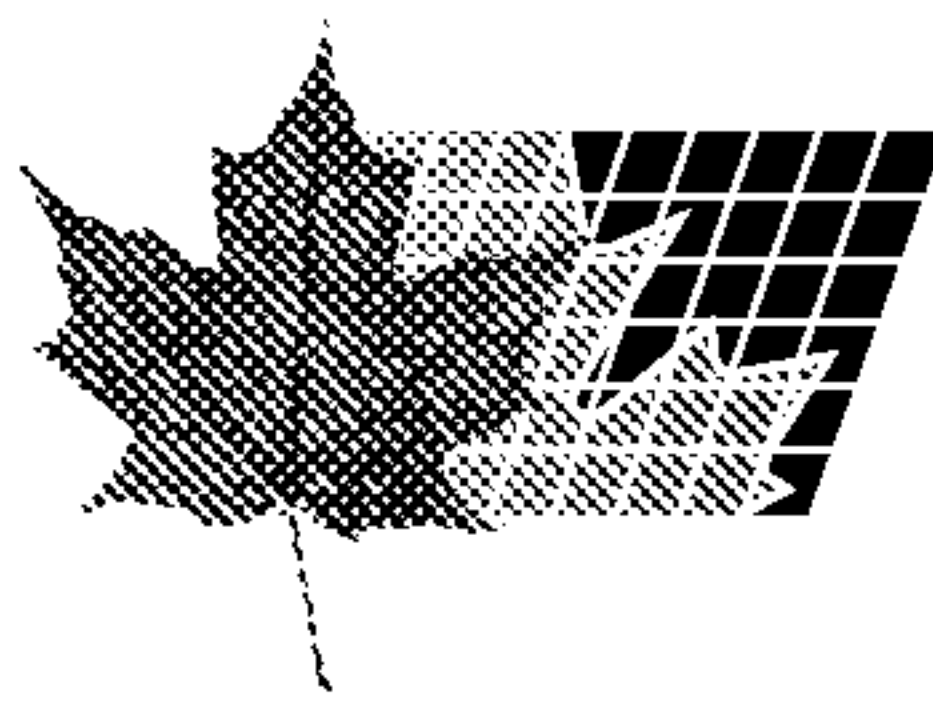




(72) SCHMIDT, RAINER, DE

(71) AUDIO CONSULTING - GESELLSCHAFT FUR STRATEGISCHES
MARKETING MBH, DE

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(54) **PROCEDE DE PRODUCTION D'UNE PIECE D'AJUSTAGE A
INTRODUIRE DANS UNE CAVITE ORGANIQUE CHEZ
L'HOMME**

(54) **METHOD FOR PRODUCING AN ADJUSTMENT PART TO BE
INTRODUCED INTO AN ORGANIC CAVITY OF THE HUMAN
BODY**

(57) Afin de réaliser une otoplastie pour des prothèses auditives de type IO et HdO ou une pièce d'ajustage nasale, il est prévu un corps creux tronconique, allant en s'amenuisant en direction de l'extrémité proximale, dont la paroi périphérique (12) consiste en une matière plastique déformable, durcissant à la lumière. A l'extrémité distale, cette paroi périphérique (12) est reliée au moyen d'une plaque d'obturation (20) amovible, fermant de manière hermétique. Un flexible (22) débouche à l'intérieur du corps creux (10) fermé hermétiquement. Après insertion du corps creux dans une oreille, ce flexible sert à gonfler ledit corps creux, jusqu'à ce que la paroi périphérique (12) épouse étroitement la surface du conduit auditif. A ce stade, la paroi périphérique est consolidée au moins en partie sous l'action de la lumière, de manière que le corps creux (10) conserve sa forme élargie, même après évacuation de la surpression intérieure. La plaque d'obturation (20) est ensuite enlevée et la paroi périphérique (12) est éventuellement durcie définitivement. L'otoplastie ainsi obtenue sert à recevoir un module de prothèse auditive placée dans l'oreille, dont la plaque de base peut être fixée par clip sur la bague extérieure (18) de la paroi périphérique (12). Ce procédé permet de produire des prothèses auditives avec une adaptation individuelle rapide très précise de l'otoplastie, en une seule séance.

(57) In order to carry out an otoplasty for IO- and HdO-type audio prostheses or for a nose adjustment part, a hollow body in the shape of a truncated cone is provided that tapers towards the proximal end and that comprises a peripheral wall (12) made of a plastic light-curable material capable of deformation. The peripheral wall (12) is connected at its distal end by a removable closure plate (20) providing a tight seal. A flexible tube (22) extends inside the tightly sealed hollow body (10). After insertion of the hollow body into the ear, the flexible tube is used for inflating said hollow body until the peripheral wall (12) tightly conforms the surface of the auditory canal. At this step, the peripheral wall is at least partially reinforced by the action of light so that the hollow body (10) keeps its expanded shape even after eliminating the inner over-pressure. The closure plate (20) is then removed and the peripheral wall (12) is optionally permanently cured. The otoplasty thus obtained is used for receiving a auditory prosthesis module which is placed within the ear and which comprises a base plate that can be clipped onto the outer ring (18) of the peripheral wall (12). This method can be used for producing audio prostheses with a rapid and very precise individual adaptation of the otoplasty during a single session.

ABSTRACT

For manufacturing an otoplastic for in-the-ear hearing aids, or a nose fitting piece, there is used a truncated cone shaped hollow body tapering towards the proximal end, whose circumferential wall (12) consists of a deformable, light-hardening plastic. The circumferential wall (12) is at the distal end connected by way of a releasable tightly closing closure plate (20). Into the inside of the hermetically closed hollow body (10) there opens a tubing (22) by way of which the hollow body after insertion into the ear is blown up so much that the circumferential wall (12) bears tightly on the auditory canal of the ear. In this condition the circumferential wall by way of the light effect is at least partly so much solidified that the widened shape of the hollow body (10) remains also after relieving from the inner excess pressure. The closure plate (20) is then removed and the circumferential wall (12) where appropriate is finally cured. The thus manufactured otoplastic then serves for the accommodation e.g. of an in-the-ear hearing aid module, whose base plate may be clipped on the outer ring (18) of the circumferential wall (12). With this method hearing aids with a highly accurate individual adaptation of the otoplastic may be manufactured at short notice and in a single sitting.

A method for manufacturing a fitting piece for insertion into a human body cavity

The invention relates to a method for manufacturing a fitting piece for insertion into a human body cavity with the use of a hollow body, an stretchable circumferential wall and a deformable plastic mass which is applied in the body cavity under an inner excess pressure and is solidified in the body cavity at least just up to a sufficient shape stability.

Such a method is known from EP-B-0 289 750. The hollow body here consists of a undeformable rigid punch and the circumferential wall is formed from a thin stretchable casing. Between the punch and the casing there is injected a curable fluid plastic and is placed so much under pressure that the casing bears on the auditory canal. Still in the ear, a curing of the plastic takes place. The fitting piece is then removed from the ear and the hollow body is then taken out of the solidified casing so that into the cavity created by way of this in the fitting piece, there may be inserted for example an in-the-ear hearing aid module. The plastic may contain a photo-initiator so that the solidifying procedure may be initiated by the application of light. A certain problem exists with the known method in that the intermediate space between the punch and casing from the distal end must be filled with the plastic mass, the plastic however must completely fill out the casing also up to the proximal end of the otoplastic, corresponding to the anatomy of the auditory canal. The viscosity of the plastic mass must be adapted very exactly to the individual anatomy of the auditory canal in order to achieve the aim that with the exit of excess plastic mass from the intermediate space through an outlet opening in the distal end-face wall the necessary widening of the circumferential wall has taken place in all regions of the auditory canal. Also the evaluation of a suitable delivery pressure for the plastic mass throws up problems in the practical application.

Further suggestions of the state of the art, in which between a non-deformable hollow body and an elastically widenable casing there is created an intermediate space which forms the later otoplastic, are represented in US-A-4,712,245 and DE-A 24 59 259. With the first suggestion the intermediate space is subdivided into two compartments, the first of which containing a resin and the other containing a hardener. With the last suggestion a double wall casing is used whose intermediate space is widened by way of an axial slider.

Known is also the use of a non-deformable hollow body, which instead of an elastically widenable casing is provided with a curable circumferential coating. With this e.g. a resin-impregnated sleeve is layed around a compressible foam core which is to serve the bearing of the sleeve on the ear wall. DE-U 87 63 354 and DE-A 38 01 392 show suggestions of this type. In both cases the degree of widening is limited and the widening may not be controlled, e.g. may not be locally set corresponding to the anatomic conditions.

It is the object of the invention to simplify the method of the initially mentioned type and to ensure that an optimal adaptation of the stretchable circumferential wall is effected in all local regions of the auditory canal.

This object with the measures of the initially mentioned type is achieved in that the stretchable circumferential wall is formed by the walling of the hollow body itself which at its proximal end is closed and partly consists of the initially mentioned plastic, that the plastic mass before producing the inner pressure is formed semi-rigid or has at least a degree of stiffness exceeding the flowability, and that the excess pressure is produced in the inside of the hollow body.

The invention is based on the concept of making the hollow body itself deformable and at least partly curable, in that the hollow body, which represents the blank for the fitting piece consists of a stretchable and curable material, which then is only widened by an inner excess pressure in the ear and in the widened condition at least partly is cured. The inner excess pressure is the same at all locations of the hollow body. Experience has shown that already a small inner pressure is sufficient in order to achieve a tight bearing of the circumferential wall also in the regions of the auditory canal in which the circumferential wall of the blank before the widening comprises larger radial distances.

The method according to the invention is not only excellently suitable for the manufacture of otoplastic fitting pieces, but is also applicable for the manufacture of fitting pieces of other body cavities, in particular nose fitting pieces. Such nose fitting pieces then for example serve the retention of tubings which lead into the inside of the body.

The method according to the invention may in one embodiment form be realised very simply in that the hollow body after insertion into the ear is pumped up by way of water, glycerine or pressurised air from a hand-actuated dispenser. The hollow body including its end-face wall is light-permeable and consists at least in the region of the circumferential wall of light-hardening material so that only by way of the application of light, in particular of visible light, the hardening of the circumferential wall in the ear is carried out so much that the fitting piece no longer changes its shape after the removal from the ear. The end solidification may then be carried out outside the ear.

An alternative to the previously described method lies in the fact that the hollow body before the insertion into the ear contains a fluid with a pressure production means which without the supply of material is activatable by outer application in order to produce the inner excess pressure. The fluid is preferably fluid and in particular viscous and contains a swelling agent which by way of the supply of heat or electromagnetic radiation is activated.

A further formation of the method according to the invention it to be seen in that the circumferential wall of the hollow body before its insertion into the body cavity is essentially shape stable and by way of energy supply may be temporarily converted into a deformable condition. In this case the circumferential wall of the hollow body preferably consists of a thermoplastic mass, which at body temperature is solid and by way of microwave radiation, ultrasound or heat is temporarily plastified outside the body cavity before the hollow body is placed in the body cavity and the inner excess pressure is built up.

According to a further formation of the method according to the invention the hollow body on its outer surface is additionally provided with a non-reactive, already crosslinked elastic coating, which e.g. may consist of silicone or urethane. Such coatings are in particular advantageous with test persons with sensitive skin and may additionally improve the seating and the function of the plastic.

If in the above examples for the solidification of the circumferential wall in the ear by way of the supply of energy has been described by way of example, it is to be understood that alternatively the solidification may also be effected by removal of energy, in particular by cooling.

An important further formation of the invention lies in the fact that the fitting shape of the hollow body after its widening in the ear is checked in that energy from the distal end of the hollow body is led in a channel which is sealed with respect to the hollow body and at the proximal end is led out of this into the residual volume of the auditory canal and the energy change in this residual volume is measured per unit of time. Thus for example in the proximal end of the auditory canal an air excess pressure may be built up when the hollow body on all sides bears well on the auditory canal. The build-up of this excess pressure per unit of time is then a measure for the quality of the fitting shape. Through the closed channel in the hollow body also however sound waves may be introduced into the proximal region of the auditory canal and the acoustics at the distal end may be measured. The lower the sound exit the better is the fitting shape of the otoplastics. Also through the channel passing through the hollow body a microphone may be introduced into the proximal end of the auditory canal with which a noise produced externally is measured in order in turn to be able to objectively ascertain the sealedness of the hollow body at the auditory canal uninfluenced by subjective sensitivities. The hearing aid specialist may thus check the fitting shape in the ear before he begins with the hardening process. If the sealedness of the bearing of the circumferential wall in the auditory canal after the effected control measurement is too small, the inner pressure is increased according to the measuring result and where appropriate a renewed control measurement is carried out before the at least part curing is effected.

The method according to the invention permits a very advantageous further formation inasmuch as at least one region of the hollow body before the production of the inner excess pressure is provided with a slight deformability than other regions of the hollow body, in particular e.g. the distal end region of the hollow body may be provided with a lesser degree of deformation than the middle region of the hollow body. The adjusting of the degree of deformation may be achieved either by a corresponding selection of the wall thickness, but even more simple by the part solidification of the regions at which a high deformability is undesired. This is as a rule the case in the distal end region of the hollow body but may also apply to the proximal end region in order to concentrate the greatest deformation on the middle region of the hollow body. With this local, part or complete curing the deformation behaviour of the hollow body may already be set for the blank, but may also be controlled for the individual adaptation.

The invention furthermore relates to a hollow body for the manufacture of a fitting piece which may be applied into a body cavity of a human, in particular to an otoplastics, with a hollow body, a stretchable circumferential wall and with a medium which may be set under inner excess pressure, wherein the circumferential

wall at the distal end of the hollow body is connected to a rigid end-face wall which comprises a connection for a pressure producer and this hollow body according to the invention is characterised in that the stretchable circumferential wall forms the walling, of the hollow body, which is closed at the proximal end, and that the connection to the end-face wall opens into the inside of the hollow body. With the initially mentioned state of the art on the other hand the circumferential wall forms a casing for the hollow body and the connection opens into the intermediate space between the hollow body and the casing.

A further formation of the invention is yet to be seen in that on the hollow body there is provided a deformable extension which connects to its distal end and which for anchoring the otoplastic in the outer region of the ear may be applied into deepenings and in the ear is at least partly solidifiable. This extension consists of a fixing profile which e.g. may be applied into an outer ear region and may be pressed into the desired position, whereupon the fastening is effected by at least partially curing, in particular by light application. Alternatively this fixing profile may also be separately adapted and solidified, wherein then however post-working is required in order to connect this profile to the end-face wall of the fitting piece.

The hollow body according to the invention consists of a plastic which by way of a reactive-softener is plastified and where appropriate contains anorganic fillers and/or pigments for setting the colour, handling, flow behaviour and hardness. Suitable as plastics are polystyrol, polyester, polycarbonate, ABS, PVC etc. As a reactive-softener, compounds are selected which are ethylenically unsaturated, in the corresponding polymer have a plastifying effect and by way of the effect of energy are polymerisable. These are phtalates with ethylenically unsaturated groups such as e.g. diallyl-phtalate or vinyl-ether, e.g. butandiolmonovinylether or triethyleneglycoldivinylether, but also monomers such as styrol and divinylbenzol. Particularly advantageous are compounds which contain (meth-)acryl groups such as e.g. methylmethacrylate, hexandioldiacrylate as well as all further mono and multimeth(acrylate) with alkoxy, hydroxyalkyl, acrylamido and aralkyl groups in their molecular structure. To the plastic mass there is preferably added a photo-initiator which initiates the curing of the hollow body by the effect of light.

The method according to the invention and the device according to the invention permit the manufacture of an individual optimally adapted otoplastic or nose plastic in a single sitting which lasts less than one hour. This adaptation does not require qualified technical personnel. In particular with one advantageous formation which lies in that the end-face wall consists of an outer ring part connected as one-piece to the circumferential wall and of a closure plate releasably applied into this circumferential wall, the handling activity is reduced to a minimum since after the removal of the closure plate which preferably is latched on the outer ring, only a fitting hearing aid module needs to be clipped into the where appropriate multi-part outer ring in order to create an in-the-ear hearing aid.

By way of the drawings which represents one embodiment example the invention is described in more detail.

There is shown:

Fig. 1 a schematic representation of a hollow body positioned in the auditory canal before the formation of an ear fitting piece,

Fig. 2 the representation according to Fig. 1, however after a widening of the hollow body with an adaptation to the anatomy of the auditory canal, and

Fig. 3 a cross section through the hollow body in an enlarged scale.

A hollow body 10, in a coarse approximation of a truncated cone shape with a plane distal end and with a rounded dome-shaped proximal end, has a circumferential wall 12 of a stretchable, light-hardening plastic and a plane end-face wall 14 which closes the circumferential wall 12 at the distal end and which is essentially rigid. As is deduced from Fig. 3 the circumferential wall 12 is formed pouch-shaped or bag-shaped and ends at the distal end in the region of an outer ring with an ovally contoured opening 18. Into this opening there is applied a closure plate 20 and in the embodiment example is releasably screwed on with circumferentially distributed screws. Alternatively the closure plate 20 may also be locked on the outer ring 16 by way of suitable latching connections. The thus formed hollow body is hermetically closed and into the hollow body there opens a tube 22 which serves as a hand grip and simultaneously via a tubing is connected to a device for producing pressure. The whole circumferential wall 12 including its proximal dome is provided with a thin elastic coating 24. A channel intersperses the closure plate 20, further the inside of the hollow body 10 and protrudes finally, with sealing, through the dome of the circumferential wall 12 out of the hollow body at its proximal end. In the case of pumping up with fluid the air escapes through a bleeding bore 32 which is subsequently closed.

The circumferential wall 12 consists of a stretchable, light-curing material. The closure plate 20 is light permeable. In the region of the outer ring 16 the circumferential wall 12 is at least part cured so that there results a rigid seat for the closure plate 20.

The thus premanufactured hollow body is applied by a specialist of a hearing aid laboratory into the auditory canal of a test person, as Fig. 1 illustrates. By actuating a device for pressure production then in the hollow body 10 an inner excess pressure is produced which according to the degree of softness of the circumferential wall 12 is sufficient in order to widen the circumferential wall 12. With this this circumferential wall 12 bears tightly on the auditory canal 28 as Fig. 2 schematically illustrates. The hollow body 10 may then be let go of and a fitting control of the hollow body 10 takes place. In the simplest case this is effected in that by way of the tubing 26 in the end region 30 of the auditory canal 28 an excess pressure is built up and the pressure reduction per unit of time is measured. If a pre-selected time period for the pressure reduction is fallen short of the inner excess pressure in the hollow body 10 is increased through the tube 22, otherwise the adaptation of the fitting piece is finished. Alternatively the tightness control may also be effected by sound measurement.

After the hollow body 10 has reached its fitting condition, whilst maintaining the excess pressure it is at least partly cured so that the fitting shape after relieving of pressure of the inner space of the hollow body remains. The at least part solidification is preferably effected by light application through the closure plate 20. Subsequently

the hollow body 10 is removed from the ear, the closure plate 20 with the channel 26 is removed. The oval opening 18 then lies free so that e.g. a hearing aid module for an in-the-ear hearing aid may be inserted into the inside of the hollow body 10. The outer ring 18 with this serves for latching so that craftman's post-work as a rule is done away with.

PATENT CLAIMS

1. A method for manufacturing a fitting piece for insertion into a human body cavity with the use of a hollow body (10), a stretchable circumferential wall (12) and a deformable plastic mass which is applied in the body cavity under an inner excess pressure and is solidified in the body cavity at least just up to a sufficient shape stability, **characterised in that** the stretchable circumferential wall (12) is formed by the walling of the hollow body (10) itself which at its proximal end is closed and at least partly consists of the plastic mass, that the plastic mass before producing the inner excess pressure is formed semi-rigid or has at least a degree of stiffness exceeding the flowability, and that the excess pressure is produced in the inside of the hollow body (10).
2. A method according to claim 1, **characterised in that** the hollow body (10) contains a fluid with a pressure production means which is activatable by external application in order to build up the inner pressure.
3. A method according to one of claims 1 or 2, **characterised in that** the circumferential wall (12) of the hollow body (10) before its insertion into the body cavity by way of energy supply is temporarily converted into a deformable condition.
4. A method according to one of claims 1 to 3, **characterised in that** the solidification of the plastic mass is effected by the supply of energy.
5. A method according to one of claims 1 to 3, **characterised in that** the solidification of the plastic mass is effected by energy removal.
6. A method according to one of claims 1 to 5, **characterised in that** after the production of the inner excess pressure in the hollow body (10) an energy medium from the distal outer side of the hollow body (10) is led through a channel (26) interspersing the hollow body (10), into the proximal end region (30) of the auditory canal (28) and the change of the energy quantum per unit of time in this region is evaluated for checking the fitting accuracy of the widened hollow body (10).
7. A method according to one of claims 1 to 6, **characterised in that** at least one end region of the hollow body (10) before the production of the inner excess pressure is provided with a lower deformability than the middle region of the hollow body (10).
8. A method according to one of the claims 1 to 7, **characterised in that** the solidification of the circumferential wall (12) is effected by way of high-frequency electro-magnetic radiation with a wavelength in the region of 200 - 5000 nanometres.
9. A method according to one of the claims 1 to 8, **characterised in that** the outer surface of the circumferential wall (12) before the insertion of the hollow body (10) into the body cavity is provided with a non-reactive, already crosslinked elastic coating (24).

10. A hollow body for manufacturing a fitting piece insertable into the body cavity of the human, in particular an otoplastic, with a stretchable circumferential wall (12) and with a medium which can be set under inner excess pressure, wherein the circumferential wall (12) at the distal end of the hollow body (10) is connected to a rigid end-face wall (18, 20), **characterised in that** the stretchable circumferential wall (12) forms the walling of the hollow body (10), which is closed at the proximal end.
11. A device according to claim 10, **characterised in that** the end-face wall (18, 20) comprises a connection (22), for a pressure producer, opening in the inside of the hollow body (10).
12. A device according to claim 10, **characterised in that** in the hollow body (10) there is contained a fluid with a predetermined quantity of a swelling agent activatable by external energy supply, and the quantity is dimensioned such that after the activation the inner excess pressure sets in the hollow body (10).
13. A device according to one of the claims 10 to 13, **characterised in that** the circumferential wall (12) at least at the distal end of the hollow body (10) has a lower deformability than in its middle region.
14. A device according to claim 13, **characterised in that** the region with a lower deformability of the circumferential wall (12) is part cured.
15. A device according to one of the claims 10 to 14, **characterised in that** the hollow body (10) comprises a deformable extension connecting to its distal end, which for anchoring the otoplastic in the outer region of the ear can bear on this and in the ear is at least partly solidifiable.
16. A device according to claim 15, **characterised in that** the extension is connected to the hollow body (10) as one piece.
17. A device according to one of the claims 10 to 16, **characterised in that** the end-face wall (18, 20) consists of an outer ring (18) connected as one piece to the circumferential wall (12) and of an closure plate (2) which can be releasably applied into this ring.
18. A device according to claim 17, **characterised in that** the closure plate (20) is latched on the outer ring (18).
19. A device according to one of the claims 10 to 18, **characterised in that** the hollow body (10) comprises a channel (26) which reaches from its distal end to the proximal end and which seals with respect to the inside of the hollow body (10).

1/2

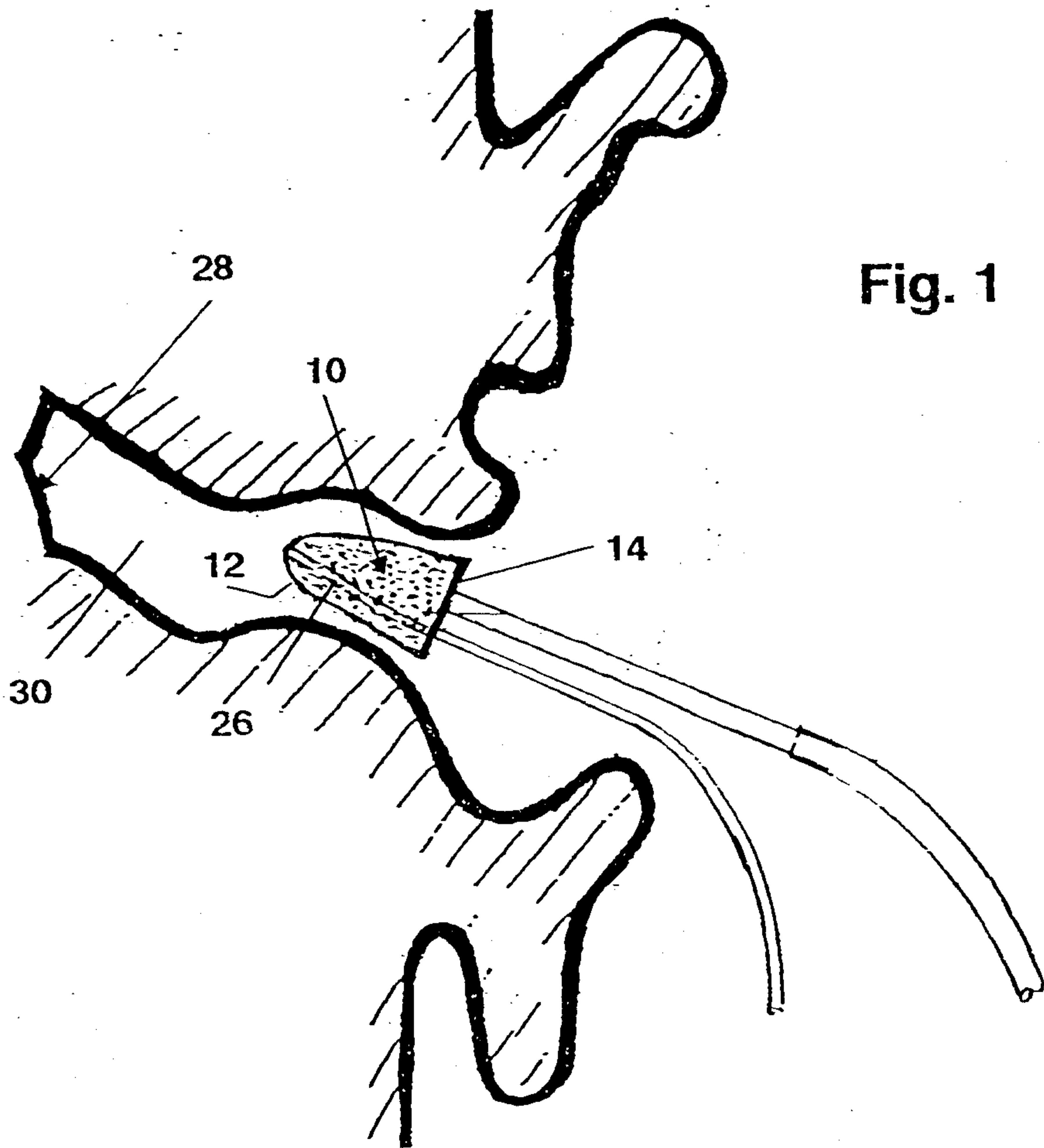


Fig. 1

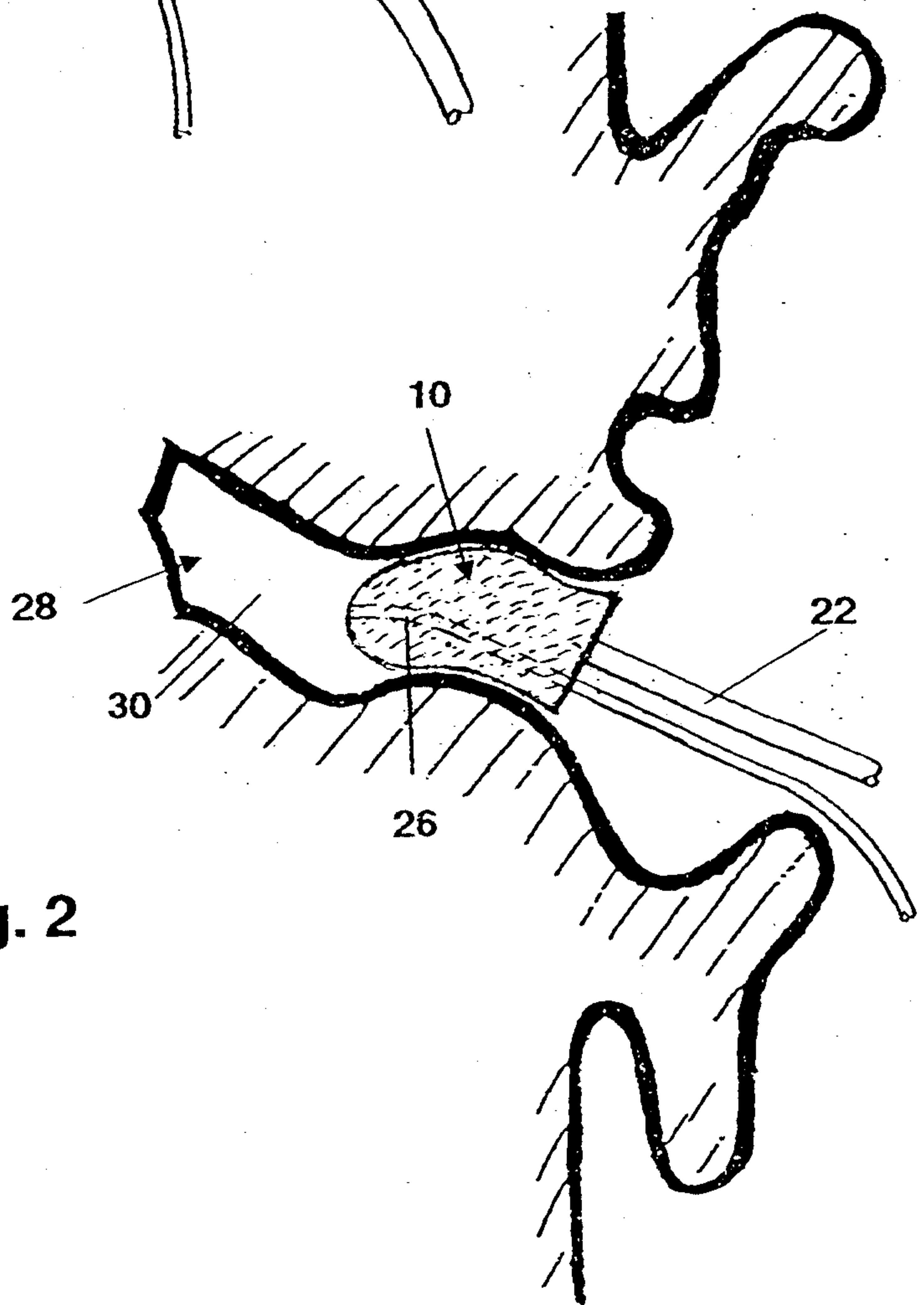


Fig. 2

Markus Clark

2/2

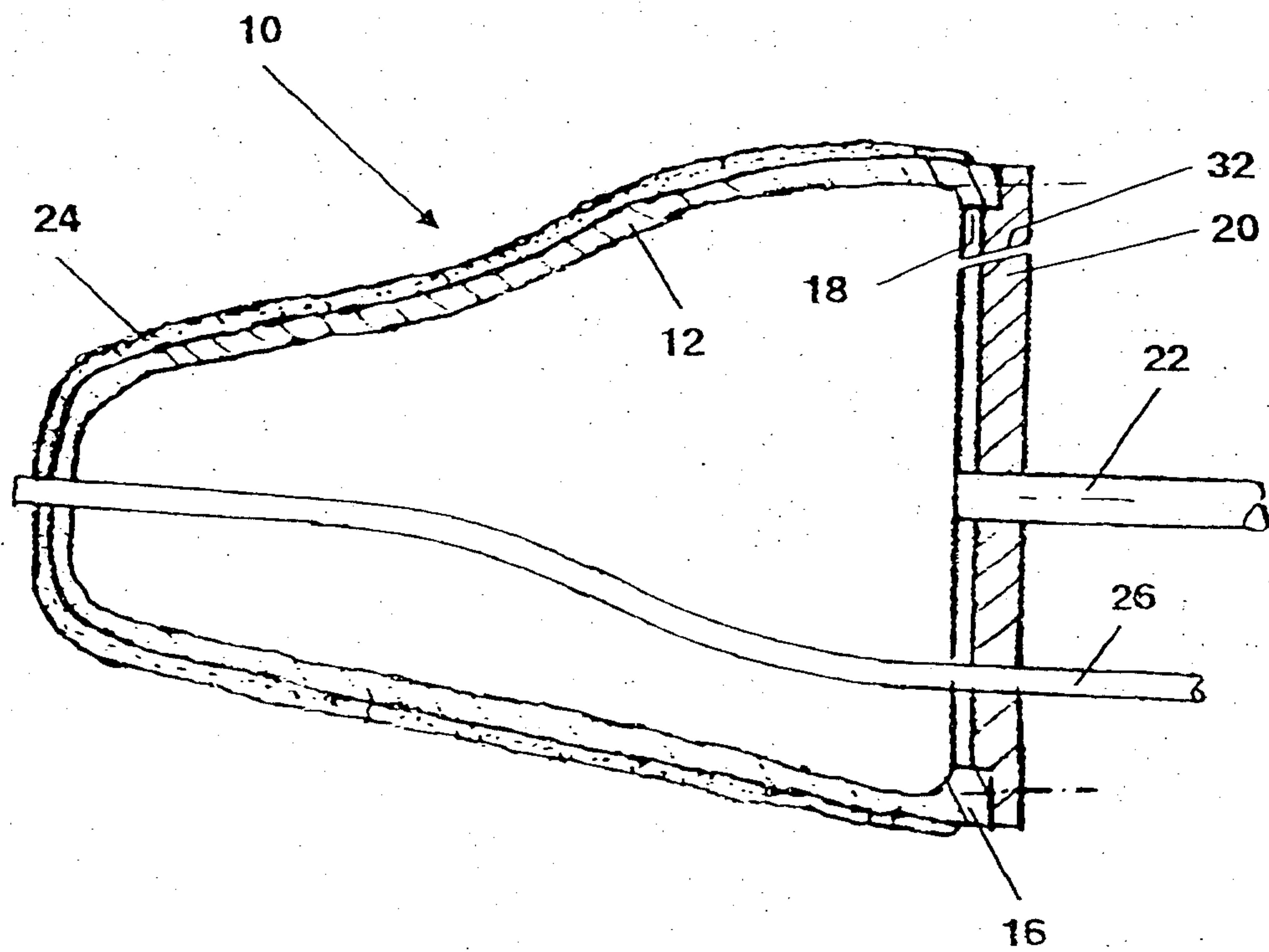


FIG. 3

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