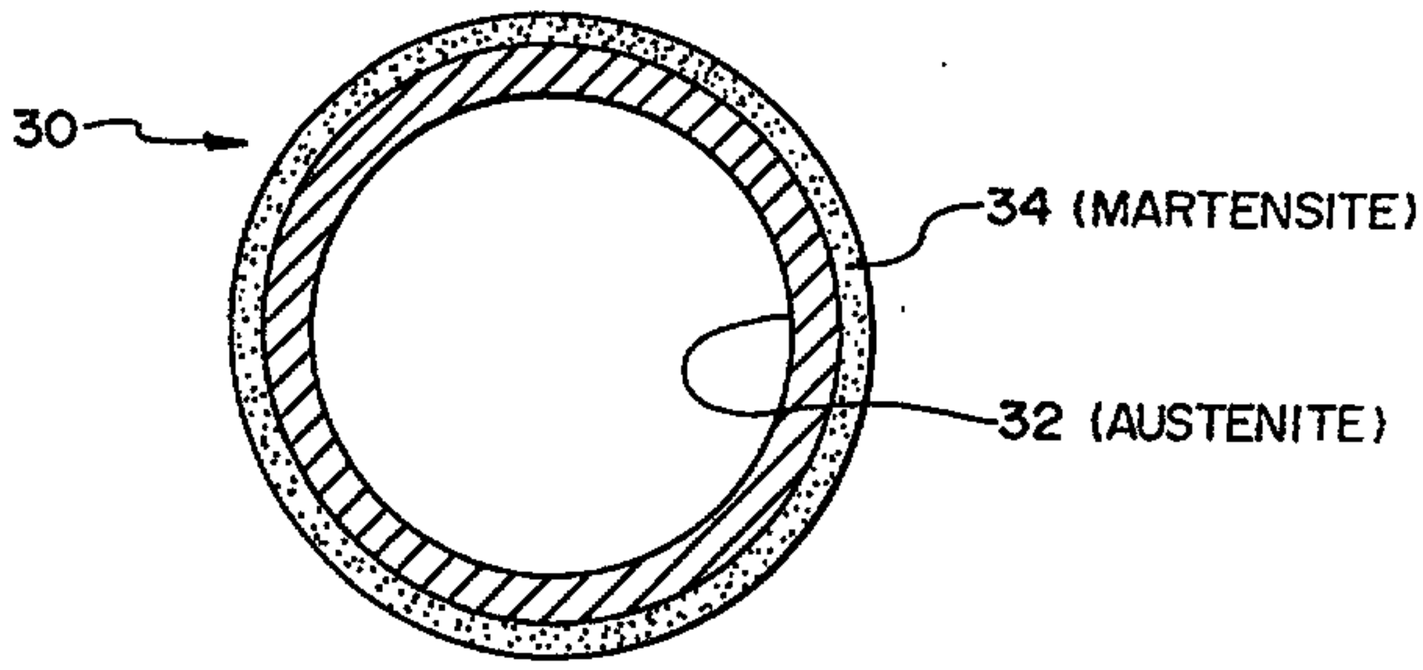
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(57) Abstract

A new multiple component stent (10) which allows for initial self-expansion and subsequent deformation to a final enlarged size. In one embodiment, stent (10) comprises a first resilient element (12) and a second deformable element (14). In another embodiment, stent (30) is made of a first austenite component (32) and a second martensite component (34).



IMPROVED TISSUE SUPPORTING DEVICES

Background of the Invention

This invention relates to tissue supporting devices in general and most particularly to vascular stents for placement in blood vessels. A primary feature of the devices of this invention is that they are expandable within the body.

In the past, such devices have been provided for implantation within body passageways. These devices have been characterized by the ability to be enlarged radially, often having been introduced into the desired position in the body as by percutaneous techniques or surgical techniques.

These devices are either expanded mechanically, such as by expansion of a balloon positioned inside the device, or are capable of releasing stored energy to self-expand themselves within the body.

References designated as defining the general state of the art but not considered to be of particular relevance to the invention disclosed and claimed herein are as follows. French Patent 2,617,721 appears to disclose a catheter used for permanently dilating a stenosis in a tubular organ or blood vessel. WO94/03127 appears to disclose a prosthetic device for sustaining a blood vessel or hollow organ lumen comprising a tubular wire frame. European Patent Application 364,787 and European Patent Application 335,341 appear to disclose expandable intraluminal vascular grafts. WO92/19310 appears to disclose a tissue supporting device of a shape memory alloy. U.S. Patent 5,147,370 appears to disclose a nitinol stent for hollow body conduits. UK Patent 2,175,824A appears to disclose a method of producing a composite metal material and a billet for jet engine turbine blades, armor, helicopter rotor blades, car suspension stress parts or sword blades made of said composite material.

The materials which have been used to make up these devices have included ordinary metals, shape memory alloys, various plastics, both biodegradable and not, and the like.

This invention is concerned with the use of these materials in a new multiple component arrangement which allows for initial self-expansion and subsequent deformation to a final enlarged diameter in the body.

AMENDED SHEET

Balloon expandable stents do not always expand uniformly around their circumference. As a result, healing may not take place in a consistent manner. If the stent is coated or covered, non-uniform expansion may tear the covering or coating. Additionally, long stents of this type may require long balloons which can be difficult to handle, difficult to size, and may not offer ideal performance in tortuous passages in blood vessels and the like.

Thus, when addressing such issues, self-expandable stents have been thought to be generally more desirable. Unfortunately, one cannot control the degree of expansion and hence the degree of embedment in the vessel wall. It has been determined that a stent must be embedded to some degree to be clinically satisfactory.

The stents of the present invention provide the best features of both of these types of stents without their drawbacks.

Summary of the Invention

The tissue supporting devices of this invention are generally cylindrical or tubular in overall shape and of such a configuration as to allow radial expansion for enlargement. They are often referred to herein in the general sense as "stents". Furthermore, the devices are comprised of at least one component, element, constituent or portion which exhibits a tendency to self-expand the device to an expanded size and at least one other component, element, constituent or portion which is deformable so as to allow an external force, such as a balloon positioned within the body of the device, to further expand it to a final, larger desired expanded size. The terms "component", "element", "constituent" and "portion" are often referred to herein collectively as "portion".

Preferably, the devices of the invention are made of metal and most preferably of shape memory alloys.

In one embodiment, a first portion is a resilient spring-like metal for self-expansion and a second portion is a deformable metal for final sizing. In a more preferred shape memory embodiment, a first portion is a self-expanding austenitic one and a second is a martensitic one capable of deformation. In the case of shape memory embodiments the "portions" may be discrete or merely different phases of an alloy.

The most preferred embodiment of the invention is a stent, preferably of shape memory alloy. The most preferred shape memory alloy is Ni-Ti, although any of the other known shape memory alloys may be used as well. Such other alloys include: Au-Cd, Cu-Zn, In-Ti, Cu-Zn-Al, Ti-Nb, Au-Cu-Zn, Cu-Zn-Sn, Cu-Zn-Si, Cu-Al-Ni, Ag-Cd, Cu-Sn, Cu-Zn-Ga, Ni-Al, Fe-Pt, U-Nb, Ti-Pd-Ni, Fe-Mn-Si, and the like. These alloys may also be doped with small amounts of other elements for various property modifications as may be desired and as is known in the art.

The invention will be specifically described hereinbelow with reference to stents, a preferred embodiment of the invention although it is broadly applicable to tissue support devices in general.

Brief Description of the Figures

Figure 1 is a braided stent according to one embodiment of this invention.

Figure 2 is a graph showing the martensitic/austenitic temperature transformation curve and the superelastic area of a shape memory alloy.

Figures 3 is an end view of a layered stent having two discrete components according to one aspect of this invention.

Figures 4a and 4b are graphs showing the martensitic/austenitic temperature transformation curves of the layers in the stent of Figure 3.

Figure 5a and 5b are views of another embodiment of the invention comprised of alternating rings of shape memory alloy.

Figure 6 is a showing of a stent fragment of a braided version of a shape memory stent of this invention.

Figure 7 is a graph showing a temperature window for a shape memory alloy to be used in yet another stent version of this invention.

Figure 7a is a graph showing expansion of a stent with temperature.

Figure 7b is a graph of the same type, the stent having been cold-worked.

Figure 7c is a graph of the same type, the stent having had pseudoelastic prestraining.

Figure 7d is a graph of the same type, the stent having amnesia inducement.

Figures 8-11 show various expandable configurations (closed and open) illustrated in fragment which may be used in the stents of this invention.

Figures 9a and 9b show a preferred embodiment of an articulated stent.

Figure 12 shows another version of an expandable stent of the invention.

Figure 13 shows yet another version of a stent which may be used with the invention.

Figure 14 is a schematic showing of a braided stent made up of a plurality of strands.

Figure 15 is a detail of a single strand from the stent of Figure 14 showing that the strand is made up of a plurality of wires of two different types.

Figure 16 is a cross-sectional view taken along line 16-16 of Figure 15 showing the two different types of wire.

Detailed Description of the Invention

Preferred embodiments of this invention are described below with particular reference to the accompanying drawing Figures.

Referring first to the embodiment shown in Figure 1, a stent 10 is shown comprised of braided or interwoven metal strands 12 and 14. Strands 12 are of a resilient spring-like metal such as spring steel, Elgiloy® for example. Preferably, strands 12 are spirally extending in the same direction, spiraling to the right as seen in Figure 1. Strands 14 are of a deformable or annealed metal such as stainless steel and are preferably spiraled in the opposite direction as strands 12, as shown in Figure 1.

Given such a stent construction of two components *i.e.*, strands 12 and 14, it can be seen that stent 10 may be readily loaded on a catheter as by placing it over an uninflated balloon on a balloon catheter and compressing it tightly around the balloon and then placing a sheath over the stent to hold it in place during the transluminal placement procedure. Once in place, the sheath is removed, for example slid back, to expose the stent, allowing it to self-expand by force of the resilient strands 12 to substantially assume a self-expanded shape/size. Some self-expansion may be restrained if held back by strands 14. To finally adjust the size of the stent, the balloon may be expanded by inflation from within the stent to exert an outward radial force on the stent and further enlarge it by stretching and deforming the deformable metal of strands 14. This may be aided by building into strands 14, a series of readily deformable structures or means such as bends or kinks 16 as shown in Figure 1. It can be seen that a permanent adjustable size beyond the self-expanded size may be obtained with this embodiment. It is to be noted that many configurations other than braided may be readily devised to take advantage of this two component concept, including various of the subsequent configurations described hereinbelow. Also, it should be noted that, although not preferred, the stent may be initially deployed without a balloon; the balloon following on a separate catheter.

Referring now to subsequent features, other preferred embodiments of the invention will be described which make use of shape memory alloys and some of

their unique properties, primarily their special types of deformation i.e., shape memory deformation in martensite and/or superelastic deformation in austenite.

The term "superelasticity" is used to describe the property of certain shape memory alloys to return to their original shape upon unloading after a substantial deformation while in their austenitic state. Superelastic alloys can be strained while in their austenitic state more than ordinary spring materials without being plastically deformed. This unusually large elasticity in the austenitic state is also called "pseudoelasticity", because the mechanism is nonconventional in nature, or is also sometimes referred to as "transformational superelasticity" because it is caused by a stress induced phase transformation. Alloys that show superelasticity also undergo a thermoelastic martensitic transformation which is also the prerequisite for the shape memory effect. Superelasticity and shape memory effects are therefore closely related. Superelasticity can even be considered part of the shape memory effect.

The shape memory and superelasticity effects are particularly pronounced in Ni-Ti alloys. This application will therefore focus on these alloys as the preferred shape memory alloys. The shape memory effect in Ni-Ti alloys has been described many times and is well known.

In near-equiatomic Ni-Ti alloys, martensite forms on cooling from the body centered cubic high temperature phase, termed austenite, by a shear type of process. This martensitic phase is heavily twinned. In the absence of any externally applied force transformation takes place with almost no external macroscopic shape change. The martensite can be easily deformed by a "flipping over" type of shear until a single orientation is achieved. This process is also called "detwinning".

If a deformed martensite is now heated, it reverts to austenite. The crystallographic restrictions are such that it transforms back to the initial orientation thereby restoring the original shape. Thus, if a straight piece of wire in the austenitic condition is cooled to form martensite it remains straight. If it is now deformed by bending, the twinned martensite is converted to deformed martensite. On heating, the transformation back to austenite occurs and the bent wire becomes straight again. This process illustrates the shape memory deformation referred to above.

The transformation from austenite to martensite and the reverse transformation from martensite to austenite do not take place at the same temperature. A plot of the volume fraction of austenite as a function of temperature provides a curve of the type shown schematically in Fig. 2. The complete transformation cycle is characterized by the following temperatures: austenite start temperature (A_s), austenite finish temperature (A_f), both of which are involved in the first part (1) of an increasing temperature cycle and martensite start temperature (M_s) and martensite finish temperature (M_f), both of which are involved in the second part (2) of a decreasing temperature cycle.

Figure 2 represents the transformation cycle without applied stress. However, if a stress is applied in the temperature range between A_s and M_d, martensite can be stress-induced. Stress induced martensite is deformed by detwinning as described above. Less energy is needed to stress induce and deform martensite than to deform the austenite by conventional mechanisms. Up to about 8% strain can be accommodated by this process (single crystals of specific alloys can show as much as about 25% pseudoelastic strain in certain directions). As austenite is the thermodynamically stable phase at temperatures between A_s and M_d under no-load conditions, the material springs back into its original shape when the stress is no longer applied.

It becomes increasingly difficult to stress-induce martensite at increasing temperatures above A_f. Eventually, it is easier to deform the material by conventional mechanisms (movement of the dislocation, slip) than by inducing and deforming martensite. The temperature at which martensite can no longer be stress-induced is called M_d. Above M_d, Ni-Ti alloys are deformed like ordinary materials by slipping.

Additional information regarding shape memory alloys is found in the following references, all of which are incorporated fully herein by reference:

"Super Elastic Nickel-Titanium Wires" by Dieter Stöckel and Weikang Yu of Raychem Corporation, Menlo Park, California, copy received November 1992;

Metals Handbook, Tenth Edition, Vol. 2, *Properties and Selection: Nonferrous Alloys and Special-Purpose Materials*, *"Shape Memory Alloys"* by Hodgson, Wu and Biermann, pp. 897 - 902; and,

In Press, *Titanium Handbook*, ASM (1994). Section entitled *"Structure and Properties of Ti-Ni Alloys* by T.W. Duerig and A.R. Pelton.

Since the most preferred shape memory alloy is Ni-Ti, the martensitic state of this alloy may be used to advantage in the two component concept of this invention.

For example, with reference to Figure 3, a layered construction may be provided in a stent 30 (shown in end view) which is generally a hollow cylindrical or tubular body in shape but which may be formed in a wide variety of specific configurations or patterns to foster radial expansion of the body as exemplified in Figures 1, 5, 6 and in subsequent Figures 8-11.

Stent 30 is comprised of at least two layers 32 and 34, one of which 32 is a Ni-Ti alloy (50.8 atomic wt. % Ni, balance Ti, transition temperature of A_f=0° C) and normally in the austenitic state, the other of which 34 is a Ni-Ti (49.4 atomic wt. % Ni, balance Ti, transition temperature A_f = 60° C) and normally in the martensitic state. Preferably, the inner layer is 32 and the outer layer is 34. However, this may be reversed and also a plurality of layers, alternating or otherwise, may be utilized in this particular embodiment.

Stent 30 is made to a fabricated size and shape (parent shape) which provides austenitic layer 32 its parent shape and size *i.e.*, its superelastic high temperature shape and size. Obviously, in its as fabricated condition, the Ni-Ti alloy of austenitic layer 32 is selected so as to have a transition temperature range between its austenitic and martensitic states which is lower than body temperature as to ensure that in the body and at body temperatures the austenitic state will always prevail.

On the other hand, martensitic layer 34 is of a Ni-Ti alloy having a transition temperature range significantly greater than body temperature so as to ensure that under body conditions the martensitic state will always prevail and the alloy will never transform to austenite in stent use. This is shown in the graphs of Figure 4a and 4b which demonstrate the relative transition temperatures of layers 32 and 34, respectively for purposes of this invention. It can be seen from these graphs that the normal condition of layer 32 (Figure 4a) at body temperatures and higher is

the austenitic state while the normal condition of layer 34 (Figure 4b) at body temperatures is martensitic.

To manufacture the layered construction, one may make the austenitic portion with any standard metallurgical technique and vapor deposit the martensitic portion on its surface. Other manufacturing techniques such as diffusion bonding, welding, ion beam deposition, and various others will be apparent to those familiar with this art.

Such a stent may be compressed or constrained (deformed to a small diameter) onto a balloon catheter as described for the previous embodiment and captured within a sheath. During the constrainment, austenitic layer 32 may stress induce to a martensitic state. In the alternative, the stent may be cooled below the transition temperature of layer 32 to facilitate its deformation and constrainment. Martensitic layer 34 merely undergoes deformation. Thus the stent may be "loaded" onto a balloon catheter. However, with temperature changes occurring up to body temperature, layer 32 will remain martensite until the constraint is removed. When released in place in the body, stent 30 will expand to a percentage of its self-expanded size and shape due to the transformation of layer 32 from martensite to austenite at which point the balloon may be used to radially expand the stent to a greater permanent diameter by deforming martensitic layer 34. On the other hand, initial deployment can take place without a balloon which may be separately inserted after deployment.

The two component concept of the invention in the layered embodiment of Figure 3 requires both the martensitic and austenitic phase characteristics of shape memory alloy(s) in the two discrete components 32 and 34.

Preferably, the stent is fabricated in such a way that the austenitic layer 32 tends to self-expand stent 30 to a predetermined fabricated diameter (parent shape). The martensitic layer 34 tends to hold back this self-expansion, preventing full expansion. For example, the stent may only be able to self-expand to 75% of its full possible diameter (as determined by the austenitic layer). Therefore, expansion beyond 75% is accomplished by an applied external force, as by the balloon inside the stent. It is suggested that the stent not be expanded beyond its normal fabricated diameter for the austenitic layer 32 will have the tendency of making the stent diameter smaller as it tries to recover its fabricated diameter

(parent shape). If the stent is subjected to a temperature above body temperature and above the transition temperature of the martensitic layer (which is clinically unlikely), the stent will self-expand to the fabricated diameter only. Depending on design size there are thus provided permanent stents capable of fulfilling any needed range of sizes with an adjustable sizing capability.

As is known in the art, the desired properties of the shape memory alloys required for use in this invention may be obtained by alloy composition and working and heat treatment of the alloys, in various combinations or singly.

Manufacturing techniques influence the phase characteristics of the material. Alloy composition, work history, and heat treatment all influence the final characteristics. At a specific operating temperature, say body temperature, the austenite phase material will have a transition temperature below body temperature (i.e., A_f=0°C). The material is capable of taking high strains and recovering after the load is released. The martensite phase material will have a higher transition temperature than body temperature (i.e., A_f=60°C), and is characteristically soft and pliable and retains the deformed shape after load removal. This martensite deformation is caused by detwinning, not the typical plastic deformation, or yielding, of crystal slip.

With reference to Figures 5 and 6, other stent constructions are shown which are similar to the layered version of Figure 3 in so far as utilization of the two component concept of this invention is concerned.

Figure 5a and 5b shows a stent 50 made up of alternating expandable rings 52 and 54 of austenitic and martensitic alloys, respectively, analogous to layers 32 and 34 of the Figure 3 embodiment. Rings 52 and 54 for example are interconnected by strut members 56 which may be of any material capable of rigidly holding the rings together. Other interconnector means may be used. As can be seen in Figure 5b, the placement of strut members 56 does not require them to take part in the radial expansion of the stent and they can therefore be of a relatively ordinary material such as stainless steel.

Referring now to Figure 6, a braided or interwoven construction is shown similar in construction to that of the embodiment of Figure 1. In this embodiment, strands 62 extending to the right in Figure 6 are an alloy in the

austenitic state whereas strands 64 extending to the left in Figure 6 are an alloy in the martensitic state.

Referring now to the graph of Figure 7, it is demonstrated that the two component concept of the invention may be embodied in two phases, i.e., components of a single shape memory alloy and need not be in the form of two discrete components such as layers, members, wires, etc. In the graph of Figure 7, it can be seen that an alloy composition can be selected such that it has a phase transition temperature window that bounds the proposed operating temperatures of the stent, such as the normal body temperature range. Within this transitional window or zone, the material undergoes the phase transition and is effectively compositionally comprised of a ratio of austenitic to martensitic phase depending on the temperature of the stent. This ratio should be selected so as to provide sufficient radial force from the austenite phase while still allowing for further expansion of the martensite phase with a mechanical expansion means such as a balloon. Selecting body temperature as the operating temperature, a Ni-Ti alloy of about 50/50 atomic wt. % composition (range about 49/51%) will provide an acceptable "window" for this embodiment, the two components are the austenite and martensite phases of the nitinol.

The method of making a stent may be described as follows. Age the shape memory material (Ni Ti) until body temperature falls somewhere within the transformation window. Therefore the stent will not fully recover to its high temperature shape at body temperature. An example of this technique is described below.

A stent of tubular 50.8% Ni balance Ti was prepared having a 1.5 mm diameter. It was substantially all austenite at room temperature, the A_f being about 15-20°C and therefore being superelastic at room temperature. The stent was cooled to below room temperature to form substantially all martensite and mechanically expanded to 4.7 mm in diameter. It was maintained at the 4.7 mm in diameter and heat treated at 500°C for 30 minutes and water quenched. Finally, it was again cooled to below room temperature to form substantially all martensite and compressed to a diameter of 1.5 mm. After deployment and at body temperature the stent has a diameter of 3.5 mm. At about 70% of full expansion, i.e., about 40°C it had a diameter of 4.5 mm and at 42°C it had a fully expanded diameter of 4.7 mm.

This method works fairly well, but due to the slope of the temperature versus diameter plot being extremely vertical at body temperature, a small change in body temperature, or manufacturing control, can have a large impact on the actual self expansion diameter. As can be seen from Figure 7, the slope of the line between A_f and A_s is rather steep with small changes in temperature leading to large changes in percent austenite and consequently large changes in diameter of a stent made of such an alloy. Figure 7a shows a temperature versus diameter plot. Three methods of modifying the slope of the line on the temperature versus diameter graph are cold work, pseudoelastic prestraining, and amnesia inducement, illustrated in Figures 7b, 7c and 7d, respectively.

COLD WORK

Residual cold work in nitinol draws out or masks the point of A_f on the diameter versus the temperature curve. This is seen by the sluggish increase in diameter as temperature increases in the last 20-30% of recover. By utilizing the effects of cold work, the effects of temperature change on diameter can be reduced in the last 20 to 30% of stent expansion. Shown in Figure 7b is an example of a temperature versus diameter plot for a cold worked part. Figure 7a above shows an example of a part without cold work.

PSEUDOELASTIC PRESTRAINING

Utilizing the effects of pseudoelastic prestraining (S. Eucken and T.W. Duerig, *ACTA Metal*, Vol. 37, No. 8, pp 2245-2252, 1989) one can create two distinct plateaus in the stress-strain behavior. This difference in stress strain behaviors can be directly linked to two distinct A_f temperatures for the two plateaus. By placing the transition between the two plateaus at the transition from self expanding to balloon expanding, i.e., 70%, one can control the characteristics of the stent at body temperature. The goal would be to place the A_f temperature for the first plateau (from maximum compression to 70% expansion) below body temperature such that the stent has self expanding characteristics. The A_f temperature for the second plateau would be above body temperature such that there is no additional self expansion in this region (70 to 100% expansion) a mechanical device, like a balloon, can then be used to custom size the stent between 70% and 100% of the high temperature shape. Results of such a technique is shown in Figure 7c.

AMNESIA INDUCEMENT

One of the characteristics of nitinol is cycle amnesia. This was also discussed about in the article referred to immediately above. As nitinol is cycled from its heat set shape as shown in Figure 7d, there is an increase in the amount of amnesia to recover to the heat set shape with each cycle. As long as this amnesia is not caused by permanent plastic deformation, the amnesia can be removed by heating the part above M_d. This shows there is martensite left in the part after cycling which is preventing full recovery in the austenite phase (just above A_f). This presence of non recoverable martensite (below M_d) is what may be used for the balloon expansion region of the stent.

Figures 8-11 represent examples of various expandable configurations (a = closed, b = expanded) which may be incorporated into the devices of this invention. The version shown in Figures 10a and 10b may be modified as shown in Figures 10c and 10d (closed and open, respectively) by omitting portions (indicated at 100 in Figures 10c and 10d) as to render the stent flexible for articulation. This may be done to other of the structures as well to improve flexibility.

Yet another version of a device incorporating the two component concept of the invention is shown in Figure 12. In this embodiment, a fragment of a stent 110 is shown. The stent includes a self-expanding component 112 and a deformable, external force expandable component 114. Self expanding component 112 may be resilient spring-like metal such a stainless steel or it may preferably be a shape memory alloy in the austenitic state. Component 114 may be any deformable metal or the like such as annealed stainless steel or preferably a shape memory alloy in the martensitic state. The two components may simply be mechanically, welded or bonded together. Functions and operations are as described hereinabove.

Referring to Figure 13 a version analogous to the embodiment of Figure 12 is shown in which the two component concept is again embodied as different zones or portions of a single metal material.

As shown in Figure 13, a stent 120 (fragment showing) is of a self-expanding component 122 and a deformable component 124, both of which may be a single metal as spring steel or austenitic Ni-Ti which has been appropriately treated with respect to component 124 as by localized heat treatment or the like to alter the characteristics of the material of the 122 component so as to render it deformable or

martensitic, depending on whether it is merely resilient or is austenitic. Again, function and operation are the same as with other embodiments.

Referring now to Figures 14-16, a multi-strand braided stent is shown in Figure 15. Each strand 150 in the stent is a micro-cable. That is, each strand is made up of a plurality of wires 152 and 154 as is seen in Figures 15 and 16. Each of the wires 152 and 154 consists of two different nitinol alloys as seen best in Figure 16, or one nitinol and one ordinary metal such as stainless steel, platinum or tantalum. The latter two would provide enhanced radiopacity. One nitinol alloy wire 154 has an austenitic finish (A_f) temperature less than body temperature. The other wire 152 could be nitinol having an A_s (austenitic start) greater than body temperature. Also, it could be an ordinary metal. Additionally, one or more of the strands may be of a biodegradable material such as a plastic or may be of a material including an absorbable drug.

Since the two alloys are stranded into micro-cable one does not have to engage in selective, discrete heat treating methods to produce both shape memory and martensitic effects.

Radiopaque portions or coatings may be included on any parts of these stents as is known in the prior art.

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

WHAT IS CLAIMED

1. As a tissue supporting device a constrainable, self-expanding member of generally tubular shape, said device comprising a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion, said second portion being deformable by an external force but being non-self-expandable; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the member being self-expanding when unconstrained to an initially deployed diameter due to the resiliency of the first portion; the first and second portions being so associated with respect to each other and the member such that the device may be further deformed due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

2. The device of claim 1 wherein the first and second portions are of metal.

3. The device of claim 2 wherein the first portion is a spring metal and the second portion is an annealed metal.

4. The device of claim 1 wherein the first and second portions are discrete portions in the circumference of the device body.

5. The device of claim 1 wherein the first and second portions are of a shape memory alloy.

6. The device of claim 5 wherein the first and second portions are of austenite and martensite, respectively.

7. The device of claim 6 wherein the first and second portions are in the form of layers.

8. The device of claim 1 wherein the first and second portions are strands.

9. The device of claim 1 wherein the first component is a nitinol alloy.

10. The device of claim 1 wherein the first component is superelastic and the second component is any deformable material.

11. The tissue supporting device of claim 1 wherein the self-expanding member comprises a permanent self-expanding stent having a generally tubular body

of a predetermined fabricated diameter; wherein at normal body temperatures the first portion is comprised of a shape-memory, superelastic austenitic alloy portion and the second portion is comprised of a shape-memory, martensitic alloy portion; the superelastic austenitic alloy portion having a transition temperature from martensitic to austenitic less than body temperature while the martensitic alloy portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensitic alloy portion and the superelastic austenitic alloy portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two alloy portions act in combination to allow, upon transformation of the first portion from austenitic to martensitic at a temperature below the transition temperature, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the first portion from martensitic back to austenitic to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the first portion, the shape memory of the superelastic austenitic first portion tending to form the stent to a larger diameter due to its shape memory but being restrained therefrom by the second martensitic alloy portion whereby the first portion can be deformed by external force without plastic deformation along with the second portion to an enlarged stent diameter beyond that of the self-expanded diameter.

12. The stent of claim 11 wherein the first and second portions are in the form of layers in overlying relationship.

13. The stent of claim 11 wherein the first and second portions are different phases in an alloy.

14. The stent of claim 11 wherein the first and second portions are in the form of longitudinally arranged interconnected alternating rings.

15. The stent of claim 11 comprised of a plurality of cable-like strands and wherein each strand is comprised of a plurality of wires some of which are of the first portion and some of which are of the second portion.

16. The stent of claim 11 wherein the alloy compositions is about 50Ni/50Ti atomic weight percent.

17. The stent of claim 11 wherein the alloy is a cold worked alloy.

18. The stent of claim 11 wherein the alloy is a prestrained alloy.

19. The stent of claim 11 wherein the alloy exhibits cycle amnesia.

20. A tissue supporting device comprising a constrainable, self-expanding member of generally tubular shape, said member comprising a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion, said second portion being deformable by an external force but being non-self-expandable; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the member being self-expanding when unconstrained to an initially deployed diameter due to the transformation of the first portion from a martensitic to an austenitic state; the first and second portions being affixed to each other or braided; the first and second portions being so associated with respect to each other such that the device may be further expanded due to the deformability of the second portions by an external force to radially enlarge the member to an enlarged self sustained fully deployed diameter for providing tissue support.

21. The device of claim 20 wherein the first and second portions are of metal.

22. The device of claim 20 wherein the first and second portions are of a shape memory alloy.

23. The tissue supporting device of claim 20 wherein the first and second portions are mechanically joined, welded together, bonded together or joined by vapor deposition or ion beam deposition of the first portion onto the second portion.

24. A tissue supporting device comprising a constrainable, self-expanding member of generally tubular shape, said member comprising a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion, said second portion being deformable by an external force but being non-self-expandable; said first and second portions being discrete portions in the circumference of said tissue supporting device; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the member being self-expanding when unconstrained to an initially deployed diameter due to the transformation of the first portion from a martensitic to an austenitic state; the first and second portions being so associated with respect to

each other such that the device may be further expanded due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing tissue support.

25. A tissue supporting device comprising a constrainable, self-expanding member of generally tubular shape, said member comprising a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion, said second portion being deformable by an external force but being non-self-expandable; said first and second portions being comprised of a shape memory alloy; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the member being self-expanding when unconstrained to an initially deployed diameter due to the transformation of the first portion from a martensitic to an austenitic state; the first and second portions being so associated with respect to each other such that the device may be further expanded due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing tissue support.

26. A tissue supporting device comprising a constrainable, self-expanding member of generally tubular shape, said member comprising a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion, wherein the first and second portions are of shape memory alloy, austenite and martensite, respectively, said second portion being deformable by an external force but being non-self-expandable; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the member being self-expanding when unconstrained to an initially deployed diameter due to the transformation of the first portion from a martensitic to an austenitic state; the first and second portions being affixed to each other or braided; the first and second portions being so associated with respect to each other such that the device may be further expanded due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged self sustained fully deployed diameter for providing tissue support.

27. A tissue supporting device comprising a constrainable, self-expanding member of generally tubular shape further comprising a predetermined fabricated

diameter; said member comprising a first portion of resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion, said second portion being deformable by an external force but being non-self-expandable; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the member being self-expanding when unconstrained to an initially deployed diameter due to the resiliency of the first portion; the first and second portions being so associated with respect to each other such that the device may be further expanded due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing tissue support; wherein at normal body temperatures the first portion is comprised of a shape-memory, superelastic austenite alloy portion and the second portion is comprised of a shape-memory, martensite alloy portion; the superelastic austenite alloy portion having a transition temperature from martensite to austenite less than body temperature while the martensite alloy portion has a transition temperature from martensite to austenite greater than body temperature, the martensite alloy portion and the superelastic austenite alloy portion being constructed, arranged and associated with respect to each other such that the two alloy portions act in combination to allow constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter, and upon transformation of the first portion from martensite back to austenite to self-expand the stent back to a self-expanded diameter that is about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the first portion, the shape memory of the superelastic austenite first portion tending to form the stent to a larger diameter than the predetermined fabricated diameter and the self-expanded diameter due to its shape memory but being restrained therefrom by the second martensite alloy portion , wherein the first portion can be deformed by external force along with the second portion to an enlarged stent diameter beyond that of the self-expanded diameter.

28. The tissue supporting device of claim 27 wherein the first and second portions are in the form of portions in overlying relationship.

29. The tissue supporting device of claim 27 wherein the alloy composition is about 50Ni/50Ti atomic weight percent.

30. The tissue supporting device of claim 27 wherein the alloy composition is a cold worked alloy.

31. The tissue supporting device of claim 27 wherein the alloy composition is a prestrained alloy.

32. The tissue supporting device of claim 27 wherein the alloy composition exhibits cycle amnesia.

33. A permanent self-expanding stent for providing permanent tissue support, said stent having a generally tubular body of a predetermined fabricated diameter and being comprised, at about normal body temperatures, of a first portion comprised of a shape-memory, superelastic, austenite alloy and a second portion comprised of a shape memory, martensite alloy; the shape-memory, superelastic austenite alloy portion having a transition temperature from martensite to austenite less than body temperature while the martensite alloy portion has a transition temperature from martensite to austenite greater than body temperature, the martensite alloy portion and superelastic austenite alloy portion being constructed, arranged and associated with respect to each other such that the two alloy portions act in combination to allow constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the first portion from martensite back to austenite to self-expand the stent back to a self-expanded diameter that is about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the first portion, the shape memory of the superelastic austenitic first portion tending to form the stent to a larger diameter than the self-expanded diameter and the predetermined fabricated diameter due to its shape memory but being restrained therefrom by the second martensitic alloy portion, wherein the first portion can be deformed by external force along with the second portion to an enlarged stent diameter beyond that of the self-expanded diameter.

34. A permanent self-expanding stent having a generally tubular body of a predetermined fabricated diameter comprised, at about normal body temperatures, of a shape-memory, superelastic, austenite alloy portion and a shape memory, martensite alloy portion, the superelastic austenite alloy portion having a transition temperature from martensite to austenite less than body temperature while the martensite alloy portion has a transition temperature from martensite to austenite greater than body

temperature, the martensite alloy portion and superelastic austenite alloy portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two alloy portions act in combination to allow, upon transformation of the austenite alloy portion to martensite at a temperature below the transition temperature, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite alloy portion from martensite back to austenite to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite superelastic portion, the shape memory of the superelastic austenite portion tending to form the stent to a larger diameter due to its shape memory but being restrained therefrom by the martensite alloy portion wherein the austenite alloy portion can be deformed by external force without plastic deformation along with the martensite portion to an enlarged stent diameter beyond that of the self-expanded diameter.

35. A permanent self-expanding stent having a generally tubular body of a predetermined fabricated diameter, comprised, at about normal body temperatures, of a shape-memory, superelastic, austenite phase portion and a shape memory, martensite phase portion, the superelastic austenite phase portion having a transition temperature from martensite to austenite less than body temperature while the martensite phase portion has a transition temperature from martensite to austenite greater than body temperature, the martensite phase portion and superelastic austenite phase portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two portions act in combination to allow, upon transformation of the austenite phase portion to martensite, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back toward the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite superelastic portion, the shape memory of the superelastic austenitic portion tending to form the stent to the fabricated diameter due to its shape memory but being restrained therefrom by the martensite portion wherein the austenite portion recovery back toward the fabricated diameter can be assisted by external force along with the deforming of the martensite portion without slip

deformation to an enlarged stent diameter beyond that of the fabricated diameter.

Fig. 1

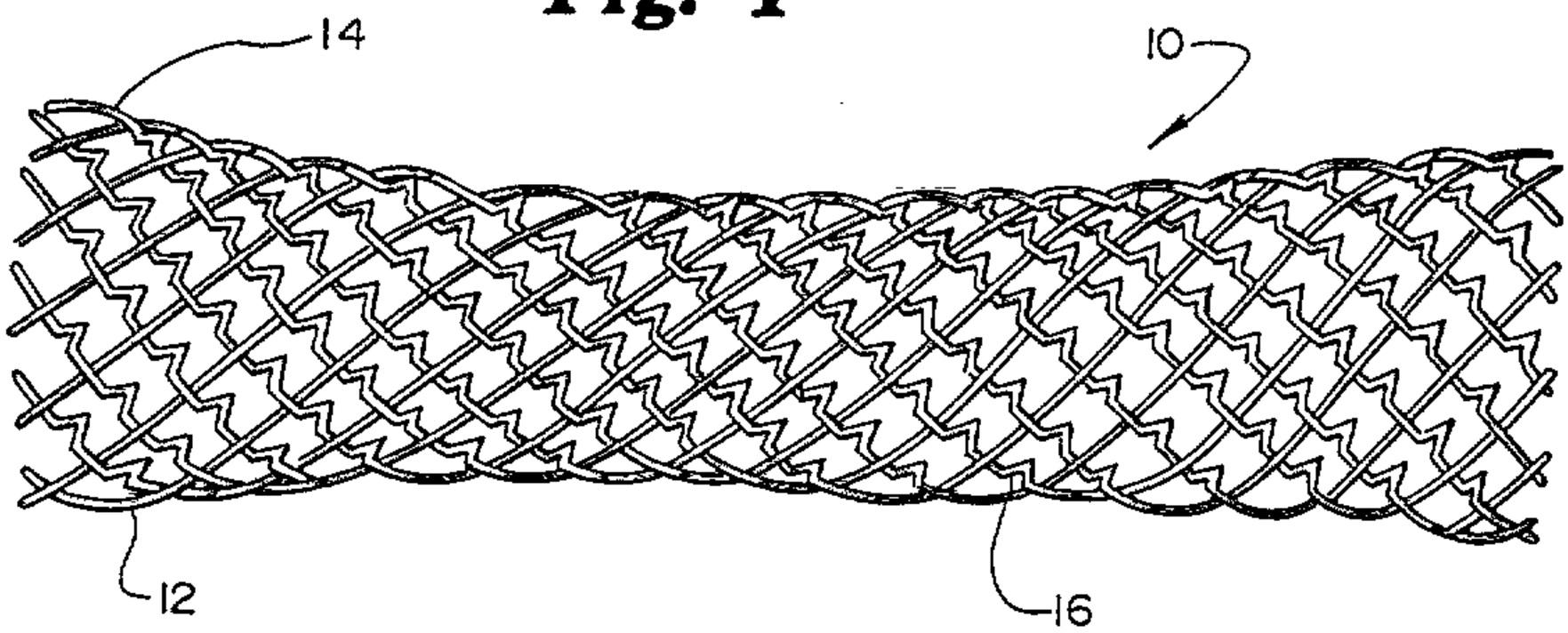


Fig. 2

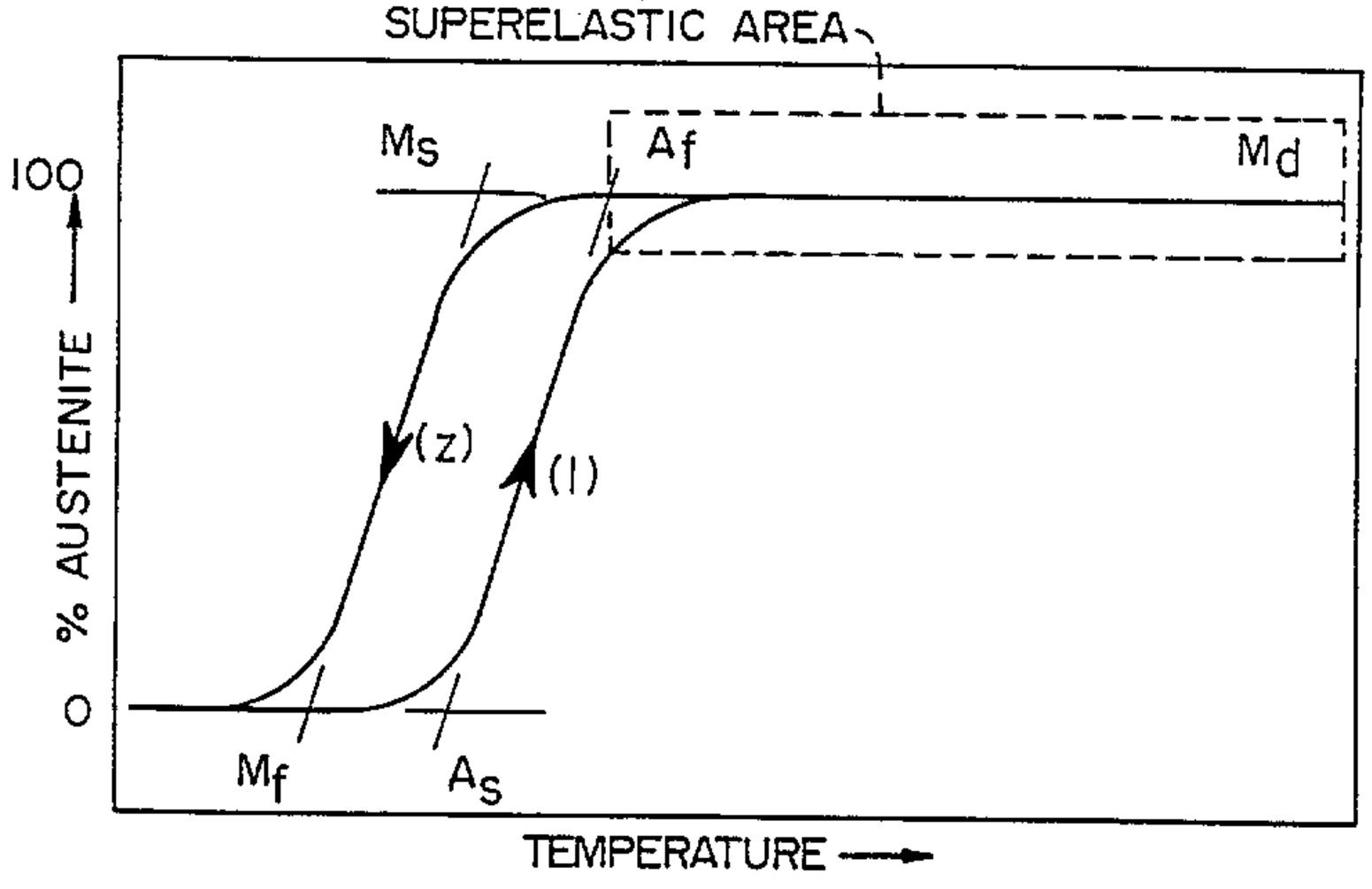


Fig. 3

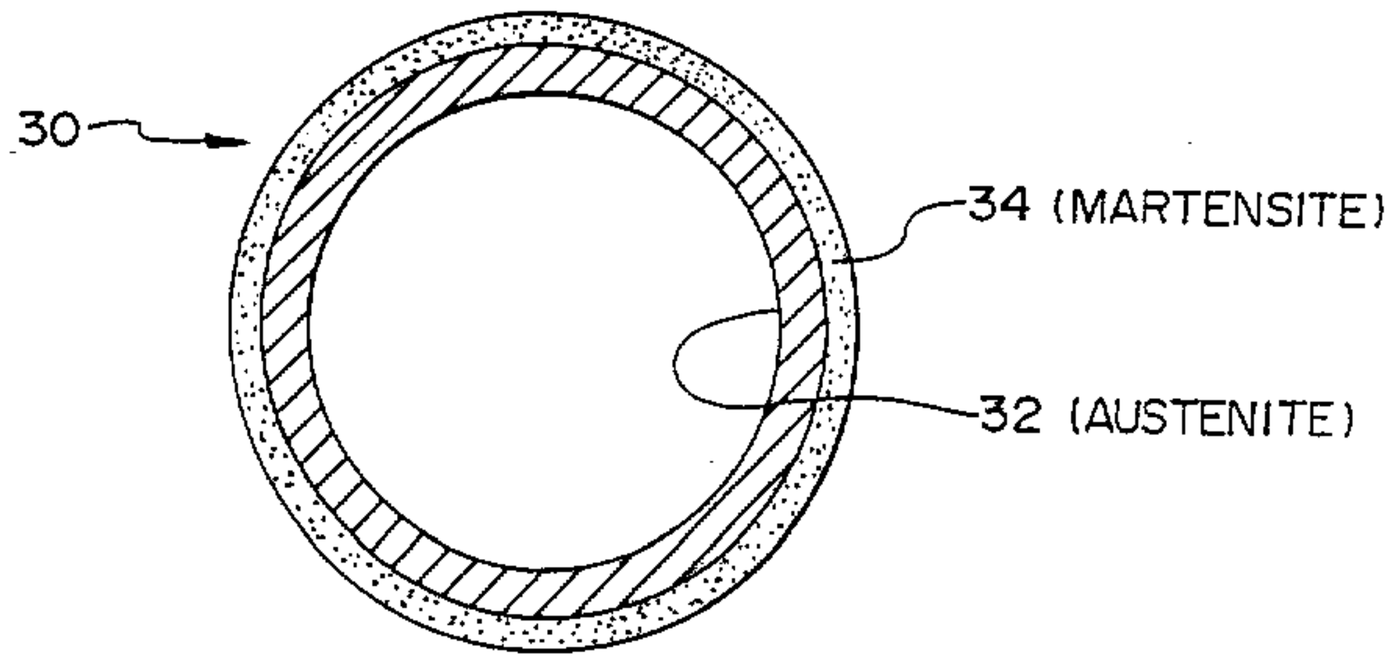


Fig. 4a (LAYER 32)

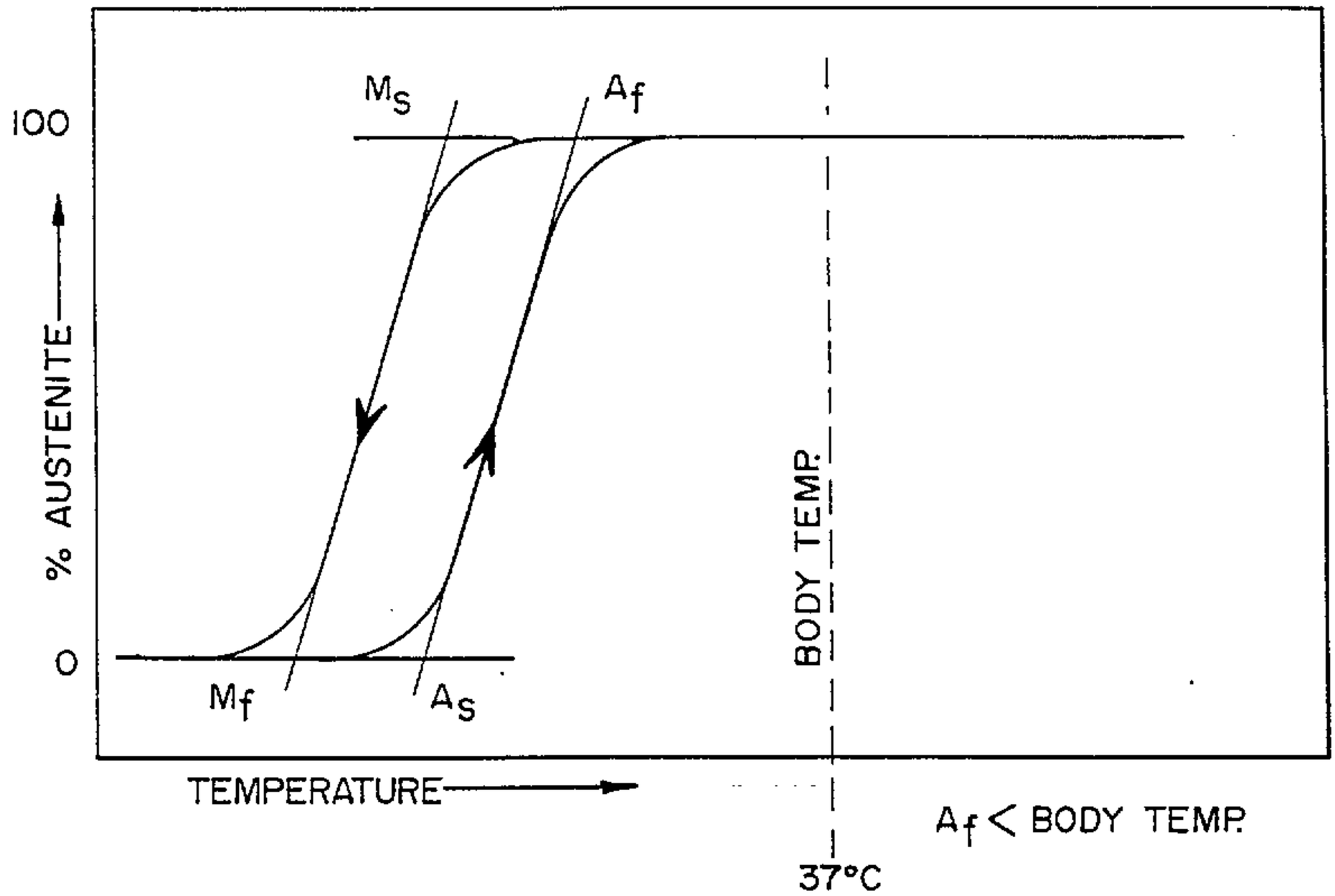


Fig. 4b (LAYER 34)

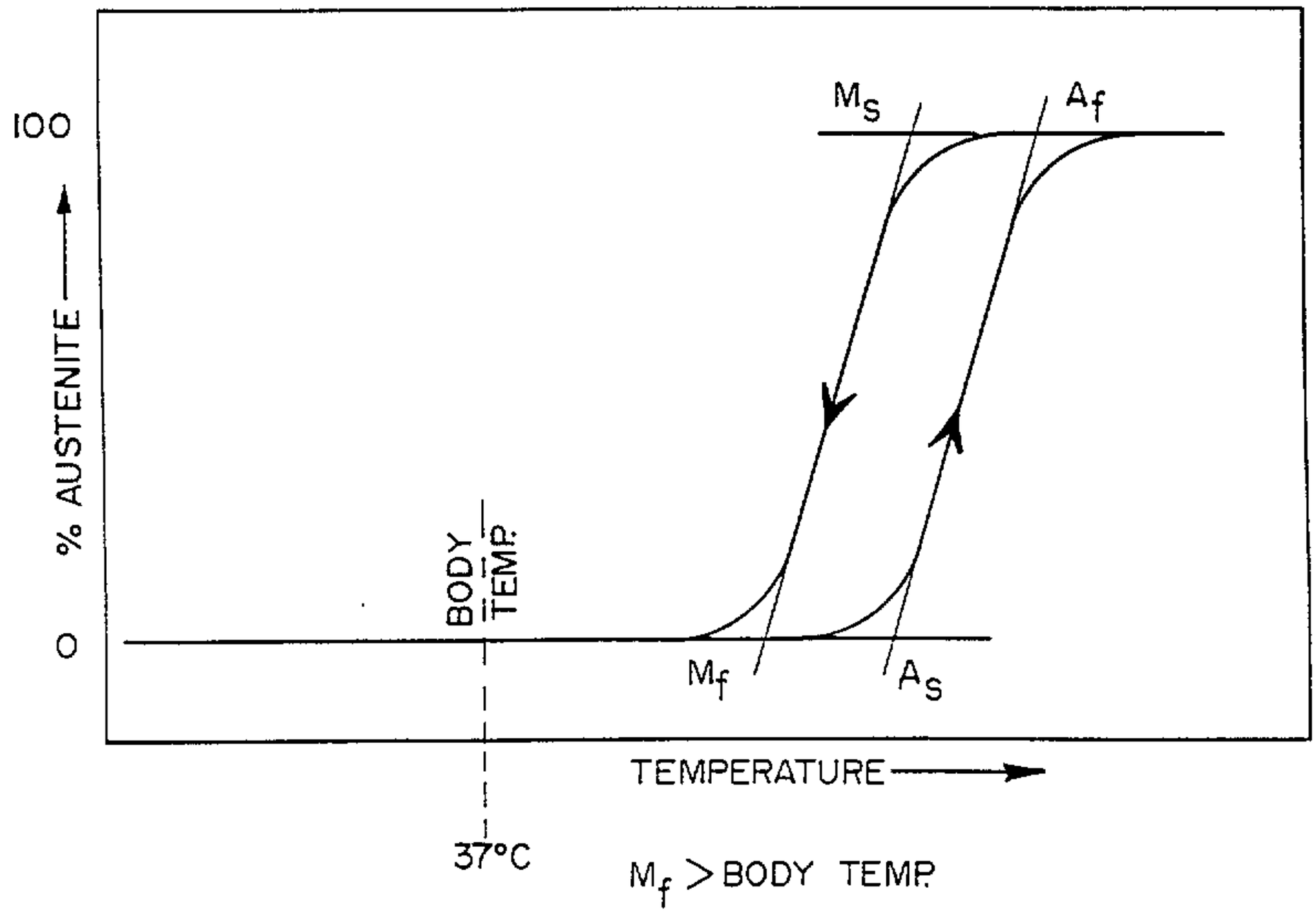


Fig. 5a

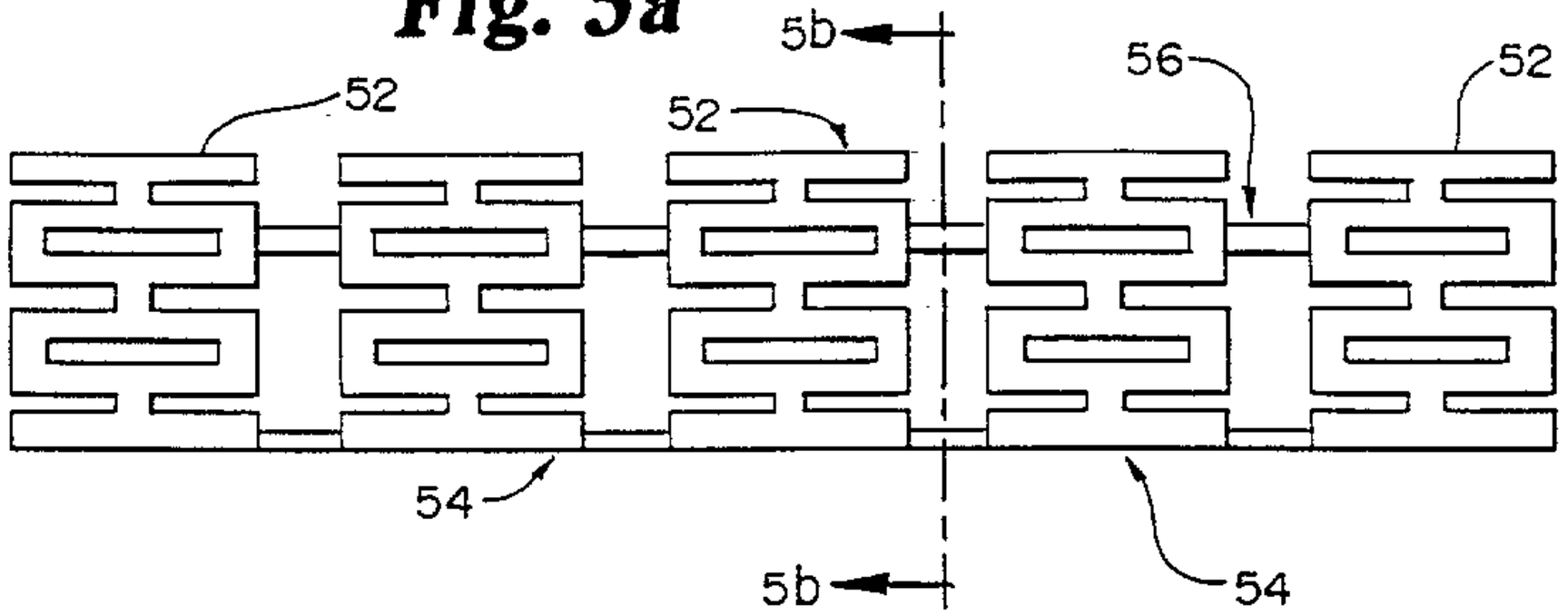


Fig. 5b

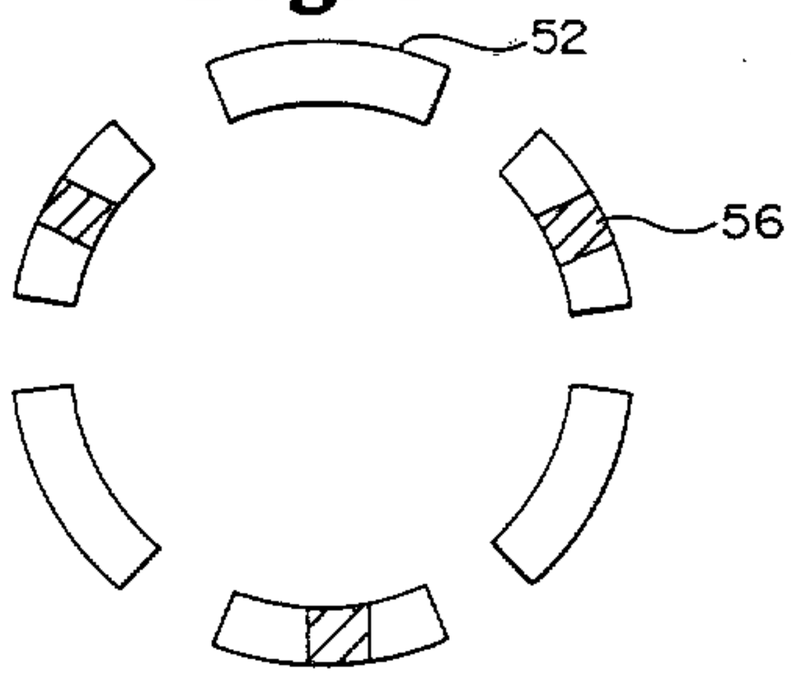


Fig. 6

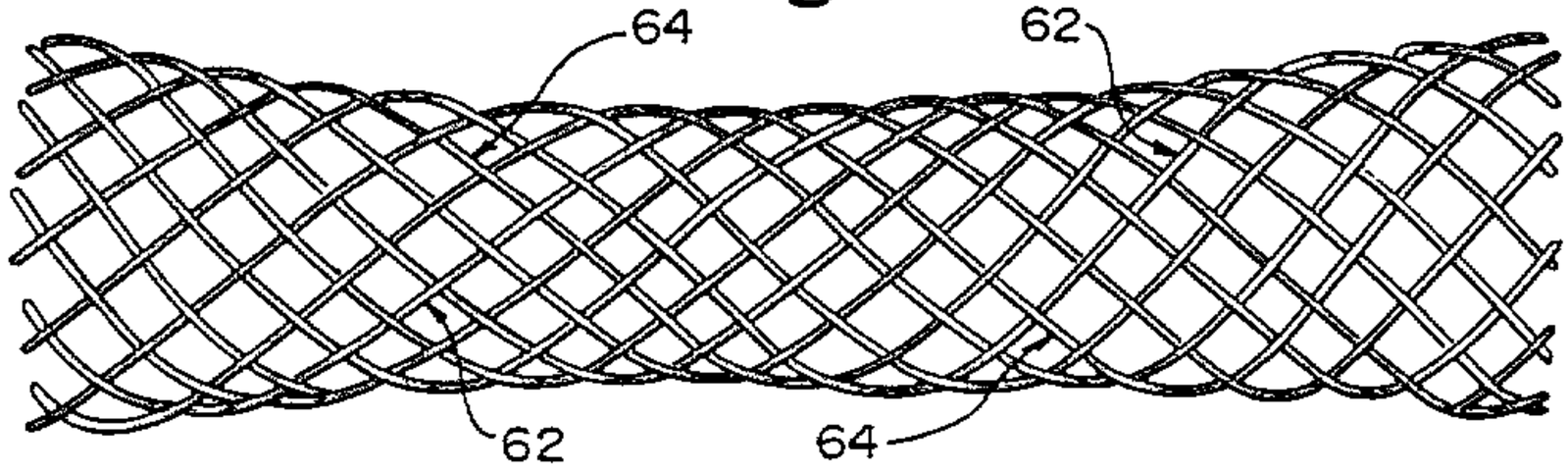


Fig. 7

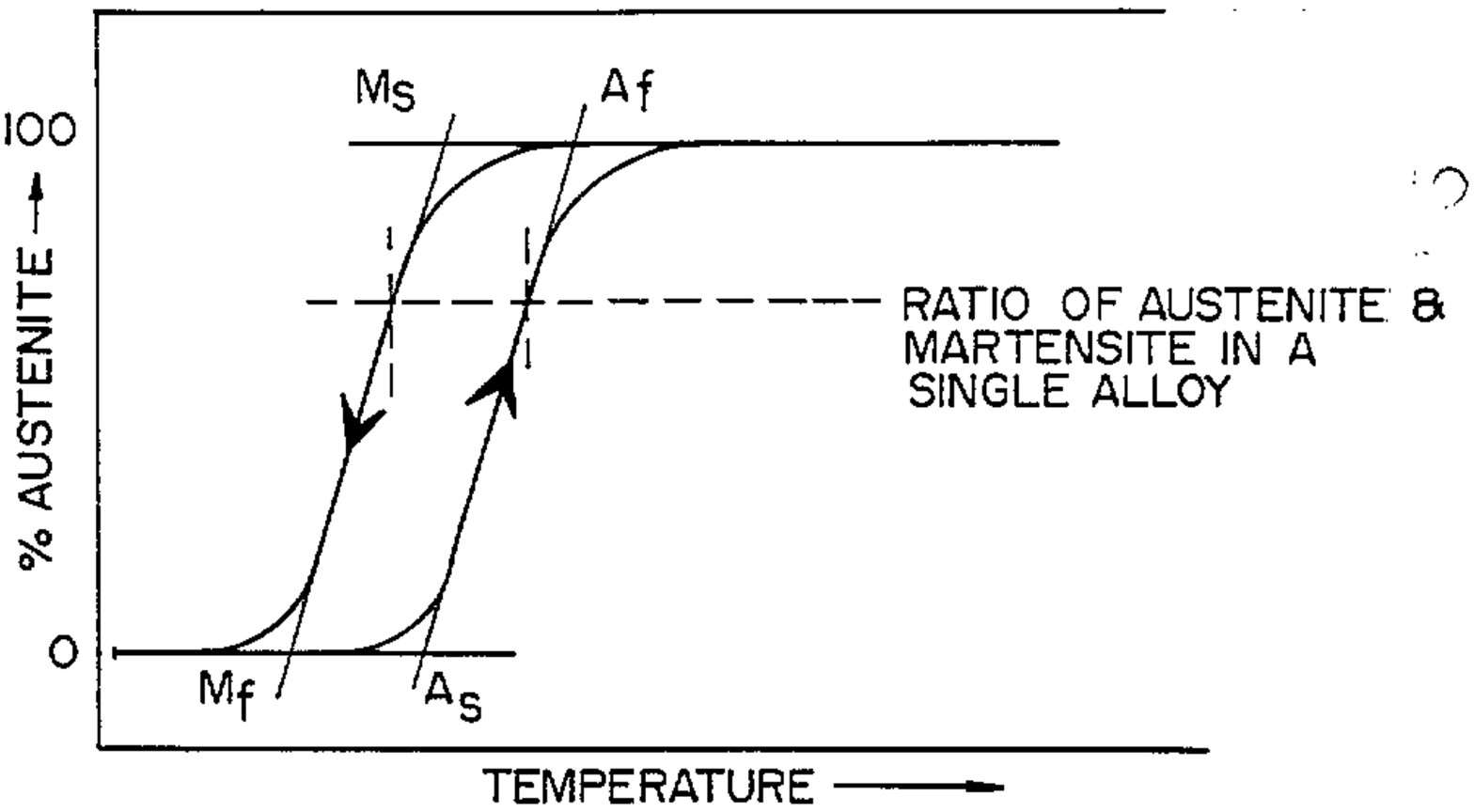


Fig. 8a

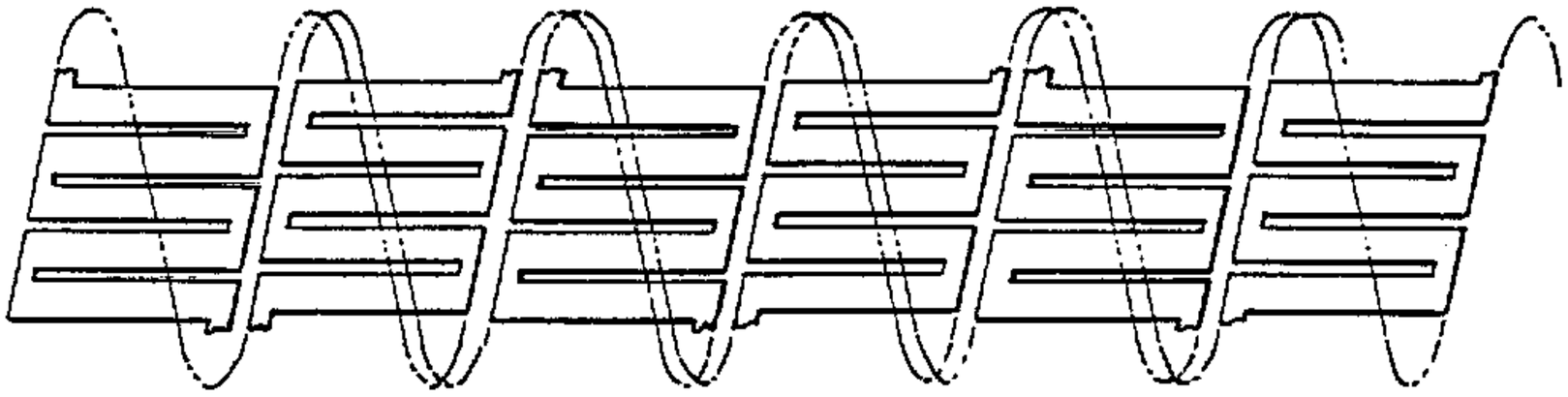


Fig. 8b

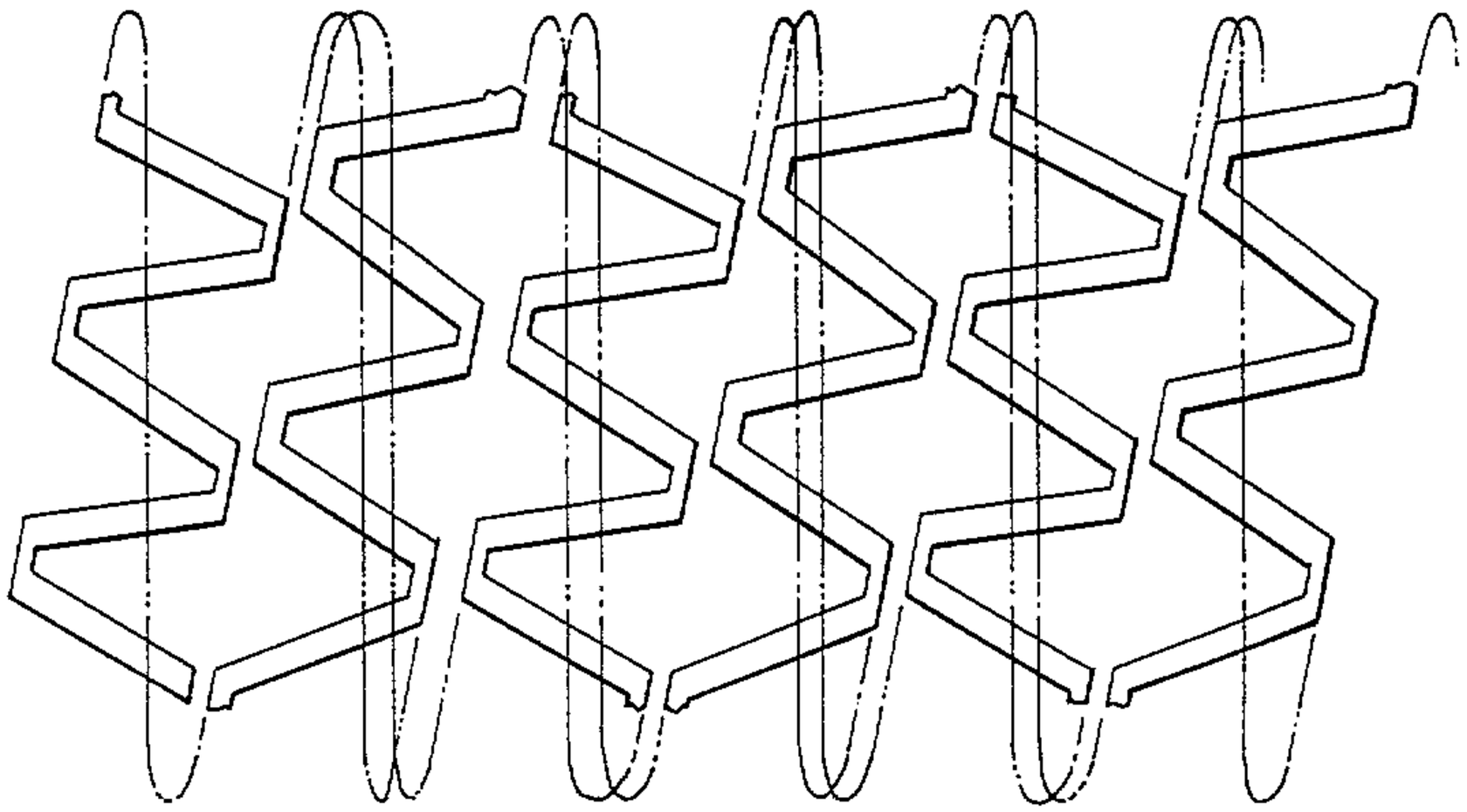


Fig. 7a

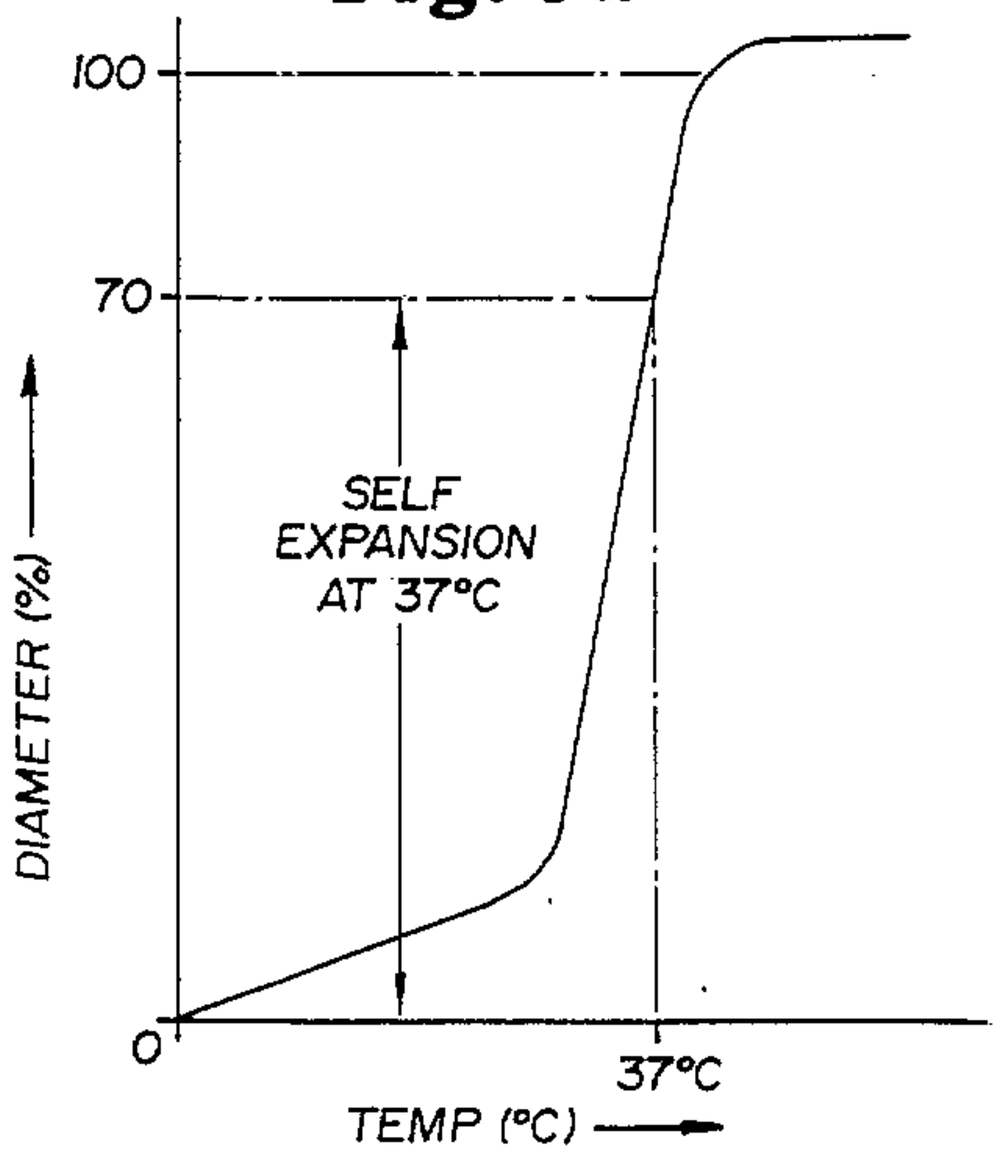

100
70
0
SELF
EXPANSION
AT 37°C
37°C
DIAMETER (%)
TEMP (°C)

Fig. 7b

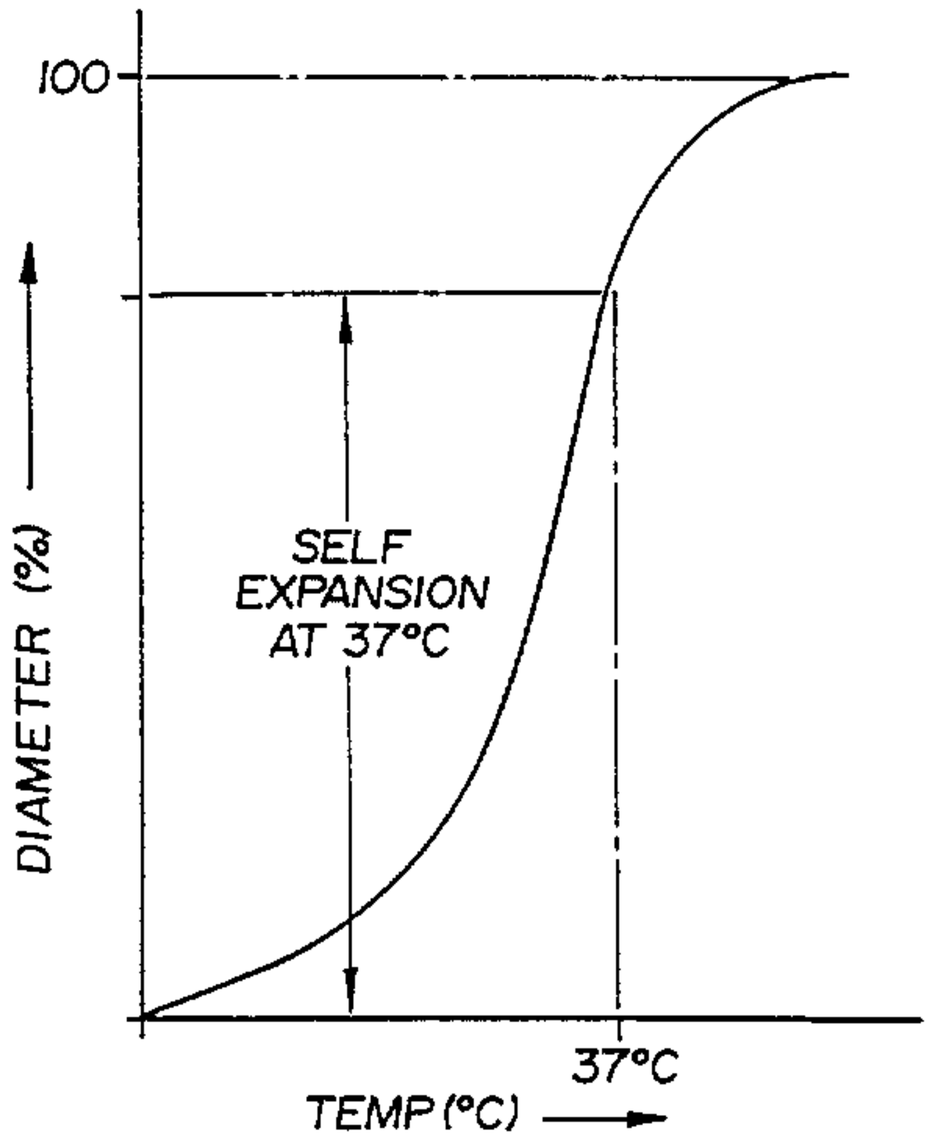

100
SELF
EXPANSION
AT 37°C
37°C
DIAMETER (%)
TEMP (°C)

Fig. 7c

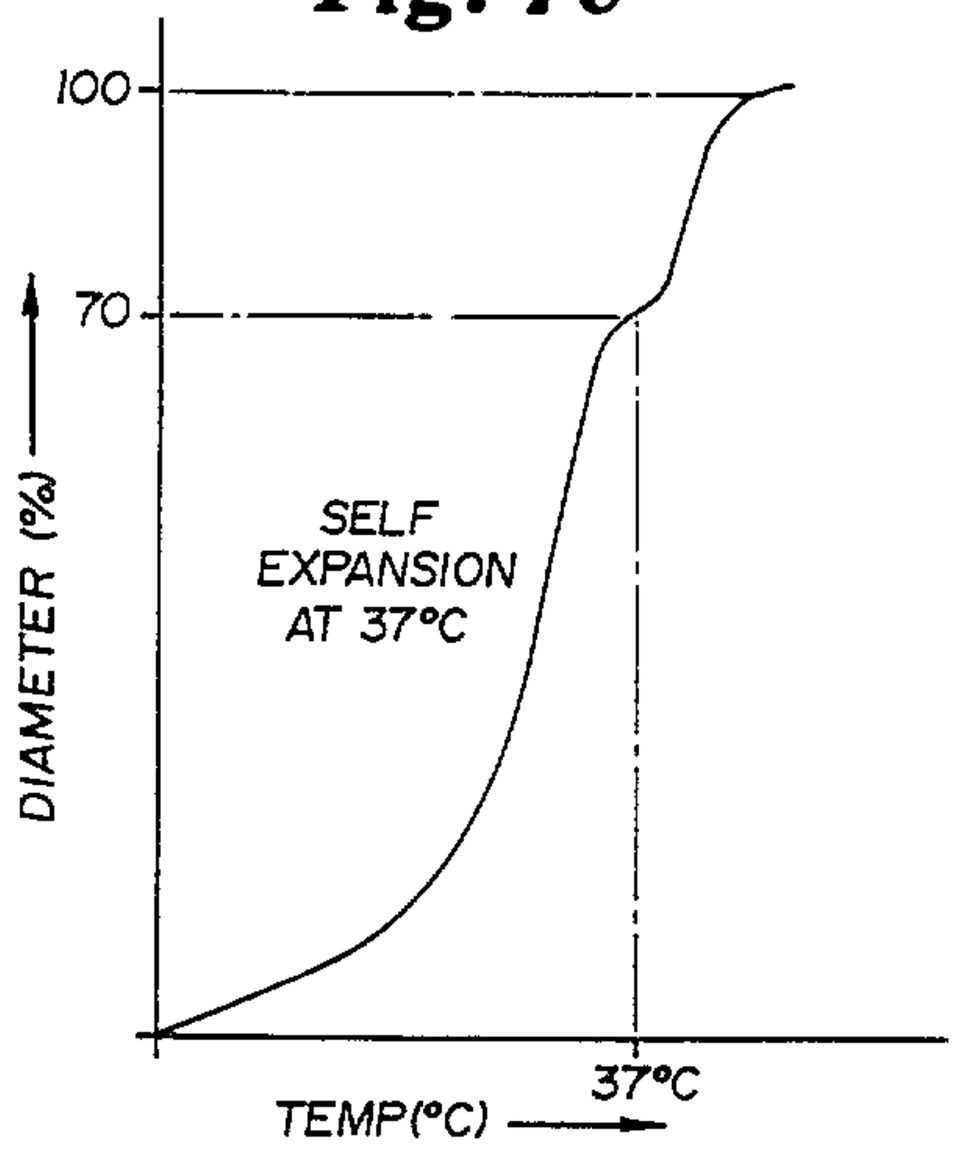
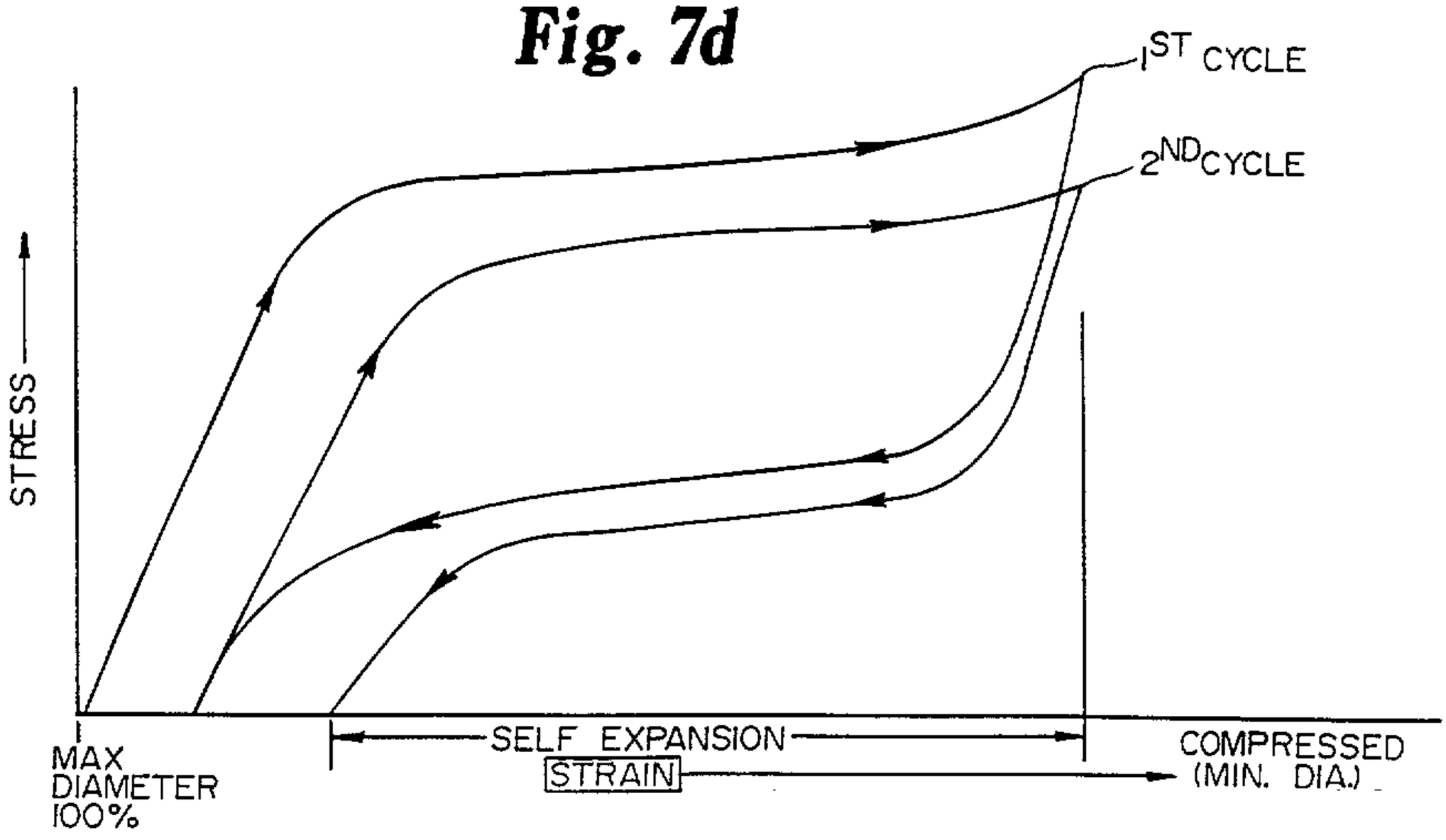

100
70
DIAMETER (%)
SELF
EXPANSION
AT 37°C
37°C
TEMP(°C)

Fig. 7d


1ST CYCLE
2ND CYCLE
STRESS
SELF EXPANSION
STRAIN
MAX
DIAMETER
100%
COMPRESSED
(MIN. DIA.)

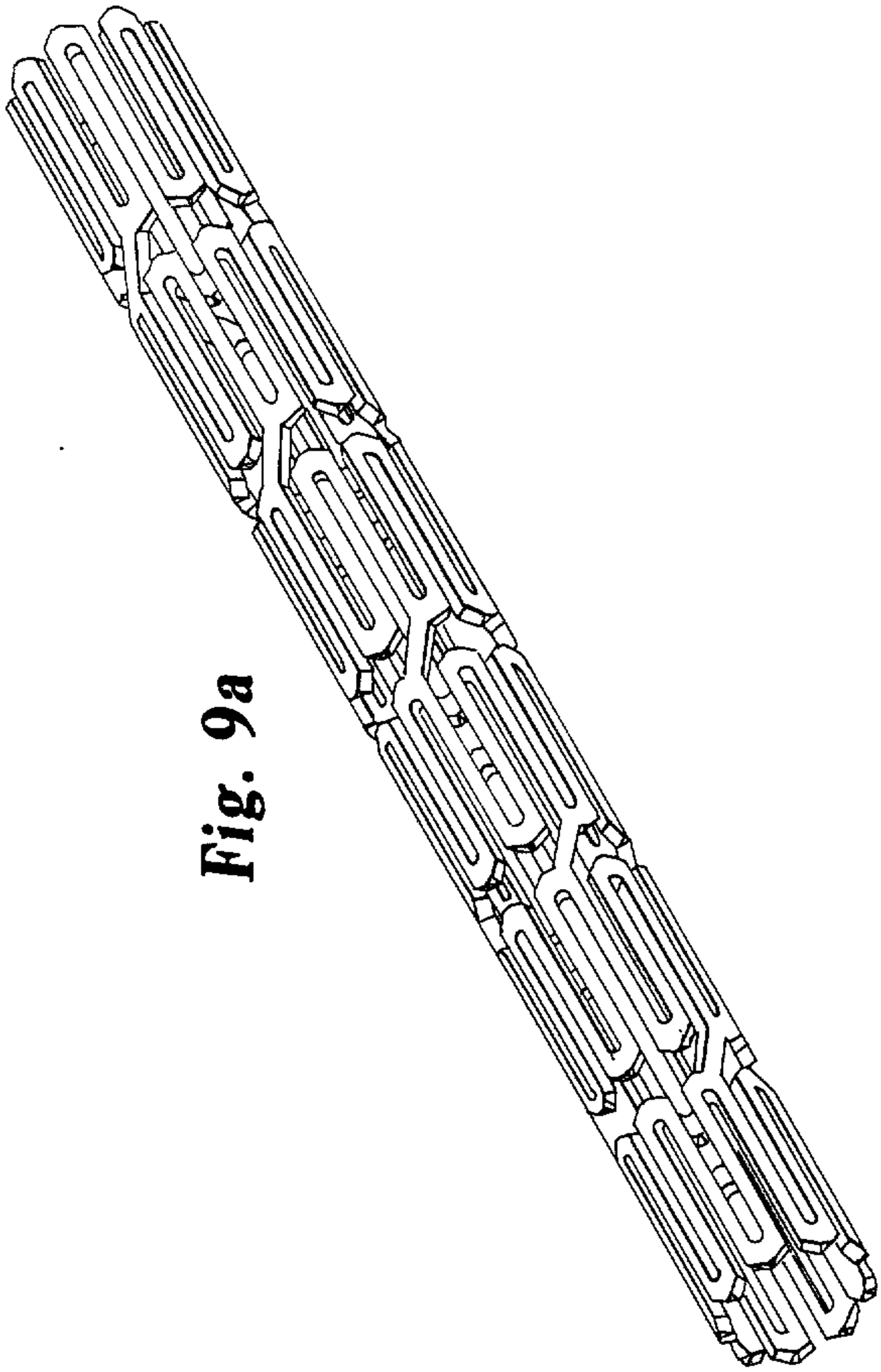


Fig. 9a

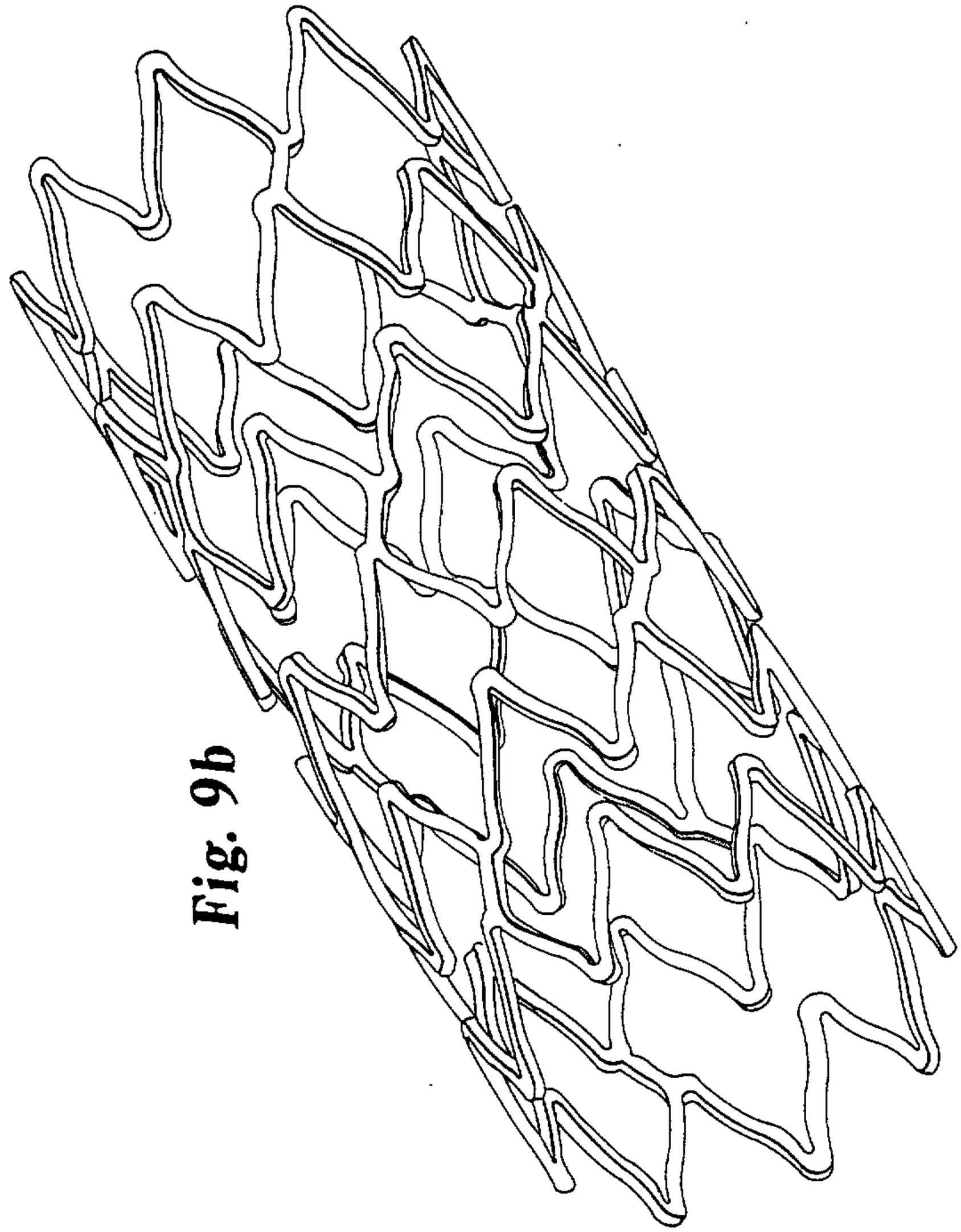


Fig. 9b

Fig. 10a

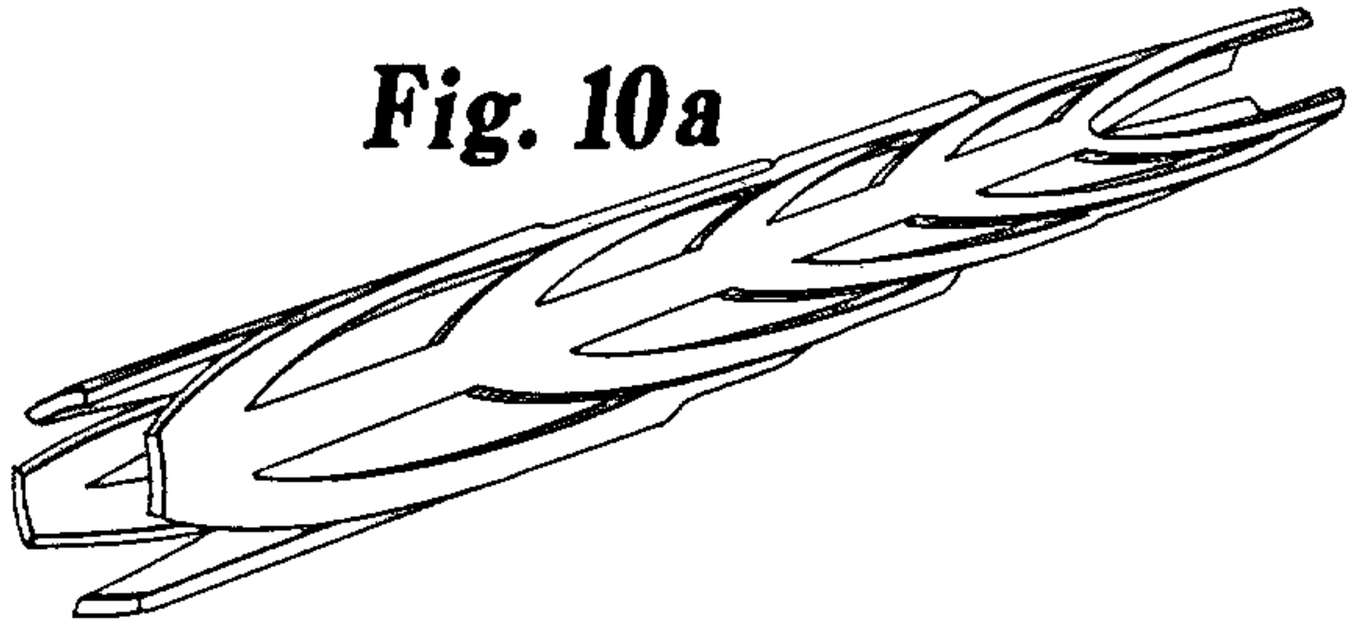


Fig. 10b

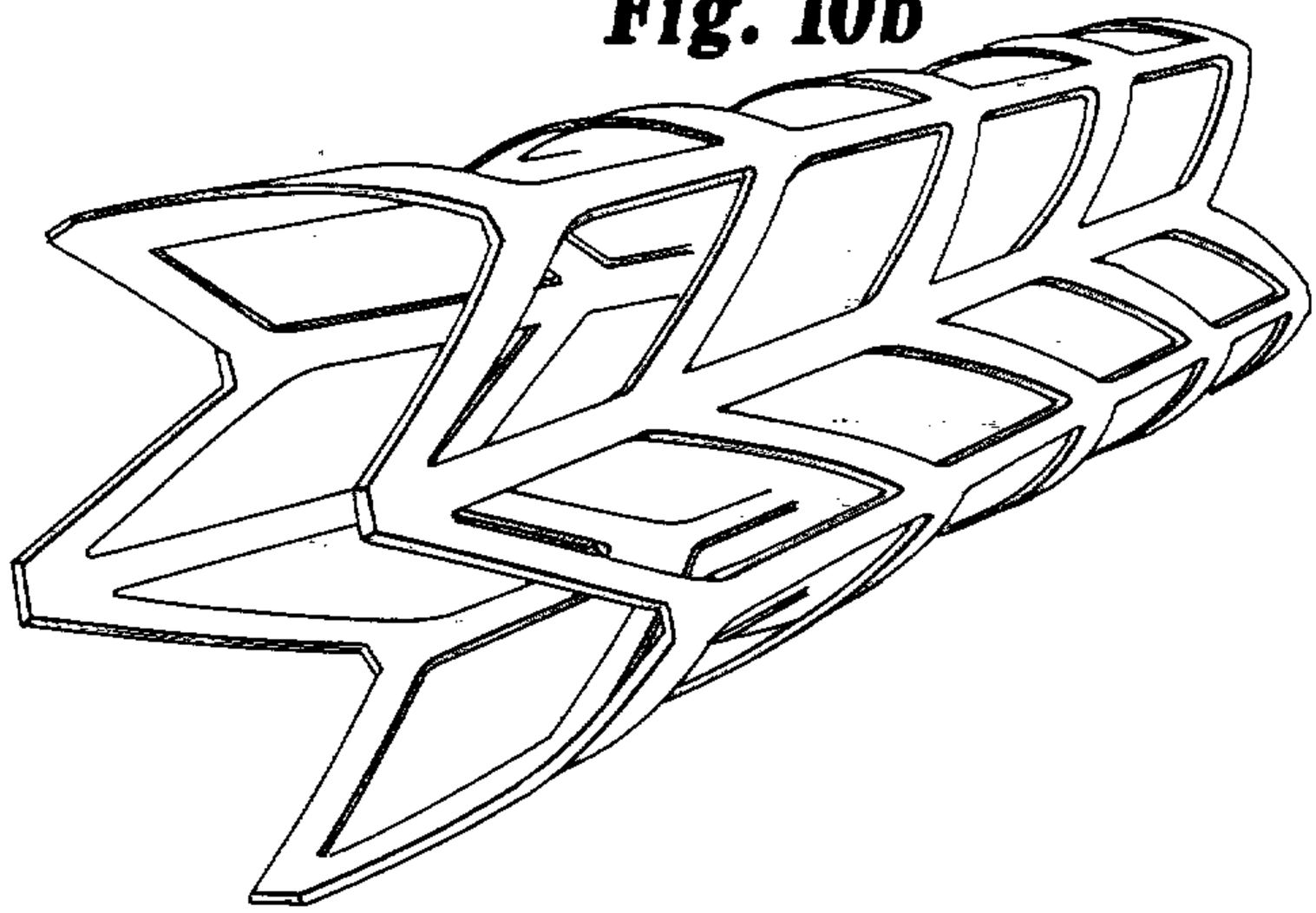


Fig. 10c

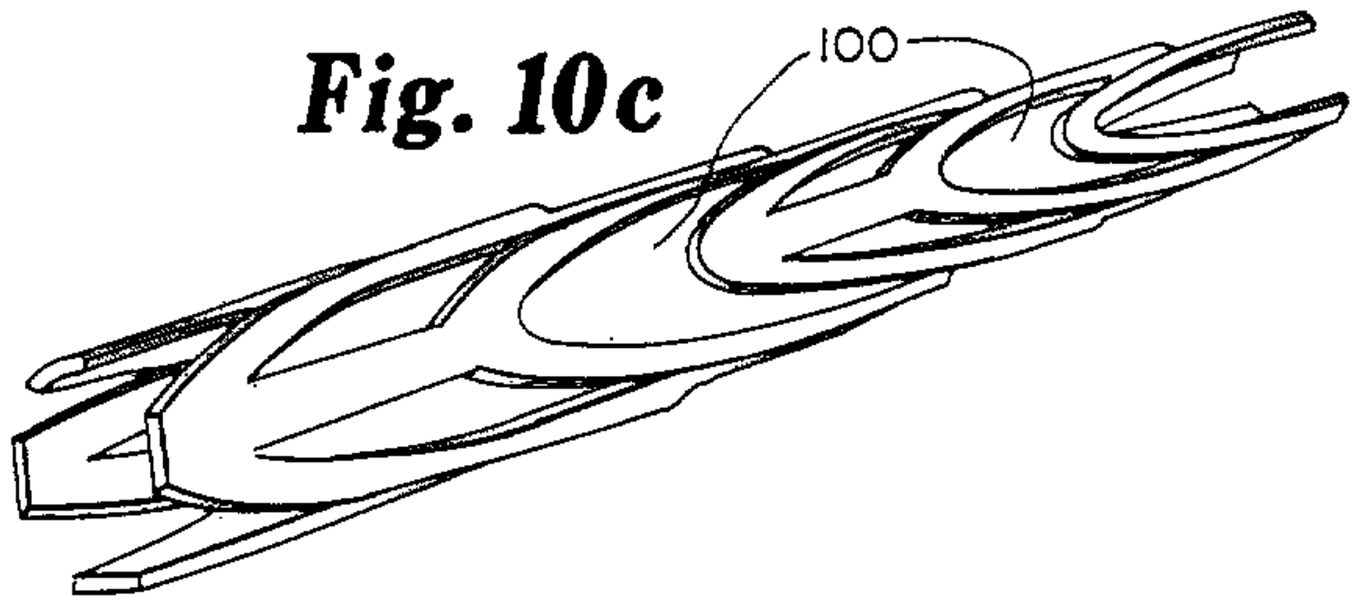


Fig. 10d

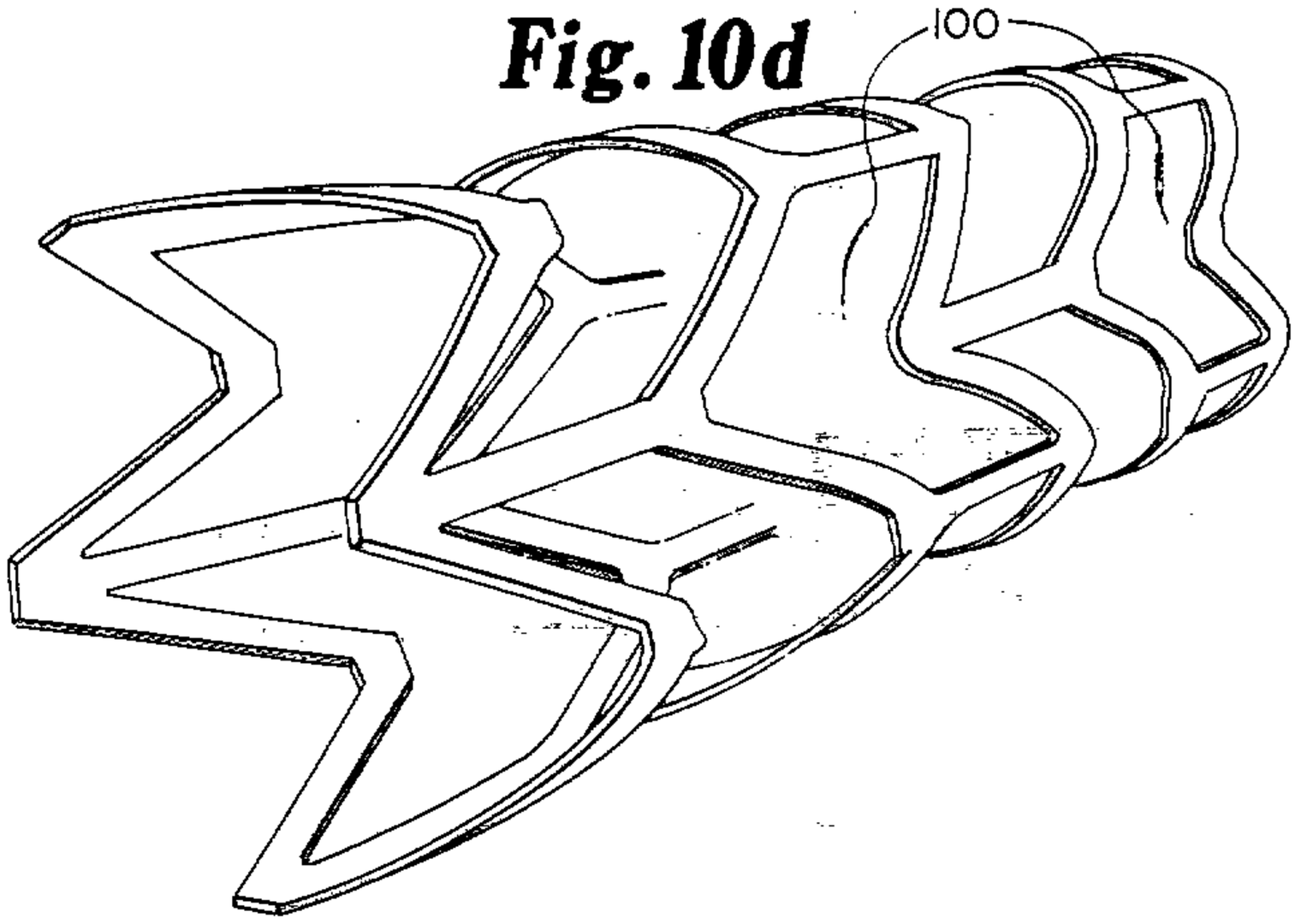


Fig. 11a

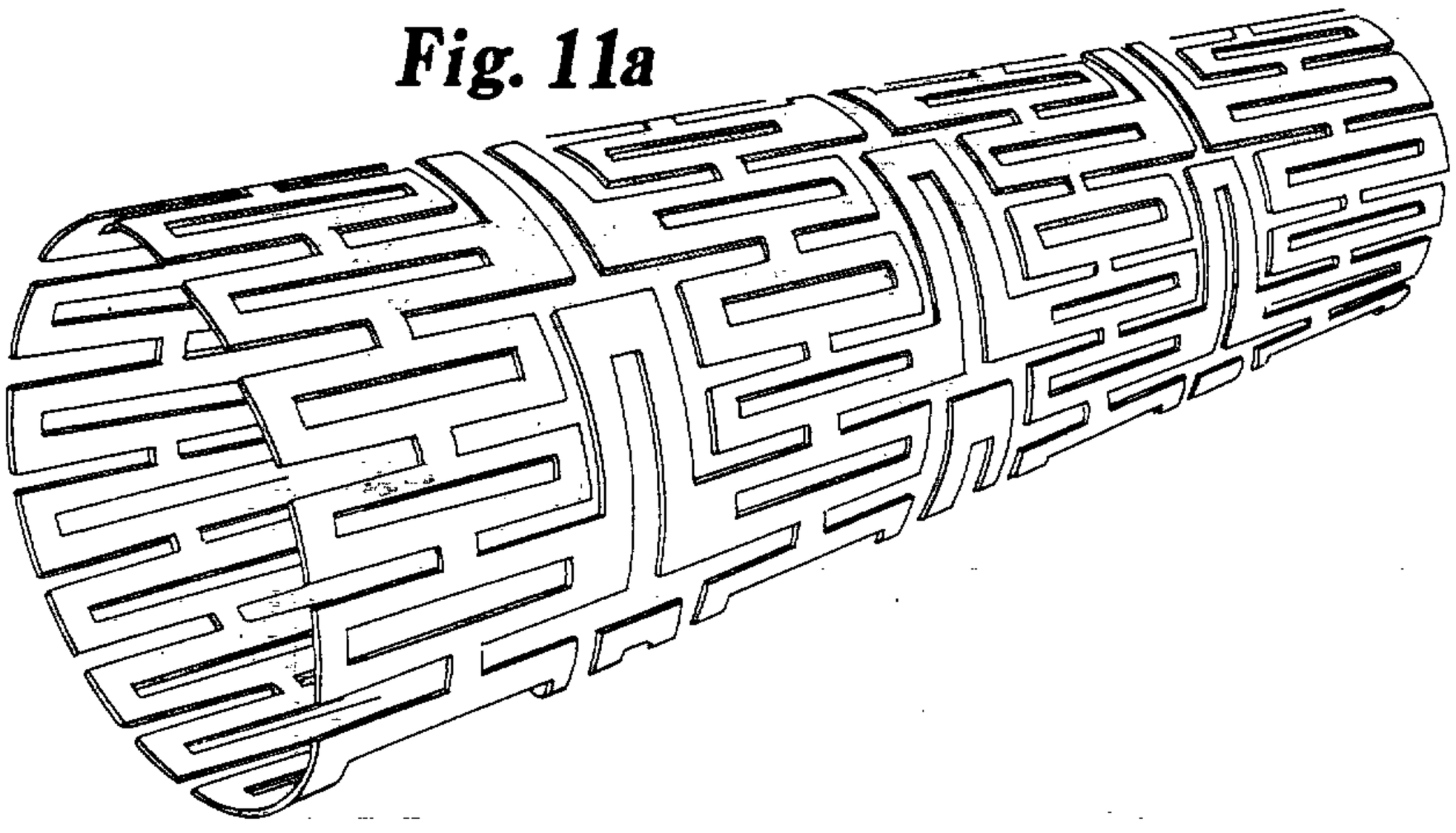


Fig. 11b

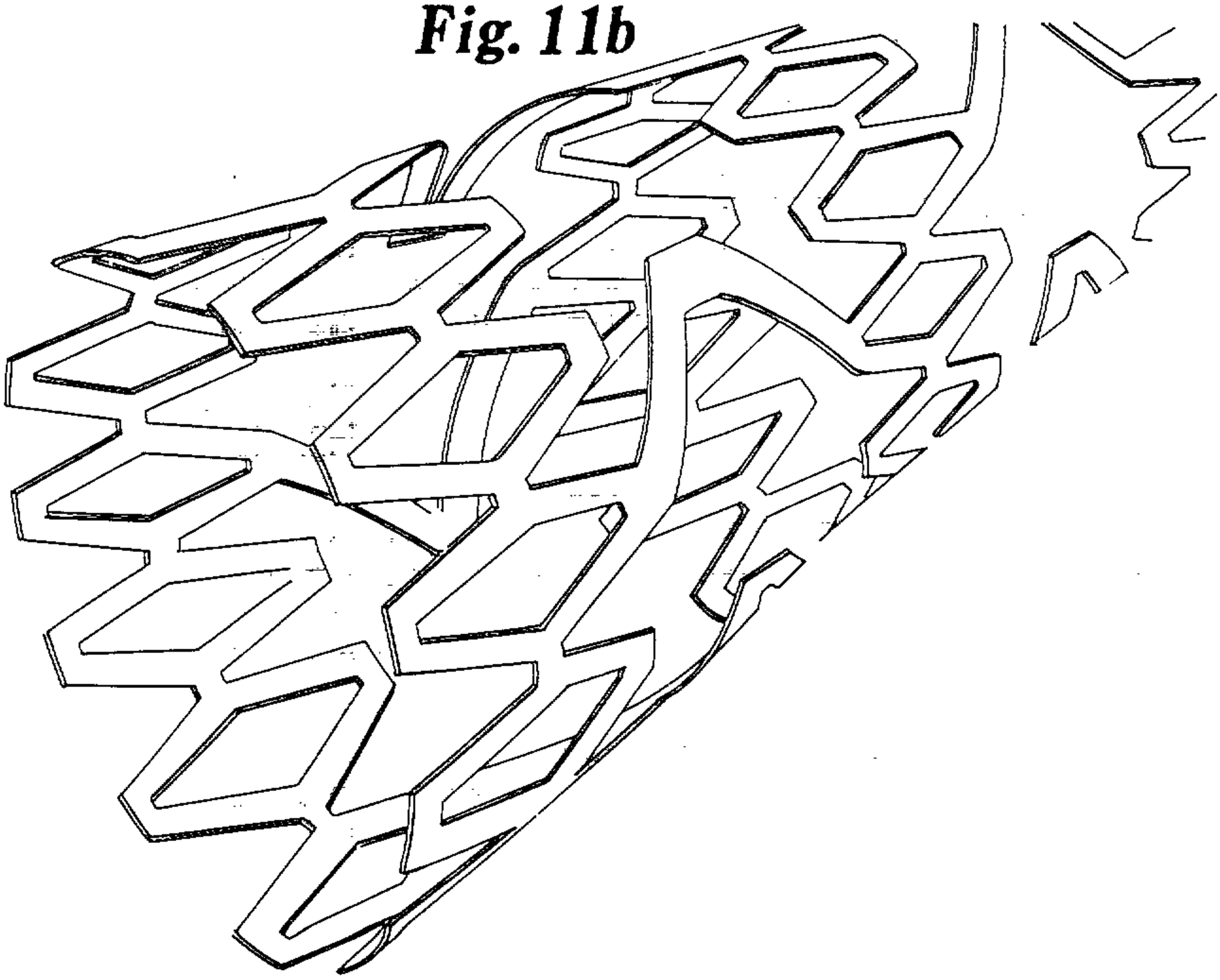


Fig. 12

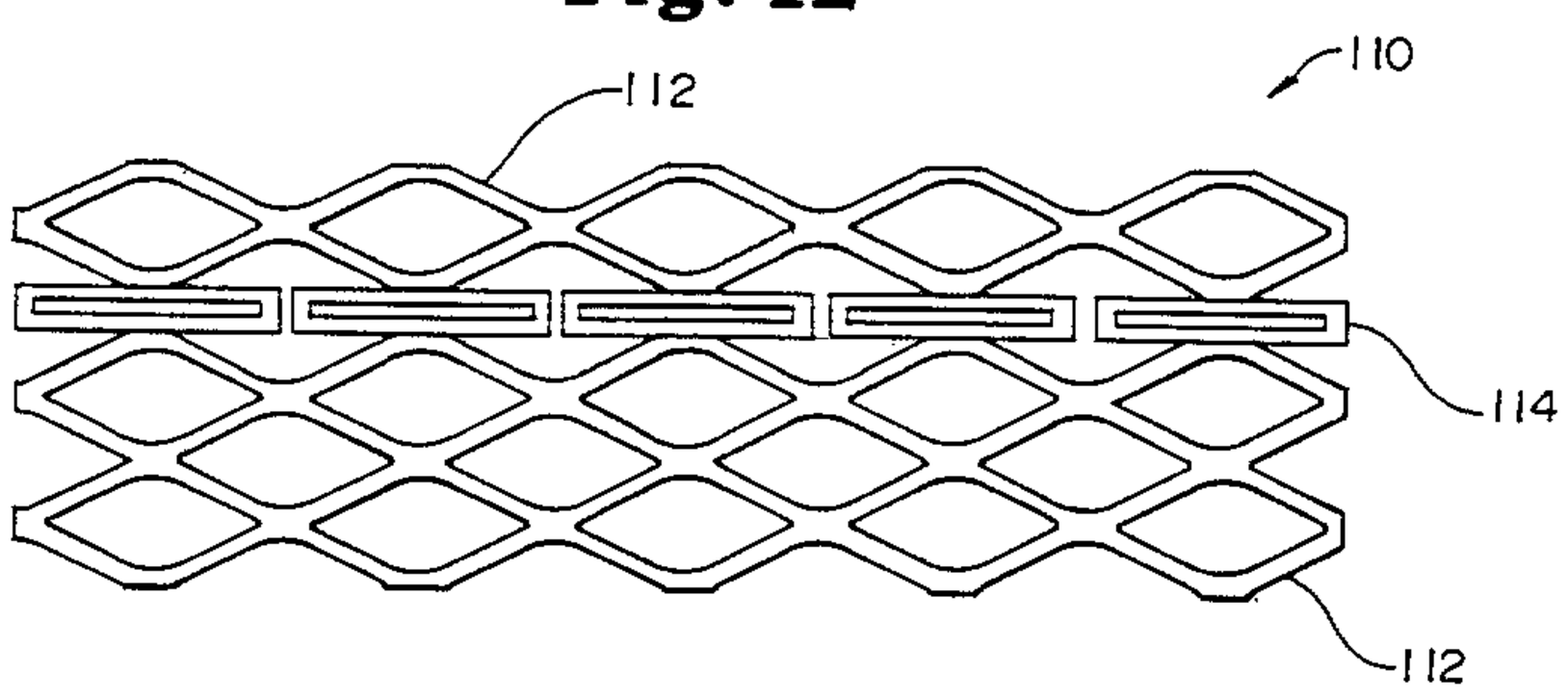


Fig. 13

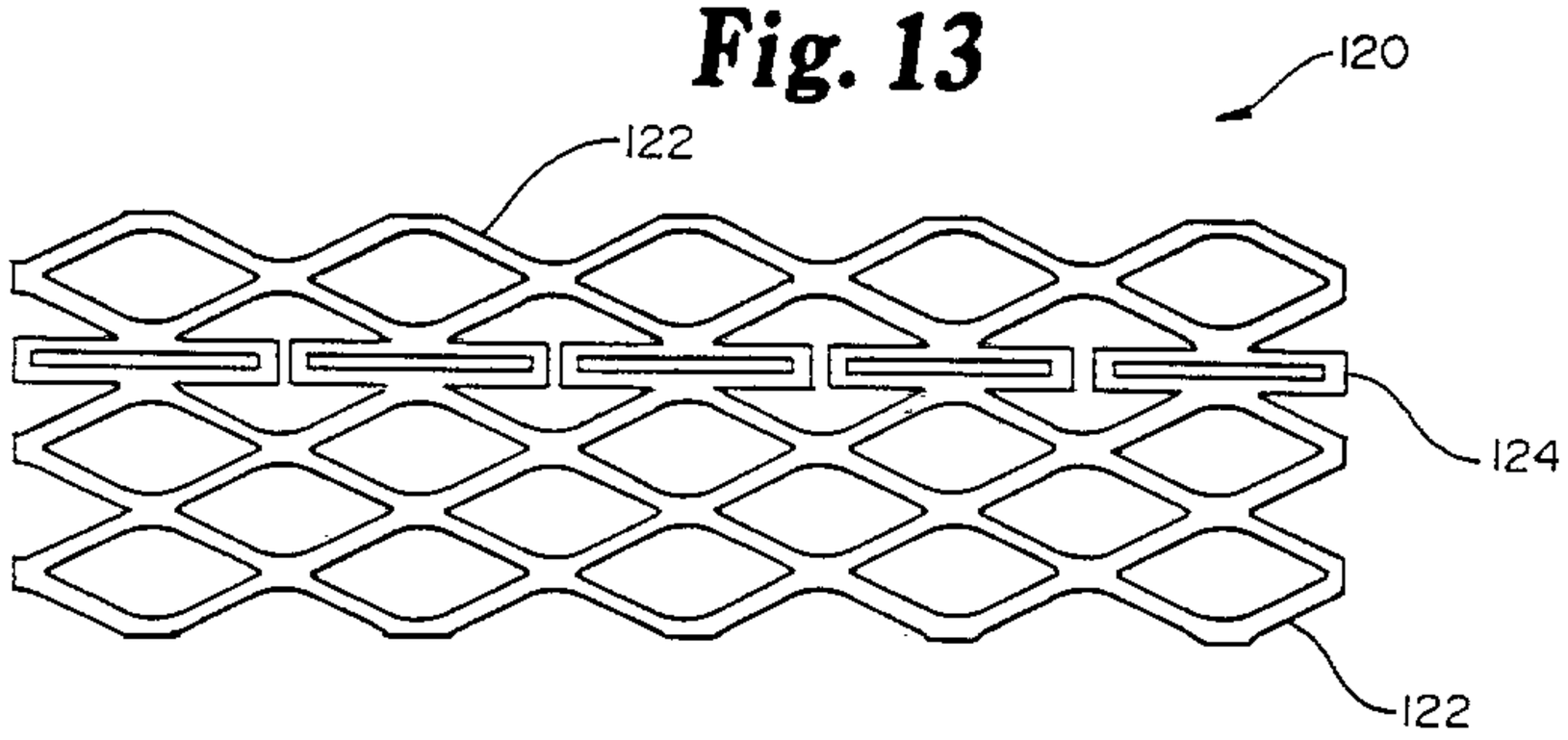


Fig. 14

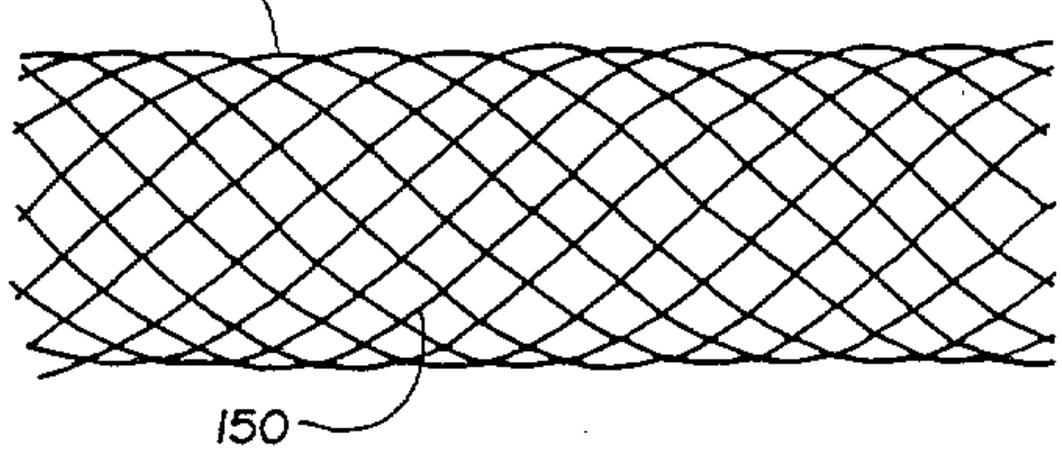


Fig. 15

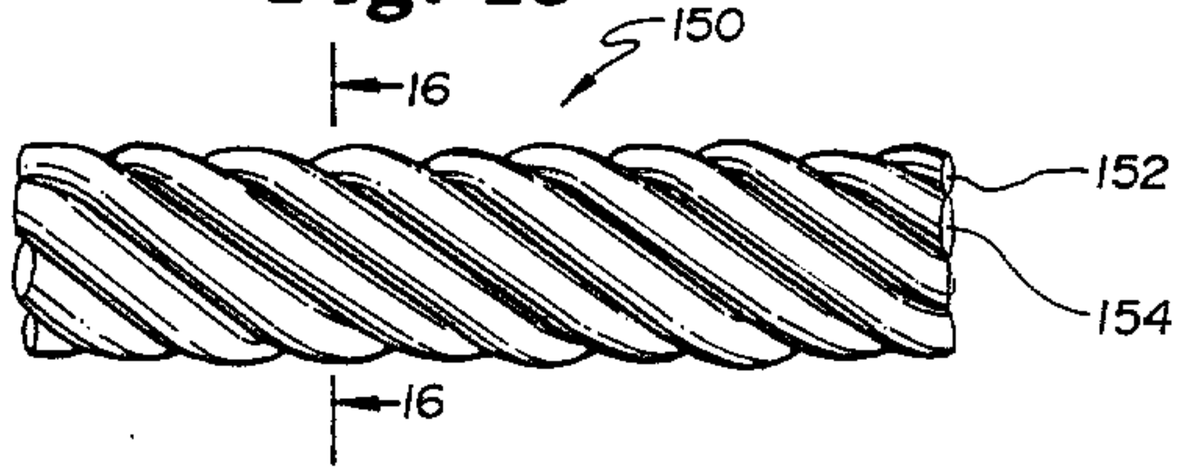
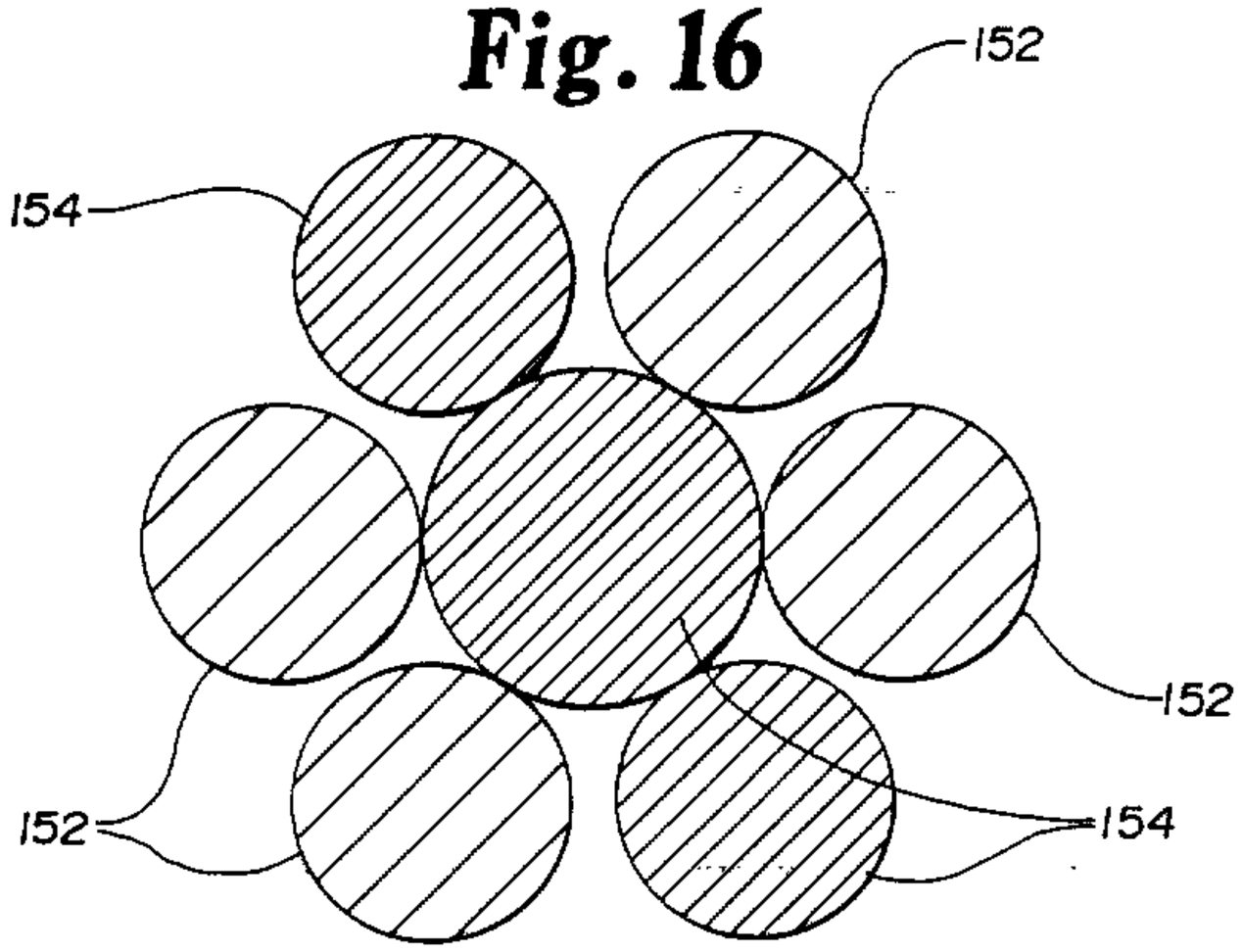
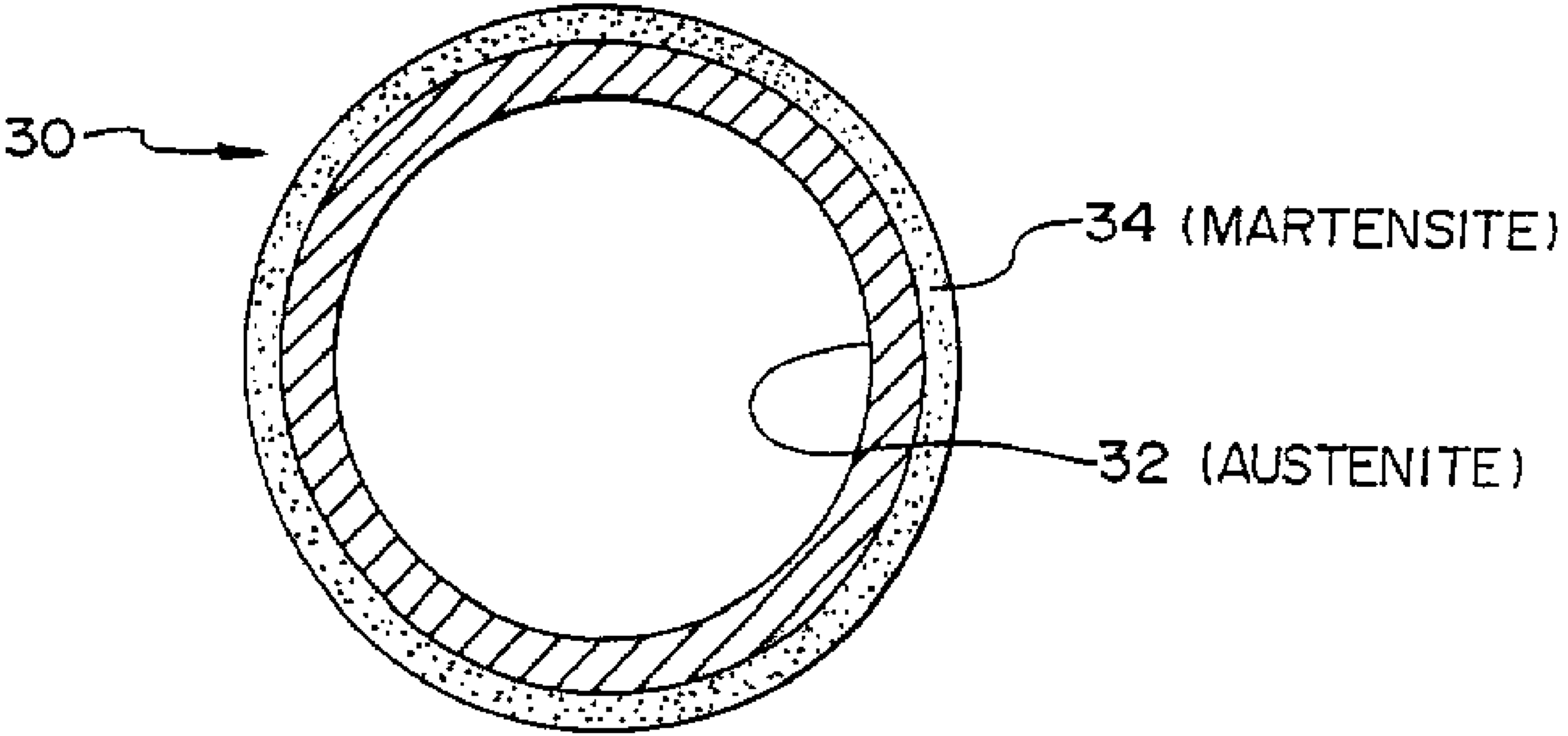


Fig. 16




30
34 (MARTENSITE)
32 (AUSTENITE)