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(54) Titre : OTOPLASTIQUE ET PROCEDE DE FABRICATION D'UN OTOPLASTIQUE
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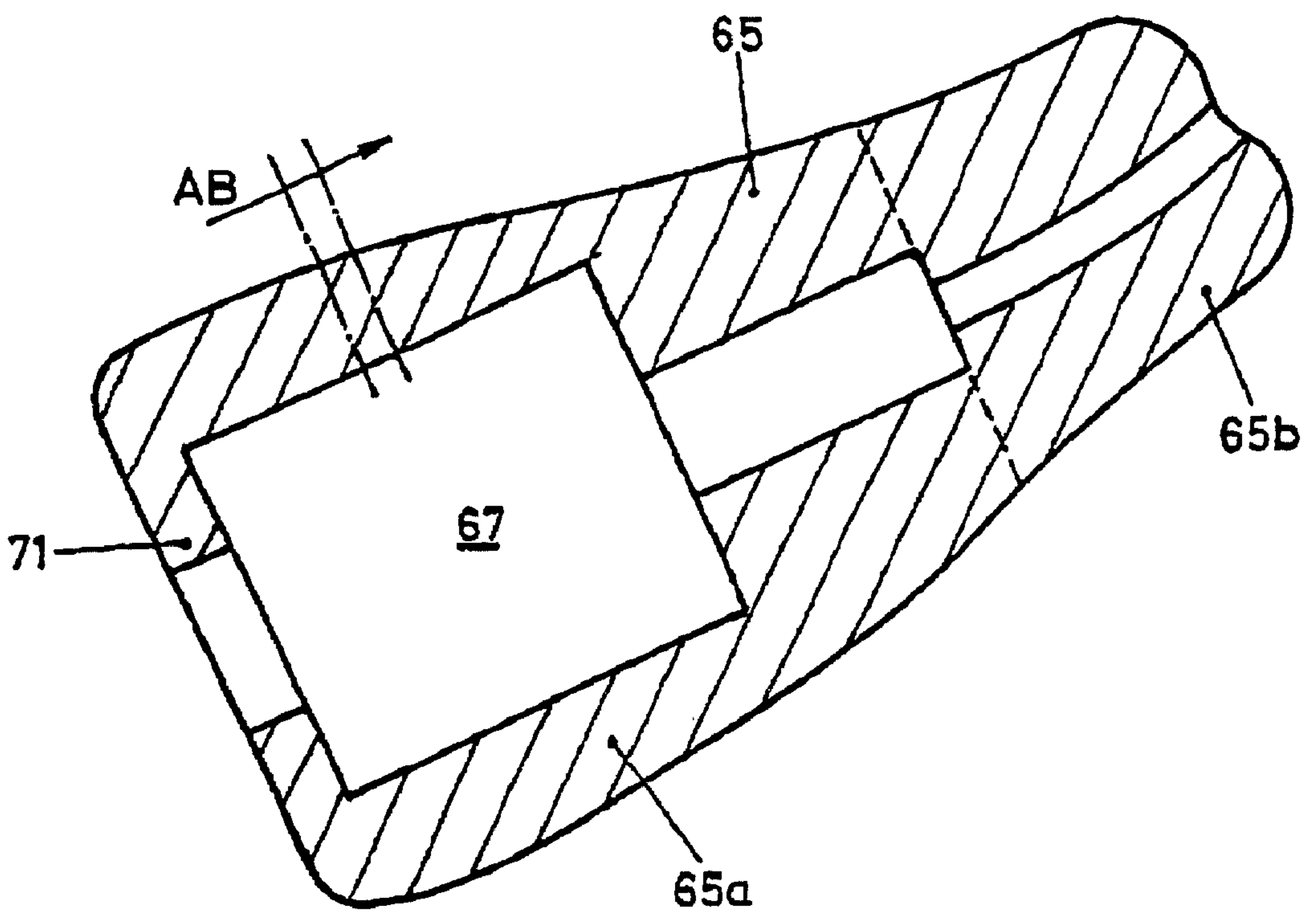

(57) Abrégé/Abstract:
The invention relates to an otoplastic with a housing forming an outer surface with characteristic projections and recesses formed thereon and a method for production of such an otoplastic, in particular for the manufacture of hearing aids.

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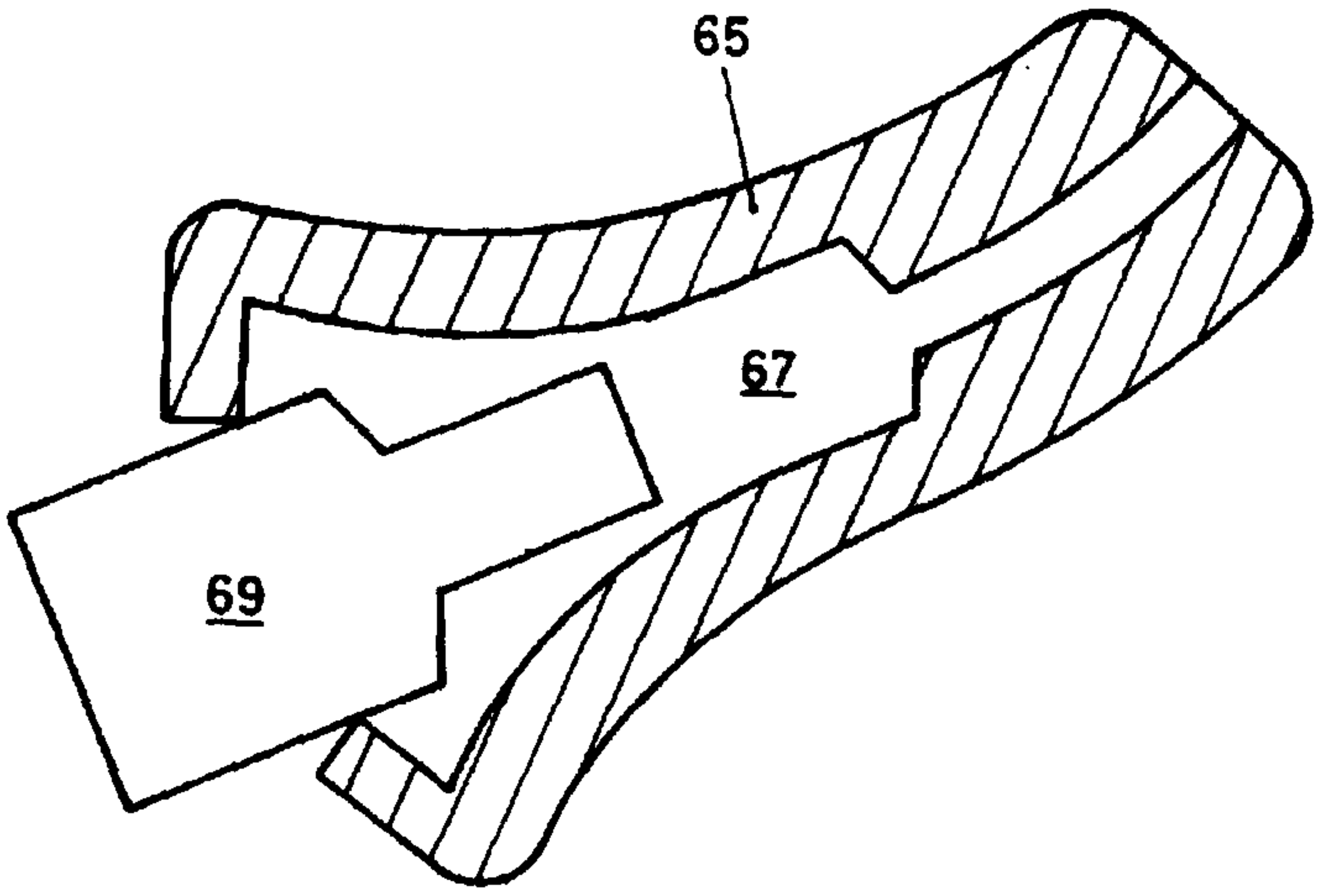
(54) **Title:** OTOPLASTIC AND METHOD FOR PRODUCING AN OTOPLASTIC

(54) **Bezeichnung:** OTOPLASTIK UND VERFAHREN ZUR FERTIGUNG EINER OTOPLASTIK



(57) **Abstract:** The invention relates to an otoplastic with a housing forming an outer surface with characteristic projections and recesses formed thereon and a method for production of such an otoplastic, in particular for the manufacture of hearing aids.

(57) **Zusammenfassung:** Otoplastik mit einer eine Außenfläche bildenden Schale, wobei an der Schale Kennzeichnungs-Ein- und/oder -Ausbuchtungen geformt sind, sowie Verfahren zur Herstellung einer derartigen Otoplastik, insbesondere für die Fertigung von Hörgeräten.

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OTOPLASTY AND METHOD FOR PRODUCING OTOPLASTY

The present invention relates to an otoplasty and starts out from the following problem:

Otoplasties must in many cases be individualized for the particular area of application. This is especially true of in-the-ear otoplasties which have to be specifically adapted to the individual shape of the auditory canal, as is known in particular for in-the-ear hearing devices. This is also extremely desirable for optimal wearing comfort of other in-the-ear otoplasties, for example for headphones and devices for protecting the ears, such as devices for protecting against noise or devices for protecting against water. The wearing comfort of otoplasties worn outside the ear can in some cases also be improved if the shape of the otoplasty is individually configured. Particularly in the production of such otoplasties, and especially if they are equipped with modules which are also individualized, such as especially electronic modules, problems arise which can be solved only with relatively considerable difficulty and which concern being able to reliably trace and avoid any confusion between, on the one hand, otoplasty shells and, on the other hand, the modules to be individually equipped with these. However, said problems also arise with otoplasties which are constructed without individualized modules, such as said electronic modules, specifically because the correct individual otoplasty must in the final analysis be sent to the correct recipient.

It is an object of the present invention to make available an otoplasty in which said problems can be solved in an extremely simple manner. To this end, the otoplasty according to the invention has, on the shell, indented and/or embossed identifications which are formed on the shell.

More specifically, the present invention concerns an otoplasty with a shell having a unitary surface of a material and identifying indentations and/or embossments wherein said identifying indentations and/or embossments individualize said shell and the surface of said indentations and/or embossments is part of said unitary surface of said shell.

In a particularly preferred embodiment of the otoplasty according to the invention, the shell material in the indented and/or embossed area is unchanged from the material of shell areas located farther away from this.

Although said indented and/or embossed identifications provided according to the invention can also include manufacturer indications, material indications, left/right ear application instructions, serial number, etc., they much more preferably identify, possibly among other details, the particular individual shell produced for a specific individual person.

In order subsequently to facilitate visual or machine recognition of said indented and/or embossed identifications, it is proposed that at least some of the indentations and/or embossings are at least partially coated with a material which is different than the shell material, preferably with a paint or a varnish. This can considerably facilitate visual recognition, but in particular machine readability, for example by laser scanning and reflection evaluation. The otoplasty according to the invention is particularly preferably a hearing device, namely a hearing device worn outside the ear or an in-the-ear hearing device, very particularly preferably an in-the-ear hearing device.

The method according to the invention for solving said problem is characterized in that a shell of the otoplasty is produced with an individualizing identification and thereafter the production is individualized by means of the shell. More specifically, the present invention also concerns a method for producing otoplasties, wherein

- a shell which form a surface and consists of one material is produced,
- a pattern of identifying indentations and/or embossments is provided on the surface of the shell,
- subsequent individualized production of the otoplasty is controlled by means of the identifying indentations and/or embossments.

In this case, the subsequent production work, in particular fitting the shell with built-in modules such as electronic modules, batteries, etc., can be individualized on the basis of the shell presented for production. At least from the shell, it is at all times possible to tell which individual shell is concerned, as a result of which, even upon manual production or fitting, the correct modules can be inserted. A particularly preferred embodiment of the method according to the invention, which makes full use of the individualizing identification according to the invention, is one in which at least some of the production steps following on from the shell production are automated by machine recognition of the identification. The method according to the invention is particularly suitable for use in the production of in-the-ear hearing devices and of hearing devices worn outside the ear, especially for in-the-ear hearing devices with which, because of the highly individual shape of the auditory canal, very particular attention must be paid to the individual production and to the avoidance of any mix-ups. Otoplasties with which the present invention can be realized, and in preferred embodiments, are explained below with reference to the figures, in which for example:

Fig. 1 shows a simplified diagram of a production installation for optimizing the industrial production of otoplasties;

Fig. 2 shows a further installation concept, in a view analogous to that in Fig. 1;

Fig. 3 shows yet another installation concept in a view analogous to that in Figures 1 and 2;

Fig. 4 shows a diagrammatic view of an in-the-ear hearing device, with an earwax protection cap fitted in a known manner;

Fig. 5 shows, in a view analogous to Fig. 4, an in-the-ear hearing device produced with an earwax protection cap;

Fig. 6 shows an in-the-ear hearing device with a ventilation groove formed in it in a known manner;

Figures 7 (a) through (f) show

perspective views of cutouts of otoplasty shell surfaces with ventilation grooves;

Fig. 8 shows, based on a diagrammatic cutout of an otoplasty surface, a ventilation groove with a cross section and cross-sectional shape varying along its longitudinal extent;

Fig. 9 shows a diagrammatic view of an in-the-ear otoplasty with lengthened ventilation groove;

Fig. 10 shows, in a view analogous to Fig. 9, an in-the-ear otoplasty with a plurality of ventilation grooves;

Figures 11 (a) through (e) show

cutouts of otoplasty shells with ventilation channels of different cross-sectional shapes and dimensions;

Fig. 12 shows, in a view analogous to that in Fig. 8, a ventilation channel in an otoplasty shell with a cross-sectional shape and cross-sectional surface varying along its longitudinal extent;

Fig. 13 shows, diagrammatically in analogy to the view in Fig. 9, an in-the-ear otoplasty with a lengthened ventilation channel formed in it;

Fig. 14 shows, in a view analogous to Fig. 10, an in-the-ear otoplasty with a plurality of ventilation channels;

Fig. 15 shows a diagrammatic view, in longitudinal section, of an in-the-ear otoplasty with ribbed inner surface;

Fig. 16 shows a cutout of the otoplasty according to Fig. 15 in cross section, the ribs having different cross-sectional surfaces;

Fig. 17 shows a perspective view of the cutout of an otoplasty shell with inner ribbing according to Fig. 15 or 16, the ribs having different cross-sectional shapes and dimensions along their longitudinal extent;

Fig. 18 shows, in a view analogous to Fig. 15, an in-the-ear otoplasty with outer ribbing;

Fig. 19 shows a diagrammatic view of a cutout of a ribbed otoplasty shell according to Fig. 18, with ribs having different cross-sectional surfaces;

Fig. 20 shows a diagrammatic view of a cross section through an otoplasty with outer ribbing, or inner ribbing, and an interior at least partly filled with filler material;

Fig. 21 shows a diagrammatic cutout, in longitudinal section, of an otoplasty shell with a part which is flexible upon bending and compression;

Fig. 22 shows a diagrammatic view, in longitudinal section, of an in-the-ear otoplasty with a receiving space for an electronic module;

Fig. 23 shows the otoplasty according to Fig. 22 being pushed on over an electronic module;

Fig. 24 shows a perspective and diagrammatic view of an in-the-ear otoplasty, such as in particular an in-the-ear hearing device, with a two-part, separable and connectable otoplasty shell;

Fig. 25 shows, in a diagrammatic and cutaway view, the integration of acoustic leads and adapter members to an acoustic/electric or electric/acoustic transducer, in an otoplasty;

Fig. 26 shows, in a view analogous to that in Fig. 25, the arrangement of two or more acoustic leads in the shell of an otoplasty shell, and

Fig. 27 shows, in a simplified signal flow chart and functional block diagram, a procedure, and an arrangement for carrying out the procedure, where the dynamics of the application area of an otoplasty are taken into consideration when configuring the latter.

The embodiments of otoplasties which are described following the production method are preferably all produced by this described production method.

Definition

An otoplasty is to be understood here as being a device which is fitted directly outside the auricle and/or on the auricle and/or in the auditory canal. These include hearing devices worn outside the ear, in-the-ear hearing devices, headphones, inserts protecting against noise and inserts protecting against water, etc.

1. Production method

In the production method preferably used to produce the otoplasties described in detail hereinafter, the shape of an individual application area for an intended otoplasty is three-dimensionally digitized, and the otoplasty or its shell is then constructed by an additive construction method. Additive construction methods are also known by the term "rapid prototyping". With regard to additive methods which have already been used in rapid prototyping, reference is made for example to:

- Wohlers Report 2000, Rapid Prototyping & Tooling State of the industry (2)

From the group of these additive methods known today for rapid prototyping, it appears that laser sintering, laser lithography or stereolithography, or the thermojet method are particularly well suited for constructing otoplasties or their shells, and in this case in particular the specific embodiments described hereinafter. Therefore, specifications of these preferably used additive construction methods will be discussed here, only in a brief summary:

- Laser sintering: Hot-melt powder is applied in a thin layer on a powder bed, for example by means of a roller. The powder layer is solidified by means of a laser beam, said laser beam being guided, inter alia according to a cutting layer of the otoplasty or otoplasty shell, by means of the 3-D shape information of the individual application area. A solidified cutting layer of the otoplasty or of its shell is obtained in the otherwise loose powder. This layer is lowered from the powder plane, and a new layer of powder is applied over it, and this layer of powder is in turn solidified by laser according to a cutting layer, etc.

- Laser lithography or stereolithography: A first cutting layer of an otoplasty or of an otoplasty shell is solidified by means of UV laser on the surface of liquid photopolymer. The solidified layer is lowered and is again covered by liquid polymer. By means of said UV laser, the second cutting layer of the otoplasty or of its shell is solidified on the already-solidified layer. Once again, the laser positioning is controlled inter alia by means of the 3-D data or information from the individual, previously recorded application area.

- Thermojet method: The contour formation in accordance with a cutting layer of the otoplasty or of the otoplasty shell is carried out, in the same way as in an ink-jet printer, by liquid application inter alia according to the digitized 3-D shape information, in particular also the individual application area. The deposited cutting "picture" is then solidified. Once again, according to the principle of the additive construction methods, the otoplasty or its shell is built up by depositing layer after layer.

As regards additive construction methods, and the preferred ones mentioned above, reference may be made to the following further publications:

- "Selective Laser Sintering (SLS) of Ceramics", Muskesh Agarwala et al., presented at the Solid Freeform Fabrication Symposium, Austin, Texas, August 1999, (4)

and

- Donald Klosterman et al., "Direct Fabrication of Polymer Composite Structures with Curved LOM", Solid Freeform Fabrication Symposium, University of Texas at Austin, August 1999. (7)

In principle, therefore, in additive construction methods, a thin layer of material is in each case deposited on a surface, either over the whole surface as in laser sintering or stereolithography, or, as in the thermojet method, already in the contour of a cut of the otoplasty or of its shell under construction. The desired cut shape is then stabilized and solidified.

Once a layer has been solidified, a new layer is deposited over this, as has been described, and this new layer is in turn solidified and connected to the already solidified layer lying below it. The otoplasty or its shell is thus constructed layer by layer by additive layer-by-layer application.

For industrial production, it is preferable not just for the cutting layer of one individual otoplasty or otoplasty shell to be deposited and solidified in each case, but for a plurality to be deposited and solidified simultaneously per individual. In laser sintering, for example, the one laser, normally under mirror control, successively solidifies the cutting layers of a plurality of otoplasties or their shells, before all the solidified cutting layers are lowered in unison. Then, after a new layer of powder has been deposited over all the already solidified and lowered cutting layers, the plurality of further cutting layers are formed in turn. Despite this parallel production, the respective otoplasties or their shells are produced individually by digital control.

In this case, in order to solidify the plurality of cutting layers, a single laser beam is used and/or several beams are operated and controlled in parallel.

In an alternative to this procedure, a cutting layer is solidified with one laser, while at the same time the layer of powder is being deposited for the formation of a further otoplasty or otoplasty shell. Thereafter, the same laser will solidify the prepared layer of powder according to the cutting layer for the next otoplasty, while the previously solidified layer is lowered and a new layer of powder is deposited there. The laser then operates intermittently between two or more otoplasties or otoplasty shells under construction, and so the idle time of the laser occasioned by the deposition of powder for the formation of one of the shells is exploited for solidification of a cutting layer of another otoplasty under construction.

Fig. 1 shows, in a diagrammatic view, how, in one embodiment, a plurality of otoplasties or their shells are produced industrially in a parallel process by means of laser sintering or laser lithography or stereolithography. The laser with control unit 5 and beam 3 is mounted above the material bed 1 for powder or liquid medium. At position 1, it solidifies the layer S_1 of a first otoplasty or its shell, controlled by the first individual set of data D_1. Thereafter, it is displaced on a displacement device 7 to a second position where, with the individual set of data D_2, it prepares the layer S_2 according to a further individual contour. Of course, a plurality of the lasers can be displaced as a unit and in each case several individual otoplasty layers are prepared simultaneously. It is only when the lasers 5 provided have prepared the respective individual layers at all the intended positions that a new layer of powder is deposited, in the case of laser sintering, by the powder delivery means represented in general at 9, whereas in laser lithography and stereolithography (not shown) the solidified layers S are lowered in the liquid bed.

According to Fig. 2, layers of individual otoplasties or their shells are solidified simultaneously on one or more liquid or powder beds 1 by a plurality of lasers 5 which are controlled individually and simultaneously. Once again, after this solidification phase has been completed and after the lasers have been stopped, the powder delivery unit 9 deposits a new layer of powder, whereas, in the case of laser lithography or stereolithography, the layers which have just solidified, or already solidified structures, are lowered in the liquid bed.

According to Fig. 3, the laser 5 solidifies the layer S_1 on a powder or liquid bed 1a and is then transferred (broken line) to the bed 1b, so that, during the solidification phase at the bed 1a, the powder application device 9b removes powder from above a previously solidified layer S_{1-} or, in laser lithography or stereolithography, the layer S_{1-} is lowered. It is only when the laser 5 is active at the bed 1b that the powder delivery device 9a deposits a new layer of powder over the layer S_1 which has just solidified at the bed 1a, or the layer S_1 is lowered in the liquid bed 1a.

When using the thermojet methods, and to similarly increase productivity, cutting layers of more than one otoplasty or its shell are deposited simultaneously, in practice through one application head or, in parallel, through several in one go.

By means of the method described, it is possible to obtain extremely complex shapes of otoplasties or their shells, specifically as regards both their outer shape, with individual adaptation to the application area, and also, in the case of a shell, as regards their inner shape. Overhangs and inward and outward protrusions can be readily achieved.

Moreover, materials for additive construction methods are known which can be shaped to give a rubber-elastic and yet dimensionally stable shell, which, if so desired, can be given local differences and even an extremely thin wall and yet remain resistant to tearing.

In a presently preferred embodiment, the digitization of the individual application area, in particular the application area for a hearing device, in particular an in-the-ear hearing device, is undertaken in a specialized institute, in the latter case by an audiologist. The individual shape recorded there as digital 3-D information is, particularly in connection with hearing devices, sent to a production center, either by transfer of a data carrier or via an Internet link, etc. The otoplasty or its shell, in the present case the shell of the in-the-ear hearing device, is shaped individually at the production center, in particular using the abovementioned methods. The fitting of the hearing device with the functional component groups is preferably also carried out there.

On account of the fact that, as has been mentioned, the thermoplastic materials used generally lead to a relatively elastic, conformable outer shape, the shaping with respect to pressure points in otoplasties or their shells is also much less critical than was hitherto the case, which is of huge importance in particular for in-the-ear otoplasties. Thus, in-the-ear otoplasties, for example as ear protectors, headphones, devices protecting against water, but in particular also for in-the-ear hearing devices, can be used similarly to rubber-elastic plugs, and their surface conforms optimally to the application area, i.e. the auditory canal. One or more ventilation channels can be easily incorporated in the in-the-ear otoplasty so that, with the resulting and possibly relatively tight fit of the otoplasty in the auditory canal, it is possible to guarantee unimpaired ventilation as far as the eardrum. The individual 3-D data from the application area can also be used during production to optimize the interior of the otoplasty and utilize this optimally, including individually with respect to the individual array of components which this interior is possibly intended to receive, as in the case of a hearing device.

Particularly in the case of otoplasties in the form of hearing devices, centralized production of their shells permits central storing and administration of individual data, both with respect to the individual application area and also to the individual functional parts and their settings. If, for whatever reasons, a shell has to be replaced, it can be newly prepared without any problem by calling up the individual sets of data, without the need for laborious readaptation, as has hitherto been the case.

On account of the fact that the methods described for the production of otoplasties are known and described in the literature, albeit only for prototyping, it is not necessary at this point to reproduce all the technical details of these methods.

At any rate, taking these technologies previously known from prototyping and using them for industrial and commercially feasible production of otoplasties surprisingly affords very considerable advantages, specifically for reasons which in themselves are not critical in prototyping, for example the elasticity of the thermoplastic materials which can be used, the possibility of individual construction with extremely thin walls, etc.

In summary, by using said additive construction methods for the production of otoplasties or their shells, it is possible to integrate various functional elements on them, which functional elements are prepared on computer during the planning of the otoplasty and which are generated with the construction of the otoplasty or its shell. Hitherto, functional elements of this kind were typically fitted into or onto the otoplasty or its shell only after the latter had been produced, which is recognizable from material interfaces or from lack of homogeneity of the material at the connection points.

For said otoplasties, in particular those with electronic inserts, for example for hearing devices, and in particular for in-the-ear hearing devices, examples of elements which can be fitted directly into the otoplasty shell by the proposed technique are:

seats and holders for structural parts, earwax protection systems, ventilation channels in the case of in-the-ear otoplasties, and support elements which hold the in-the-ear otoplasty in the auditory canal, for example channel locks.

Fig. 4 shows, in diagrammatic form, an example of an in-the-ear otoplasty 11, for example an in-the-ear hearing device in which the acoustic outlet 13 to the eardrum is protected by means of an earwax protection cap 15. This protection cap 15 has hitherto been produced as a separate part and attached to the shell 16 of the otoplasty 11 and fixed, for example, by adhesion or welding. As Fig. 5 shows in the same view, by using said additive construction methods, the earwax protection cap 15a is integrated directly on the shell 16a of the otherwise identical in-the-ear otoplasty 11a. At the connection points indicated schematically at P in Fig. 4, where in conventional methods there is necessarily a lack of homogeneity of the material or a material interface, there are no such interfaces according to Fig. 5, and the material of the shell 16a merges homogeneously into that of the earwax protection cap 15a.

This is just an example of how known earwax protection systems and other functional elements can be integrally incorporated by using said production method.

A number of specific, novel otoplasties are presented below:

2. In-the-ear otoplasties with ventilation

In the case of in-the-ear otoplasties, in particular in-the-ear hearing devices, it is known to provide a ventilation groove on the outside, as is shown diagrammatically in Fig. 6. Such ventilation grooves, as they are used today, are not by any means optimal, and for different reasons:

- As regards acoustics: The ventilation grooves known today are not really adapted to the particular acoustic requirements. Thus, in active otoplasties, for example in-the-ear hearing devices, they can do little to help effectively solve the problems of feedback from electro-mechanical output transducer to acoustic/electric input transducer. In the case of passive in-the-ear otoplasties too, for example ear protectors, they are not able to support the desired protective action and simultaneously maintain the desired ventilation properties.

- Earwax sensitivity: The ventilation grooves used today in the outer surfaces of in-the-ear otoplasties are extremely sensitive to formation of earwax. Depending on its intensity, the earwax formation can quickly impair the ventilation properties of the ventilation grooves provided, if not completely obstruct them.

Ventilation measures are proposed below for in-the-ear otoplasties, in particular for in-the-ear hearing devices or ear protectors, but also for otoplasties which extend only partially into the auditory canal, for example headphones, these ventilation measures at least partly avoiding the abovementioned disadvantages of known measures.

In this connection, a distinction is made below between ventilation systems which

- are groove-like and at least partially open toward the wall of the auditory canal,

- are completely closed off from the wall of the auditory canal.

2a) Ventilation systems open toward the wall of the auditory canal

In Figures 7(a) through (f), which are perspective diagrammatic views of cutouts of the outer wall 18 of in-the-ear otoplasties which bears against the auditory canal, novel ventilation groove profiles are shown in cutaway view. According to Fig. 7(a), the profile of the ventilation groove 20a is rectangular or square with predetermined and exactly observed dimensional relationships. According to Fig. 7(b), the profile of the ventilation groove 20b is in the shape of a sector of a circle or ellipse, again with an exactly predetermined cross-sectional edge curve 21b. By exact determination and execution of the cross-sectional shape of the ventilation grooves 20 provided, it is already possible to a certain extent to predict and influence the acoustic transmission conditions along this groove, upon bearing against the inner wall of the auditory canal. Of course, the acoustic behavior also depends on the length by which the groove 20 extends along the outer wall 18 of the otoplasty.

Figures 7(c) through (f) show further ventilation groove profiles which are additionally protected against earwax. The profile of the groove 20c according to Fig. 7(c) is T-shaped.

Regarding the wide cross-sectional surface of the groove at 27c, the inwardly jutting portions 23c and the resulting constriction 25c, toward the wall of the auditory canal, already give a considerable protective action against earwax. Even if earwax penetrates into the constriction 25c and hardens there, this does not cause any real constriction or even blockage of the ventilation groove, which now becomes an enclosed ventilation channel. In Figures 7(d) through 7(f), which follow the principle of Fig. 7(c) already explained, the cross-sectional shape of the wide groove portion 27d through 27f is designed with different shapes: in Fig. 7(d) in the shape of a sector of a circle or the sector of an ellipse, in Fig. 7(e) in the shape of a triangle, and in Fig. 7(f) in the shape of a circle or ellipse.

By specific configuration of the cross-sectional surface of the groove, shown simply by way of example in Figures 7(a) through 7(f), it is already possible to achieve a considerably improved effect, both with respect to the acoustic properties and also with respect to the protection against earwax, compared to conventional ventilation grooves which have more or less random profiles. In this case, the profiles are first computer-modeled, taking into consideration said protection against earwax and the acoustic effect, and are integrated exactly into the finished otoplasties. The additive construction methods discussed above are very particularly suitable in this respect. In order now to further optimize the acoustic effect of the ventilation groove, a very wide variety of acoustic impedances can be obtained along the length of the novel ventilation grooves, which results, for example as in Fig. 8, in ventilation grooves 29 defining different profiles along their longitudinal extent, which in Fig. 8 are made up of profiles according to Fig. 7.

Like the configuring of passive electrical networks, the acoustic transmission behavior of the groove which bears on the auditory canal can thus be computer-modeled and checked and then integrated into the in-the-ear otoplasty or its shell.

More areas protected against earwax can be specifically provided on exposed portions for this purpose, as is indicated at A in Fig. 8.

Moreover, with a view to optimizing the acoustic conditions, it may be entirely desirable for the provided ventilation grooves to be made longer than is permitted in principle by the longitudinal extent of a given in-the-ear otoplasty. As is shown in Fig. 9, this is achieved by the fact that such grooves 31, designed in the manner shown for example in Figures 7 and 8, are guided in predetermined curves along the surface of the otoplasty, for example as is shown in Fig. 9, in practice as grooves running round the otoplasty like a thread. Further optimization flexibility is achieved by the fact that not just one ventilation groove, but a plurality are guided across the surface of the otoplasty, as is shown diagrammatically in Fig. 10. The high degree of flexibility of the groove design means that, depending on the application area in the auditory canal, differently dimensioned ventilation grooves specifically optimized in each case with respect to earwax protection and acoustic transmission behavior can be formed along the surface of the otoplasty.

2b) Ventilation systems with fully integrated channels

This alternative embodiment of the novel ventilation systems is based on ventilation channels which are fully integrated into the otoplasty, at least in some areas, and closed off from the wall of the auditory canal. This system is explained below on the basis of its design on an otoplasty shell. It should be stressed, however, that when no other units are to be integrated on the otoplasty in question and the latter is designed as a solid otoplasty, the following explanations naturally relate also to a channel passage in any form right through said solid otoplasty.

Fig. 11 shows, in analogy to Fig. 7, different cross-sectional shapes and surface relationships of the proposed ventilation channels 33a through 33e. According to Fig. 11(a), the ventilation channel 33a built into the otoplasty shell 35a has a rectangular or square cross-sectional shape. In the embodiment according to Fig. 11(b), it has, at 35b, a channel cross-sectional shape in the form of a sector of a circle or sector of an ellipse. In the embodiment according to Fig. 11(c), the ventilation channel 33c provided has a circular or elliptic cross section, and, in the embodiment according to Fig. 11(d), it has a triangular cross-sectional shape.

In the embodiment according to Fig. 11(e), the otoplasty shell has a complex inner shape, for example a retention part 37 integrated thereon. For optimal utilization of space, the ventilation channel 35e provided here is designed with a cross-sectional shape which also makes use of complex shapes of the otoplasty shell. Accordingly, its cross-sectional shape extends in a complicated manner partially into the retention strip 37 built onto the shell 35e.

Looking back at the variant embodiment in accordance with section 2a), it should be noted that these complex cross-sectional shapes optimally utilizing the available space can also be realized on ventilation grooves which are open toward the auditory canal, and, conversely, channel passages as shown for open grooves in Figures 9 and 10 can be realized on closed ventilation channels.

Fig. 12 shows, finally, an alternative embodiment of a fully integrated ventilation channel 39 which has different cross-sectional shapes and/or cross-sectional dimensions along its longitudinal extent, as is represented for example in the otoplasty shell 41, in which case the acoustic transmission behavior can be optimized in the sense of executing different acoustic impedance elements. In this connection, and with reference to subsequent section 5), it may also be noted that, because of the possibility of realizing complex acoustic impedance conditions, ventilation channels, in particular of the closed configuration presented in this section, can at the same time be used, at least in some sections, as acoustic lead sections on the output side of active electromechanical transducers, for example on the output side of microphones, for example in in-the-ear hearing devices.

Figures 13 and 14, in analogy to Figures 9 and 10, show, on the one hand, how the integrated ventilation channels discussed in this section are lengthened on the respective otoplasty 43 by appropriate guiding of their course, and, on the other hand, how two and more of said channels, if appropriate with different and/or varying channel cross sections, in analogy to Fig. 12, are integrated on the otoplasty.

The possibilities which are presented in sections 2a) and 2b), and which can also be combined in any desired manner, afford the skilled person a countless number of design variants of the novel ventilation systems and in particular, because of the different independently dimensionable parameters, a large degree of freedom in creating optimum earwax protection and optimum acoustic transmission conditions for the respective individual otoplasty. In all the embodiment variants, the specific individual configuration of the system is preferably calculated or computer-modeled, taking the stated requirements into account. The individual otoplasty is then made. Once again, the production method with the additive construction principle, which is known from prototyping and which is explained in the introduction, is suitable for this purpose, which method is then controlled with the optimized model result.

3. Otoplasties with optimized shape stability

This section deals with providing novel otoplasties which are optimally adapted to the dynamics of the application areas. It is known, for example, that conventional in-the-ear otoplasties are unable to accommodate the relatively great dynamics of the auditory canal, for example during chewing, because their shape stability is substantially identical in all parts. Similarly, for example, the acoustic leads between hearing devices worn outside the ear, and the auditory canal are unable to freely follow the dynamics of the application area. The same problem arises with in-the-ear otoplasties, to a slightly lesser extent, and also with ear protectors, headphones, inserts protecting against water, etc.

In particular, their intrinsic function, for example their protective action, in this case partially deteriorates if the stated dynamics of the application area are increasingly taken into consideration. By way of example, reference may be made in this connection to known ear protectors which are made of elastically deformable plastics and which indeed take considerable account of the stated dynamics of the application area, but at the expense of their acoustic transmission behavior.

Fig. 15 shows a diagrammatic view of a longitudinal section of an in-the-ear otoplasty, and Fig. 16 shows a diagrammatic cross-sectional view of a portion of this otoplasty. The otoplasty, for example for receiving electronic components, has a shell 45 which is made, like a pair of tights, as a thin wall of elastic material. The shape stability of the shell skin, which is smooth on the outside in the illustrative embodiment shown, is ensured, where so desired, by ribs 47 which are applied integrally on the inside of the shell and which are made of the same material as the shell skin.

Depending on the required dynamics of the in-the-ear otoplasty on the one hand, in order for example to take account of the dynamics of the auditory canal, and the requirements in respect of the support and protection of built-in components, as in an in-the-ear hearing device, the course of the wall thickness of shell skin 45 and the density and configuration of the ribs 47 are calculated in advance, and the otoplasty is thereafter constructed according to the calculated data. Once again, the above-discussed production method using additive construction methods is outstandingly suitable for this purpose. Of course, the design of the in-the-ear otoplasty just discussed can be readily combined with a ventilation system of the kind discussed with reference to Figures 7 through 14. In particular, the ribs provided to influence the shape stability or bendability can also be designed with different cross-sectional profile in certain areas of the otoplasty, if appropriate also advancing from one cross section to the other in their longitudinal extent.

In the form of a perspective view, Fig. 17 shows purely by way of example and diagrammatically the design of the outer skin 45 with ribs 47 having varying cross-sectional surfaces along their longitudinal extent.

Instead of or in addition to the specific wall strengthening and the specific configuration of the bending and torsion behavior, in short of the shaping behavior of the in-the-ear otoplasty, it is possible, as has been mentioned, in addition to the internal ribbing pattern as is shown in Figures 17 and 18, also to provide an external ribbing pattern. According to Figures 18 and 19, a pattern of ribs 51 is worked on the outer surface of the otoplasty 49, if appropriate with different density, orientation and profile shape in different areas.

According to Fig. 19, this can be used for the otoplasties in question here which have a hollow cavity, but also for otoplasties with no hollow cavity, that is to say, for example, with no electronic components, e.g. for ear protector devices and devices protecting against water. One such otoplasty is shown diagrammatically in a cross-sectional view in Fig. 20. Here, the interior 53 is made, for example, from extremely compressible absorption material and is surrounded by a shape-giving skin shell 55 with rib pattern 57. Here, the "skin" 55 and the rib pattern 57 are integrally produced together. The production method discussed in the introduction and using additive construction methods is once again suitable for this purpose. How far these additive construction methods will be able to be used, in the near future, on a workpiece with changing of the processed materials remains to be seen. Should this become possible, then the way is clear, for example in the illustrative embodiment according to Fig. 20, to sequentially also construct the filler 53 at the same time as the shell skin 55 and the ribs 57 in respective construction layers.

Looking back in particular to Figures 18 and 19, it will be seen that ventilation channels or free spaces can at the same time be formed with the aid of the external ribbing pattern, as is shown purely schematically and by way of example by the path P.

Returning once more to Fig. 20, it is entirely possible, if so required, and as is shown by broken line 57_i in Fig. 20, to provide an internal ribbing pattern 57_i on the shell skin 55 even if the in-the-ear otoplasty is filled with material, that is to say if it is not intended to receive further components, such as electronic components.

As is also shown by the broken line 59 in Fig. 20, otoplasties can also be created which indeed leave free a hollow cavity to receive units such as electronic components, but in which the interspace, between such a hollow cavity 59, is designed specifically to the necessary volumes and shapes of the units additionally to be received, and the shell skin 55 is filled for example with a resilient or sound-damping material, or components to be incorporated are surrounded by such a material as far as the shell skin 55.

The shell skin 55 or 45 according to Figures 15, 16 and 17 can be made entirely of electrically conductive material, by which means an electrical screening effect is at the same time created for electronic components lying on the inside. This also applies, if appropriate, to the filling 53 according to Fig. 20.

Figures 15 through 20 have shown an example of an otoplasty in the form of an in-the-ear otoplasty whose shell is shape-stabilized with ribs lying on the inside and/or outside, resulting in an extraordinarily light and deliberately formable structure. If necessary, this structure can of course also be used for otoplasties worn outside the ear.

Fig. 21 shows a further alternative embodiment of an in-the-ear otoplasty which is deliberately bendable or compressible in one area. For this purpose, the shell 61 of an otoplasty, such as in particular the shell of an in-the-ear hearing device, has an undulated or creased configuration 63 at one or more predetermined regions where, in accordance with the particular requirements, it is bendable or compressible. Although Fig. 21 shows this measure on the basis of the shell of an in-the-ear otoplasty, it is entirely possible, if necessary, to provide this measure also for an otoplasty worn outside the ear. For this purpose, the production method discussed in the introduction is once again preferably used.

In this illustrative embodiment too, it is possible, as was explained with reference to Fig. 20, for the internal volume of the otoplasty to be filled with filler material in accordance with the requirements, and built-in components integrated therein can be embedded in such filler material, resulting in a higher degree of stability of the appliance and improved acoustic conditions.

4. Modular housing/built-in components

Particularly in the case of in-the-ear hearing devices, the problem is that the application area, i.e. the auditory canal, changes its shape. This is obviously the case when a person is growing up. In adults too, however, the auditory canal changes, sometimes considerably, and in most cases in the sense of narrowing (e.g. what is called diver's ear).

In the case of in-the-ear hearing devices, the problem thus generally arises that, even if the components built into the hearing device could themselves be maintained over long periods of the user's life, for example with only the transmission behavior of the hearing device having to be readjusted to the particular hearing conditions, new hearing devices nevertheless have to be constantly designed, simply because of the fact that the previous ones no longer fit satisfactorily into the auditory canal.

The measures discussed in section 3 already make it possible to improve this, on account of the fact that automatic shape adjustment of the otoplasty to the changing application areas is thus permitted. In this section, further measures in this connection will be discussed, particularly with reference to in-the-ear otoplasties. However, it should be noted that also in the case of otoplasties worn outside the ear, for example hearing devices worn outside the ear, this opens up the possibility of changing the "housing", and of doing so not only when this is necessary for reasons of wearing comfort, but also as and when desired, for example in order to change the esthetic appearance of such hearing devices worn outside the ear.

Fig. 22 shows a diagrammatic view of an in-the-ear otoplasty 65 in longitudinal section, the design of the interior 67 corresponding substantially to the shape of the electronic module 69 to be received, which is shown diagrammatically in Fig. 23. The otoplasty 65 is made of rubber-elastic material and, as is shown in Fig. 23, can be pushed on over the electronic modules 69. The shaping of the interior 67 is such that the module or the plurality of modules to be received are positioned and held directly with a form fit by the otoplasty 65. By means of this measure, it is easily possible to provide one and the same electronic modules 69 with different otoplasties 65, for example in order thereby to take account of the changing shape of the auditory canal in a growing child. The otoplasty in practice becomes an easily exchangeable throw-way accessory for the in-the-ear hearing device. The otoplasty 65 can be easily changed not only to take account of changing conditions in the application area, namely the auditory canal, but also simply for reasons of soiling. This concept can even be used, if appropriate, for example in cases of inflammation of the auditory canal, to apply medicines, for example by application of medicines to the outer surface of the otoplasty, or at least in order to use sterilized otoplasties at regular intervals.

The concept shown with reference to Figures 22 and 23 can of course be combined with the concepts set out in sections 2) and 3), and the otoplasty 65 is preferably produced using the production method discussed in section 1), which permits the design of highly complex internal shapes for receiving the module 69 in a manner free from play and vibration.

As can be seen from Figures 22 and 23, the phase plate 1 otherwise provided in conventional in-the-ear hearing devices is built integrally with the otoplasty, for example as part of the module holder. The same applies to other holders and receiving seats for electronic components of the hearing device. If the layer-by-layer construction method set out in section 1) is carried out, as is indicated by broken lines in Fig. 22 and in the direction shown by the arrow AB, then it ought to be easily possible to produce the otoplasty from different materials in said construction direction AB, according to the requirements in the respective areas. This applies also to the otoplasties set out in sections 2) and 3), and to those discussed in sections 5), 6) and 7) below. Taking the example in Fig. 22, it is thus quite possible to produce the area 65_a using rubber-elastic material, and by contrast the outlet area 65_b using more shape-stable material.

Fig. 24 shows a further embodiment of an otoplasty, again taking the example of an in-the-ear hearing device, which allows the internal built-in components to be easily and quickly changed. In principle it is proposed here that the otoplasty shell of an in-the-ear otoplasty with built-in components is designed in a plurality of parts which can be fitted together, as is shown in Fig. 24. By means of quick-acting couplings, such as snap-in couplings, catches or even bayonet-like couplings, it is possible for housing parts 73a and 73b of the in-the-ear otoplasty to be quickly separated from one another, for the built-in components such as electronic modules to be removed, and for these to be inserted again into a new shell, if appropriate with different outer shape, or in principle into a new shell even when this is necessary, for example, for cleaning reasons, sterility reasons, etc. If provision is made for the already used shell to be disposed of, it is easily possible to design the connections of the shell parts in such a way that the shell can only be opened by destroying it, for example by providing locking members, such as catches, which are not accessible from the outside and by the shell being cut open in order to remove them.

This embodiment can of course also be combined with the alternative embodiments described above and those still to be described.

5. Integration of acoustic leads in otoplasties and their shells

In hearing devices worn outside the ear, and also in in-the-ear hearing devices, it is customary for the provided acoustic/electric transducers or electro-acoustic output transducers to be coupled, on the input side or output side, to the environment of the hearing device via acoustic leads assembled as independent parts, namely tube-like structures, or, in particular with acoustic/electric transducers on the input side, to place these with their receiving surface immediately in the area of the surfaces of the hearing device, if appropriate separated from the environment only by small hollow spaces and protective measures.

In the design of such hearing devices, there is therefore a relatively large join where the actual transducers are to be provided in the hearing device and where the actual coupling openings to the environment are to be provided on said hearing device. As regards the arrangement of coupling openings to the environment and the arrangement of said transducers inside the hearing device, it would be highly desirable to have the greatest possible design freedom.

This is in principle achieved by the fact that said acoustic leads - at the input side of acoustic/electric transducers or output side of electric/acoustic transducers - are integrated into the otoplasty or into the wall of otoplasty shells.

This is shown purely schematically in Fig. 25. A transducer module 75 has an acoustic input/output 77. The shell 79 of the otoplasty of an in-the-ear hearing device, or of a hearing device worn outside the ear, or of headphones, has an acoustic lead 81 integrated within it. This lies at least partially within the wall of the otoplasty shell 79, as is shown in Fig. 25. The respective acoustic impedance of the acoustic lead 81 is preferably adapted by means of acoustic stub lines or line sections 83. This concept, taking the example of hearing devices worn outside the ear, makes it possible to provide acoustic input openings 85 staggered along the hearing device and at desired locations, and to couple said inlet openings 85 to the provided acoustic/electric transducers 91 via acoustic leads 89 integrated in the otoplasty or its shell 87, and largely irrespective of where these transducers 91 are built into the hearing device. Thus, Fig. 26 shows, only by way of example, how two transducers are centralized into one module and their inputs are connected to the desired receiving openings 85 via said path of the acoustic leads 89. In the light of Figures 25 and 26 and the statements in section 2) regarding the novel ventilation systems, it will be evident that it is quite possible to use ventilation channels also as acoustic lead channels, especially if, as is shown diagrammatically in Fig. 25, the acoustic impedance conditions are specifically configured by means of acoustic adapter members 83.

6. Identification of otoplasties

In the production of otoplasties, in particular of in-the-ear otoplasties, each one is individually adapted to its respective wearer. For this reason, it would be highly desirable to identify each finished otoplasty, as mentioned in particular each in-the-ear otoplasty, and very particularly each in-the-ear hearing device. It is therefore proposed to provide an individual identification in the otoplasty or its shell by means of indentations and/or embossings, which identification, in addition to giving the individual orderer, for example manufacturer, can contain the product serial number, left/right application, etc. Such an identification is created in a much preferred manner during the production of the otoplasty using the removal method described under 1). This ensures that any mix-up of the otoplasties is ruled out starting from the time of production. This is particularly important in the subsequent and possibly automatic fitting with further modules, for example the fitting of in-the-ear hearing devices.

This measure can of course be combined with one or more of the aspects described under sections 2) through 5).

<u>7. Optimization of otoplasties with respect to the dynamics of the application area</u>

When molding otoplasties for in-the-ear application, for example for in-the-ear hearing devices, it is at present customary to take an impression of the auditory canal, for example using silicone. If one now considers the quite substantial dynamics of movement of the auditory canal, for example during chewing, it is evident that basing the shape of the in-the-ear otoplasty on an impression, which corresponds in practice to a momentary record, can scarcely yield a result which will be entirely satisfactory in use. As is now shown in Fig. 27, which is a simplified functional block diagram/signal flow chart, a mold is taken from the dynamic application area, represented by the block 93, at several of the positions corresponding to the dynamics occurring in practice, or the dynamics of the application area are recorded per se in the manner of a film. The resulting data sets are stored in a memory unit 95. Also in the conventional procedure with impression-taking, this can be readily done by taking impressions, corresponding to the practical dynamics, of the application area at two or more positions.

These impressions are then scanned and the respective digital data sets are stored in the memory unit 95. As a further possibility, the dynamics of the application area can be recorded by X-ray, for example.

Thus, depending on the accuracy which is to be achieved, a number of "images" or even in practice a "film" of the pattern of movement of the application area in question are recorded. The data recorded in the memory unit 95 are then fed to a computer unit 97. At its output, the computer unit 97 controls the production process 99 for the otoplasty. If, for example, as is still customary today, in-the-ear otoplasties are produced with a relatively hard shell, the computer unit 97 uses the dynamics data stored in the memory unit 95 and, if appropriate, further production parameters as shown schematically at K, to calculate the best matching shape for the otoplasty, so that optimum wearing comfort in everyday use is achieved while maintaining its functionality. If the otoplasty to be produced is realized using the principle set out in section 3), the computer unit 97 determines which otoplasty areas are to be configured and how in terms of their flexibility, bendability, compressibilty, etc. At its output, the computer unit 97, as has been stated, controls the production process 99, preferably in this case the production process as was set out in section 1) as the preferred process.

WHAT IS CLAIMED IS:

1. An otoplasty with a shell having a unitary surface of a material and identifying indentations and/or embossments wherein said identifying indentations and/or embossments individualize said shell and the surface of said indentations and/or embossments is part of said unitary surface of said shell.

2. The otoplasty according to claim 1, wherein the indentations and/or embossments individualize a respective shell.

3. The otoplasty according to claim 1 or 2, wherein the surface of the indentations and/or embossments is at least partly and at least in part coated with a further material.

4. The otoplasty according to claim 3, wherein the further material is a paint or a varnish.

5. The otoplasty according to any one of claims 1 to 4, wherein the otoplasty is a hearing device.

6. Method for producing otoplasties, wherein

- a shell which form a surface and consists of one material is produced,
- a pattern of identifying indentations and/or embossments is provided on the surface of the shell,
- subsequent individualized production of the otoplasty is controlled by means of the identifying indentations and/or embossments.

7. The method according to claim 6, wherein the production is automated at least in part by machine detection of the pattern of identifying indentations and/or embossments.

8. Use of the method according to claim 6 or 7 for producing hearing devices.

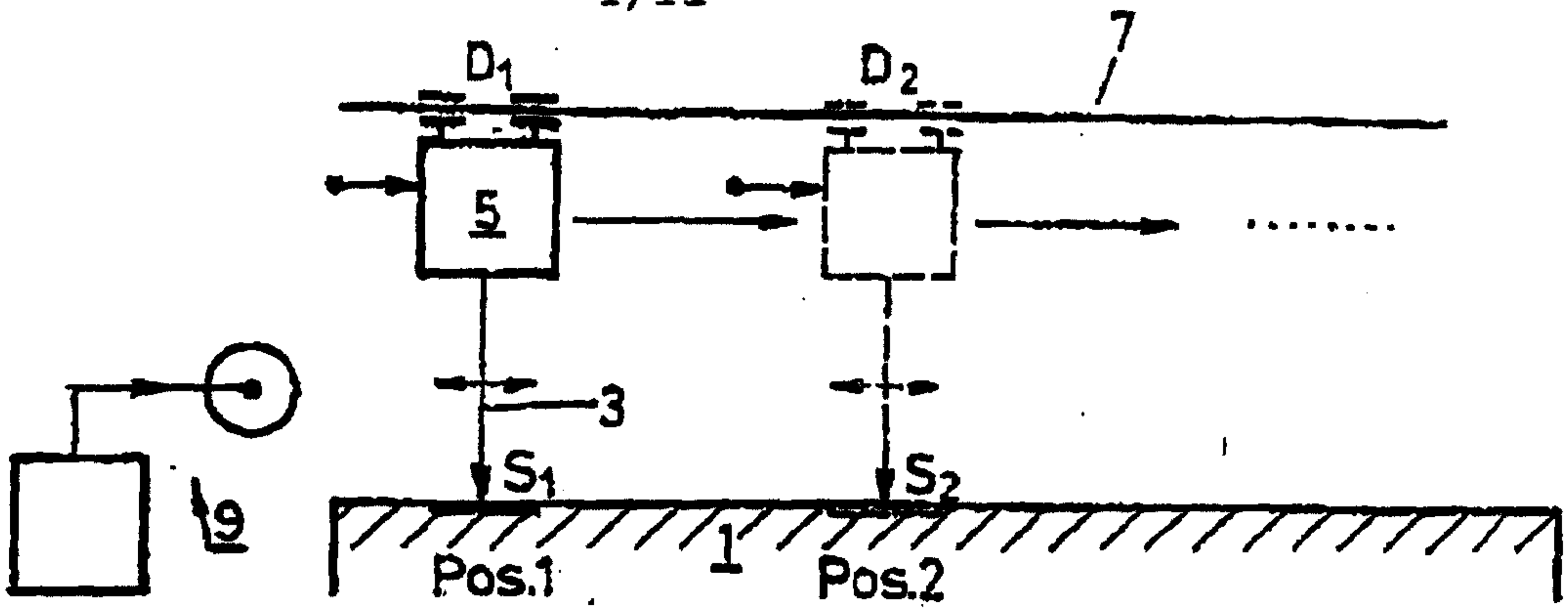


FIG.1

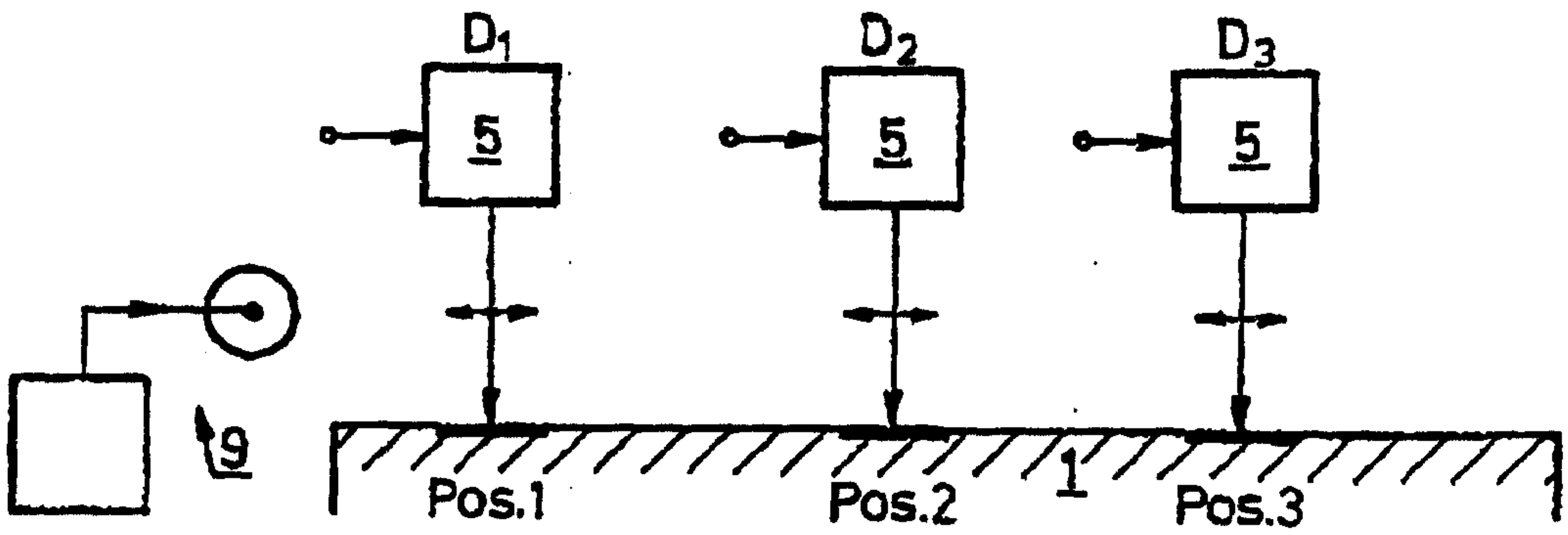


FIG.2

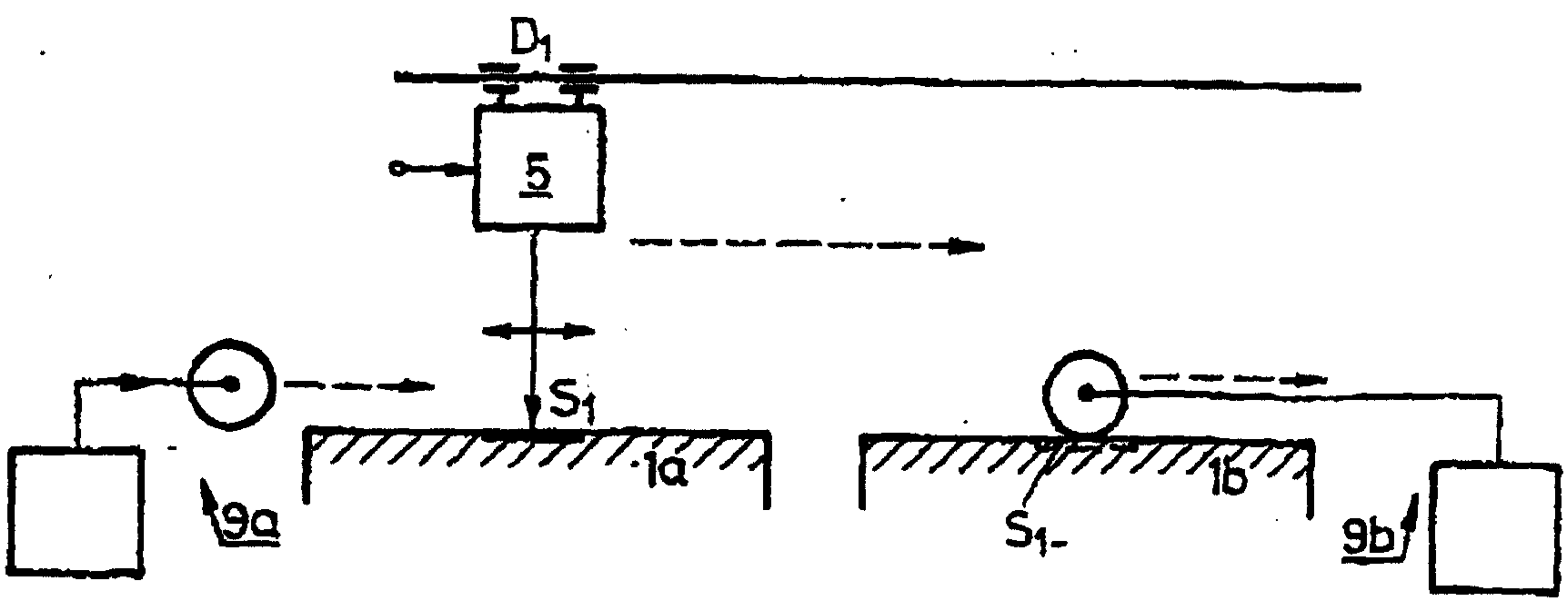


FIG.3

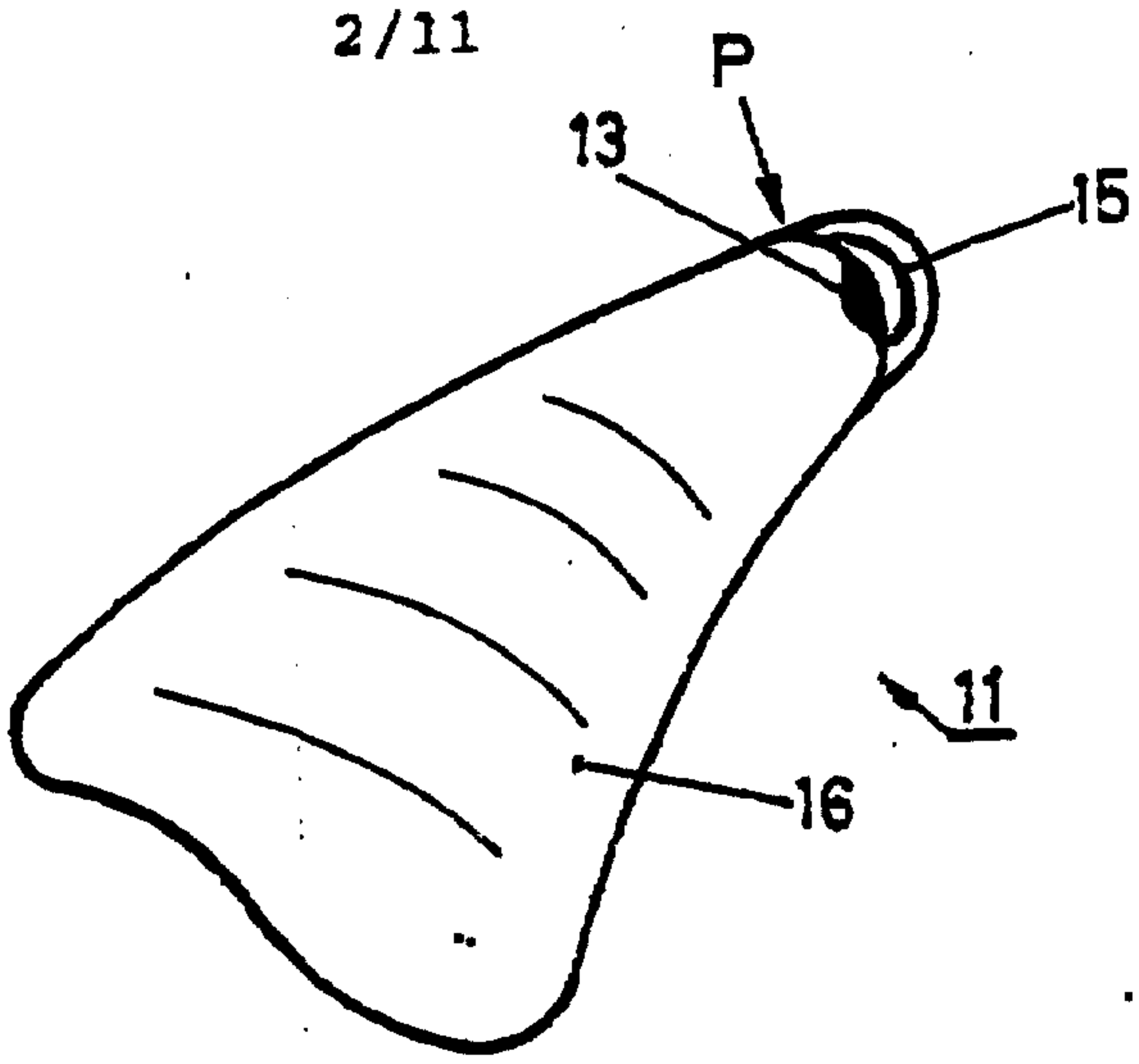


FIG.4

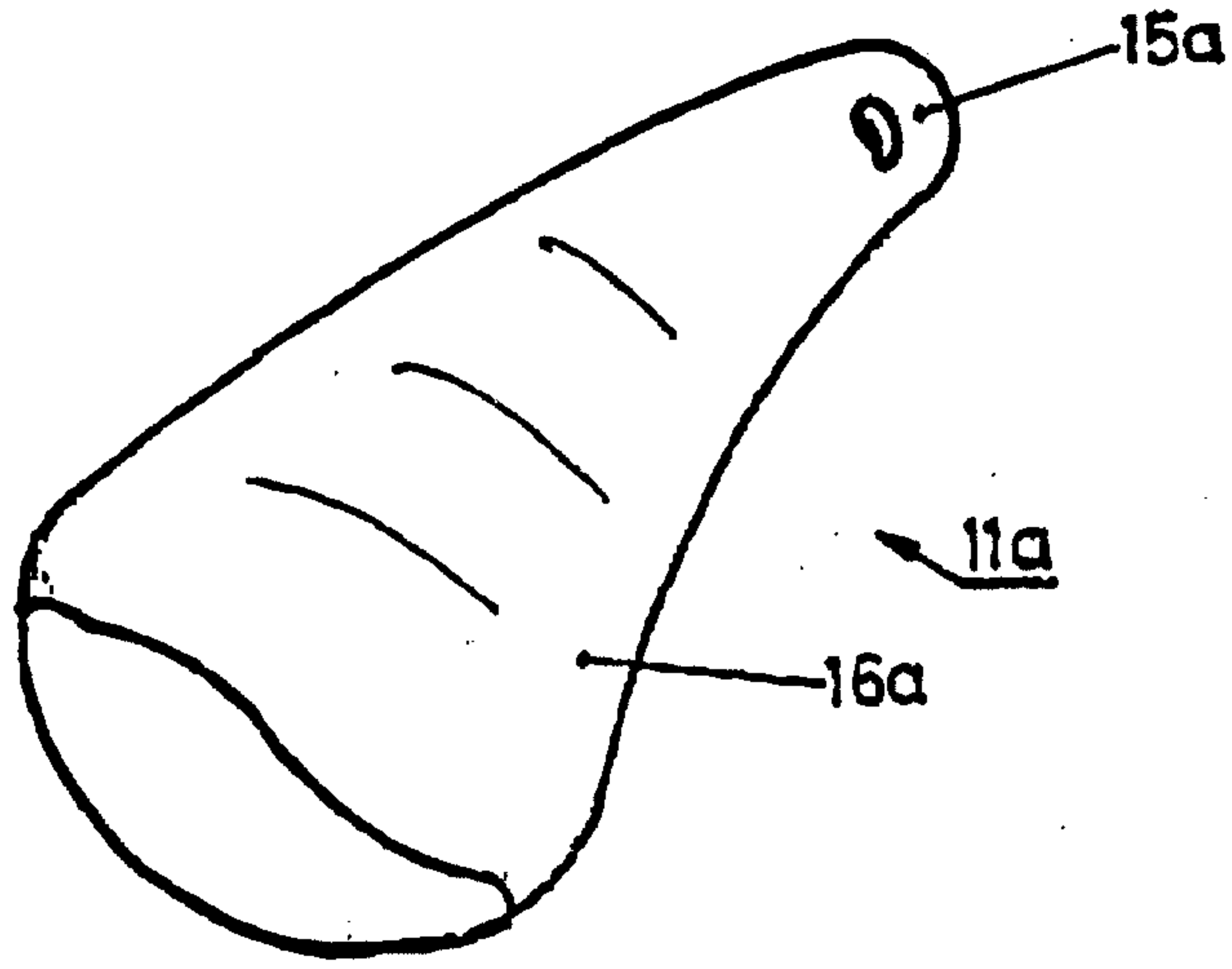


FIG.5

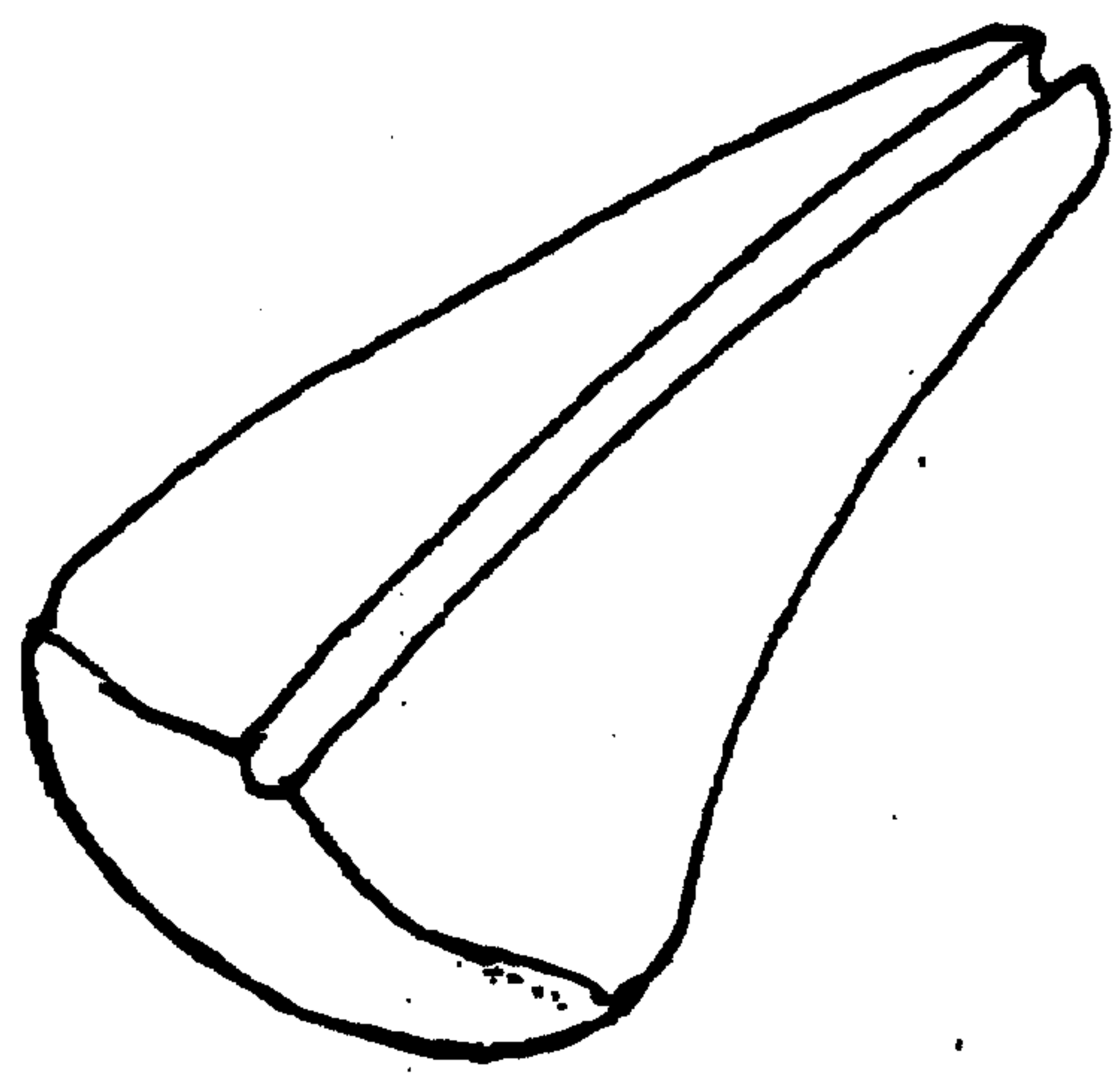


FIG.6

REPLACEMENT SHEET (RULE 26)

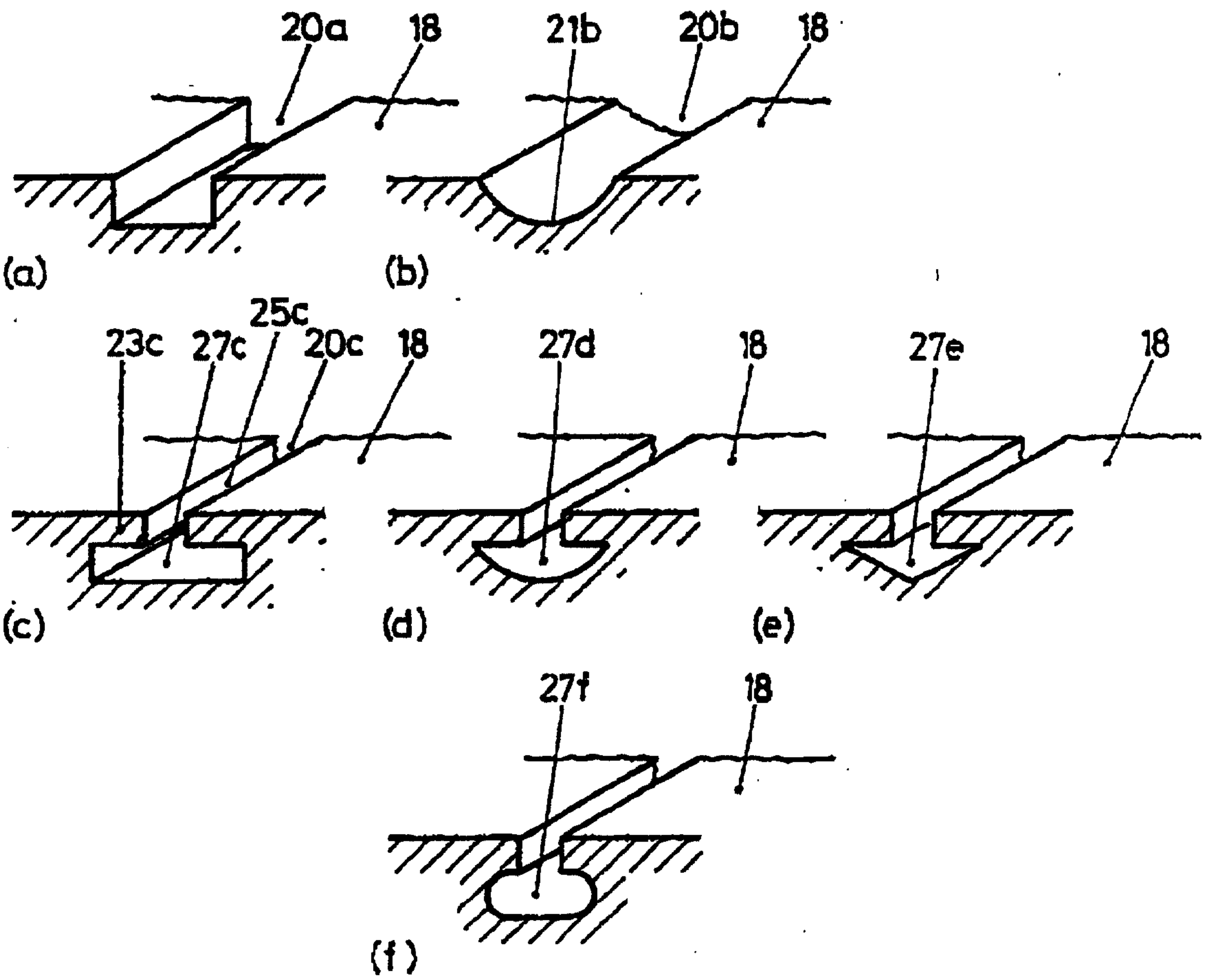

20a
18
21b
20b
18
(a)
(b)
25c
23c
27c
20c
18
27d
18
27e
18
(c)
(d)
(e)
27f
18
(f)

FIG.7

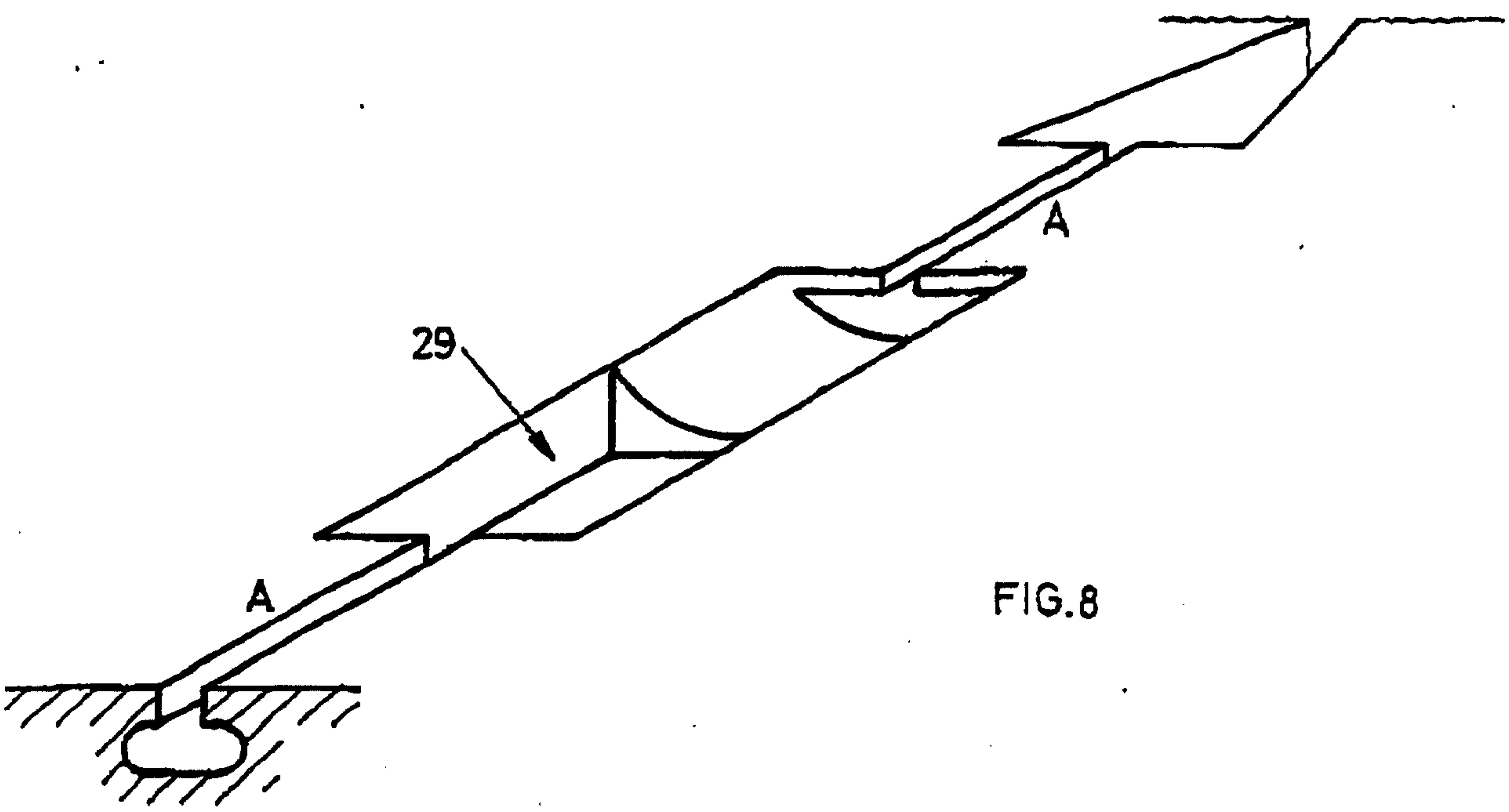

A
29
A

FIG.8

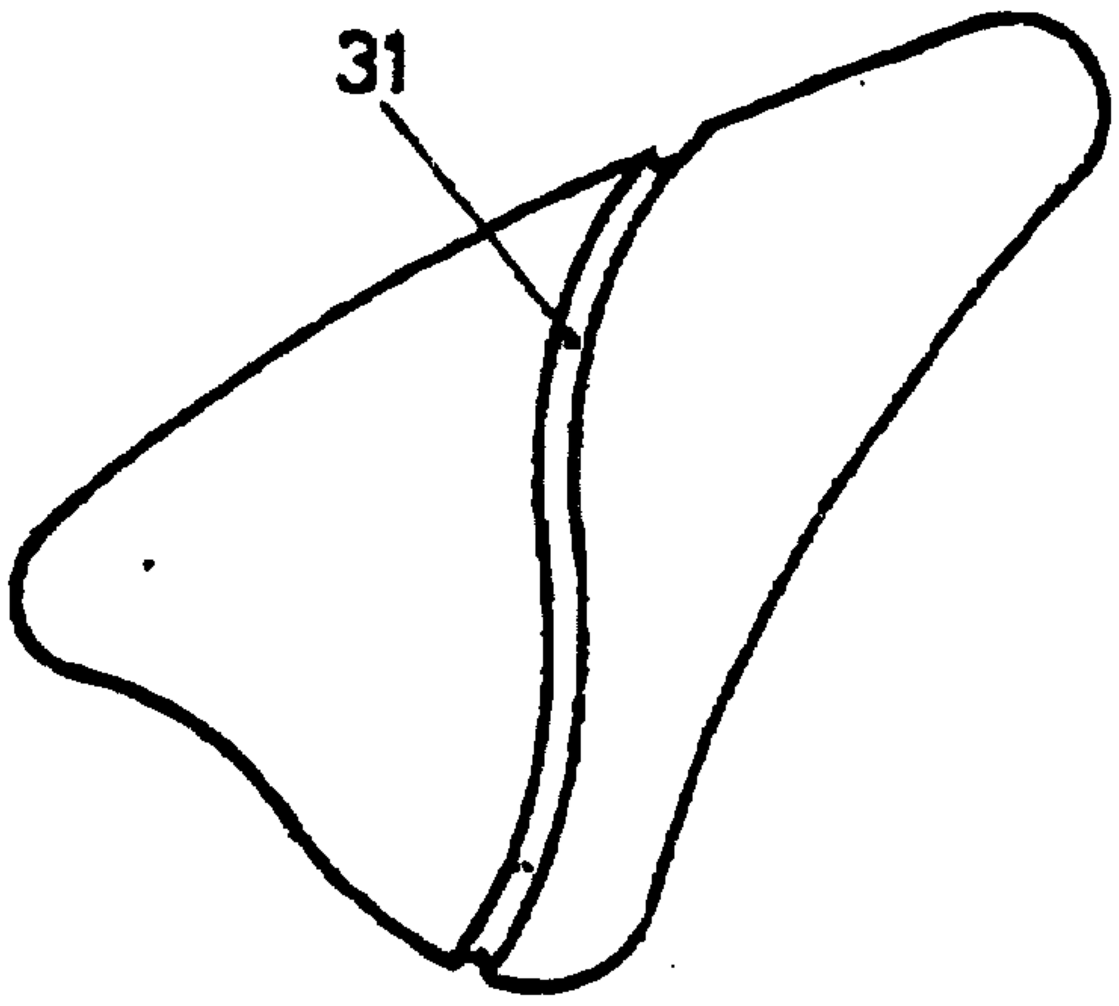


FIG.9

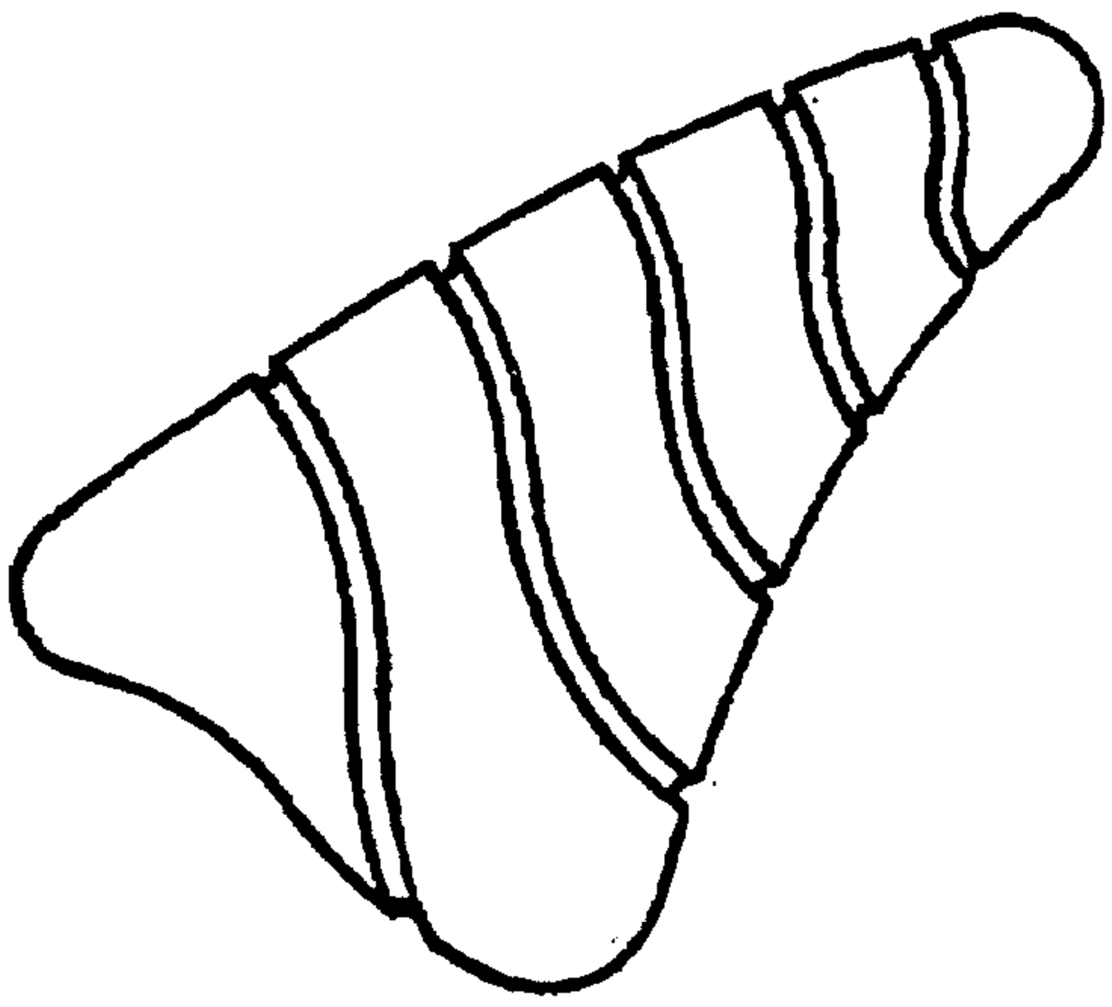


FIG.10

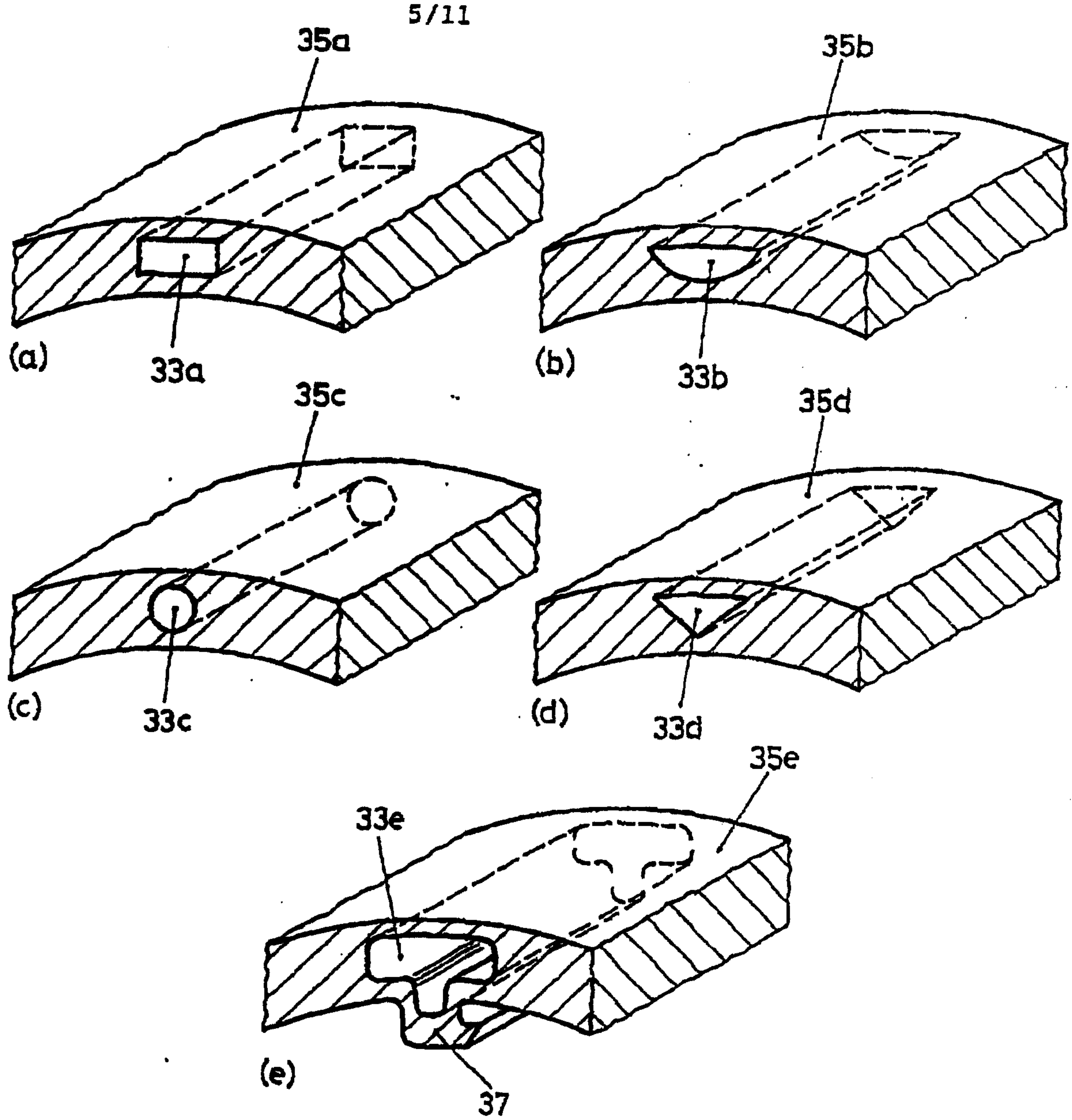


FIG.11

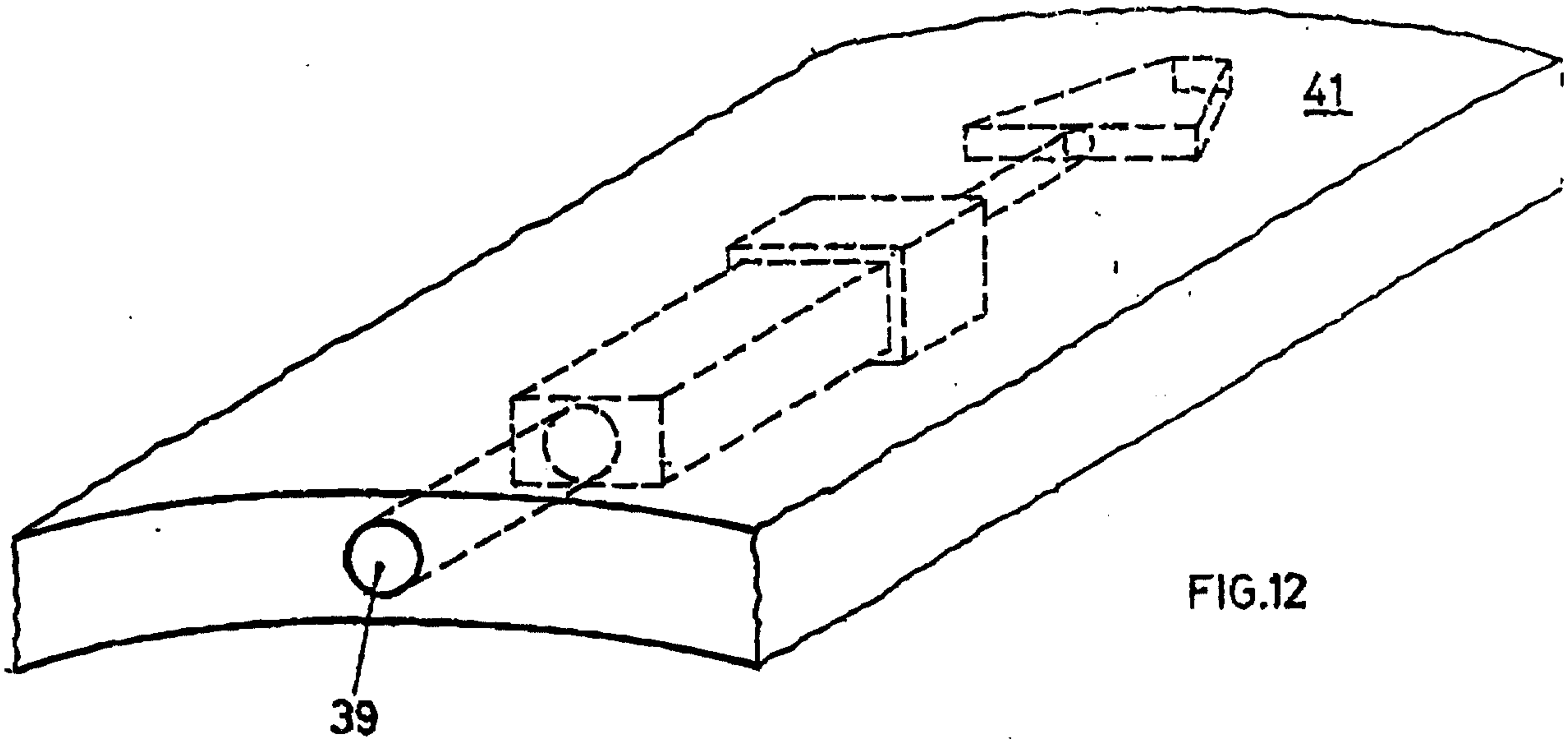


FIG.12

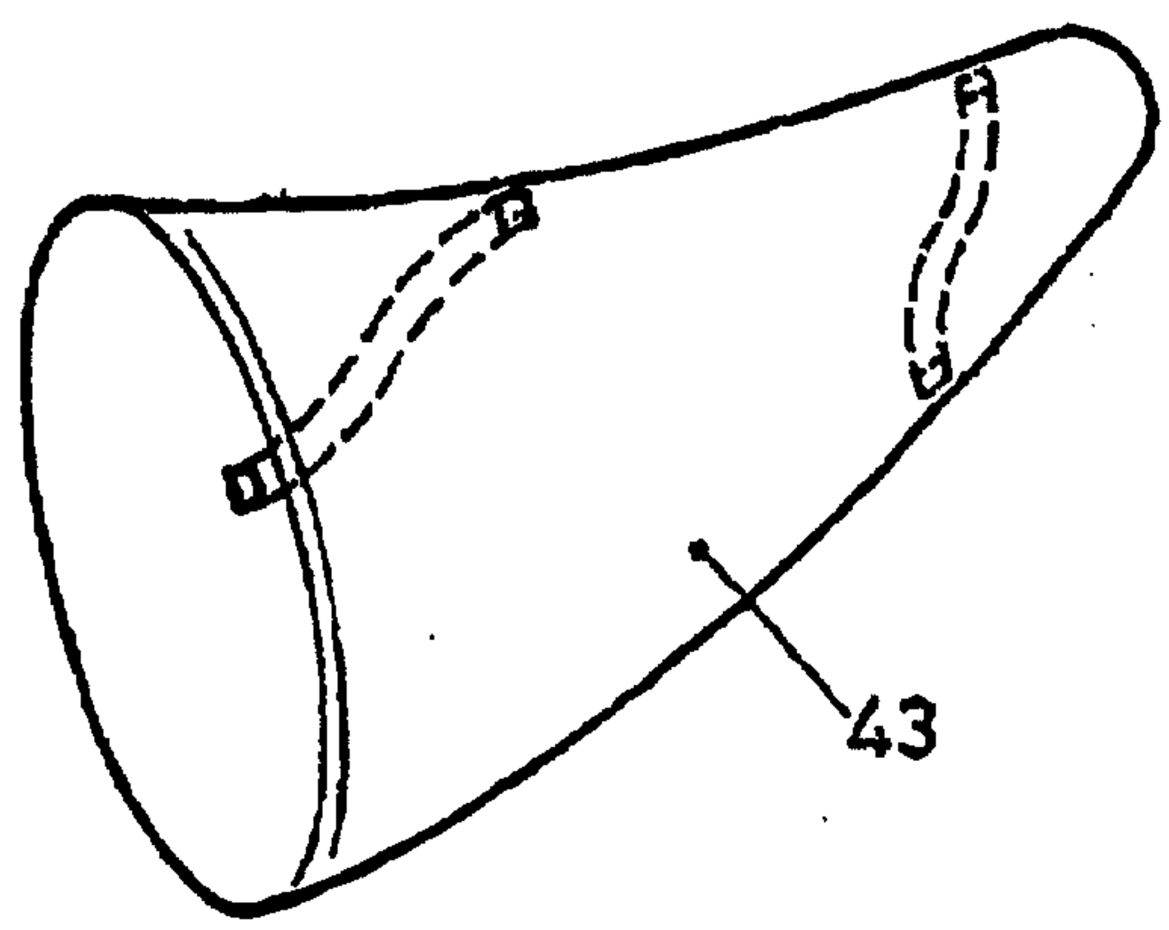


FIG.13

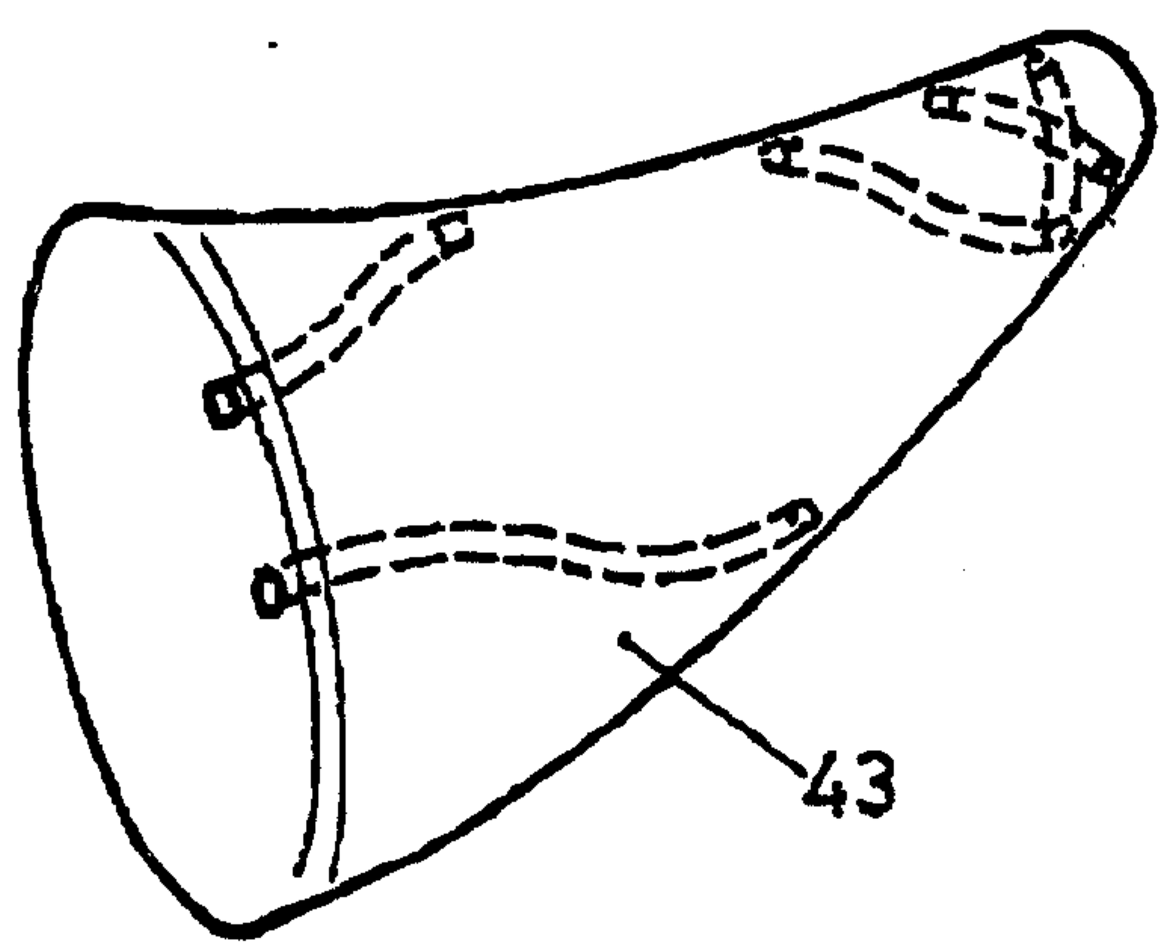


FIG.14

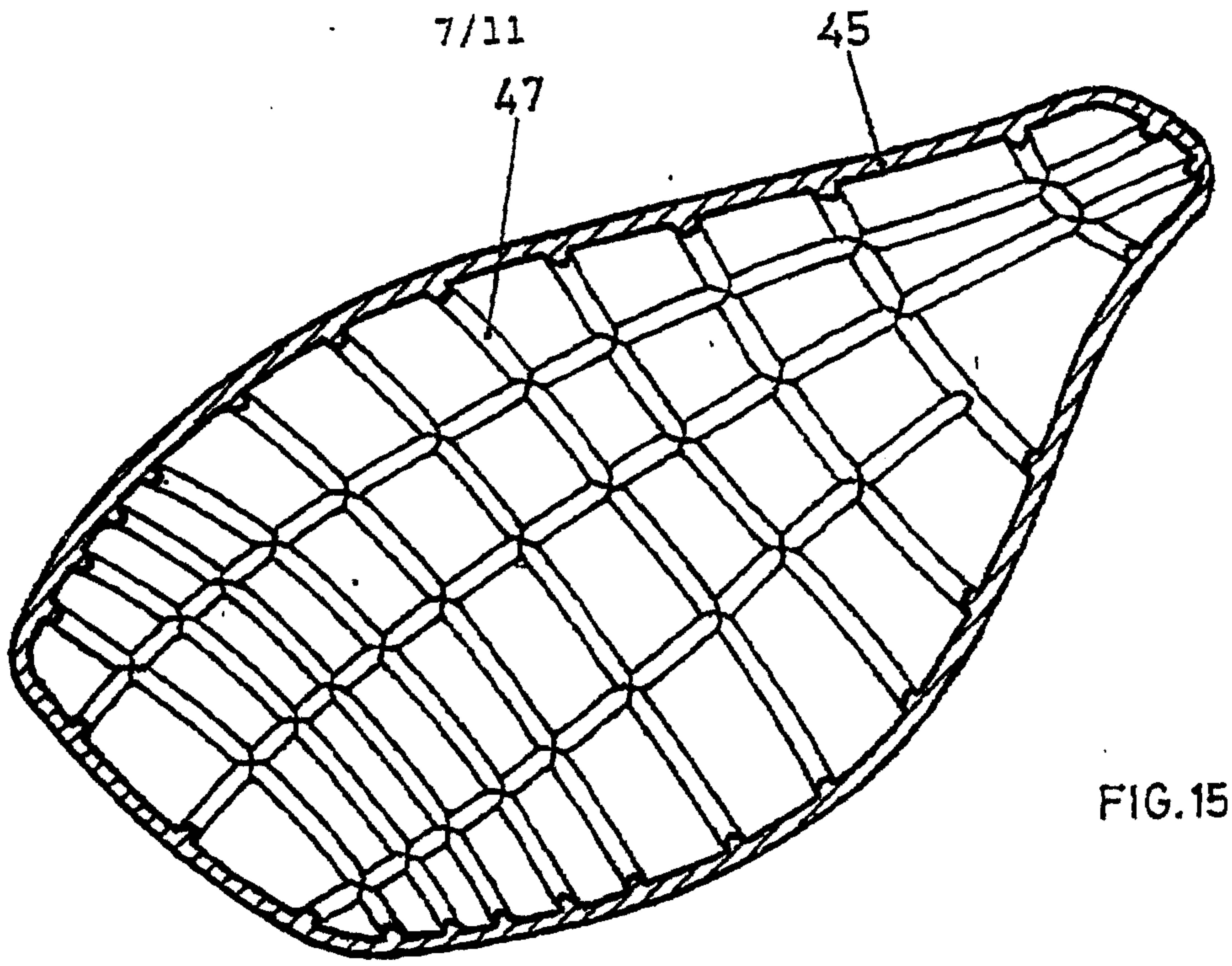


FIG.15

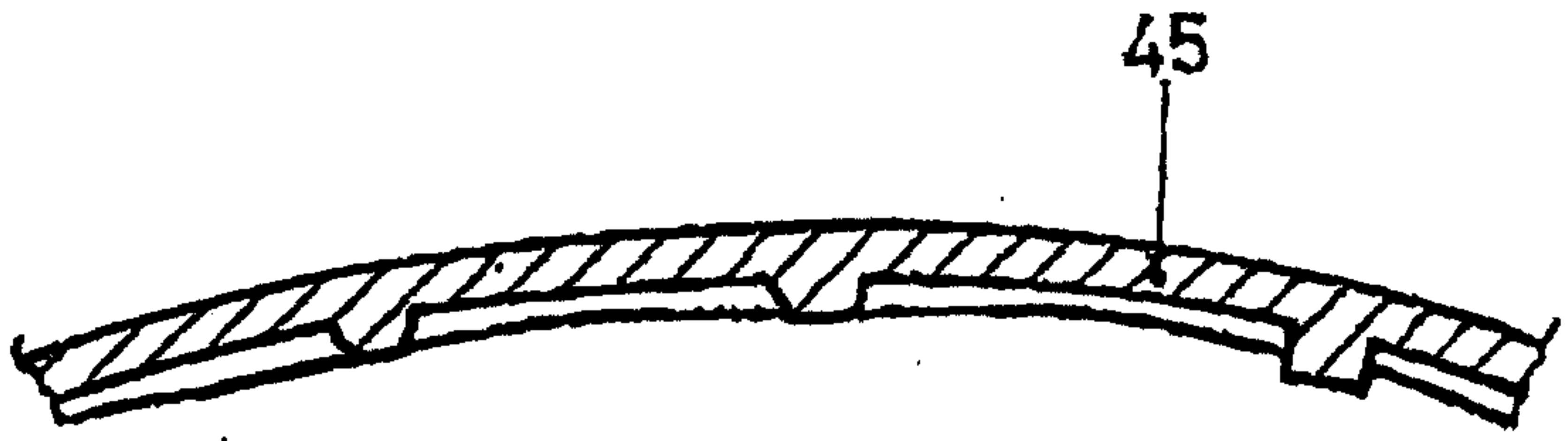


FIG.16

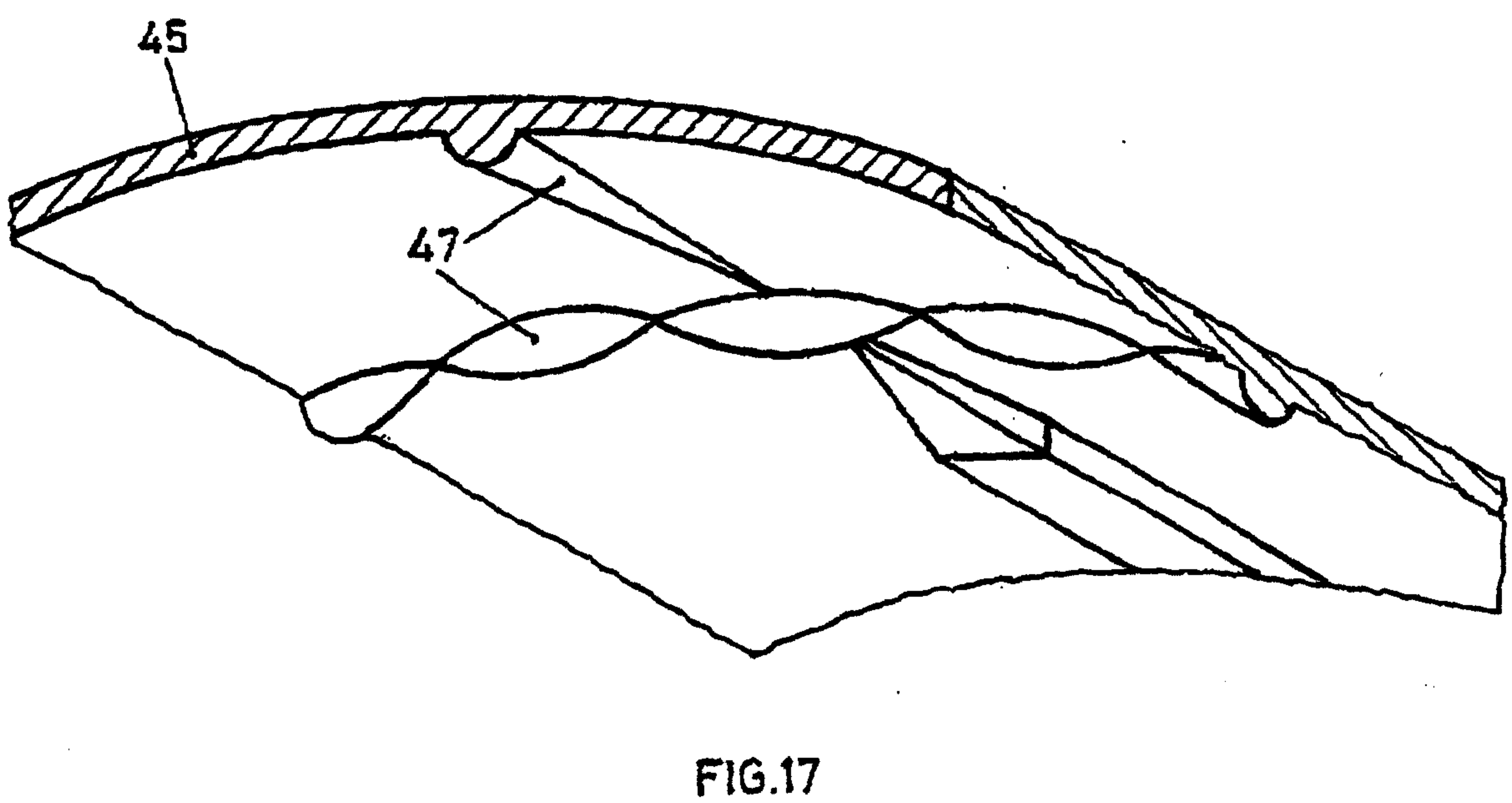


FIG.17

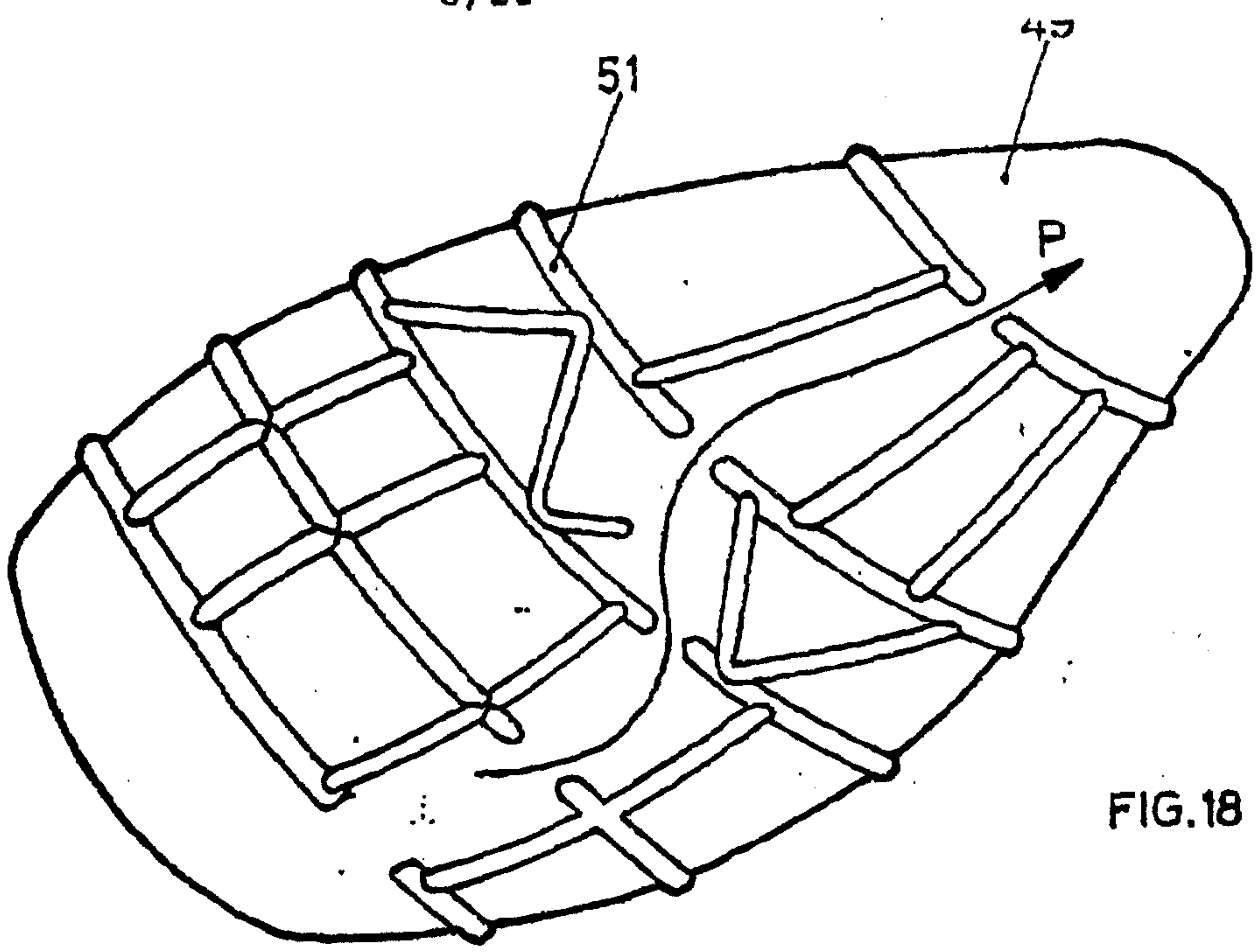


FIG.18

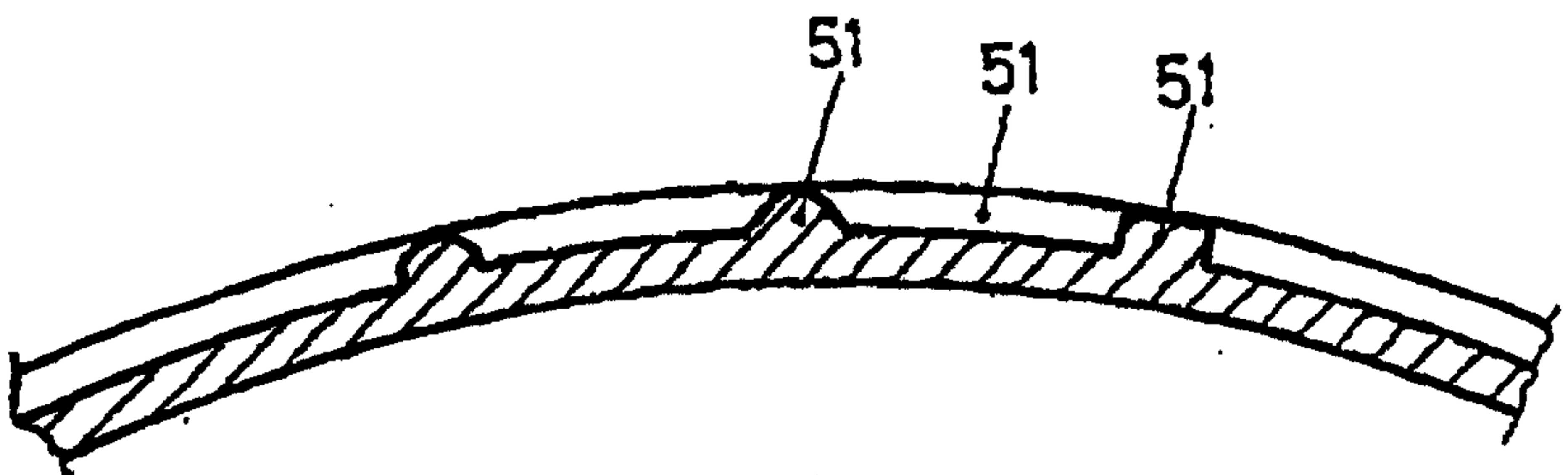


FIG.19

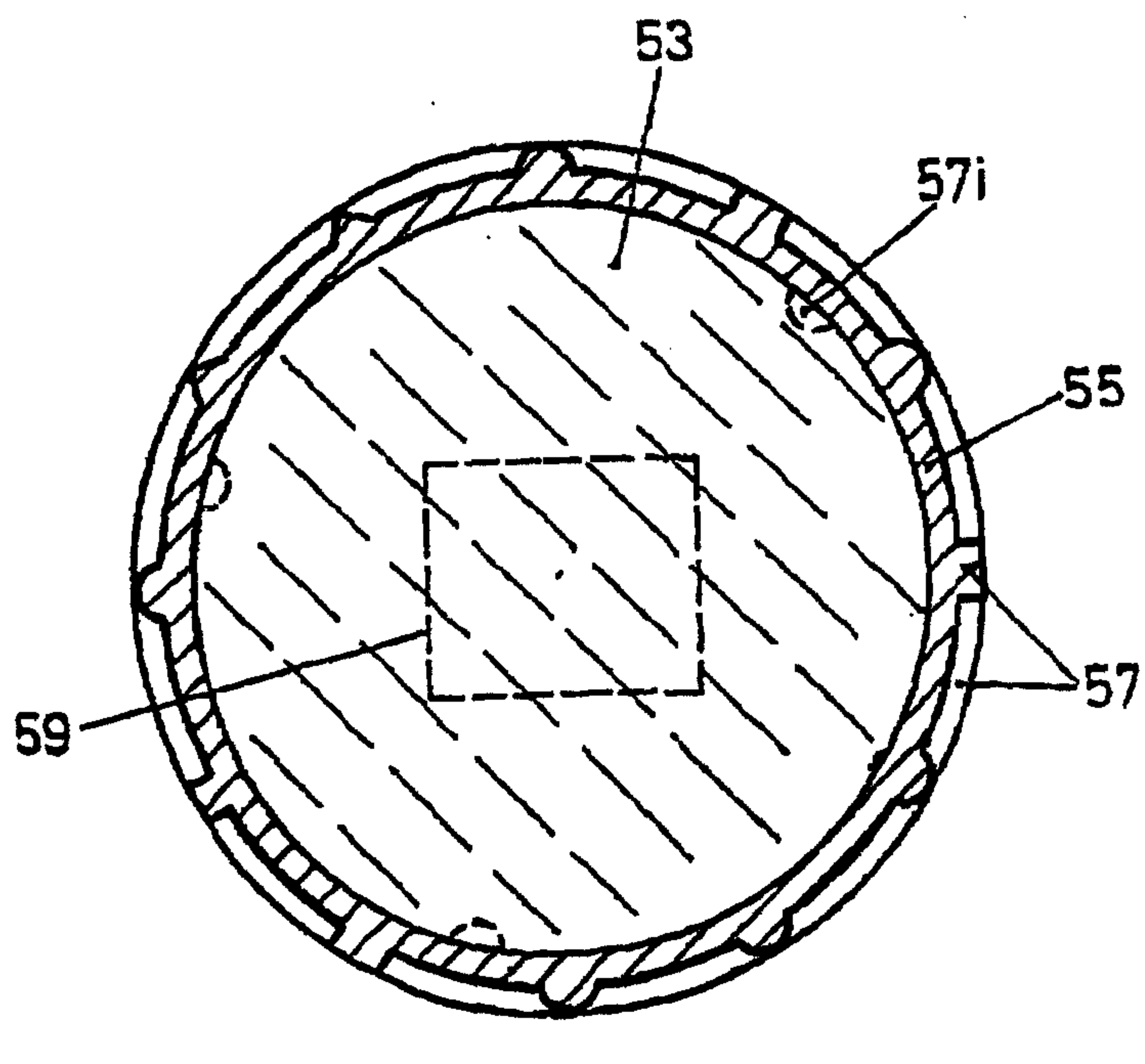


FIG.20

REPLACEMENT SHEET (RULE 26)

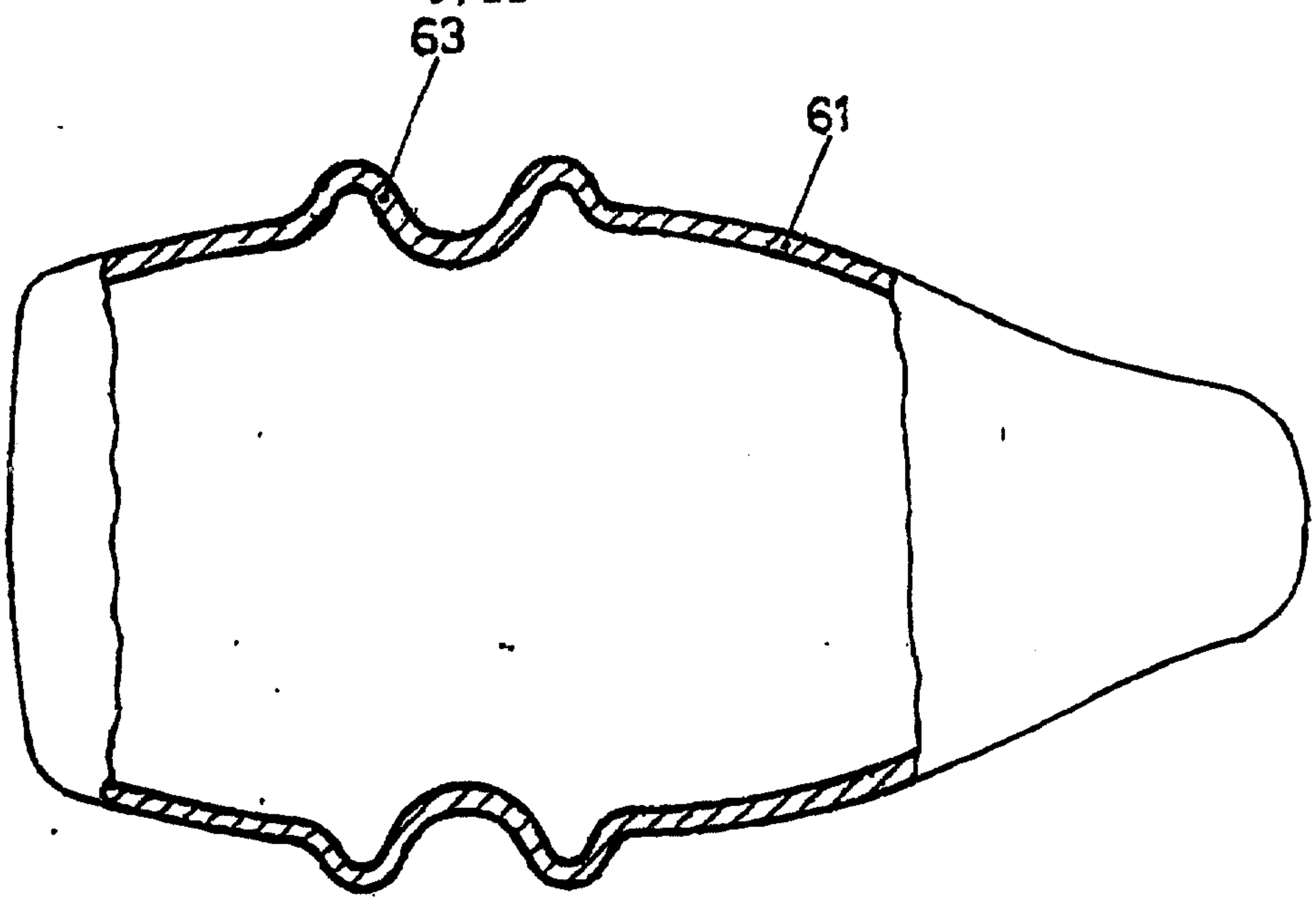


FIG.21

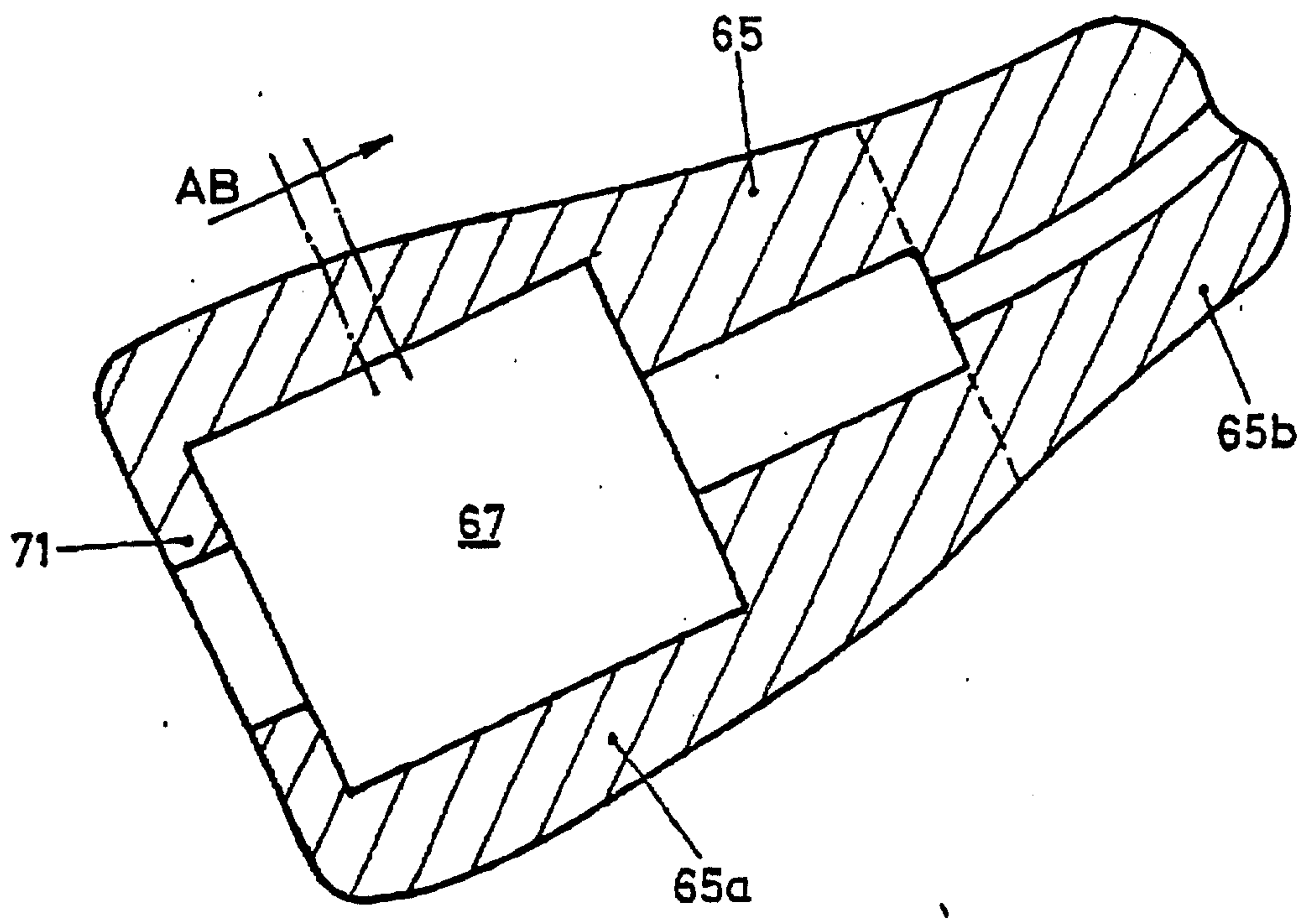


FIG.22

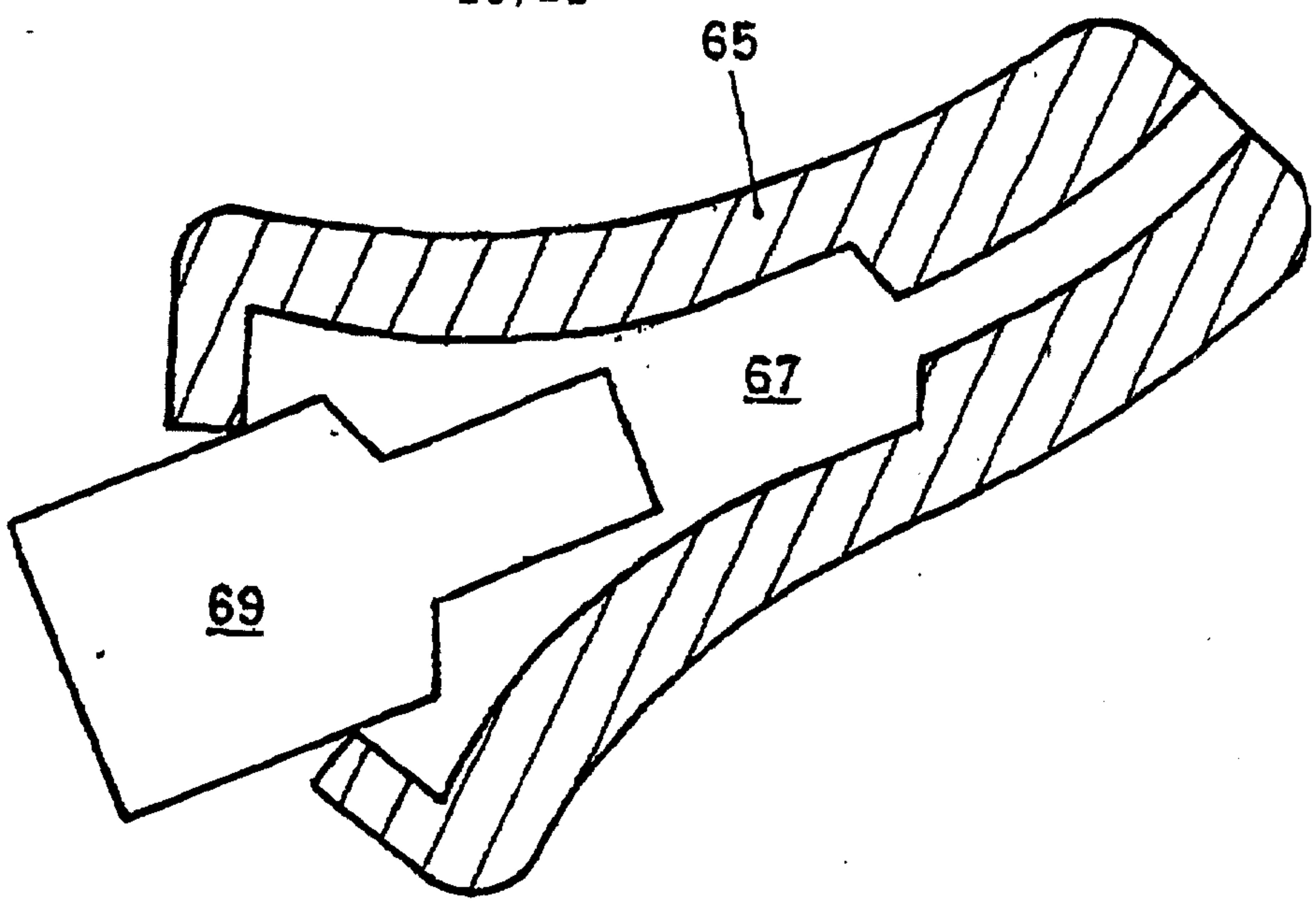


FIG.23

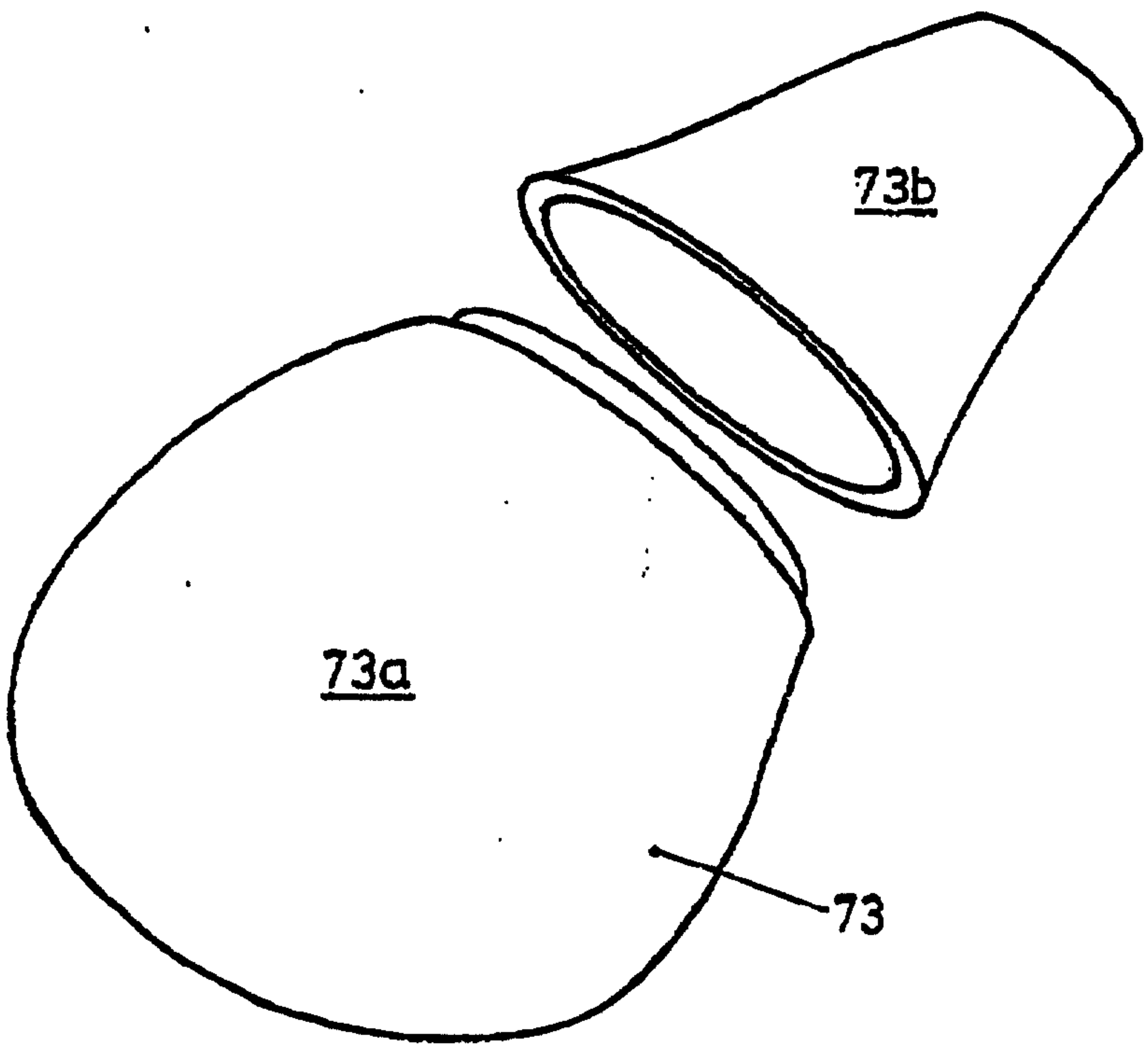


FIG.24

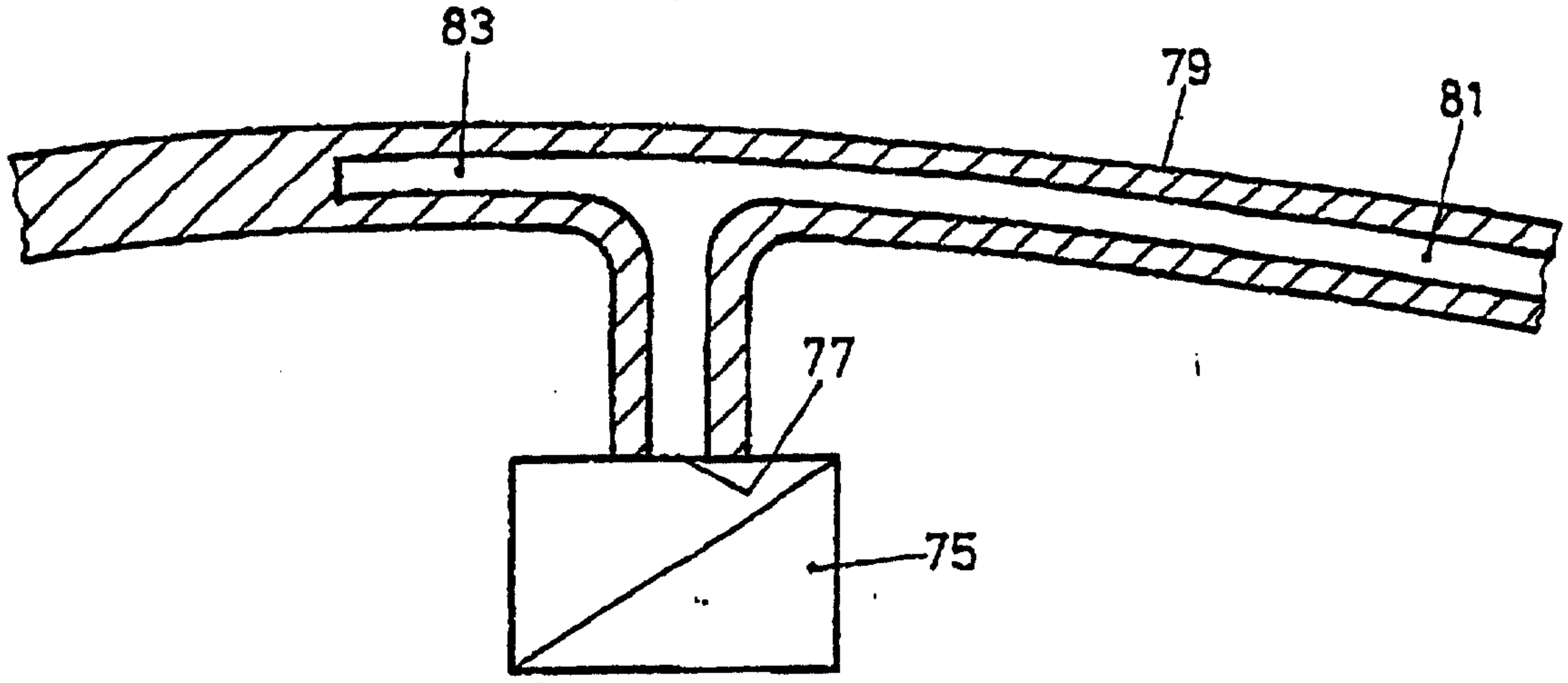


FIG.25

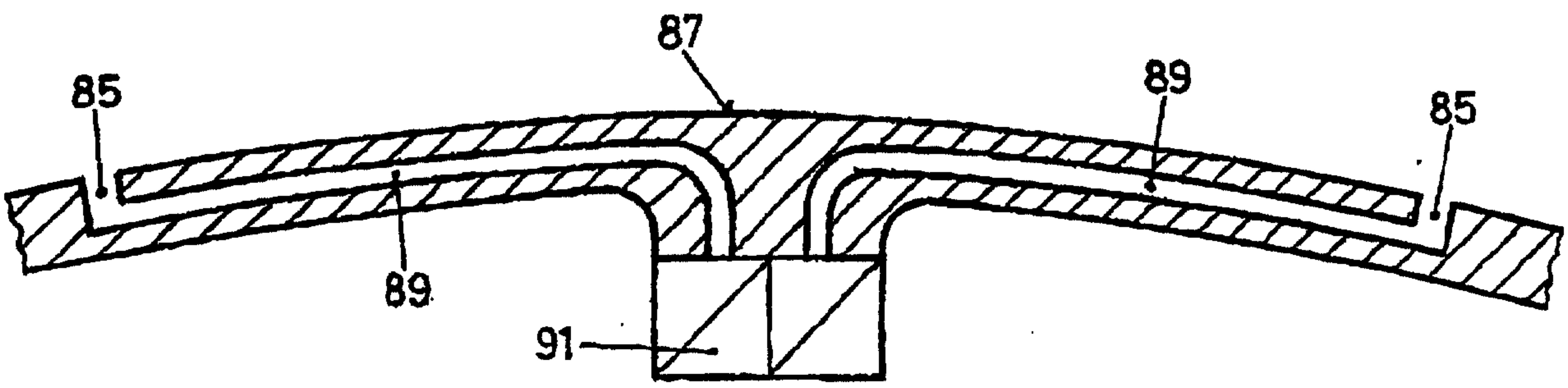


FIG.26

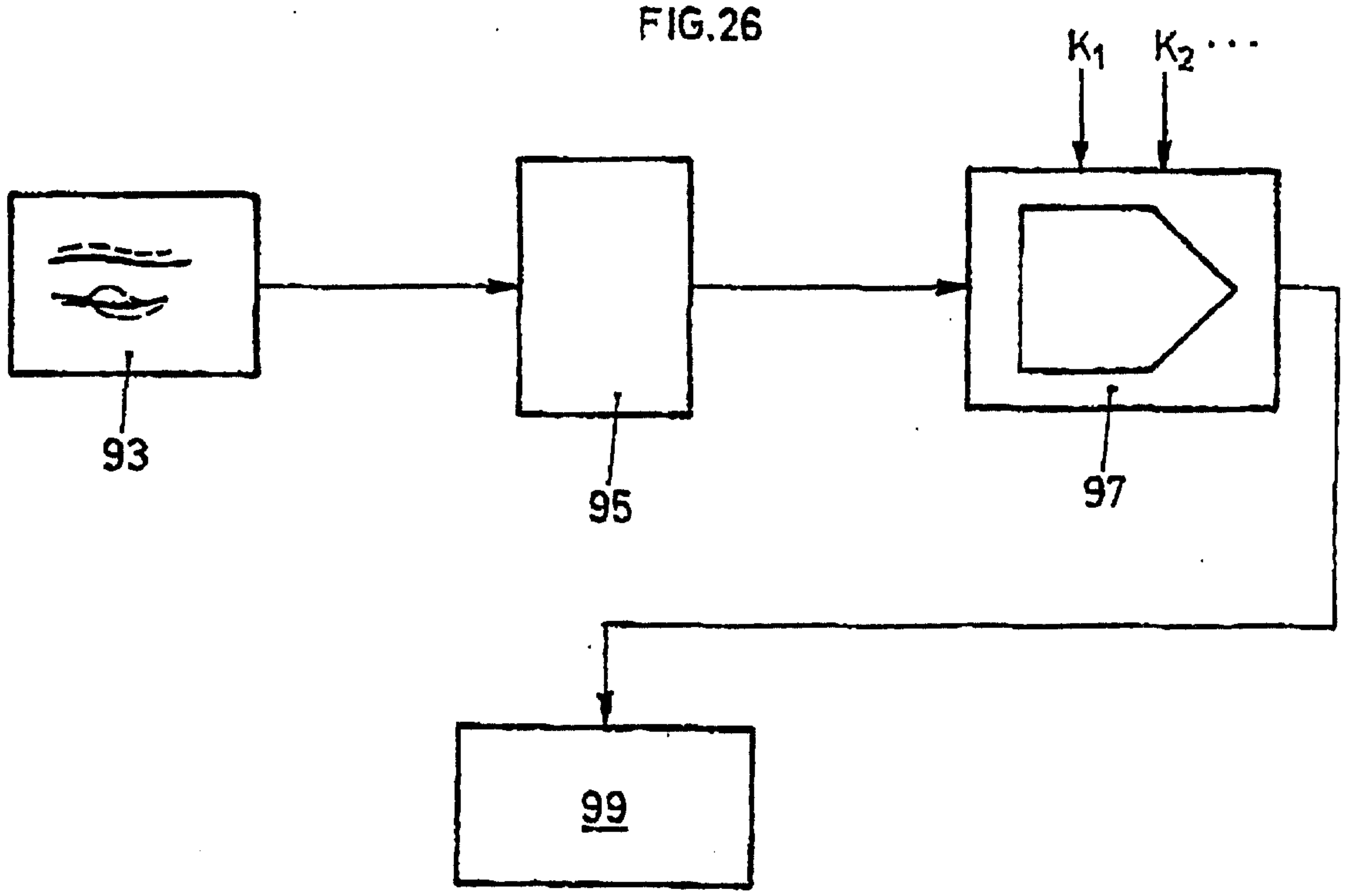
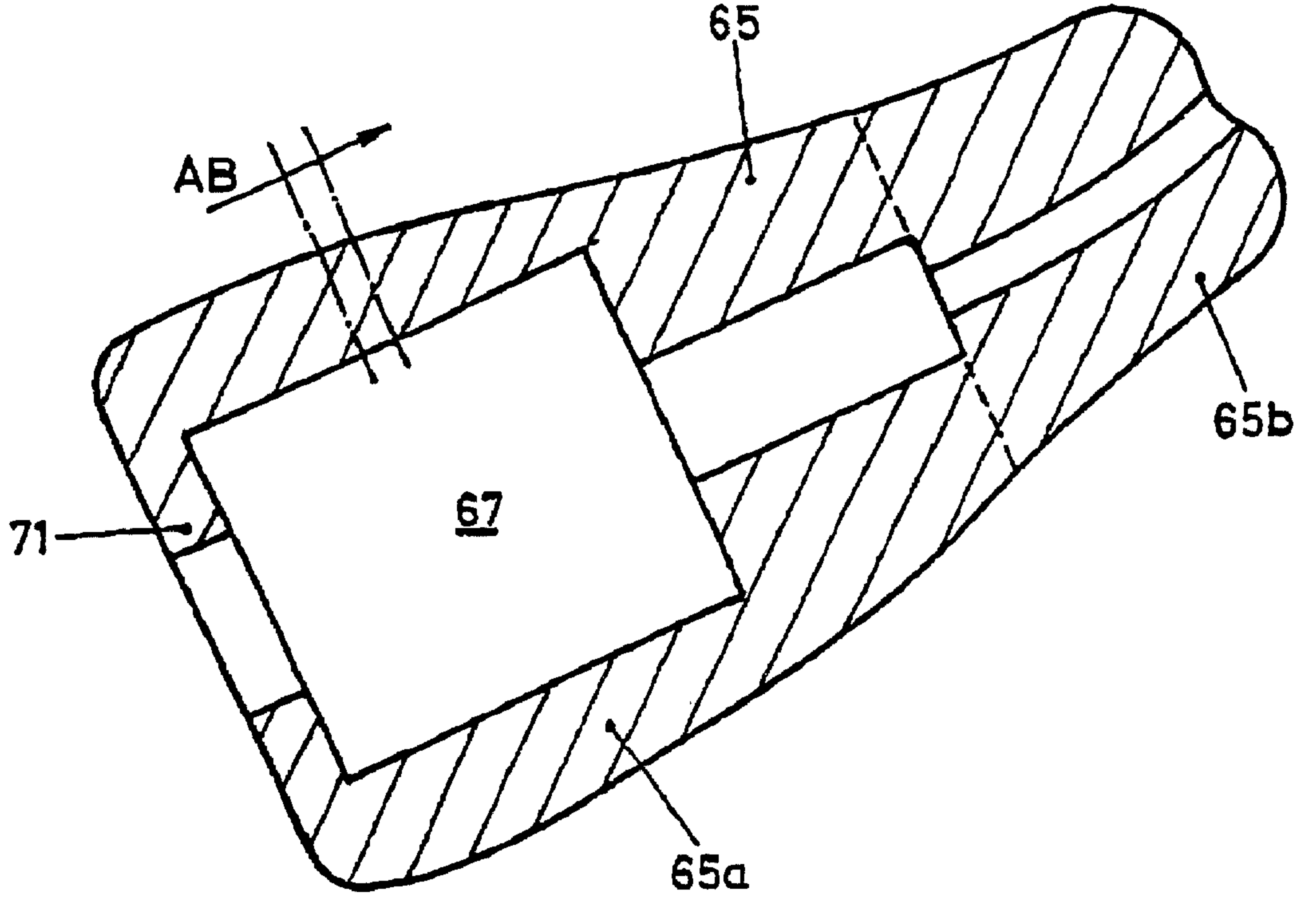


FIG.27


65
AB
65b
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