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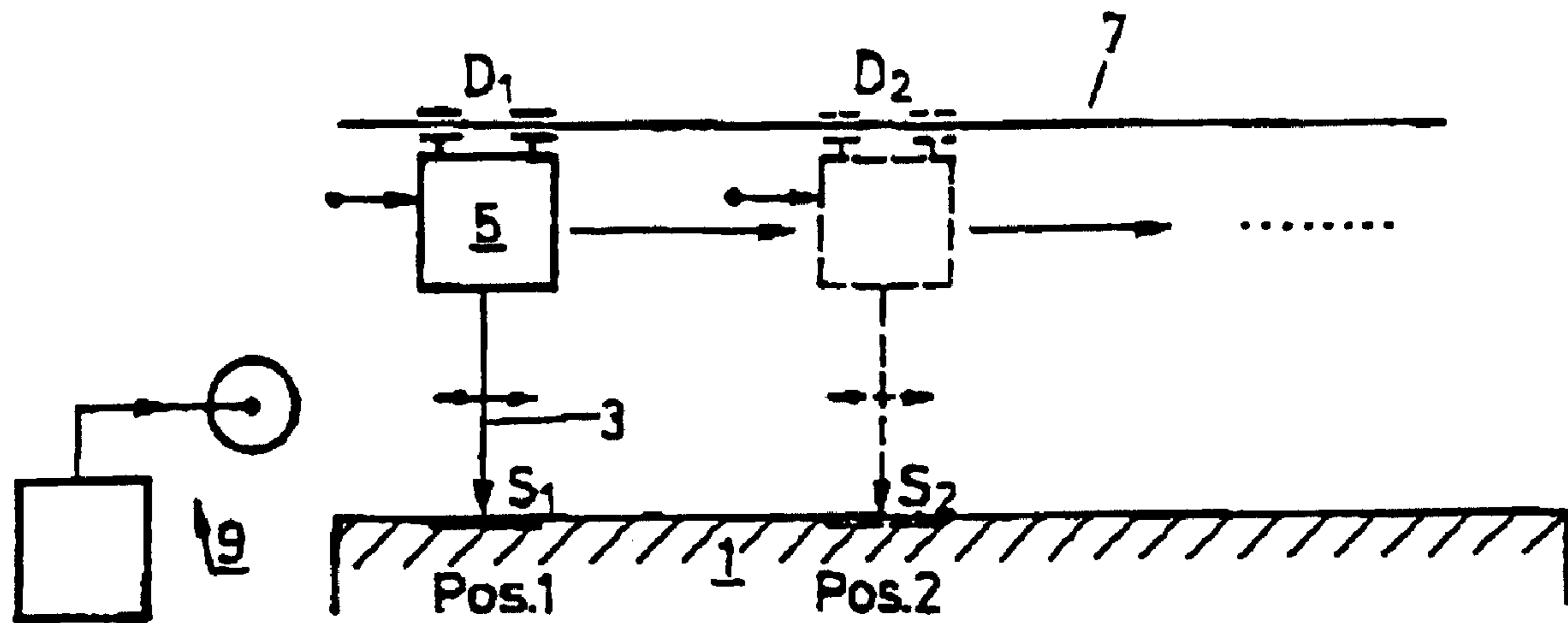
(71) Demandeur/Applicant:
PHONAK AG, CH

(72) Inventeurs/Inventors:
WIDMER, CHRISTOPH, CH;
DUTTA, JOYDEEP, CH

(74) Agent: ROBIC

(54) Titre : PROCEDE DE FABRICATION D'OTOPLASTIQUES ET OTOPLASTIQUE Y RELATIF

(54) Title: METHOD FOR THE PRODUCTION OF OTOPLASTICS AND CORRESPONDING OTOPLASTIC



(57) Abrégé/Abstract:

An impression of the shape of the individual auditory canal is taken in order to produce shells for hearing aids implanted in the ear that very precisely adapt to the individual shape of the auditory canal and a hearing aid shell is produced by means of an additive fabrication process such as laser sintering, stereolithography or a thermojet process that is controlled by means of data pertaining to the shape.

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(72) Erfinder; und

(75) Erfinder/Anmelder (nur für US): **WIDMER, Christoph** [CH/CH]; Glärnischstrasse 48c, CH-8712 Stäfa (CH).
DUTTA, Joydeep [IN/CH]; Avenue Reymondin 28, CH-1009 Pully (CH).(74) Anwalt: **TROESCH SCHEIDEGGER WERNER AG**;
Schwättenmos 14, CH-8126 Zumikon (CH).(81) Bestimmungsstaaten (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.(84) Bestimmungsstaaten (*regional*): ARIPO-Patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI-Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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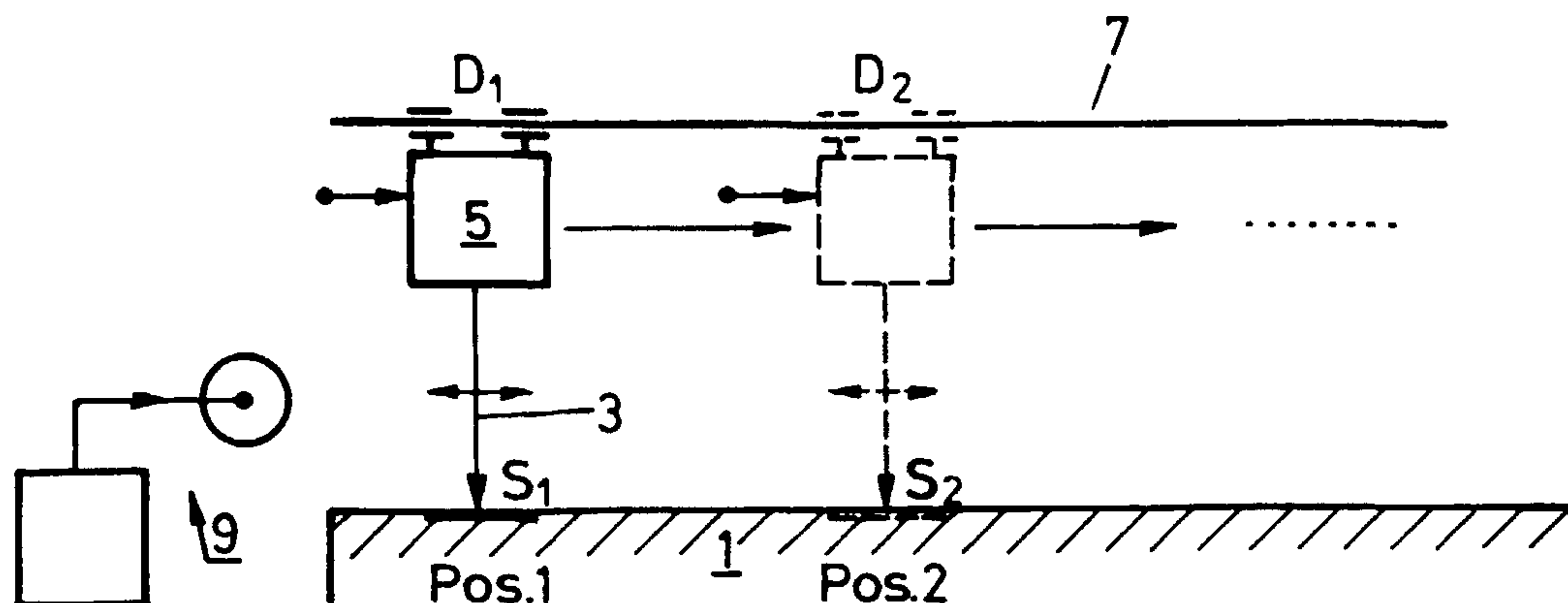
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(54) Title: METHOD FOR THE PRODUCTION OF OTOPLASTICS AND CORRESPONDING OTOPLASTIC

(54) Bezeichnung: VERFAHREN ZUR HERSTELLUNG VON OTOPLASTIKEN UND OTOPLASTIK



(57) Abstract: An impression of the shape of the individual auditory canal is taken in order to produce shells for hearing aids implanted in the ear that very precisely adapt to the individual shape of the auditory canal and a hearing aid shell is produced by means of an additive fabrication process such as laser sintering, stereolithography or a thermojet process that is controlled by means of data pertaining to the shape.

(57) Zusammenfassung: Für die Herstellung von Schalen für Im-Ohr-Hörgeräte, welche sehr exakt der individuellen Gehörgangform anzupassen sind, wird vom individuellen Gehörgang Form genommen, und eine Hörgeräteschale durch ein additives Aufbauverfahren erstellt, wie durch Lasersintern, Stereolithographie oder Thermojetverfahren, das durch die Formdaten gesteuert wird.



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Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

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Method for the production of otoplastics and corresponding otoplastic

5 The present invention relates to a method according to the preamble of claim 1 and to an otoplastic according to the preamble of claim 7.

10 The present invention starts out from problems which have arisen in the production of in-the-ear hearing devices. However, the solution which has been found to these problems can be applied in general to otoplastics whose definition is referred to further below.

15 In the production of shells for in-the-ear hearing devices, the customary practice followed at present by the audiologist is to make a mold in the shape of the individual auditory canal, by taking an impression, usually of silicone.

20 This mold is subsequently sent to the producer of the hearing devices where the hearing device shell is molded from a plastic on the basis of this mold.

This procedure is problematic from various aspects:

25

• In the production method based on the aforementioned impression, polymer materials which lead to relatively hard, dimensionally stable shells have to be used. This virtually always
30 leads to the shell having to be re-worked on account of remaining pressure points when the finished in-the-ear hearing device is fitted into the individual ear.

35 • The aforementioned procedure no doubt permits the resulting relatively hard shell to have an outer shape corresponding to the impression, but it does not permit complex internal/external shapes to be

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formed, as would be desirable, for example, in order for functional parts of the hearing device to be received in an optimized way in terms of fitting. In this respect, we understand functional parts as meaning all units which are responsible for picking up, processing and reproducing the audio signals, that is to say of microphones, digital processors, loudspeakers and the associated auxiliary units, such as for remote controls, binaural signal transmissions, batteries, etc. In this respect, it must be pointed out that optimum packing of these functional parts in a way which utilizes the available space can only be carried out on an individual basis, since the geometry of the auditory canal may vary greatly individually.

The procedure described is, on the one hand, highly labor-intensive, and the resulting hearing device usually remains less than optimum with respect to its wearing comfort and space utilization. The materials used in said conventional production method also entail a relatively great wall thickness of the shell of the in-the-ear hearing device, which reduces the space available for said functional parts more than is the case anyway.

The present invention has the purpose of overcoming these stated disadvantages. For this purpose, it is characterized by the fact that the at least one mold is digitized three-dimensionally to obtain a set of data, and the otoplastic or its shell is created by an additive construction method, controlled using the set of data. Although this production method is suitable particularly for in-the-ear hearing devices, it can also be used with similar advantages for hearing devices worn outside the ear, and also for other otoplastics, for example for the production of headphones of all types, inserts for protecting against

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water, inserts for protecting against noise, etc. In a preferred embodiment of the method according to the invention, account is taken of the fact that the site of application of otoplastics, particularly of in-the-ear otoplastics, is routinely subject to considerable dynamics, for example the auditory canal is subject to the dynamics of chewing movements. Taking a single impression of the application site, as it were like an instantaneous image, it is not possible for these dynamics to be taken into account when producing the otoplastic. Therefore, in a preferred embodiment of the method according to the invention, it is proposed to take a plurality of impressions of the individual application site in natural movement or in positions of the natural movement and record the dynamics of the application site like a film and thus control the additive construction method as a function of the set of data thereby obtained.

The production method according to the invention, and otoplastics realized using this method, are also 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 otoplastics which operates in accordance with the method according to the invention;

30

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;

35

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

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

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

10

Figures 7 (a) through (f) show,

with the aid of perspective views of cutouts of otoplastic shell surfaces, ventilation grooves produced by the method according to the invention;

15

Fig. 8 shows, based on a diagrammatic cutout of an otoplastic surface, a ventilation groove produced by the method according to the invention with a cross section and cross-sectional shape varying along its longitudinal extent;

20

Fig. 9 shows a diagrammatic view of an in-the-ear otoplastic with lengthened ventilation groove processed in accordance with the method according to the invention;

25

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

30

Figures 11 (a) through (e) show

35

cutouts of otoplastic shells with ventilation channels of different cross-sectional shapes and dimensions formed in accordance with the

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method according to the invention;

- Fig. 12 shows, in a view analogous to that in Fig. 8,
a ventilation channel produced in accordance
5 with the method according to the invention in
an otoplastic shell with a cross-sectional
shape and cross-sectional surface varying
along its longitudinal extent;
- 10 Fig. 13 shows, diagrammatically in analogy to the
view in Fig. 9, an in-the-ear otoplastic with
a lengthened ventilation channel formed in
accordance with the method according to the
invention;
- 15 Fig. 14 shows, in a view analogous to Fig. 10, an in-
the-ear otoplastic with a plurality of
ventilation channels produced in accordance
with the method according to the invention;
- 20 Fig. 15 shows a diagrammatic view, in longitudinal
section, of an in-the-ear otoplastic with
ribbed inner surface;
- 25 Fig. 16 shows a cutout of the otoplastic according to
Fig. 15 in cross section, the ribs having
different cross-sectional surfaces;
- 30 Fig. 17 shows a perspective view of the cutout of an
otoplastic shell with inner ribbing according
to Fig. 15 or 16, the ribs having different
cross-sectional shapes and dimensions along
their longitudinal extent;
- 35 Fig. 18 shows, in a view analogous to Fig. 15, an in-
the-ear otoplastic with outer ribbing
produced in accordance with the invention;
- Fig. 19 shows a diagrammatic view of a cutout of a

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ribbed otoplastic shell according to Fig. 18, with ribs having different cross-sectional surfaces;

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

10 Fig. 21 shows a diagrammatic cutout, in longitudinal section, of an otoplastic shell produced in accordance with the invention with a part which is flexible upon bending and compression;

15 Fig. 22 shows a diagrammatic view, in longitudinal section, of an in-the-ear otoplastic produced in accordance with the invention with a receiving space for an electronic module;

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

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

30 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
35 otoplastic produced in accordance with the invention;

Fig. 26 shows, in a view analogous to that in Fig. 25, the arrangement of two or more acoustic

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leads in the shell of an otoplastic shell
produced in accordance with the invention,
and

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

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

Definition

An otoplastic is to be understood here as being a
20 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,
25 etc.

1. Production method

In the production method preferably used to produce the
30 otoplastics described in detail hereinafter, the shape
of an individual application area for an intended
otoplastic is three-dimensionally digitized, and the
otoplastic or its shell is then constructed by an
additive construction method. Additive construction
35 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:

- <http://ltk.hut.fi/~koukka/RP/rptree.html> (1)

or to

- 5 · 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,
10 laser lithography or stereolithography, or the thermojet method are particularly well suited for constructing otoplastics or their shells, and in this case in particular the specific embodiments described hereinafter. Therefore, specifications of these
15 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
20 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 otoplastic or otoplastic shell, by means of the 3-D shape information of the individual
25 application area. A solidified cutting layer of the otoplastic 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
30 turn solidified by laser according to a cutting layer, etc.

- Laser lithography or stereolithography: A first cutting layer of an otoplastic or of an otoplastic
35 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 otoplastic or of its shell is

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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.

5

• Thermojet method: The contour formation in accordance with a cutting layer of the otoplastic or of the otoplastic 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 otoplastic or its shell is built up by depositing layer after layer.

10

15

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

20

• http://www.padtinc.com/srv_rpm_sls.html (3)

25

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

30

• http://www.caip.rutgers.edu/RP_Library/process.html (5)

• <http://www.biba.uni-bremen.de/groups/rp/lom.html>

and

35 • http://www.biba.uni-bremen.de/groups/rp/rp_intro.html (6)

• Donald Klosterman et al., "Direct Fabrication of Polymer Composite Structures with Curved LOM",

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Solid Freeform Fabrication Symposium, University
of Texas at Austin, August 1999, (7)

• <http://lff.me.utexas.edu/sls.html> (8)

5

• http://www.padtinc.com/srv_rpm_sla.html (9)

• <http://www.cs.hut.fi/~ado/rp/rp.html> (10)

10

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
15 the thermojet method, already in the contour of a cut of the otoplastic or of its shell under construction. The desired cut shape is then stabilized and solidified.

20 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 otoplastic or its shell is thus constructed layer by layer by
25 additive layer-by-layer application.

For industrial production, it is preferable not just for the cutting layer of one individual otoplastic or otoplastic shell to be deposited and solidified in each
30 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 otoplastics or their shells,
35 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,

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the respective otoplastics or their shells are produced individually by digital control.

5 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.

10 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 otoplastic or otoplastic shell. Thereafter, the same laser will solidify the prepared layer of powder according to the cutting layer for the next otoplastic, while the previously solidified layer is
15 lowered and a new layer of powder is deposited there. The laser then operates intermittently between two or more otoplastics or otoplastic shells under construction, and so the idle time of the laser occasioned by the deposition of powder for the
20 formation of one of the shells is exploited for solidification of a cutting layer of another otoplastic under construction.

Fig. 1 shows, in a diagrammatic view, how, in one
25 embodiment, a plurality of otoplastics 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
30 or liquid medium. At position 1, it solidifies the layer S_1 of a first otoplastic 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
35 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 otoplastic layers are prepared simultaneously. It is only when the lasers 5 provided have prepared the

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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 otoplastics or their shells are solidified simultaneously on one or more liquid or powder beds 1 by a plurality of lasers 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 otoplastic 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

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obtain extremely complex shapes of otoplastics 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
5 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
10 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.

15 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
20 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 otoplastic or its shell, in the present
25 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.

30 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 otoplastics
35 or their shells is also much less critical than was hitherto the case, which is of huge importance in particular for in-the-ear otoplastics. Thus, in-the-ear otoplastics, for example as ear protectors, headphones, devices protecting against water, but in particular

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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 otoplastic so that, with the resulting and possibly relatively tight fit of the otoplastic 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 otoplastic 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 otoplastics 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 otoplastics 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 otoplastics surprisingly affords very considerable advantages, specifically for reasons which in themselves are not critical in prototyping, for example the elasticity of

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the thermoplastic materials which can be used, the possibility of individual construction with extremely thin walls, etc.

5 In summary, by using said additive construction methods for the production of otoplastics 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 otoplastic and
10 which are generated with the construction of the otoplastic or its shell. Hitherto, functional elements of this kind were typically fitted into or onto the otoplastic or its shell only after the latter had been produced, which is recognizable from material
15 interfaces or from lack of homogeneity of the material at the connection points.

For said otoplastics, in particular those with electronic inserts, for example for hearing devices,
20 and in particular for in-the-ear hearing devices, examples of elements which can be fitted directly into the otoplastic shell by the proposed technique are: seats and holders for structural parts, earwax protection systems, ventilation channels in the case of
25 in-the-ear otoplastics, and support elements which hold the in-the-ear otoplastic in the auditory canal, for example channel locks.

Fig. 4 shows, in diagrammatic form, an example of an
30 in-the-ear otoplastic 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
35 16 of the otoplastic 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 otoplastic

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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 otoplastics are presented below:

15

2. In-the-ear otoplastics with ventilation

In the case of in-the-ear otoplastics, 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:

25 - As regards acoustics: The ventilation grooves known today are not really adapted to the particular acoustic requirements. Thus, in active otoplastics, 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 otoplastics too, for example ear protectors, they are not able to support the desired protective action and simultaneously maintain the desired ventilation properties.

35

- Earwax sensitivity: The ventilation grooves used today in the outer surfaces of in-the-ear

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otoplastics 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 otoplastics, in particular for in-the-ear hearing devices or ear protectors, but also for otoplastics 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 of in-the-ear otoplastics 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

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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
5 along the outer wall 18 of the otoplastics.

Figures 7(c) through (f) show further ventilation groove profiles which are additionally protected against earwax. The profile of the groove 20c according
10 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
15 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
20 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
25 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
30 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
35 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 otoplastics.

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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 otoplastic 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 otoplastic. 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 otoplastic, for example as is shown in Fig. 9, in practice as grooves running round the otoplastic 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 otoplastic, 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

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specifically optimized in each case with respect to earwax protection and acoustic transmission behavior can be formed along the surface of the otoplastic.

5 2b) Ventilation systems with fully integrated channels

10 This alternative embodiment of the novel ventilation systems is based on ventilation channels which are fully integrated into the otoplastic, 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 otoplastic shell. It should be stressed, however, that when no other units are to be integrated on the otoplastic in question and the latter
15 is designed as a solid otoplastic, the following explanations naturally relate also to a channel passage in any form right through said solid otoplastic.

20 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 otoplastic shell 35a has a rectangular or square cross-sectional shape. In the embodiment
25 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,
30 in the embodiment according to Fig. 11(d), it has a triangular cross-sectional shape.

In the embodiment according to Fig. 11(e), the otoplastic shell has a complex inner shape, for example
35 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 otoplastic shell. Accordingly, its cross-sectional

- 21 -

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 otoplastic 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 otoplastic 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 otoplastic.

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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 otoplastic. 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 otoplastic 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.

20 3. Otoplastics with optimized shape stability

This section deals with providing novel otoplastics which are optimally adapted to the dynamics of the application areas. It is known, for example, that conventional in-the-ear otoplastics 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 otoplastics, 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

- 23 -

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
5 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
10 section of an in-the-ear otoplastic, and Fig. 16 shows a diagrammatic cross-sectional view of a portion of this otoplastic. The otoplastic, for example for receiving electronic components, has a shell 45 which is made, like a pair of tights, as a thin wall of
15 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
20 material as the shell skin.

Depending on the required dynamics of the in-the-ear otoplastic on the one hand, in order for example to take account of the dynamics of the auditory canal, and
25 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 otoplastic
30 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 otoplastic just discussed can be readily
35 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

- 24 -

the otoplastic, if appropriate also advancing from one cross section to the other in their longitudinal extent.

- 5 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.
- 10 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 otoplastic, it is possible, as has been mentioned, in addition to the internal
- 15 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 otoplastic 49, if appropriate with different density, orientation and profile shape
- 20 in different areas.

According to Fig. 19, this can be used for the otoplastics in question here which have a hollow cavity, but also for otoplastics with no hollow cavity, that is to say, for example, with no electronic

25 components, e.g. for ear protector devices and devices protecting against water. One such otoplastic is shown diagrammatically in a cross-sectional view in Fig. 20. Here, the interior 53 is made, for example, from

30 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

35 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

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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
5 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
10 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
15 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 otoplastic is filled with material, that is to say if it is not intended to receive further components, such as electronic components.

20

As is also shown by the broken line 59 in Fig. 20, otoplastics 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
25 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
30 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
35 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

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otoplastic in the form of an in-the-ear otoplastic whose shell is shape-stabilized with ribs lying on the inside and/or outside, resulting in an extraordinarily light and deliberately formable structure. If
5 necessary, this structure can of course also be used for otoplastics worn outside the ear.

Fig. 21 shows a further alternative embodiment of an in-the-ear otoplastic which is deliberately bendable or
10 compressible in one area. For this purpose, the shell 61 of an otoplastic, 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
15 requirements, it is bendable or compressible. Although Fig. 21 shows this measure on the basis of the shell of an in-the-ear otoplastic, it is entirely possible, if necessary, to provide this measure also for an otoplastic worn outside the ear. For this purpose, the
20 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
25 internal volume of the otoplastic 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
30 acoustic conditions.

4. Modular housing/built-in components

Particularly in the case of in-the-ear hearing devices,
35 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

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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
5 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
10 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
15 possible to improve this, on account of the fact that automatic shape adjustment of the otoplastic 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
20 otoplastics. However, it should be noted that also in the case of otoplastics 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
25 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
30 otoplastic 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 otoplastic 65 is made of rubber-elastic material and, as is shown in
35 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 otoplastic 65. By means of this measure, it is easily

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possible to provide one and the same electronic modules
69 with different otoplastics 65, for example in order
thereby to take account of the changing shape of the
auditory canal in a growing child. The otoplastic in
5 practice becomes an easily exchangeable throw-way
accessory for the in-the-ear hearing device. The
otoplastic 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
10 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
otoplastic, or at least in order to use sterilized
15 otoplastics 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 otoplastic 65 is preferably
20 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.

25 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 otoplastic, for
example as part of the module holder. The same applies
to other holders and receiving seats for electronic
30 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 otoplastic from
35 different materials in said construction direction AB,
according to the requirements in the respective areas.
This applies also to the otoplastics 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

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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.

- 5 Fig. 24 shows a further embodiment of an otoplastic, 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 otoplastic shell of an in-the-
10 ear otoplastic 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
15 parts 73a and 73b of the in-the-ear otoplastic 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
20 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
25 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.
- 30 This embodiment can of course also be combined with the alternative embodiments described above and those still to be described.

35 5. Integration of acoustic leads in otoplastics 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-

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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
5 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.

10

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
15 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.

20

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 otoplastic or
25 into the wall of otoplastic shells.

This is shown purely schematically in Fig. 25. A transducer module 75 has an acoustic input/output 77. The shell 79 of the otoplastic of an in-the-ear hearing device, or of a hearing device worn outside the ear, or
30 of headphones, has an acoustic lead 81 integrated within it. This lies at least partially within the wall of the otoplastic shell 79, as is shown in Fig. 25. The respective acoustic impedance of the acoustic lead 81
35 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

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locations, and to couple said inlet openings 85 to the provided acoustic/electric transducers 91 via acoustic leads 89 integrated in the otoplastic 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 otoplastics

In the production of otoplastics, in particular of in-the-ear otoplastics, each one is individually adapted to its respective wearer. For this reason, it would be highly desirable to identify each finished otoplastic, as mentioned in particular each in-the-ear otoplastic, and very particularly each in-the-ear hearing device. It is therefore proposed to provide an individual identification in the otoplastic 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 otoplastic using the removal method described under 1). This ensures that any mix-up of the otoplastics 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.

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

5 7. Optimization of otoplastics with respect to the dynamics of the application area

When molding otoplastics 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 otoplastic 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.

30

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.

35

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

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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 otoplastic. If, for example, as is still customary today, in-the-ear
5 otoplastics 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 otoplastic,
10 so that optimum wearing comfort in everyday use is achieved while maintaining its functionality. If the otoplastic to be produced is realized using the principle set out in section 3), the computer unit 97 determines which otoplastic areas are to be configured
15 and how in terms of their flexibility, bendability, compressibility, 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.

Proposed claims

1. A method for the production of otoplastics, in which at least one mold of the individual application site is digitized three-dimensionally to obtain a set of data (p. 8, l. 1) and the otoplastic is created as follows:
- (a) deposition of a layer of material (p. 12, l. 10);
- (b) solidification of a sectional layer with the individual shape of the individual otoplastic, controlled using the set of data;
- (c) application of a further layer of the material over the solidified sectional layer and repetition of steps (b) and (c),
- characterized in that sectional layers with individual shapes of a plurality of otoplastics, controlled by respective sets of data, are solidified in the layer.
2. A method for the production of otoplastics, in which at least one mold of the individual application site is digitized three-dimensionally to obtain a set of data, and the otoplastic is constructed as follows:
- (a) application of a sectional layer with the individual shape of the individual otoplastic;
- (b) solidification of the applied sectional layer;
- (c) application of a further sectional layer over the solidified layer and repetition of steps

(a) to (c),

characterized in that sectional layers of a plurality of individual otoplastics are deposited in a common operation, controlled by means of the sets of data, and are then solidified before further sectional layers are deposited on the solidified layers.

3. A method for the production of otoplastics, in which at least one mold of the individual application site is digitized three-dimensionally to obtain a set of data, and the otoplastic is constructed as follows:

- (a) deposition of a layer of a material;
- (b) solidification of a sectional layer with the individual shape of the individual otoplastic, controlled using the set of data;
- (c) application of a further layer of the material over the solidified sectional layer and repetition of steps (b) and (c),

characterized in that during solidification of the sectional layer of one otoplastic, a layer of material for a further individual otoplastic is deposited.

4. The method as claimed in one of claims 1 through 3, characterized in that the impression is taken by creating at least one mold of the application site, the mold or the molds are scanned and the scanning signals are digitized.

5. The method as claimed in one of claims 1 through 4, characterized in that the impression-taking, and if appropriate the digitization, is performed

at distributed front centers, and the sets of data are transmitted to a production center, where the otoplastic is created.

- 5 6. The method as claimed in one of claims 1 through 5, characterized in that laser sintering, stereolithography or a thermojet method is used as the additive construction method.
- 10 7. An otoplastic, characterized in that at least its covering consists of thermoplastic material solidified in layers.
- 15 8. The otoplastic as claimed in claim 7, characterized in that it is an in-the-ear hearing device or a hearing device worn outside the ear or a headphone or an insert protecting against noise or water.
- 20 9. Use of the method as claimed in one of claims 1 through 6 for in-the-ear hearing devices, hearing devices worn outside the ear, headphones, ear inserts protecting against noise or water.

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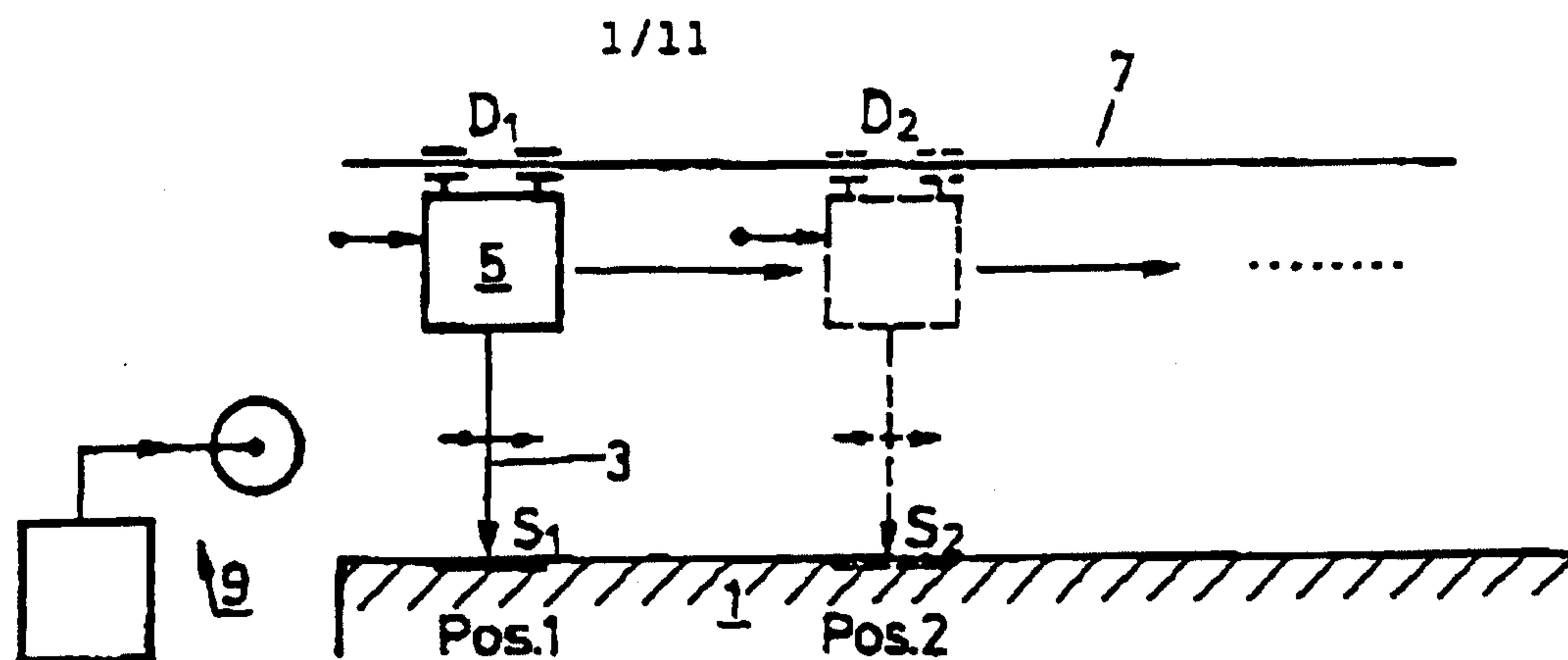


FIG. 1

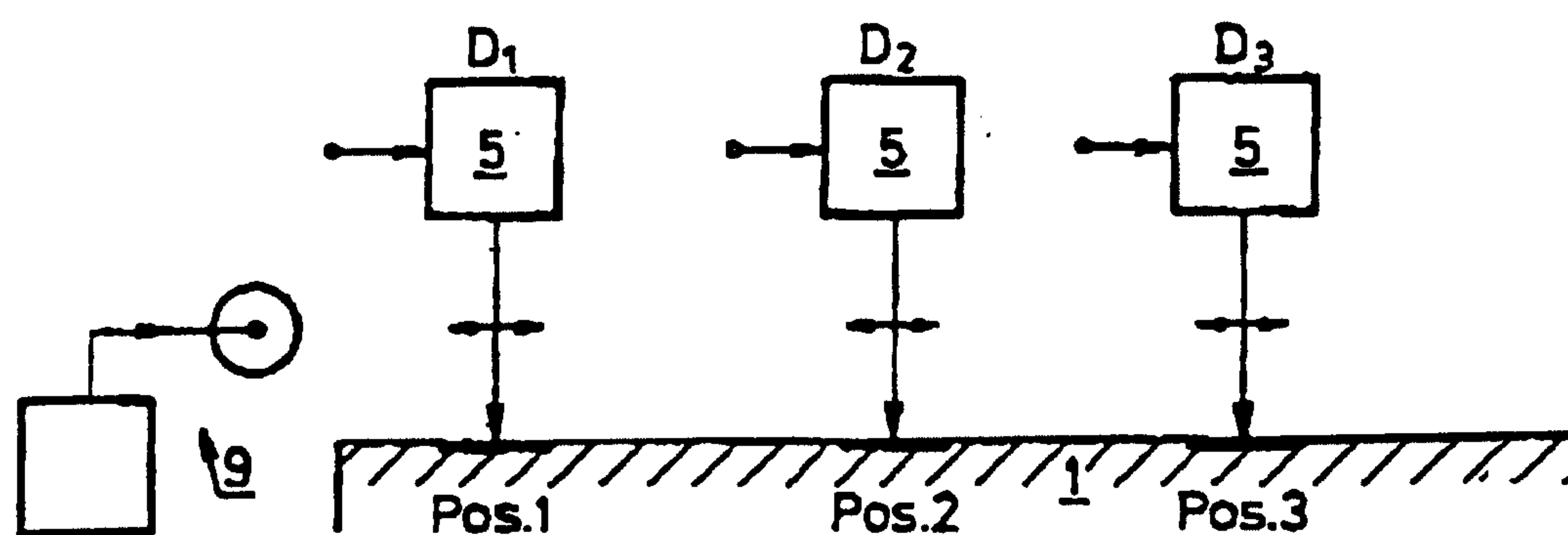


FIG. 2

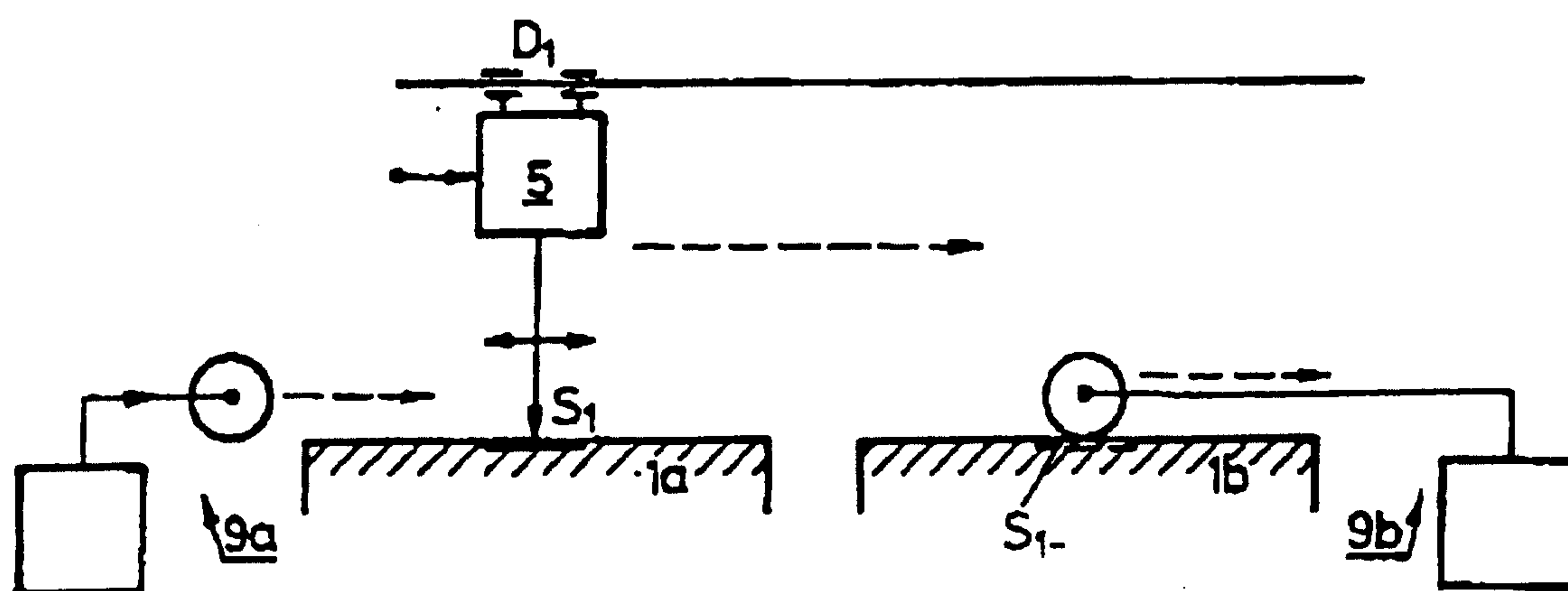


FIG. 3

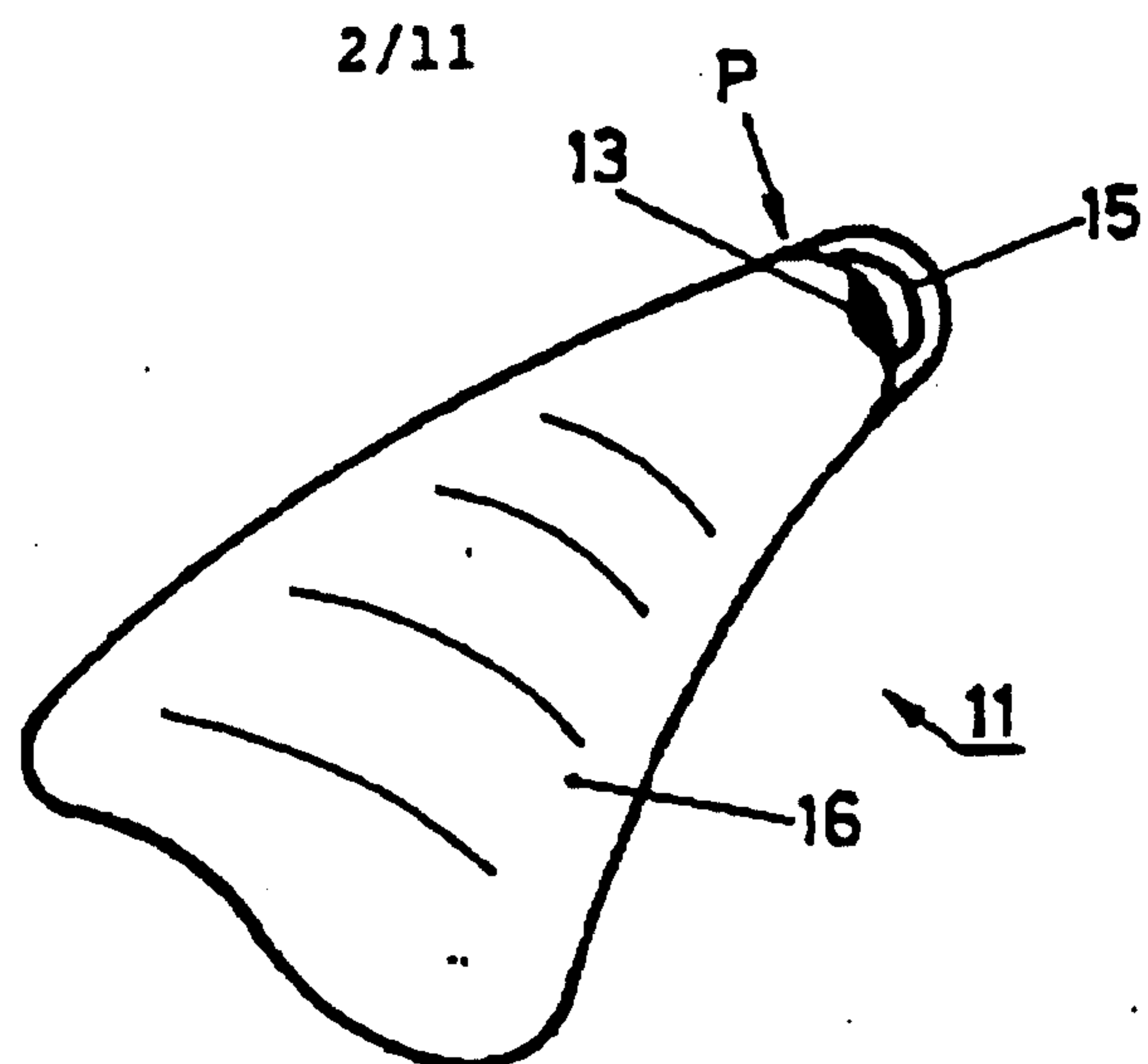


FIG. 4

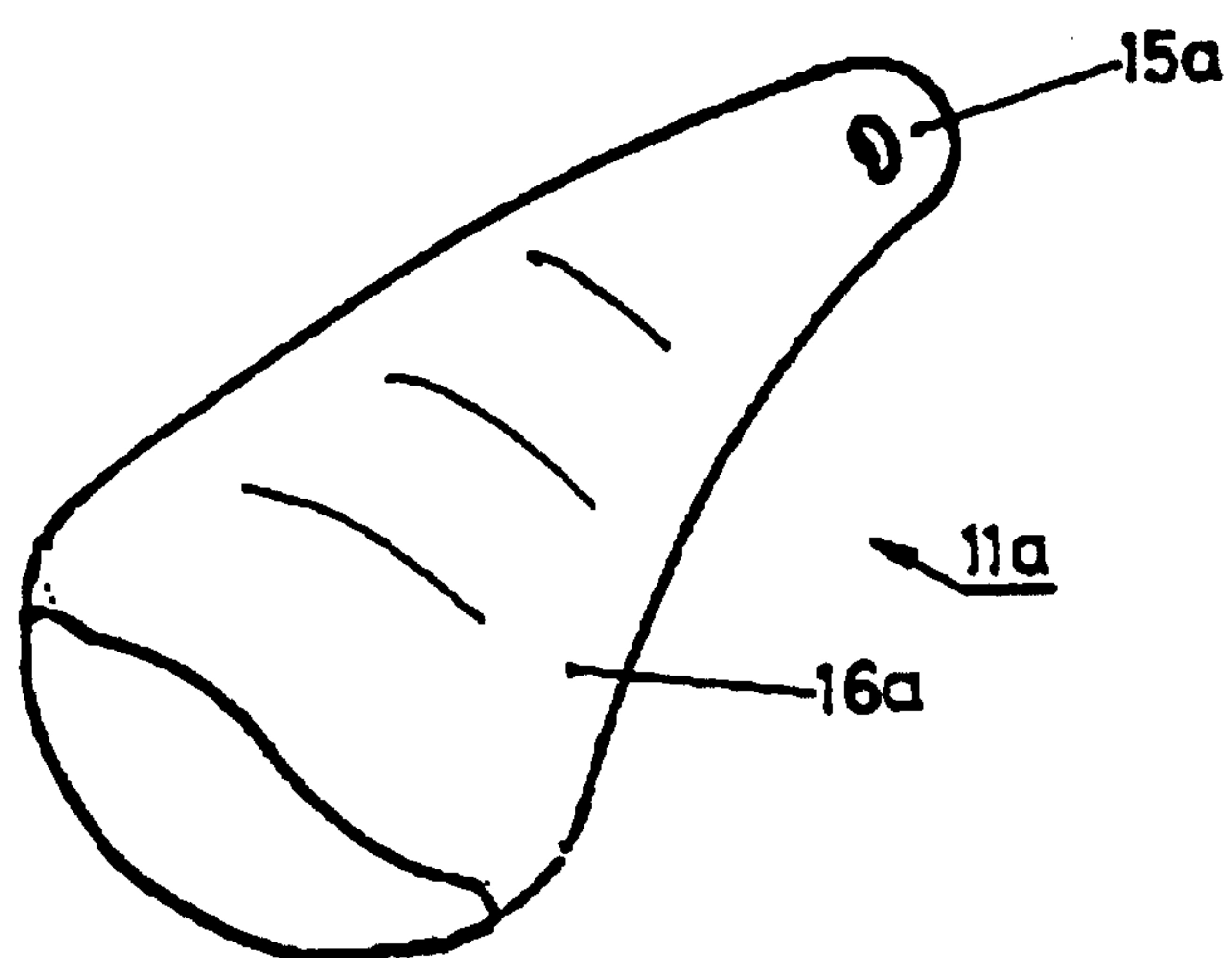


FIG. 5

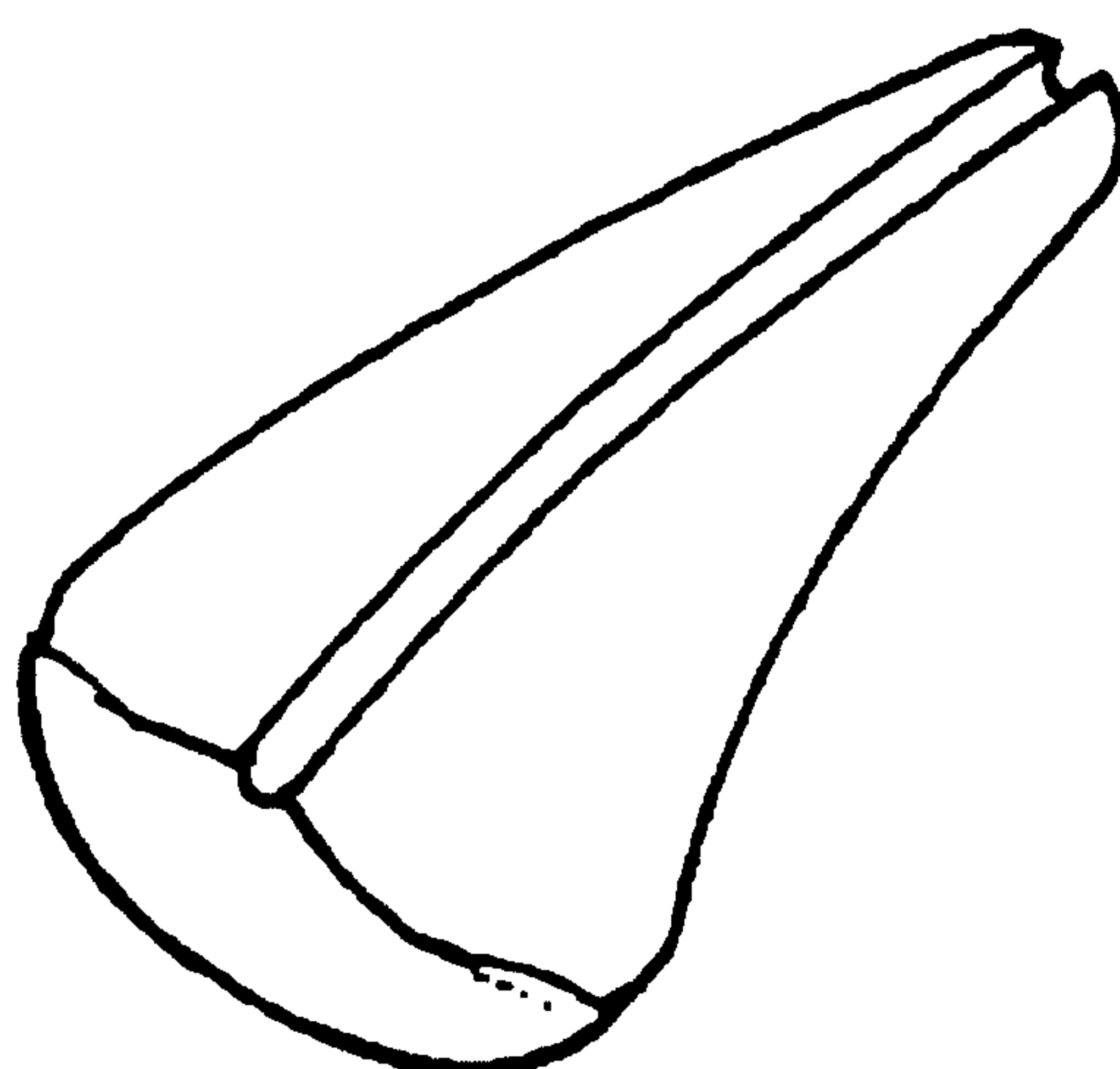


FIG. 6

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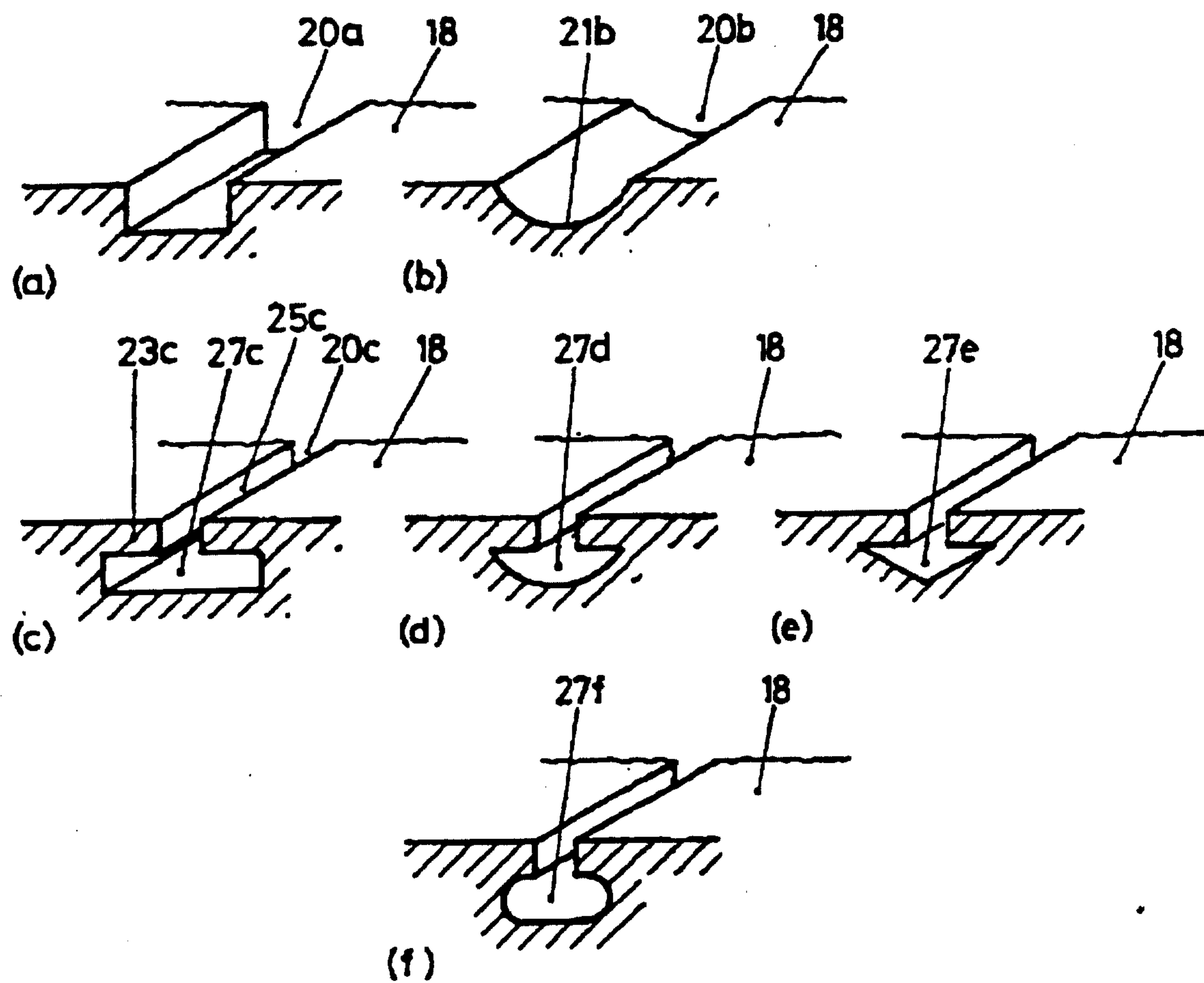


FIG. 7

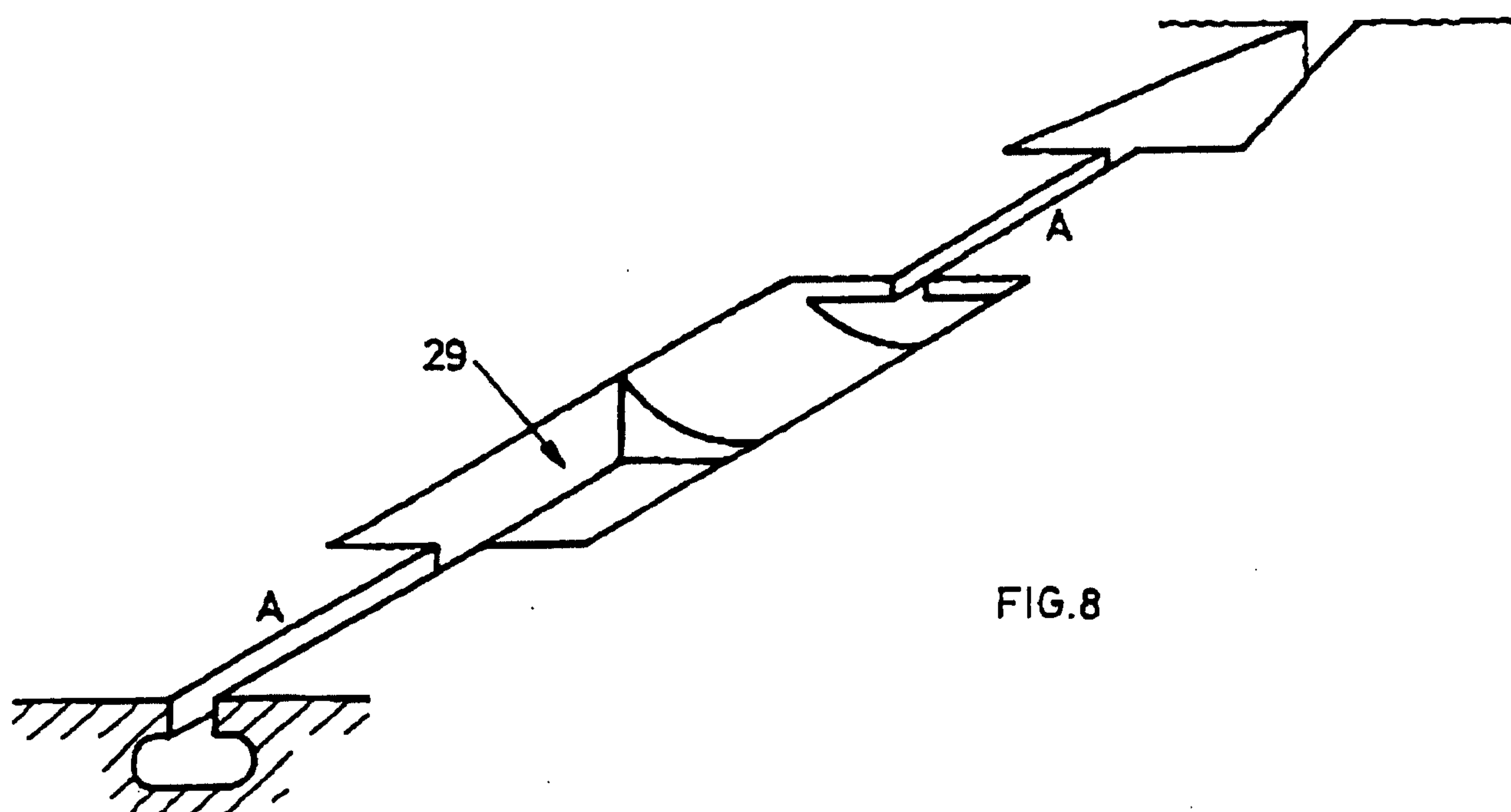


FIG. 8

Replacement sheet (Rule 26)

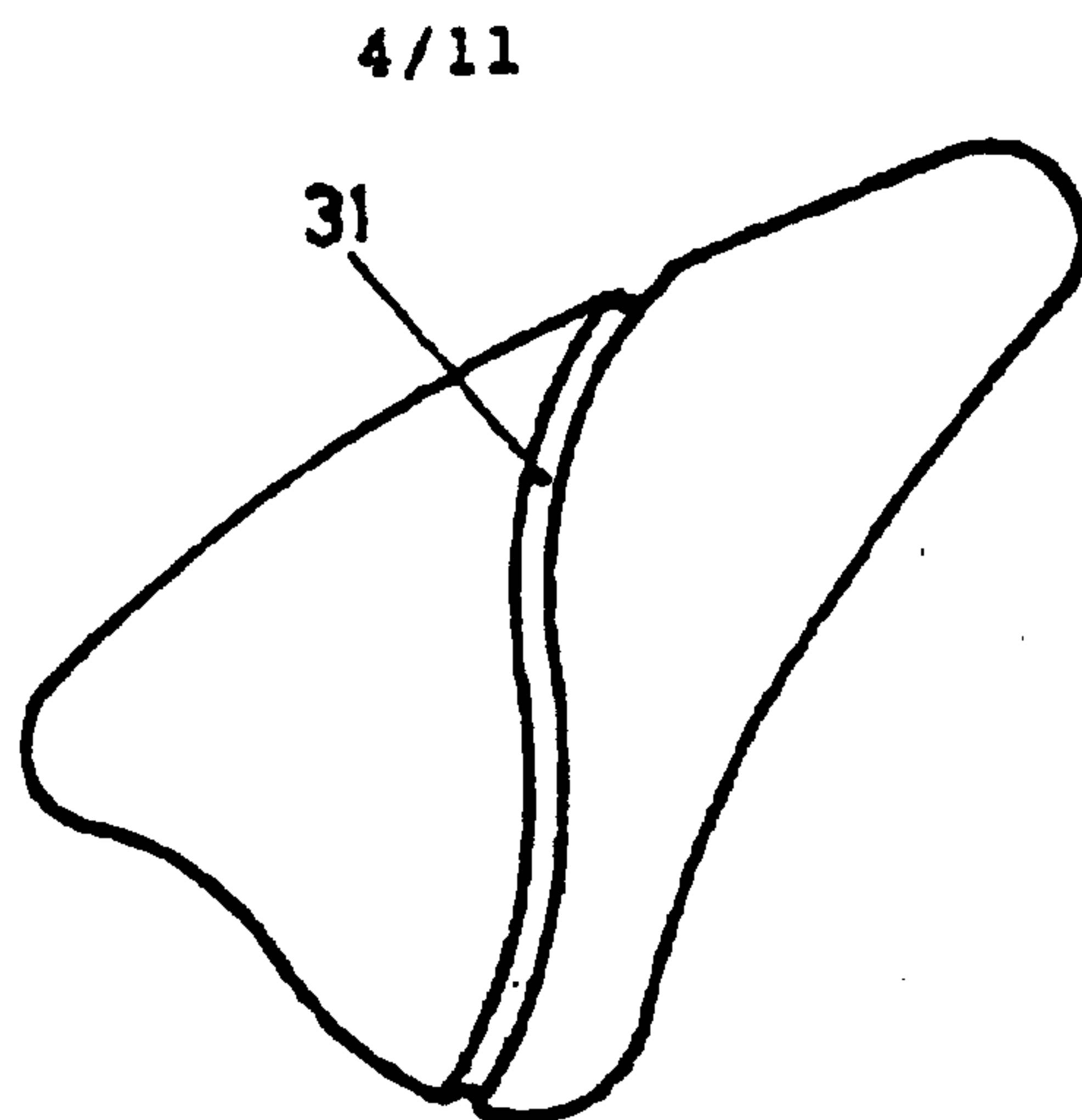


FIG. 9

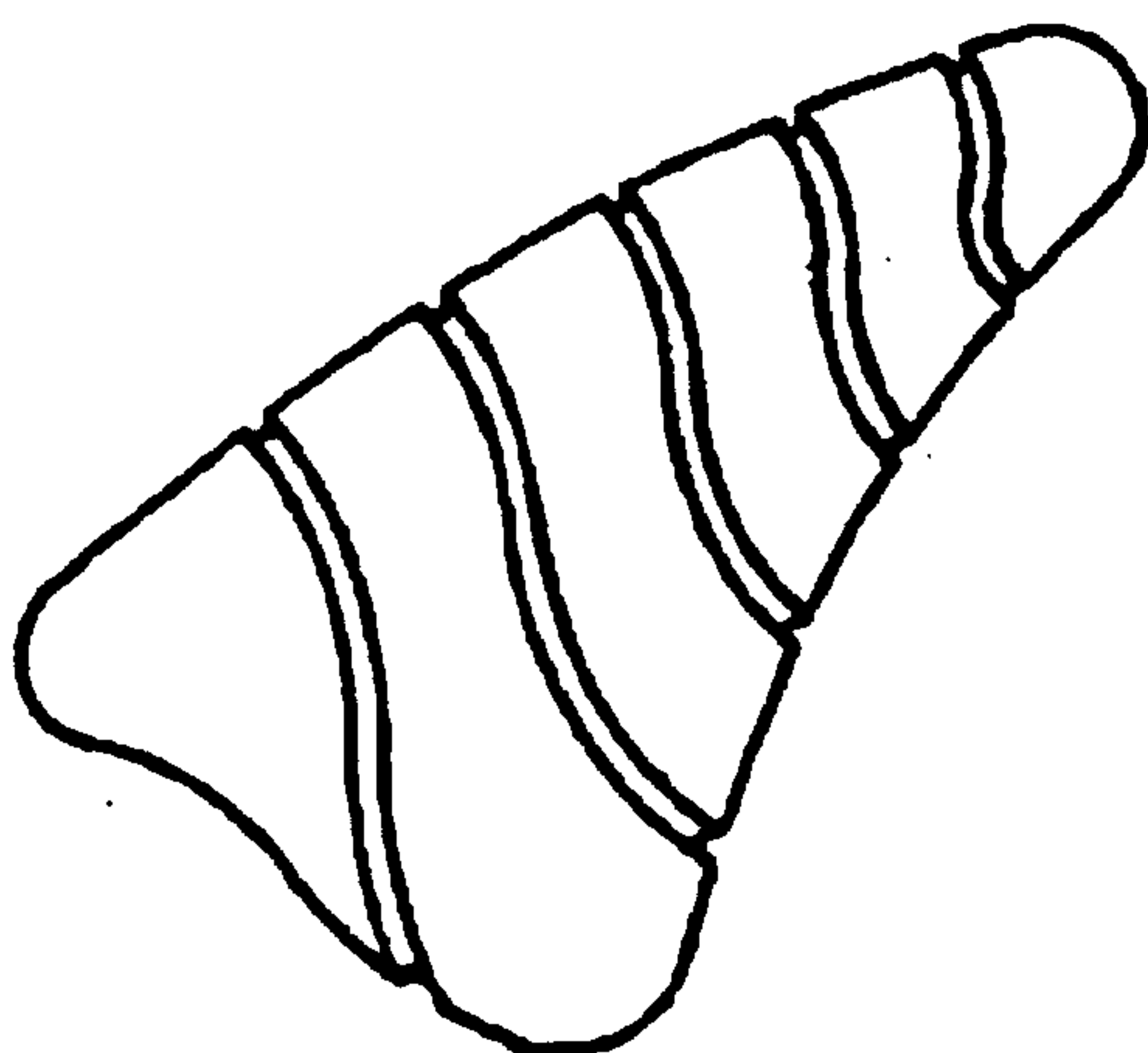


FIG. 10

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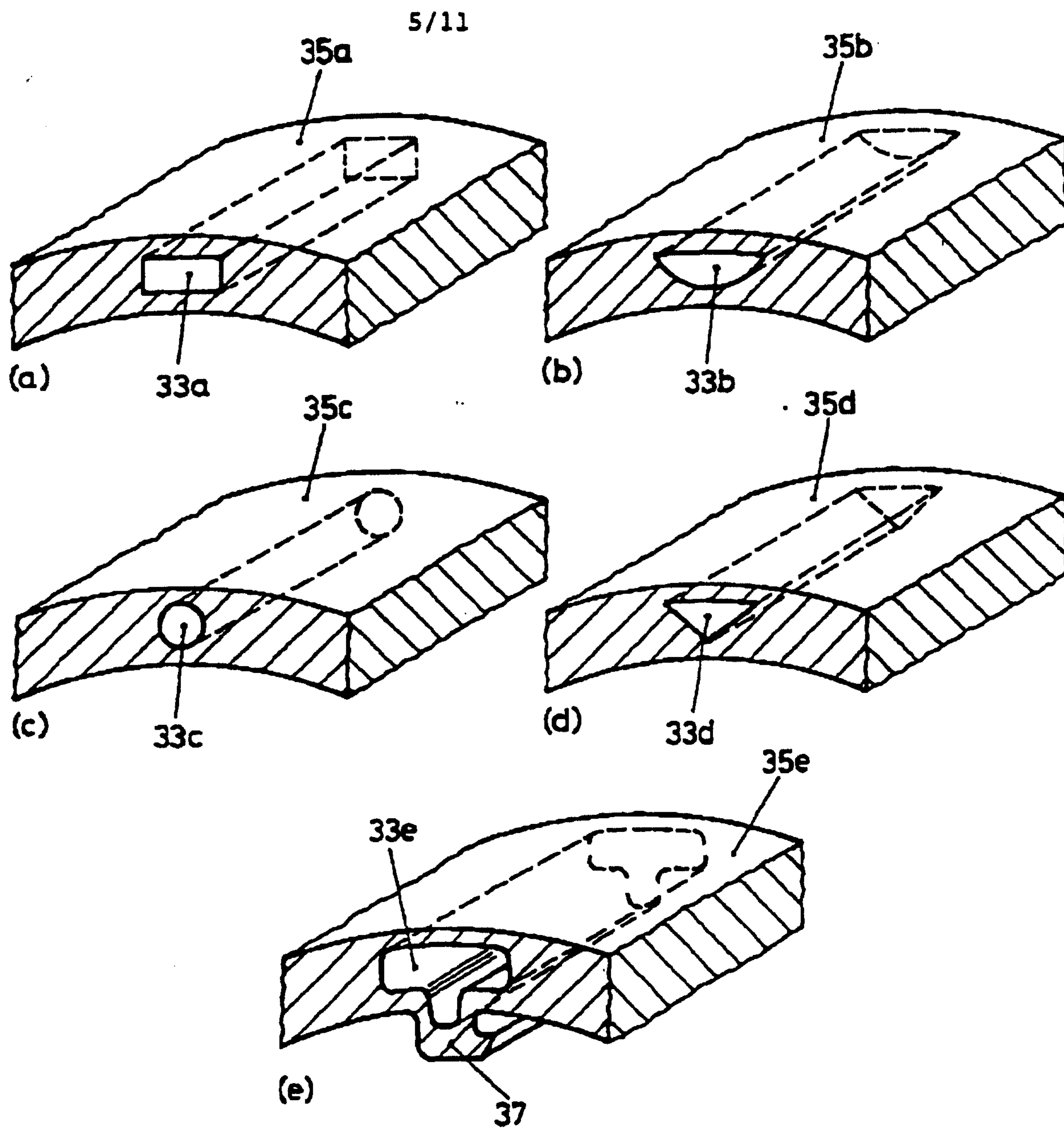
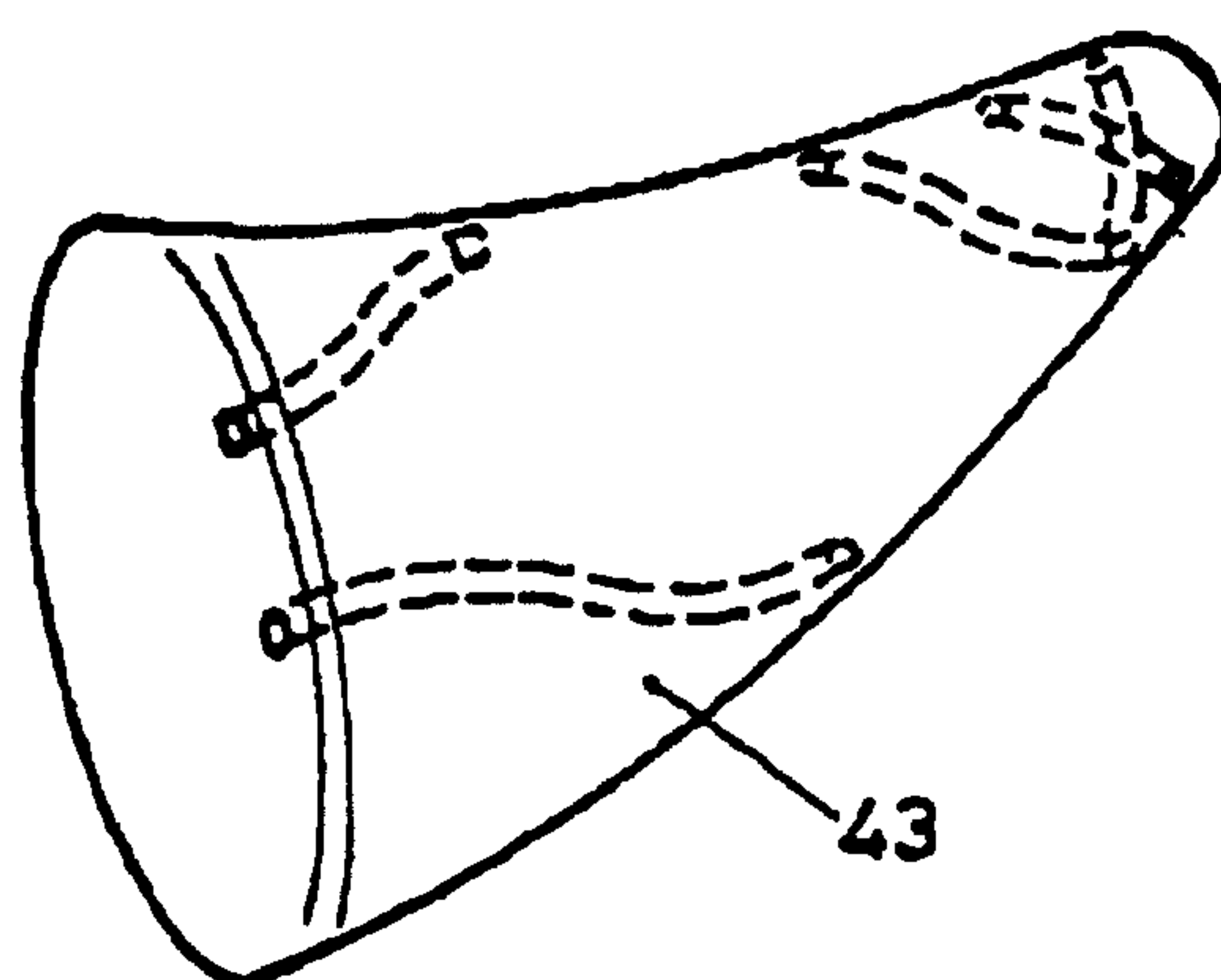
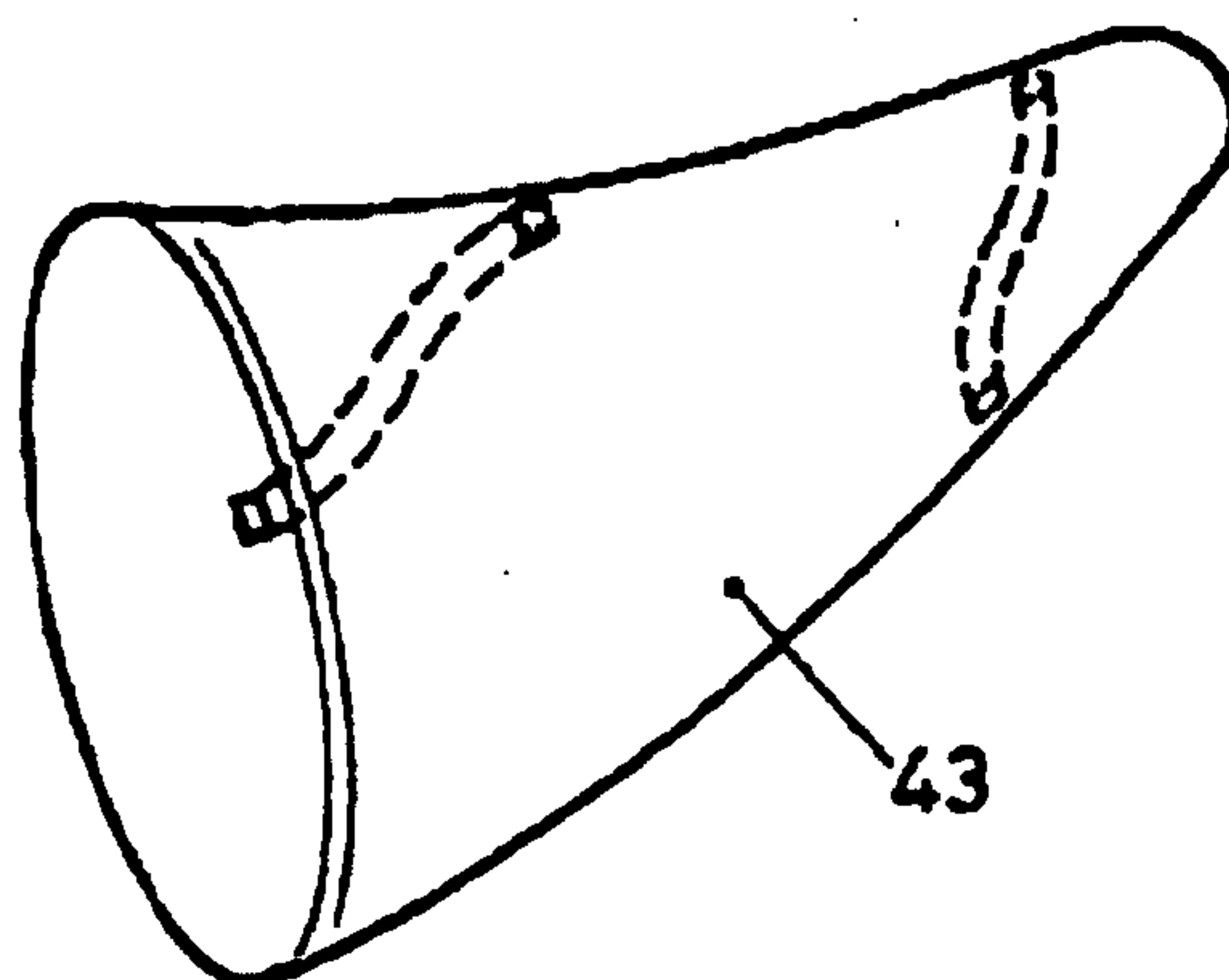
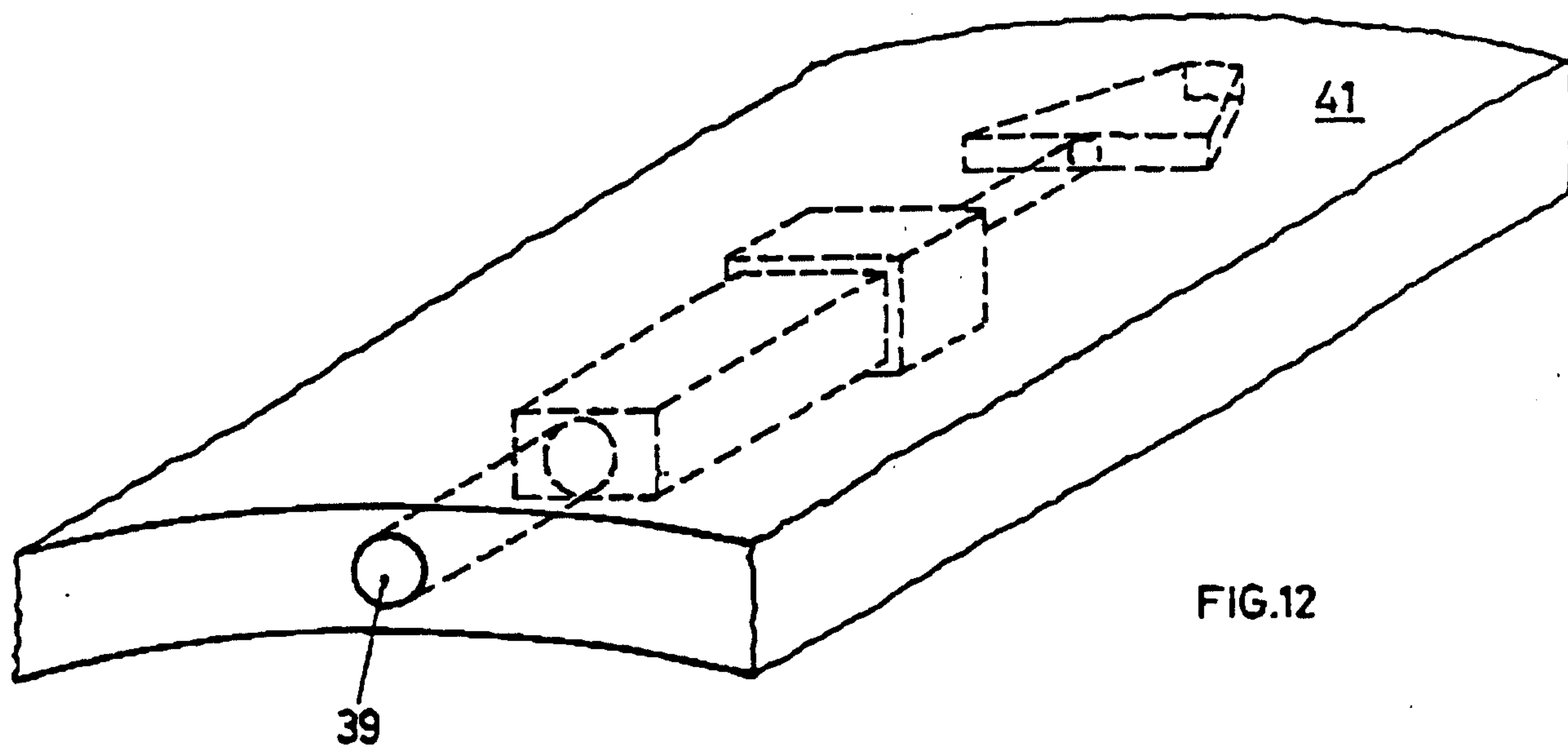


FIG. 11

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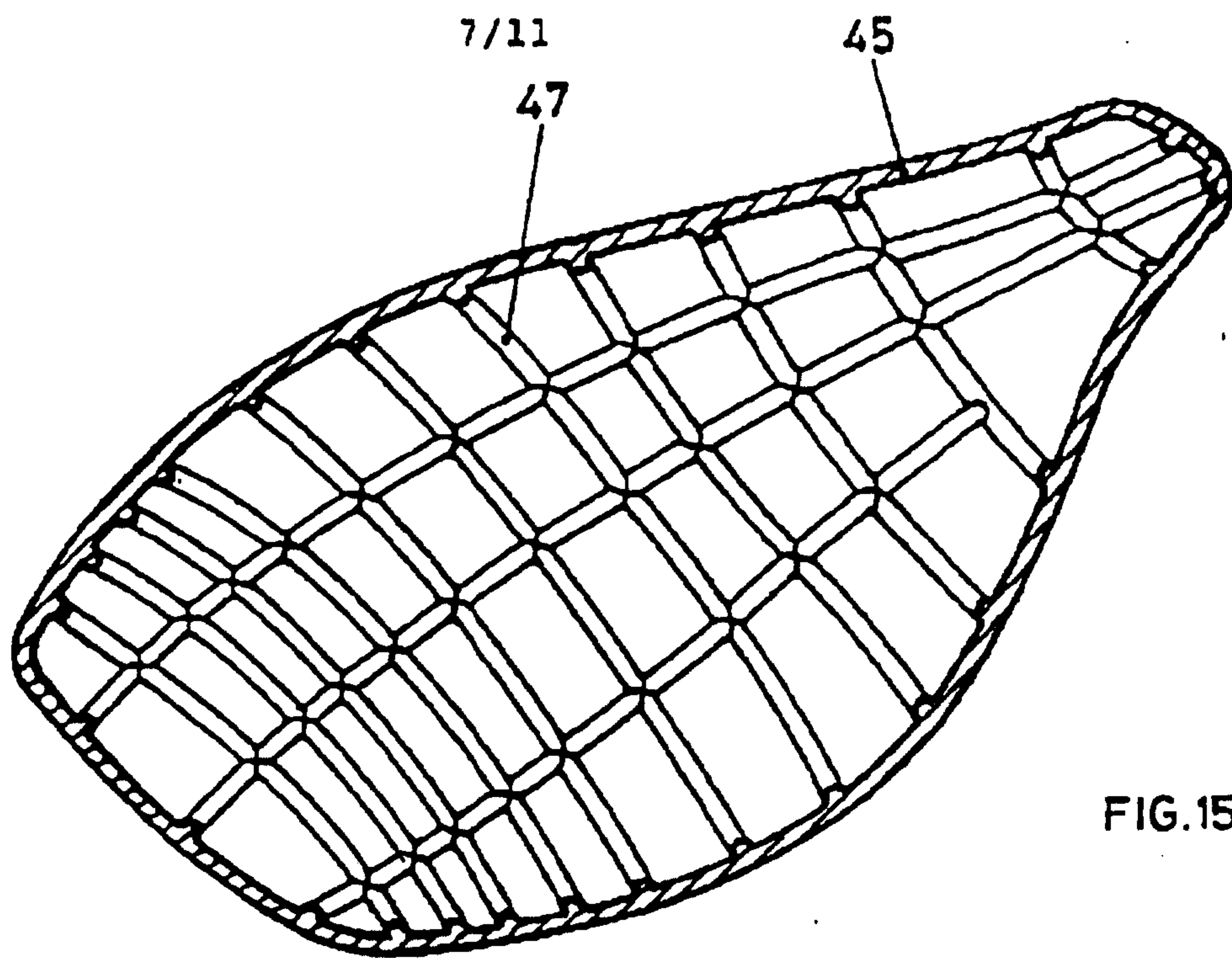


FIG. 15

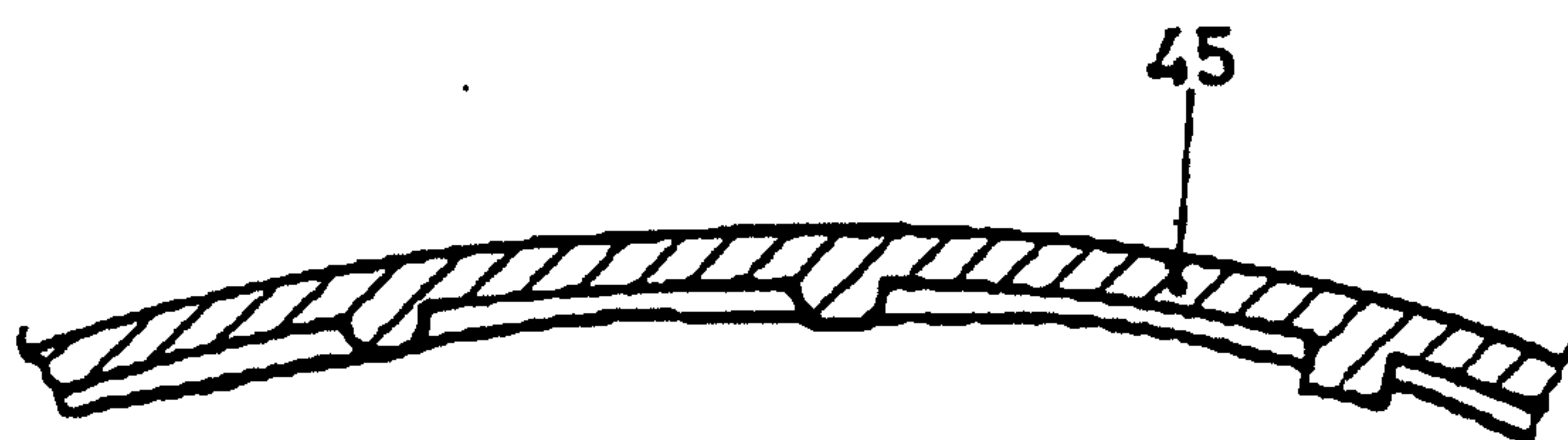


FIG. 16

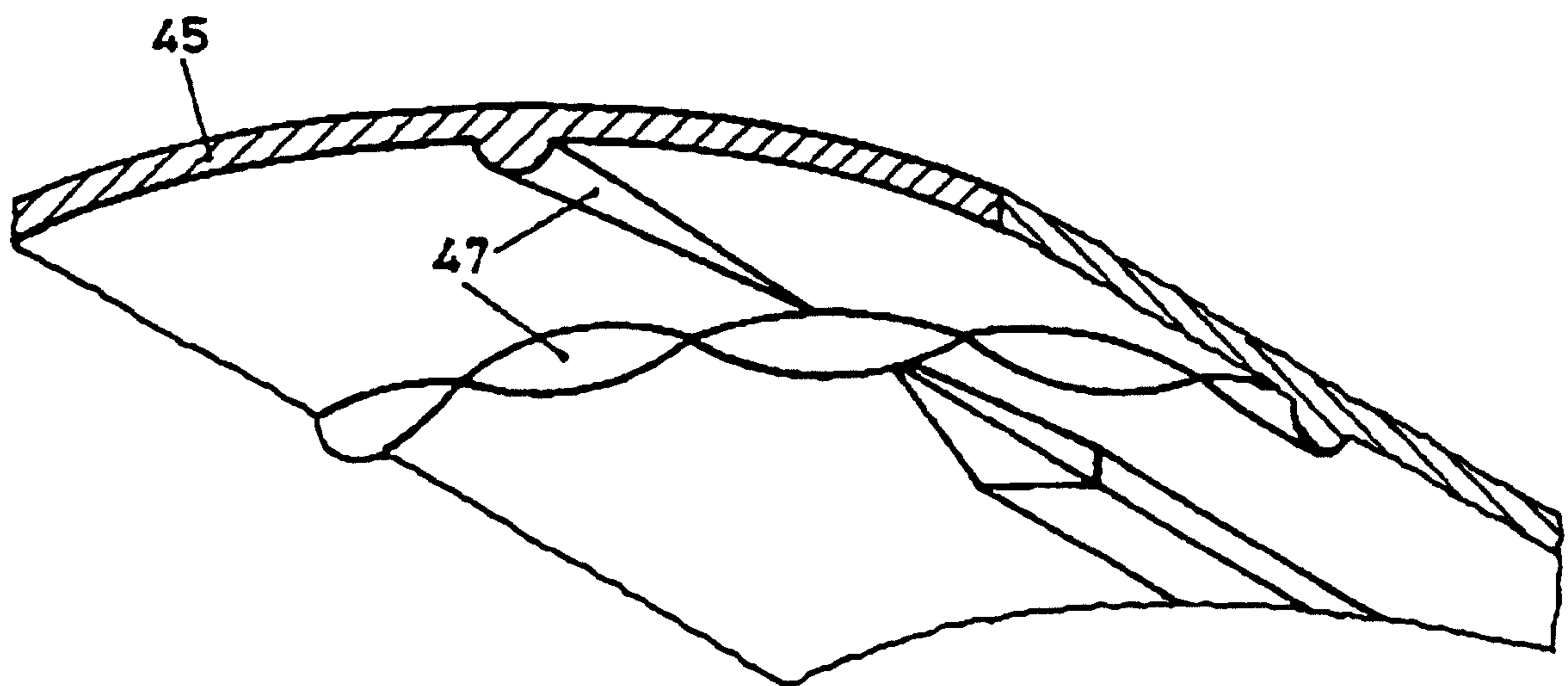
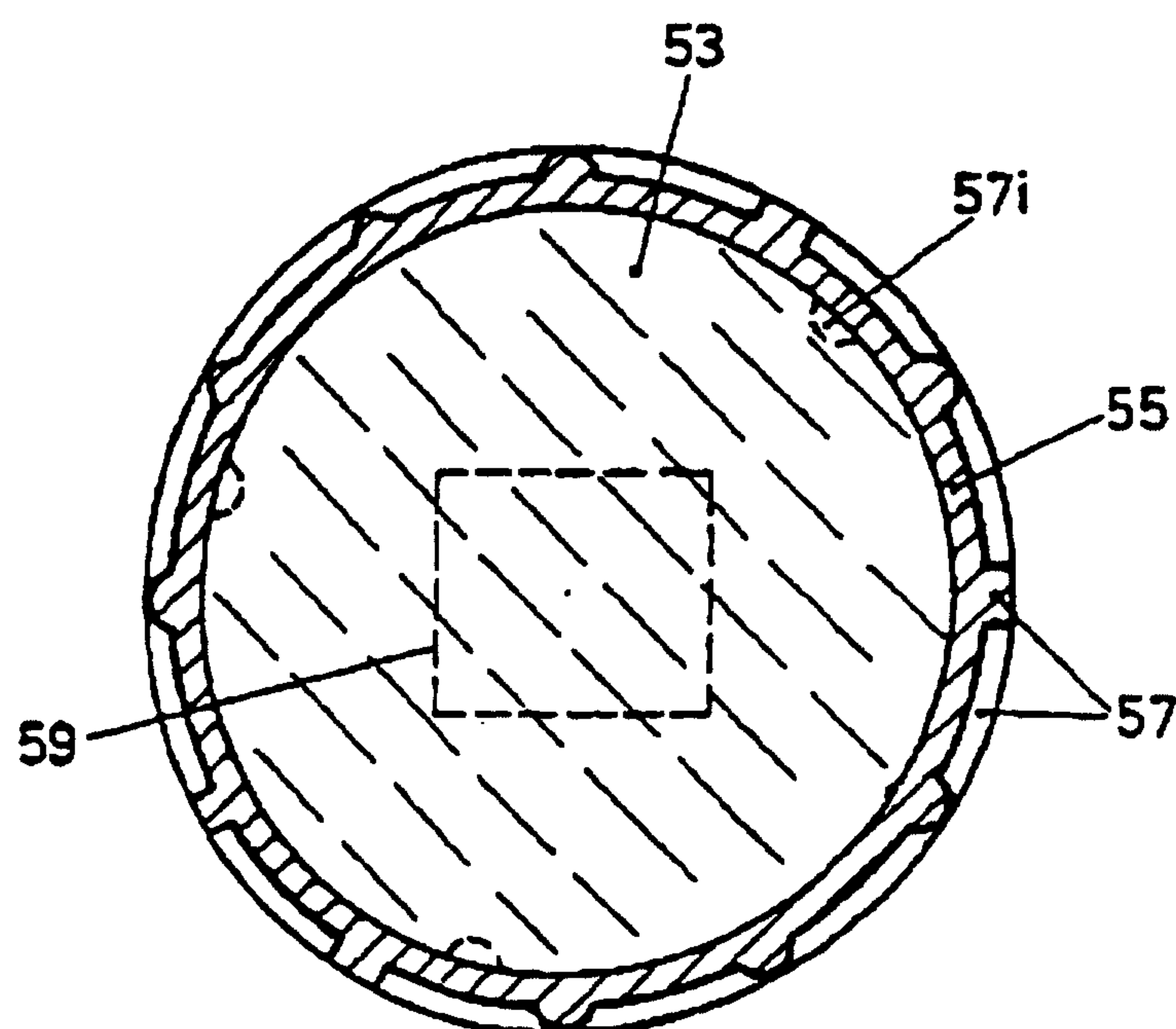
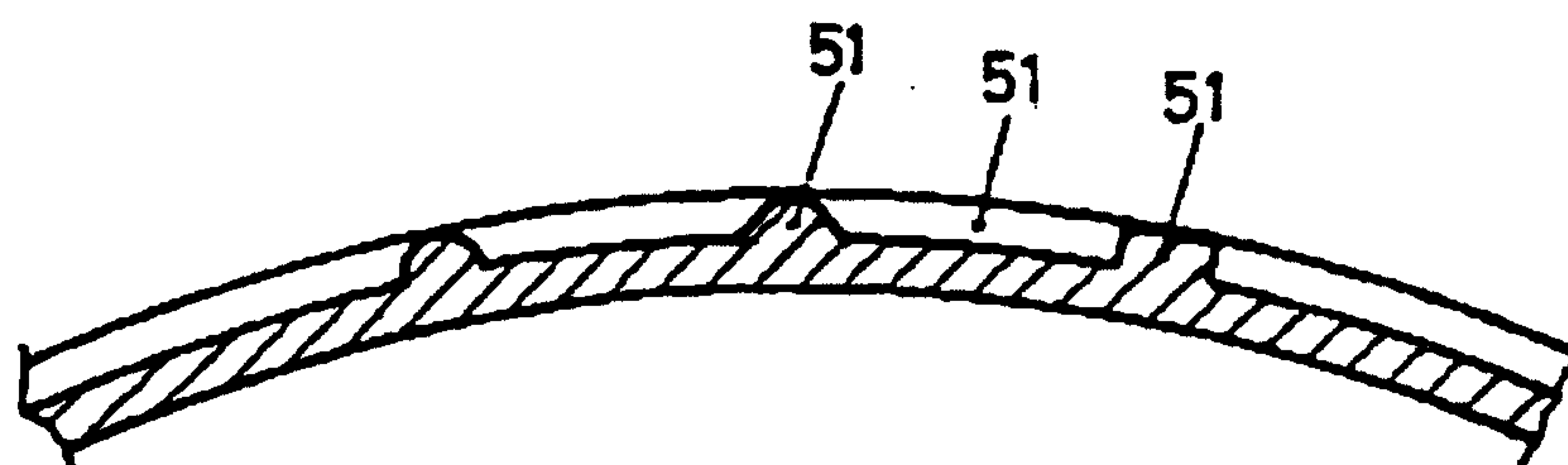
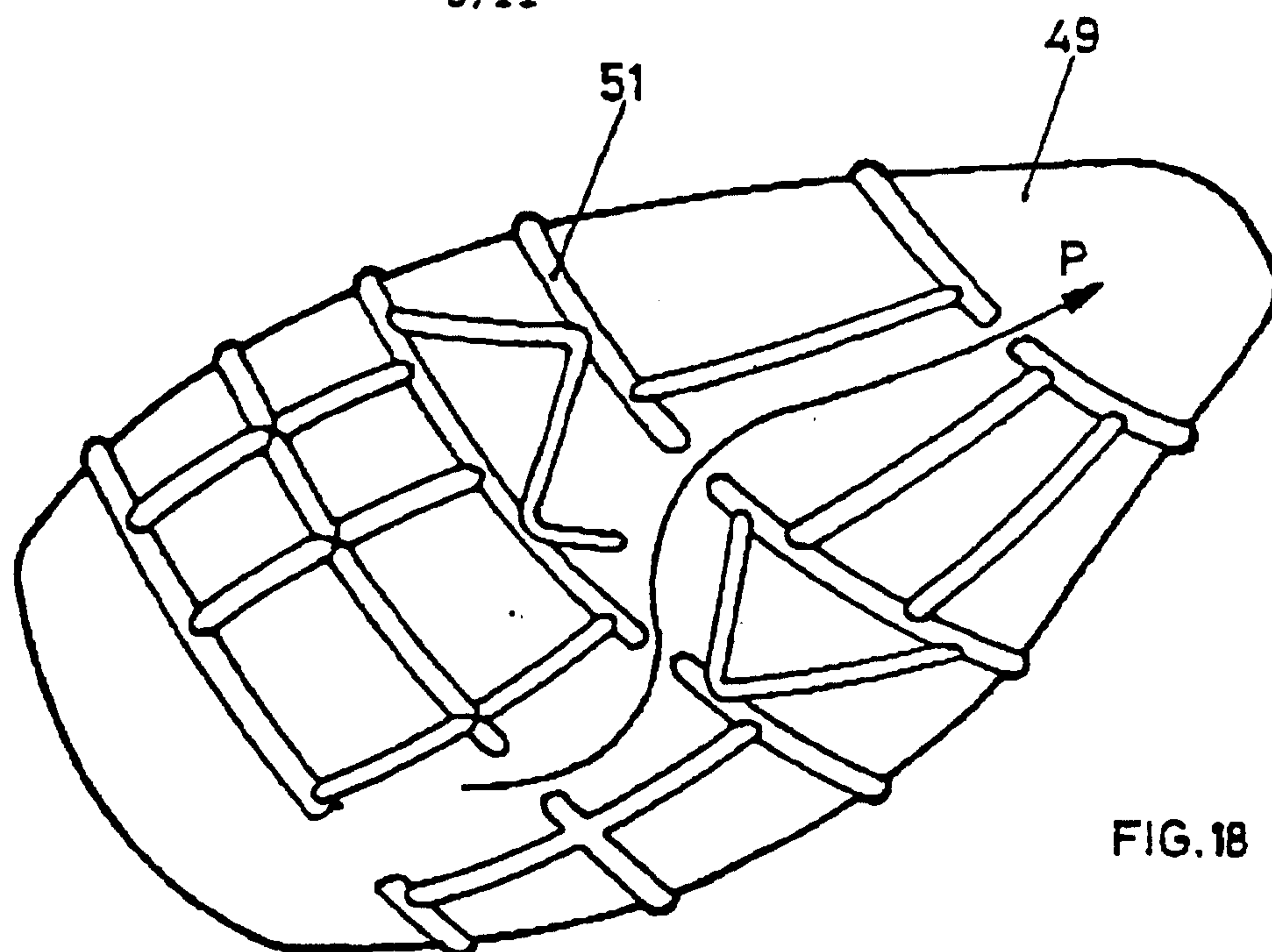


FIG. 17

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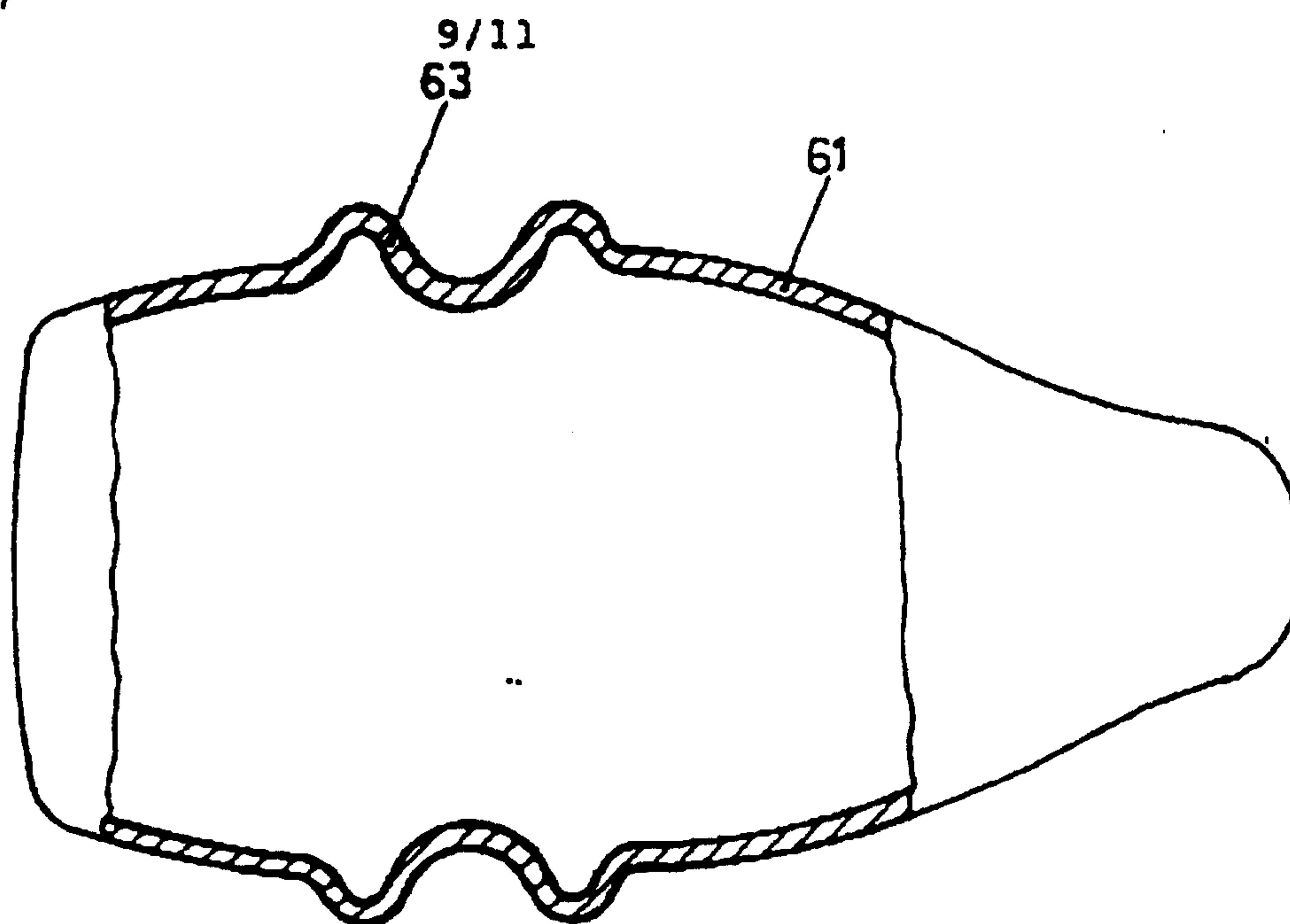


FIG. 21

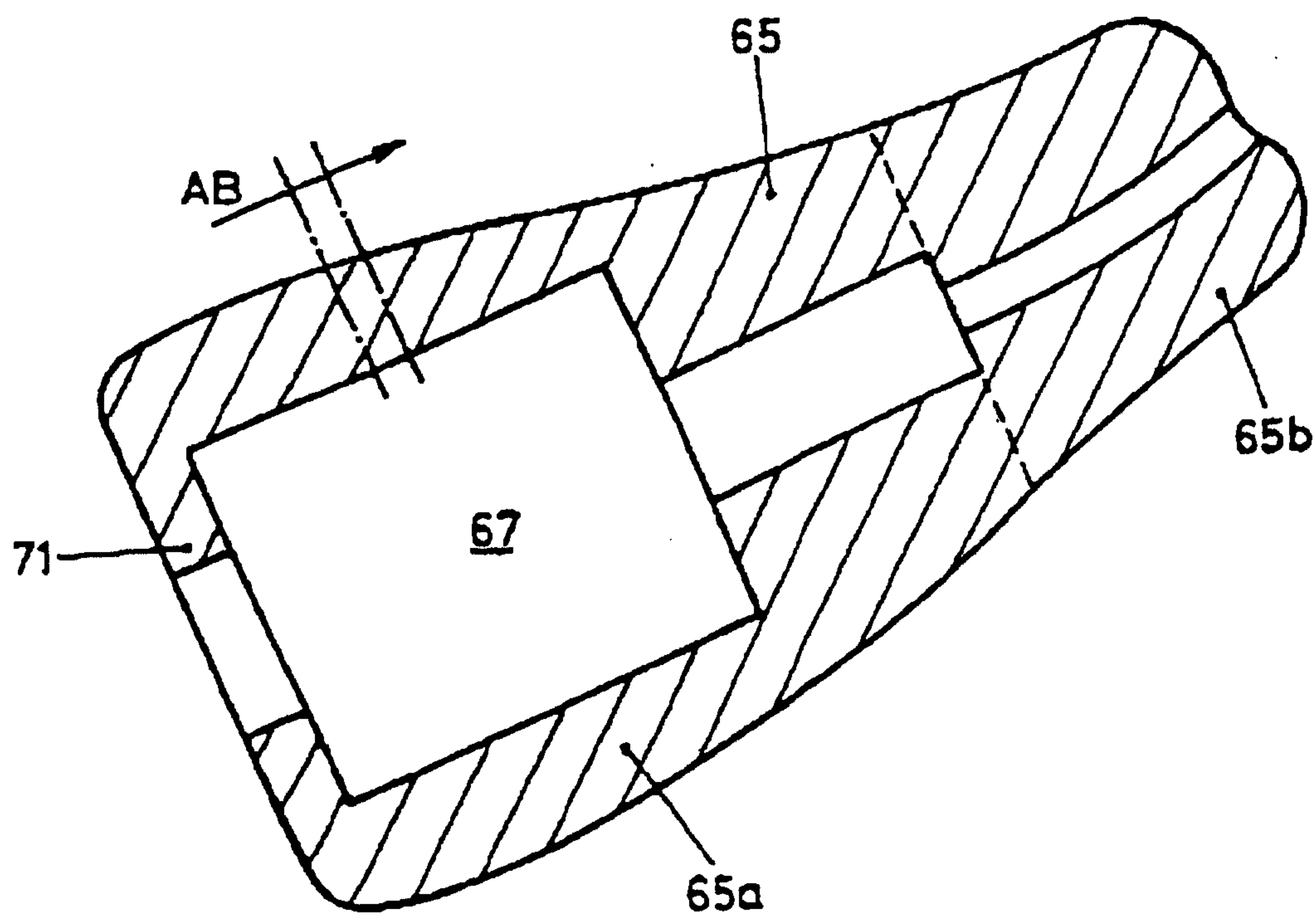


FIG. 22

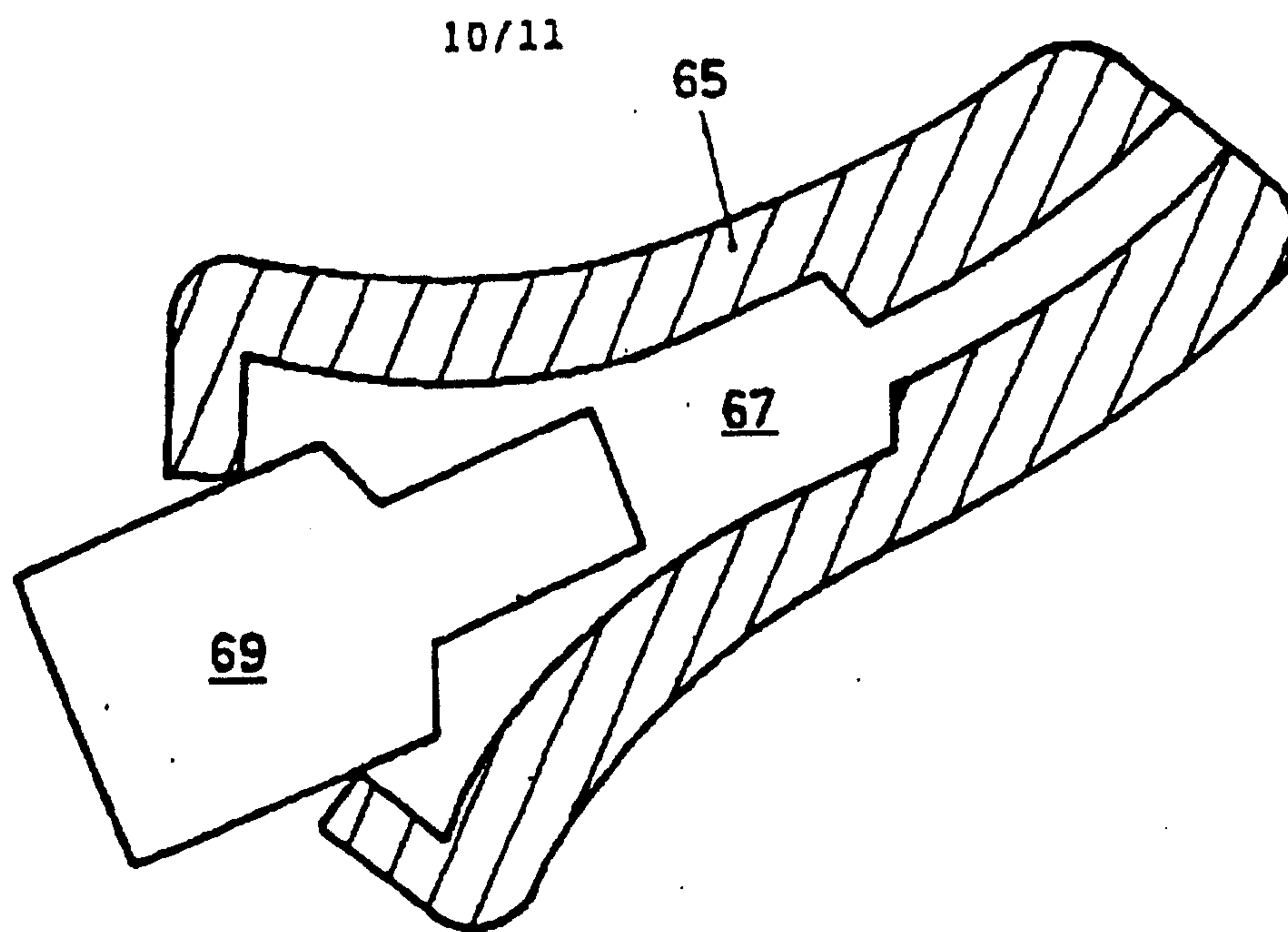


FIG. 23

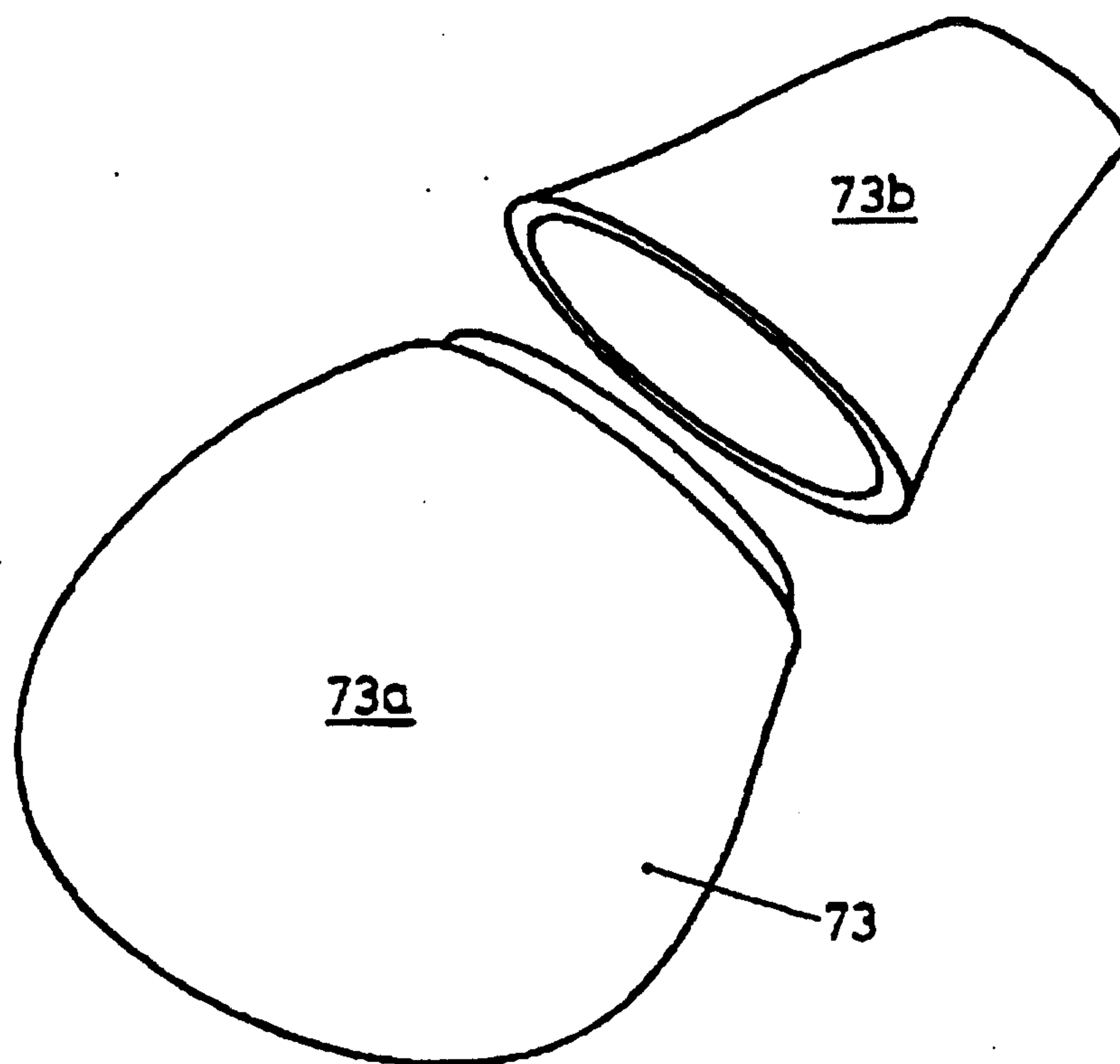


FIG. 24

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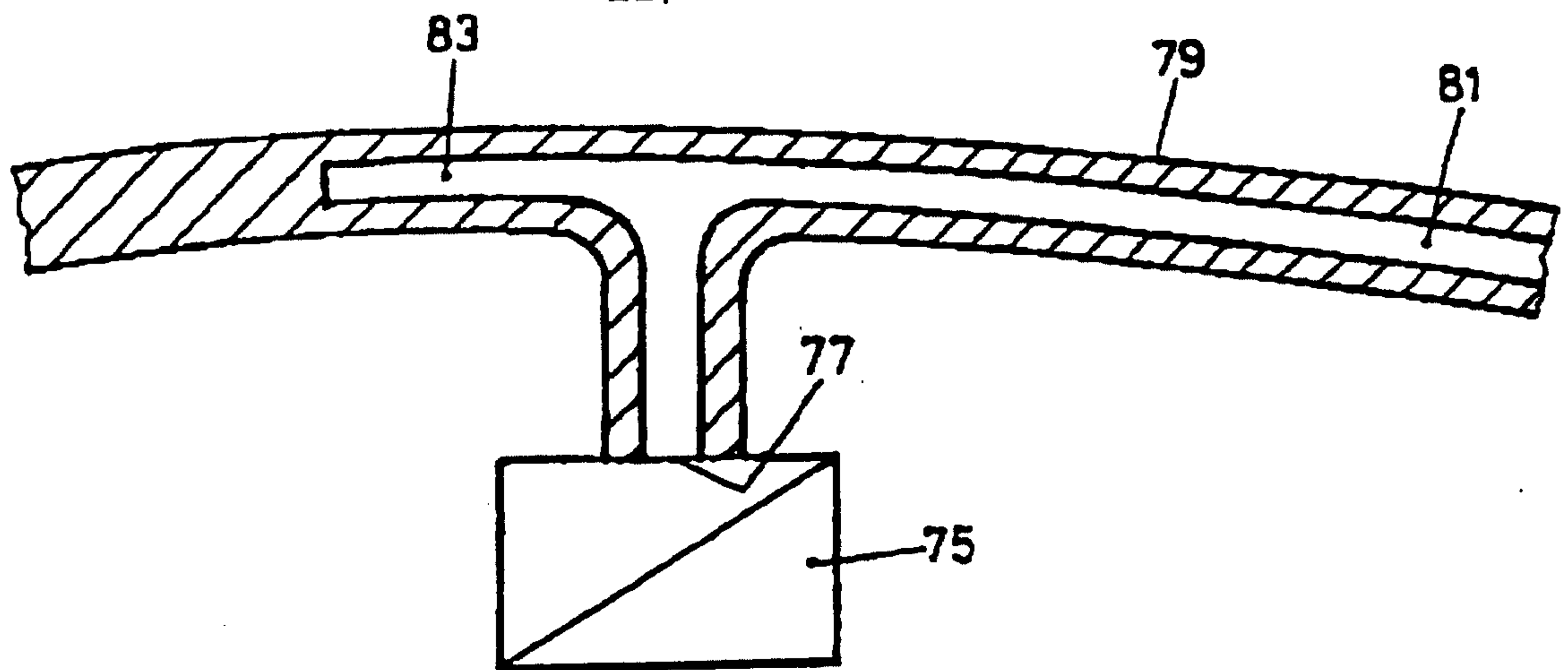


FIG. 25

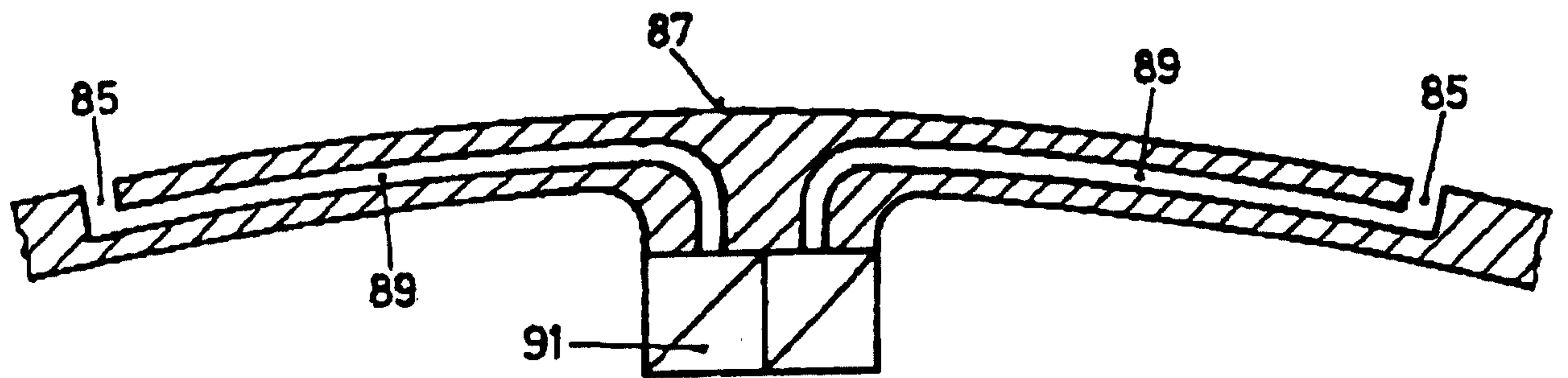


FIG. 26

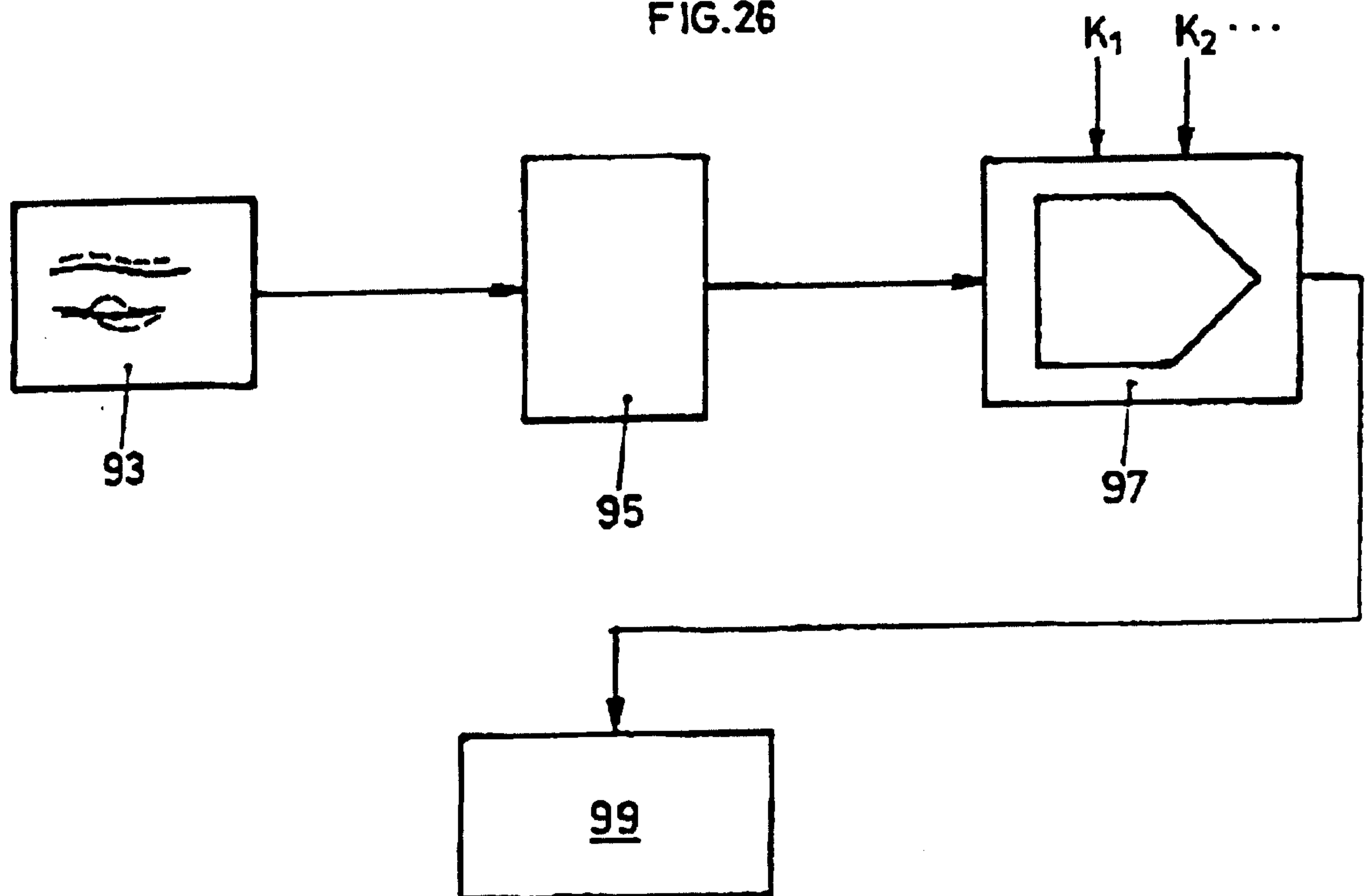


FIG. 27

Replacement sheet (Rule 26)

