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(54) Titre : CONSTRUCTION SPONGIEUSE A DEUX ELEMENTS DESTINEE A LA REPARATION DE CARTILAGE
(54) Title: TWO PIECE CANCELLOUS CONSTRUCT FOR CARTILAGE REPAIR

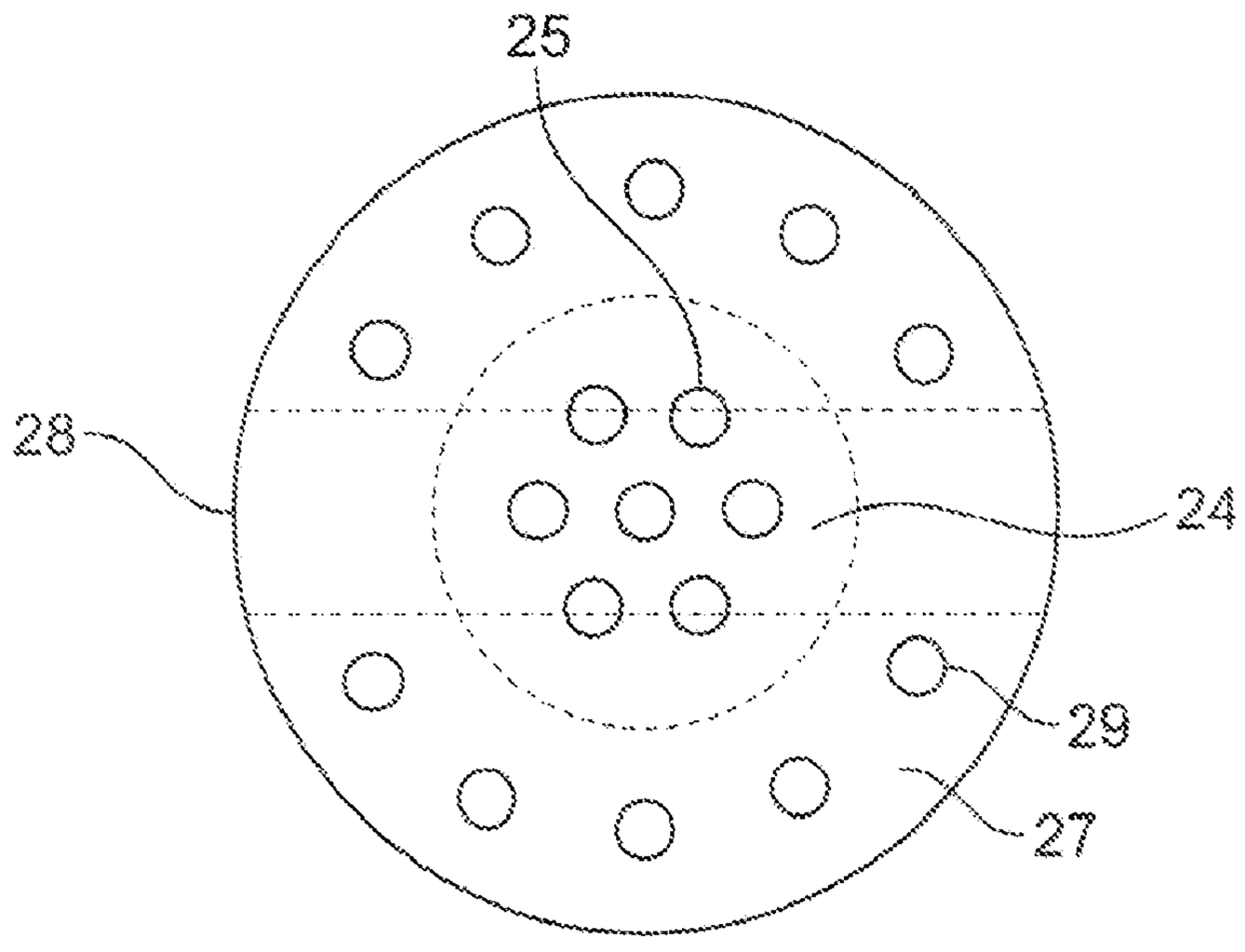

Fig. 4

(57) Abrégé/Abstract:
The invention is directed toward a cartilage repair assembly comprising a shaped allograft two piece construct (20) with a demineralized cancellous cap (30) and a mineralized cylindrical base member (22) defining a blind bore (23) wrth a through going transverse bore (28) intersecting the blind bore (23). The demineralized cancellous cap (30) has a cylindrical top portion (32) and a smaller diameter cylindrical stem (36) extending away from the top portion (32) which fits into the blind bore (23) of the mineralized base member (22). The cap stem (36) defines a transverse through going bore (37) which is aligned with the through going bore (28) of the base member (22) to receive a cylindrical cortical pin (40) holding the cap (30) within the base member (22). The shaped structure (20) is dimensioned to fit in a drilled bore in a cartilage delect area so that the assembly engages the side wall of the drilled bore in an interference fit.

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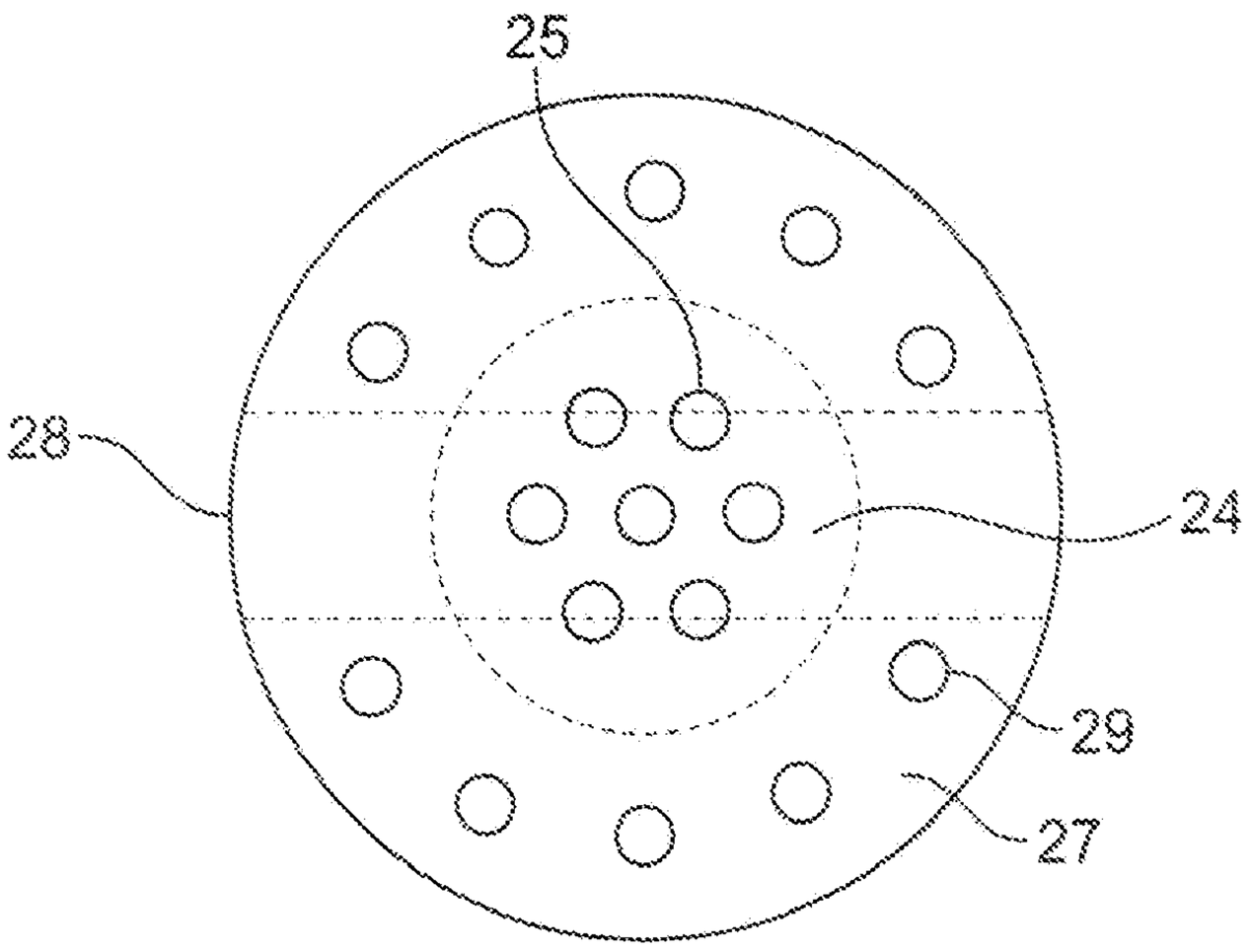

Fig. 4

(57) Abstract: The invention is directed toward a cartilage repair assembly comprising a shaped allograft two piece construct (20) with a demineralized cancellous cap (30) and a mineralized cylindrical base member (22) defining a blind bore (23) wrth a through going transverse bore (28) intersecting the blind bore (23). The demineralized cancellous cap (30) has a cylindrical top portion (32) and a smaller diameter cylindrical stem (36) extending away from the top portion (32) which fits into the blind bore (23) of the mineralized base member (22). The cap stem (36) defines a transverse through going bore (37) which is aligned with the through going bore (28) of the base member (22) to receive a cylindrical cortical pin (40) holding the cap (30) within the base member (22). The shaped structure (20) is dimensioned to fit in a drilled bore in a cartilage delect area so that the assembly engages the side wall of the drilled bore in an interference fit.

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TWO PIECE CANCELLOUS CONSTRUCT FOR CARTILAGE REPAIR

RELATED APPLICATIONS

There is no related application.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

REFERENCE TO SEQUENCE LISTING, A TABLE OR A COMPUTER PROGRAM LISTING COMPACT DISC APPENDIX

None.

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention is generally directed toward an allograft cartilage repair implant and is more specifically directed toward a two piece allograft cancellous bone implant having a demineralized cancellous bone cap member and a mineralized or partially demineralized cancellous bone base member, both pieces being held together with an allograft bone pin. The construct is shaped for an interference fit implantation in a shoulder, knee, hip, or ankle joint. The base member is provided with an axially positioned blind bore and a plurality of smaller diameter through going bores which allow transport of cellular materials throughout the implant site to stimulate cartilage growth

2. Description of the Prior Art

Articular cartilage injury and degeneration present medical problems to the general population which is constantly addressed by orthopedic surgeons. Every year in the United States,

over 500,000 arthroplastic or joint repair procedures are performed. These include approximately 125,000 total hip and 150,000 total knee arthroplastics and over 41,000 open arthroscopic procedures to repair cartilaginous defects of the knee.

In the knee joint, the articular cartilage tissue forms a lining which faces the joint cavity on one side and is linked to the subchondral bone plate by a narrow layer of calcified cartilage tissue on the other. Articular cartilage (hyaline cartilage) consists primarily of extracellular matrix with a sparse population of chondrocytes distributed throughout the tissue. Articular cartilage is composed of chondrocytes, type II collagen fibril meshwork, proteoglycans and water. Active chondrocytes are unique in that they have a relatively low turnover rate and are sparsely distributed within the surrounding matrix. The collagens give the tissue its form and tensile strength and the interaction of proteoglycans with water give the tissue its stiffness to compression, resilience and durability. The hyaline cartilage provides a low friction bearing surface over the bony parts of the joint. If the lining becomes worn or damaged resulting in lesions, joint movement may be painful or severely restricted. Whereas damaged bone typically can regenerate successfully, hyaline cartilage regeneration is quite limited because of it's limited regenerative and reparative abilities.

Articular cartilage lesions generally do not heal, or heal only partially under certain biological conditions due to the lack of nerves, blood vessels and a lymphatic system. The limited reparative capabilities of hyaline cartilage usually results in the generation of repair tissue that lacks the structure and biomechanical properties of normal cartilage. Generally, the healing of the defect results in a fibrocartilaginous repair tissue that lacks the structure and biomedical properties of hyaline cartilage and degrades over the course of time. Articular cartilage lesions are frequently associated with disability and with symptoms such as joint pain, locking phenomena and reduced or disturbed function. These lesions are difficult to treat because of the distinctive structure and function of hyaline cartilage. Such lesions are believed to progress to severe forms of osteoarthritis. Osteoarthritis is the leading cause of disability and impairment in middle-aged and older individuals, entailing significant economic, social and psychological costs. Each year, osteoarthritis accounts for as many as 39 million physician visits and more than 500,000 hospitalizations. By the year 2020, arthritis is expected to affect almost 60 million persons in the United States and to limit the activity of 11.6 million persons.

There are many current therapeutic methods being used. None of these therapies has resulted in the successful regeneration of hyaline-like tissue that withstands normal joint loading and activity over prolonged periods. Currently, the techniques most widely utilized clinically for cartilage defects and degeneration are not articular cartilage substitution procedures, but rather lavage, arthroscopic debridement, and repair stimulation. The direct transplantation of cells or tissue into a defect and the replacement of the defect with biologic or synthetic substitutions presently accounts for only a small percentage of surgical interventions. The optimum surgical goal is to replace the defects with cartilage-like substitutes so as to provide pain relief, reduce effusions and inflammation, restore function, reduce disability and postpone or alleviate the need for prosthetic replacement.

Lavage and arthroscopic debridement involve irrigation of the joint with solutions of sodium chloride, Ringer or Ringer and lactate. The temporary pain relief is believed to result from removing degenerative cartilage debris, proteolytic enzymes and inflammatory mediators. These techniques provide temporary pain relief, but have little or no potential for further healing.

Repair stimulation is conducted by means of drilling, abrasion arthroplasty or microfracture. Penetration into the subchondral bone induces bleeding and fibrin clot formation which promotes initial repair, however, the tissue formed is fibrous in nature and not durable. Pain relief is temporary as the tissue exhibits degeneration, loss of resilience, stiffness and wear characteristics over time.

The periosteum and perichondrium have been shown to contain mesenchymal progenitor cells capable of differentiation and proliferation. They have been used as grafts in both animal and human models to repair articular defects. Few patients over 40 years of age obtain good clinical results, which most likely reflect the decreasing population of osteochondral progenitor cells with increasing age. There have also been problems with adhesion and stability of the grafts, which result in their displacement or loss from the repair site.

Transplantation of cells grown in culture provides another method of introducing a new cell population into chondral and osteochondral defects. CARTICEL® is a commercial process to culture a patient's own cartilage cells for use in the repair of cartilage defects in the femoral condyle marketed by Genzyme Biosurgery in the United States and Europe. The procedure uses arthroscopy to take a biopsy from a healthy, less loaded area of articular cartilage. Enzymatic digestion of the

harvested tissue releases the cells that are sent to a laboratory where they are grown for a period ranging from 2-5 weeks. Once cultivated, the cells are injected during a more open and extensive knee procedure into areas of defective cartilage where it is hoped that they will facilitate the repair of damaged tissue. An autologous periosteal flap with a cambium layer is used to seal the transplanted cells in place and act as a mechanical barrier. Fibrin glue is used to seal the edges of the flap. This technique preserves the subchondral bone plate and has reported a high success rate. Proponents of this procedure report that it produces satisfactory results, including the ability to return to demanding physical activities, in more than 90% of patients and those biopsy specimens of the tissue in the graft sites show hyaline-like cartilage repair. More work is needed to assess the function and durability of the new tissue and determine whether it improves joint function and delays or prevents joint degeneration. As with the perichondrial graft, patient/donor age may compromise the success of this procedure as chondrocyte population decreases with increasing age. Disadvantages to this procedure include the need for two separate surgical procedures, potential damage to surrounding cartilage when the periosteal patch is sutured in place, the requirement of demanding microsurgical techniques, and the expensive cost of the procedure which is currently not covered by insurance.

Osteochondral transplantation or mosaicplasty involves excising all injured or unstable tissue from the articular defect and creating cylindrical holes in the base of the defect and underlying bone. These holes are filled with autologous cylindrical plugs of healthy cartilage and bone in a mosaic fashion. The osteochondral plugs are harvested from a lower weight-bearing area of lesser importance in the same joint. This technique, shown in Prior Art Figure 2, can be performed as arthroscopic or open procedures. Reports of results of osteochondral plug autografts in a small numbers of patients indicate that they decrease pain and improve joint function, however, long-term results have not been reported. Factors that can compromise the results include donor site morbidity, effects of joint incongruity on the opposing surface of the donor site, damage to the chondrocytes at the articular margins of the donor and recipient sites during preparation and implantation, and collapse or settling of the graft over time. The limited availability of sites for harvest of osteochondral autografts restricts the use of this approach to treatment of relatively small articular defects and the healing of the chondral portion of the autograft to the adjacent articular cartilage remains a concern.

Transplantation of large allografts of bone and overlying articular cartilage is another treatment option that involves a greater area than is suitable for autologous cylindrical plugs, as well as for a non-contained defect. The advantages of osteochondral allografts are the potential to restore the anatomic contour of the joint, lack of morbidity related to graft harvesting, greater availability than autografts and the ability to prepare allografts in any size to reconstruct large defects. Clinical experience with fresh and frozen osteochondral allografts shows that these grafts can decrease joint pain, and that the osseous portion of an allograft can heal to the host bone and the chondral portion can function as an articular surface. Drawbacks associated with this methodology in the clinical situation include the scarcity of fresh donor material and problems connected with the handling and storage of frozen tissue. Fresh allografts carry the risk of immune response or disease transmission. Musculoskeletal Transplant Foundation (MTF) has preserved fresh allografts in a media that maintains a cell viability of 50% for 35 days for use as implants. Frozen allografts lack cell viability and have shown a decreased amount of proteoglycan content which contribute to deterioration of the tissue.

A number of United States Patents have been specifically directed towards bone plugs which are implanted into a bone defect. Examples of such bone plugs are U.S. Patent Number 4,950,296 issued August 21, 1990 which discloses a bone graft device comprising a cortical shell having a selected outer shape and a cavity formed therein for receiving a cancellous plug, which is fitted into the cavity in a manner to expose at least one surface; U.S. Patent Number 6,039,762 issued March 21, 2000 discloses a cylindrical shell with an interior body of deactivated bone material and U.S. Patent Number 6,398,811 issued June 4 ,2002 directed toward a bone spacer which has a cylindrical cortical bone plug with an internal through going bore designed to hold a reinforcing member. U.S. Patent Number 6,383,211 issued May 7, 2002 discloses an invertebral implant having a substantially cylindrical body with a through going bore dimensioned to receive bone growth materials.

U.S. Patent Number 6,379,385 issued April 30, 2002 discloses an implant base body of spongious bone material into which a load carrying support element is embedded. The support element can take the shape of a diagonal cross or a plurality of cylindrical pins. See also, U.S. Patent Number 6,294,187 issued September 25, 2001 which is directed to a load bearing osteoimplant made of compressed bone particles in the form of a cylinder. The cylinder is provided with a plurality of

through going bores to promote blood flow through the osteoimplant or to hold a demineralized bone and glycerol paste mixture. U.S. Patent Number 6,096,081 issued August 1, 2000 shows a bone dowel with a cortical end cap or caps at both ends, a brittle cancellous body and a through going bore.

While these implants have been used for bone tissue regeneration, the same will not work to repair cartilage areas due to the osteoinductive nature of the bone which causes bone growth.

The use of implants for cartilage defects is much more limited. Aside from the fresh allograft implants and autologous implants, U.S. Patent Number 6,110,209 issued November 5, 1998 shows the use an autologous articular cartilage cancellous bone paste to fill arthritic defects. The surgical technique is arthroscopic and includes debriding (shaving away loose or fragmented articular cartilage), followed by morselizing the base of the arthritic defect with an awl until bleeding occurs. An osteochondral graft is then harvested from the inner rim of the intercondylar notch using a trephine. The graft is then morselized in a bone graft crusher, mixing the articular cartilage with the cancellous bone. The paste is then pushed into the defect and secured by the adhesive properties of the bleeding bone. The paste can also be mixed with a cartilage stimulating factor, a plurality of cells, or a biological glue. All patients are kept non-weight bearing for four weeks and used a continuous passive motion machine for six hours each night. Histologic appearance of the biopsies has mainly shown a mixture of fibrocartilage with hyaline cartilage. Concerns associated with this method are harvest site morbidity and availability, similar to the mosaicplasty method.

U.S. Patent Number 6,379,367 issued April 30, 2002 discloses a plug with a base membrane, a control plug, and a top membrane which overlies the surface of the cartilage covering the defective area of the joint.

SUMMARY OF THE INVENTION

A cartilage repair allograft construct implant comprising a two piece allograft bone construct with a mineralized cylindrical cancellous bone base member and a demineralized and non-osteoinductive cancellous bone cap member mounted in a blind bore cut in the cancellous bone base member, the two members being held together by an allograft bone pin. The two piece construct is used for replacing articular cartilage defects and is placed in a bore which has been cut into the

patient to remove the lesion defect area. The bone base member has an axially aligned blind bore, a transverse through going bore which intersects the blind bore and has a plurality of through going bores which run parallel to the axis of the cylindrical bone base member. The cap member has a stem which fits into the blind bore of the base member with the stem defining a transverse through going bore. The base surface of the cap member body overlies the upper surface of the cylindrical base member with the stem bore and the base member transverse bore being aligned to receive a cortical pin. Additives may be applied to the internal bores, blind bore or the cap member of the construct in order to increase or accelerate cartilaginous or bony tissue formation

Each allograft construct can support the addition of a variety of chondrogenic stimulating factors including, but not limited to morselized allogeneic cartilage, growth factors (FGF-2, FGF-5, IGF-1, TGF-β, BMP-2, BMP-7, PDGF, VEGF), human allogenic or autologous chondrocytes, human allogenic or autologous bone marrow cells, stem cells, demineralized bone matrix, insulin, insulin-like growth factor-1, transforming growth factor-B, interleukin-1 receptor antagonist, hepatocyte growth factor, platelet-derived growth factor, Indian hedgehog and parathyroid hormone-related peptide or bioactive glue.

It is an object of the invention to provide an allograft implant for joints which provides pain relief, restores normal function and will postpone or alleviate the need for prosthetic replacement.

It is also an object of the invention to provide a cartilage repair implant which is easily placed in a defect area by the surgeon using an arthroscopic, minimally invasive technique.

It is still another object of the invention to provide an allograft implant which has load bearing capabilities.

It is further an object of the invention to provide an allograft implant procedure which is applicable for both partial and full thickness lesions.

It is yet another object of the invention to provide an allograft implant which facilitates growth of hyaline cartilage.

It is an additional object of the invention to provide a cancellous construct which is treated with chondrogenic stimulating factors.

These and other objects, advantages, and novel features of the present invention will become apparent when considered with the teachings contained in the detailed disclosure along with the

accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows the anatomy of a knee joint;

Figure 2 shows a schematic mosaicplasty as known in the prior art;

Figure 3 shows an exploded perspective view of the inventive two piece cancellous construct;

Figure 4 shows a top plan view of the two piece allograft cancellous construct assembly showing the blind bore and plurality of through going bores in phantom;

Figure 5 shows a side elevation view of the two piece construct shown in Figure 4;

Figure 6 is a side elevation view of the two piece construct of Figure 4 turned 90 ° with the blind and parallel bores shown in phantom;

Figure 7 shows a perspective view of the base member of the cancellous construct with the cap member removed;

Figure 8 shows a perspective view of the cap member of the cancellous construct;

Figure 9 is a side elevation view of the cap member shown in Figure 8; and

Figure 10 is a side elevation view of the cap member of the construct of Figure 9 turned 90°.

DESCRIPTION OF THE INVENTION

The term "tissue" is used in the general sense herein to mean any transplantable or implantable tissue, the survivability of which is improved by the methods described herein upon implantation. In particular, the overall durability and longevity of the implant are improved, and host-immune system mediated responses, are substantially eliminated.

The terms "transplant" and "implant" are used interchangeably to refer to tissue, material or cells (xenogeneic or allogeneic) which may be introduced into the body of a patient.

The terms "autologous" and "autograft" refer to tissue or cells which originate with or are derived from the recipient, whereas the terms "allogeneic" and "allograft" refer to cells and tissue which originate with or are derived from a donor of the same species as the recipient. The terms "xenogeneic" and "xenograft" refer to cells or tissue which originates with or are derived from a

species other than that of the recipient.

The present invention is directed towards a cartilage repair construct constructed of two separate pieces of allograft cancellous bone.

Both pieces of the two-piece allograft construct are to be derived from dense cancellous bone that may originate from proximal or distal femur, proximal or distal tibia, proximal humerus, talus, calceneus, patella, or ilium. Cancellous tissue is first processed into blocks and then milled into the desired shapes. The top piece or cap member is substantially demineralized in dilute acid until the bone contains less than 0.2% wt/wt residual calcium. Subsequently, the resultant tissue form is predominantly Type I collagen, which is sponge-like in nature with an elastic quality. Following decalcification, the tissue is further cleaned and may also be treated so that the cancellous tissue is non-osteoinductive. This inactivation of inherent osteoinductivity may be accomplished via chemical or thermal treatment or by high energy irradiation. In a preferred embodiment, the cancellous cap member is treated with an oxidizing agent such as hydrogen peroxide in order to achieve a non-osteoinductive material. The bottom piece will be formed from mineralized cancellous bone or partially demineralized cancellous bone.

The two piece allograft cancellous construct 20 has a base member 22 with a cap member 30 which is held fixed in place in the base member by a pin 40. The base member 22 is preferably constructed of mineralized cancellous bone and is shaped in the form of a cylinder for easy insertion into bores cut into the patient to cut away cartilage defect areas. However, the base member 22 may be surface or partially demineralized or contain a region of cortical bone so that it is cortical/cancellous. The body of the base member 22 defines a blind bore 23 which holds the stem 36 of the cap member 30. The bottom surface 24 of the blind bore as seen in Figures 5-7 has a plurality of longitudinal through going bores 25 extending through the base member 22 and ending on the distal end surface 26 of the base member which is preferably planar. The top surface 27 of the base member 22 is also preferably planar forming a seat for the cap member 30. A transverse bore 28 extends through the diameter of the cylindrical base above the bottom surface 24 of the blind bore 23 and intersects the blind bore 23. A second plurality of through going bores 29 are circumferentially positioned around the blind bore 23 parallel to the central axis of the base member

22 and extend from the top surface 27 to the bottom surface 26. The through going bores 25 and 29 have a smaller diameter than the blind bore 23 with a diameter ranging from 0.5 to 2.0 mm

The cap member 30 has a cylindrical top section 32 which has a thickness of about 3mm with a top planar surface 33, an outer curved wall 34 and a bottom planar surface 35 which is seated adjacent the top surface 27 of the base member 22 when the components are mounted together. The top surface 33 while preferably planar may be milled to a degree of curvature that makes the implant construct match the physiological curvature in the knee. Larger constructs may have a cap member that has multiple stem sections and a base with an inverse "female" pattern which receives the stem sections. An integral cylindrical stem 36 extends away from the bottom planar surface 35 a length which is not longer than the depth of the blind bore 23 and has a diameter equal to or less than the diameter of the blind bore 23. The stem 36 defines a transverse through going bore 37 which is aligned with transverse bore 28 of the base member to receive a cylindrical pin 40 which is inserted radially through the construct to hold the cap member 30 in place within the base member 22. The cap member 30 is preferably formed of demineralized cancellous allograft bone with a calcium content less than of 0.2 % calcium or has a substantially demineralized region such as the entire top section with a calcium content less than 0.2% calcium. The cylindrical pin 40 is preferably constructed of cortical bone and has a length equal to or less than the diameter of the base member 22. The pin can also be constructed of a synthetic material.

The cap member 30 can be secured to the base member 22 by a staple, suture, press fit or an adhesive compound such as fibrin based glue.

The construct 20 is placed in a defect area bore which has been cut in the lesion area of the bone of a patient with the upper surface 26 of the cap member 30 being slightly proud, slightly below, or substantially flush with the surface of the original cartilage remaining at the area being treated. The construct 20 has a length which can be the same as the depth of the defect or more or less than the depth of the bore. If the construct 20 is the same as the depth of the bore 60, the base of the implant is supported by the bottom surface of the bore and the top surface 33 of cap 30 is substantially level with the articular cartilage. If the construct 20 is of a lesser length, the base of the construct is not supported but support is provided by the wall of the defect area bore or respective cut out area as the plug is interference fit within the bore or cut out area with the cap being slightly

proud, slightly below, or flush with the surrounding articular cartilage depending on the surgeon's preference. With such load bearing support the graft surface is not damaged by weight or bearing loads which can cause micromotion interfering with the graft interface producing fibrous tissue interfaces and subchondral cysts.

If desired, a plurality of through going bores 25 and 29 in the construct allow cell migration throughout the construct to promote cartilage growth in the cartilage area and bone growth in the adjacent bore region.

In operation, the lesion or defect is removed by cutting a bore removing a lesion in the implant area. If desired, the open cancellous structure of the cap member 30 may be loaded with a cartilage paste or gel as noted below and/or one or more additives namely recombinant or native growth factors (FGF-2, FGF-5, FGF-7, IGF-1, TGF-β, BMP-2, BMP-4, BMP-7, PDGF, VEGF), human allogenic or autologous chondrocytes, human allogenic cells, human allogenic or autologous bone marrow cells, human allogenic or autologous stem cells, demineralized bone matrix, insulin, insulin-like growth factor-1, interleukin-1 receptor antagonist, hepatocyte growth factor, platelet-derived growth factor, Indian hedgehog parathyroid hormone-related peptide, viral vectors for growth factor or DNA delivery, nanoparticles, or platelet-rich plasma. The construct 20 is then placed in the bore or cut away area in an interface fit with the surrounding walls.

If the construct is moveable within the bore, suitable organic glue material can be used to keep the implant fixed in place in the implant area. Suitable organic glue material can be found commercially, such as for example; TISSEEL® or TISSUCOL® (fibrin based adhesive; Immuno AG, Austria), Adhesive Protein (Sigma Chemical, USA), Dow Corning Medical Adhesive B (Dow Corning, USA), fibrinogen thrombin, elastin, collagen, cascin, albumin, keratin and the like.

The base of the blind bore 33 of the construct can alternatively be provided with a matrix of minced cartilage putty or gel consisting of minced or milled allograft cartilage which has been lyophilized so that its water content ranges from 0.1% to 8.0% ranging from 25% to 50% by weight, mixed with a carrier of sodium hyaluronate solution (HA) (molecular weight ranging from 7.0×10^5 to 1.2×10^6) or any other bioabsorbable carrier such as hyaluronic acid and its derivatives, gelatin, collagen, chitosan, alginate, buffered PBS, Dextran, or polymers, the carrier ranging from ranging from 75% to 50% by weight. The cartilage is milled to a size ranging up to 1 mm.

In the gel form, the minced cartilage has been lyophilized so that its water content ranges from 0.1% to 8.0%, ranging from 15% to 30% by weight and the carrier ranges from 85% to 70% by weight. The particle size of the cartilage when milled is less than or equal to 1 mm dry. The cartilage pieces can be processed to varying particle sizes and the HA or other carrier can have different viscosities depending on the desired consistency of the putty or gel. This cartilage matrix can be deposited into the matrix of the demineralized cap member. The putty or gel enhances the tissue integration between the plug and host tissue.

It is also envisioned that demineralized bone matrix and/or growth factors such as (FGF-2, FGF-5, FGF-7, IGF-1, TGF-β, BMP-2, BMP-4, BMP-7, PDGF, VEGF) or soluble factors such as insulin, interleukin-1 receptor antagonist, hepatocyte growth factor, Indian hedgehog and parathyroid hormone-related peptide, viral vectors for growth factor or DNA delivery, nanoparticles may be adsorbed or combined with the scaffold or the cartilage fragments. In another embodiment, platelet-rich plasma may be added to the scaffold.

It is also envisioned that cells which have been grown outside the patient can be inserted by syringe into the cancellous cap matrix before, during or after deposit of the construct 20 into the defect area. Such cells include allogenic or autologous, bone marrow cells, stem cells and chondrocyte cells. The cellular density of the cells preferably ranges from 1.0×10^8 to 5.0×10^8 or from about 100 million to about 500 million cells per cc of putty or gel mixture. This matrix can support the previously mentioned chondrogenic stimulating factors.

The principles, preferred embodiments and modes of operation of the present invention have been described in the foregoing specification. However, the invention should not be construed as limited to the particular embodiments which have been described above. Instead, the embodiments described here should be regarded as illustrative rather than restrictive. Variations and changes may be made by others without departing from the scope of the present invention as defined by the following claims:

What we claim is:

1. A cartilage repair assembly for repair of a defect in articular cartilage comprising an allograft bone base member and a cancellous allograft bone cap member mounted to said base member, said cap member possessing at least one substantially demineralized region.

2. A cartilage repair assembly for repair of a defect in articular cartilage comprising a sterile mineralized allograft bone base member defining an axial bore and a through going bore intersecting said axial bore, a demineralized cancellous allograft bone cap member mounted to said base member in said axial bore, said cap member being treated to be non-osteoinductive, said cap member defining a through going bore which is adapted to be aligned with said base member through going bore, said allograft bone base member being sized to have an interference fit in a cut away opening in a cartilage defect area and fastening means inserted through said base member and cap member hold the same in a fixed relationship.

3. A cartilage repair assembly as claimed in claim 2 wherein said mineralized allograft bone base member is cylindrically shaped.

4. A cartilage repair assembly as claimed in claim 2 wherein said allograft bone base member axial bore is a blind bore with at least one through going bore running from the base of said blind bore to the distal end of the base member.

5. A cartilage repair assembly as claimed in claim 2 wherein said allograft bone base member has a plurality of through going bores running the length of the base member.

6. A cartilage repair assembly as claimed in claim 2 wherein said cap member comprises a top disc shaped section and a stem extending from said top disc shaped section.

7. A cartilage repair assembly as claimed in claim 6 wherein said stem defines a through going bore running transverse the axis of the stem.

8. A cartilage repair assembly as claimed in claim 6 wherein said cap member top section is cylindrical and is about 3mm in thickness.

9. A cartilage repair assembly as claimed in claim 5 wherein said plurality of through going bores run parallel to the center axis of the base member.

10. A cartilage repair assembly as claimed in claim 2 wherein said cap member is demineralized to a calcium content of less than 0.2 percent and treated to remove osteoinductivity.

11. A cartilage repair assembly as claimed in claim 9 wherein said bores have a diameter ranging from about 0.5mm to about 2.0mm.

12. A cartilage repair assembly as claimed in claim 2 wherein said fastening means is a cylindrical pin member mounted in said base member bore and said cap member through going bore.

13. A cartilage repair assembly as claimed in claim 2 wherein said fastening means is constructed of allograft cortical bone.

14. A cartilage repair assembly as claimed in claim 6 wherein said cap member top section has a top surface is milled to a degree of curvature that matches the physiological curvature of the cartilage area being repaired.

15. A cartilage repair assembly as claimed in claim 2 wherein said cap member contains milled cartilage pieces and a carrier.

16. A cartilage repair assembly as claimed in claim 2 wherein said cap member contains one or more additives taken from a group consisting of growth factors(FGF-2, FGF-5, FGF-7, IGF-1, TGF-β, BMP-2, BMP-4, BMP-7, PDGF, VEGF), human allogenic or autologous chondrocyies, human allogenic or autologous bone marrow cells, stem cells, demineralized bone matrix, insulin, insulin-like growth factor-1, transforming growth factor-B, interleukin-1 receptor antagonist, hepatocyte growth factor, platelet-derived growth factor, Indian hedgehog and parathyroid hormone-related peptide or bioactive glue.

17. A cartilage repair assembly as claimed in claim 2 wherein on the top section of said cap member is demineralized to a residual calcium content less than 0.2%.

18. A cartilage repair assembly as claimed in claim 2 wherein said cap member is constructed with a disc shaped section having at least a top portion non-osteoinductive and a cylindrical shaped stem section extending from said disc shaped section.

19. A cartilage repair assembly for repair of a defect in articular cartilage comprising a cylindrical sterile mineralized allograft bone base member defining a blind bore and a through going bore communicating with said blind bore and positioned transverse to a central axis of said cylindrical base member, an allograft cancellous bone cap member demineralized to have a calcium content of less than 0.2 percent and treated to remove osteoinductivity mounted in said base member blind bore, said cap member including an extended stem which defines a through going bore which can be aligned with said base member through going bore, said allograft bone base member being sized to have an interference fit in a drilled bore in a cartilage defect area and cylindrical pin member mounted in said base member through going bore and said cap member stem through going bore.

20. A cartilage repair assembly for repair of a defect in articular cartilage comprising a sterile mineralized allograft bone base member defining a blind bore, a transverse through going bore intersecting said blind bore, a plurality of through going bores running through said base member parallel to a central axis of the base member and a demineralized cancellous allograft bone cap

member mounted to said base member, said cap member being treated to remove osteoinductivity, said cap member defining a through going bore which can be aligned with said bore member bone cartilage cap, said allograft bone base member being sized to have an interference fit in a drilled bore in a cartilage defect area.

21. A cartilage repair assembly as claimed in claim 20 wherein said cap member is demineralized so that it has a calcium content less than 0.2 percent.

22. A cartilage repair assembly as claimed in claim 20 wherein said cartilage repair assembly is cylindrically shaped.

23. A cartilage repair assembly as claimed in claim 20 wherein said cap member contains one or more additives taken from a group consisting of growth factors(FGF-2, FGF-5, FGF-7, IGF-1, TGF-β, BMP-2, BMP-4, BMP-7, PDGF, VEGF), human allogenic or autologous chondrocytes, human allogenic or autologous bone marrow cells, stem cells, demineralized bone matrix, insulin, insulin-like growth factor-1, transforming growth factor-B, interleukin-1 receptor antagonist, hepatocyte growth factor, platelet-derived growth factor, Indian hedgehog and parathyroid hormone-related peptide or bioactive glue.

24. A cartilage repair assembly as claimed in claim 20 wherein said cap member has a top surface that is curved to match the physiological curvature of the cartilage area being replaced.

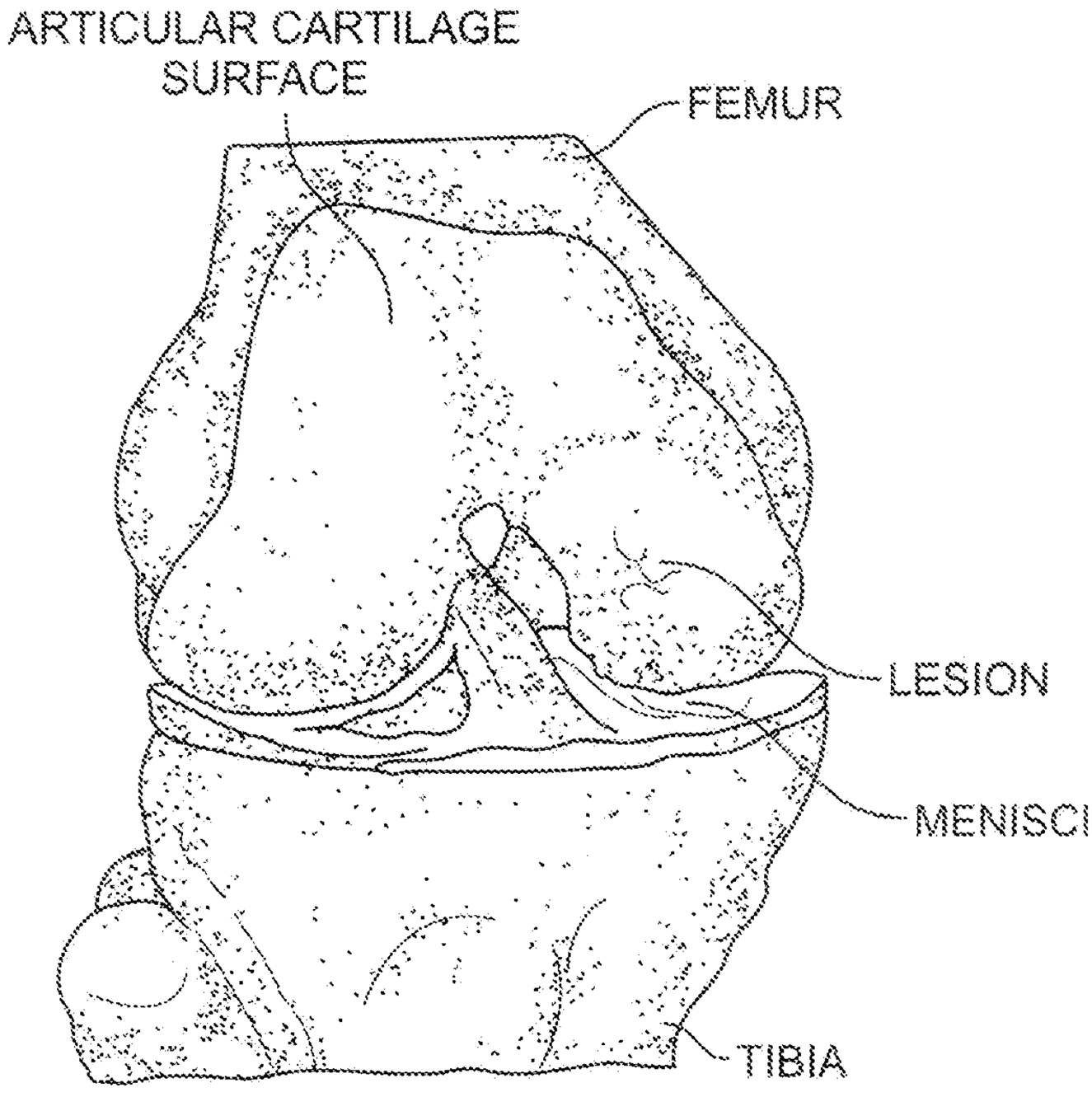

Fig. 1

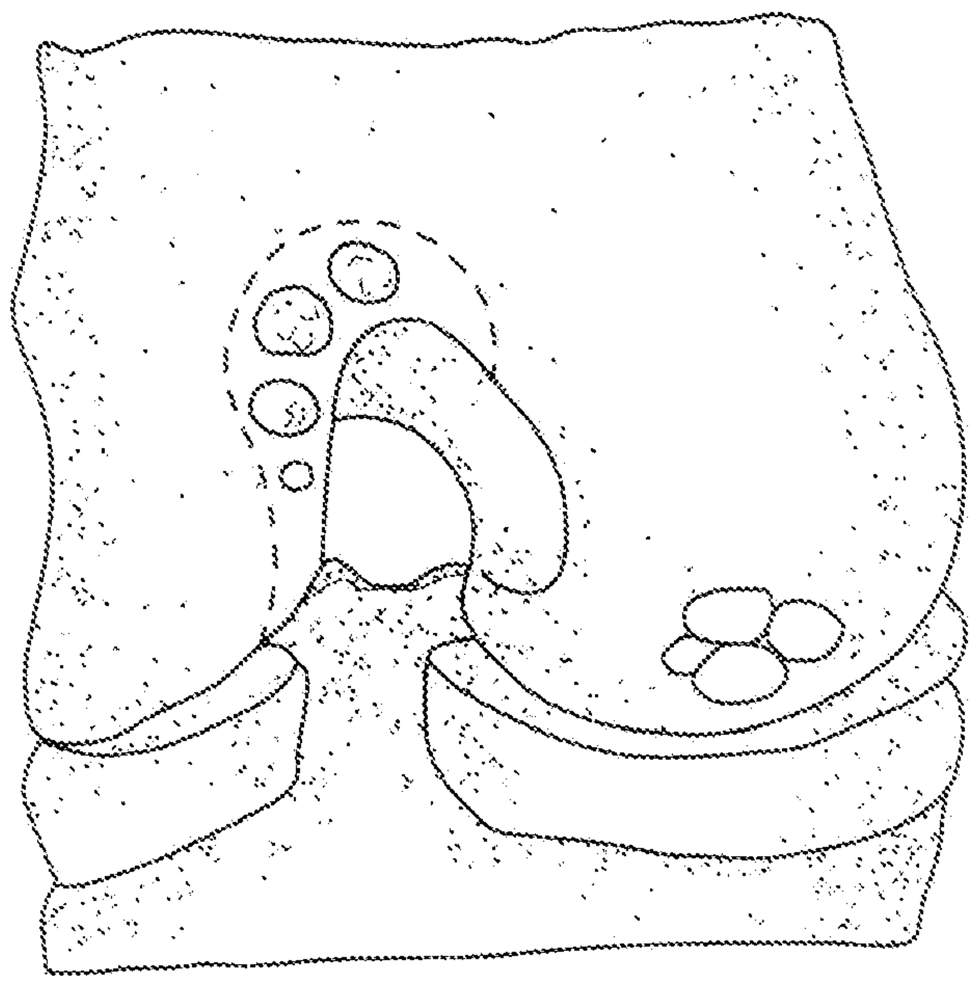

Fig. 2
(Prior Art)

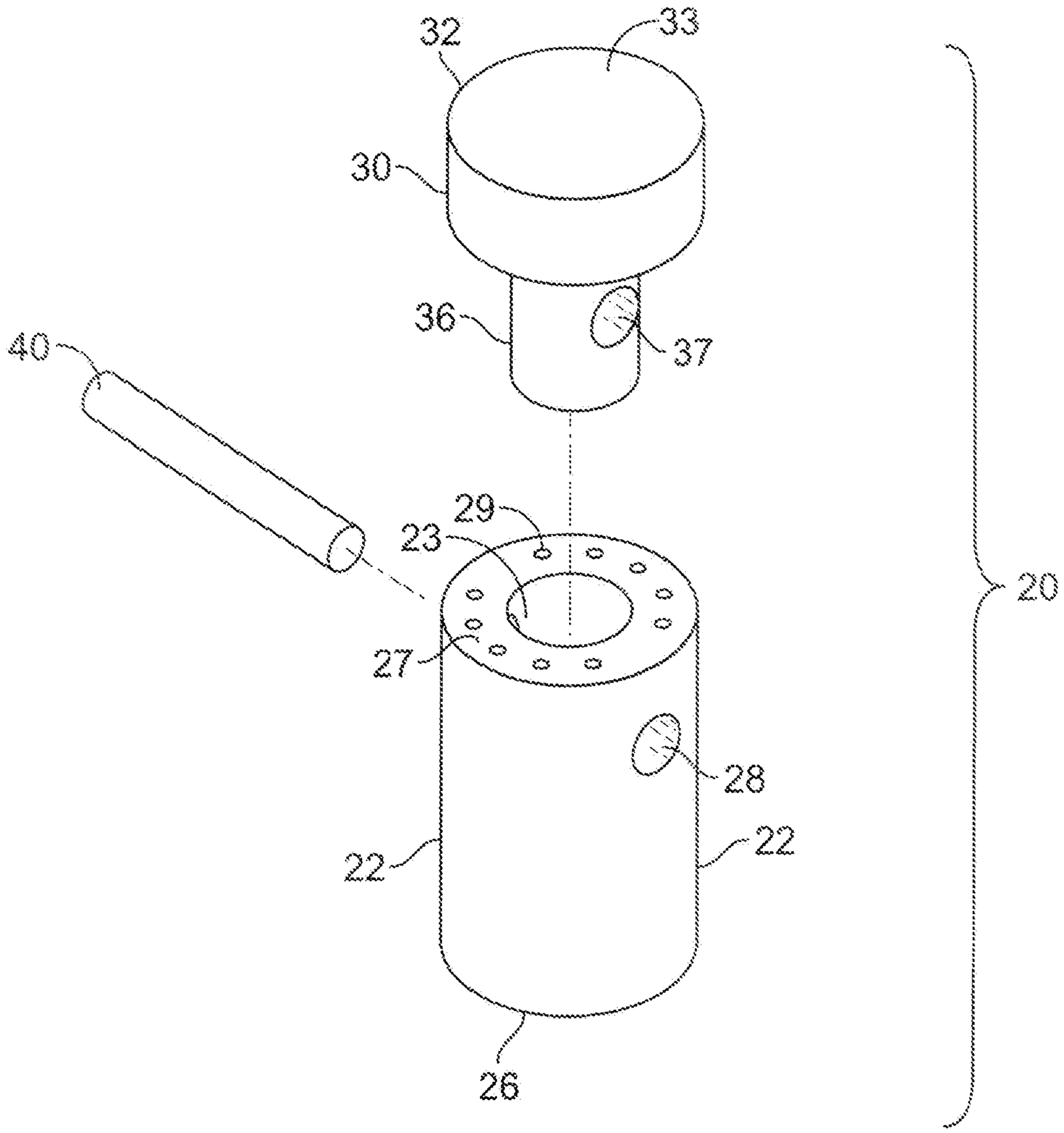

Fig. 3

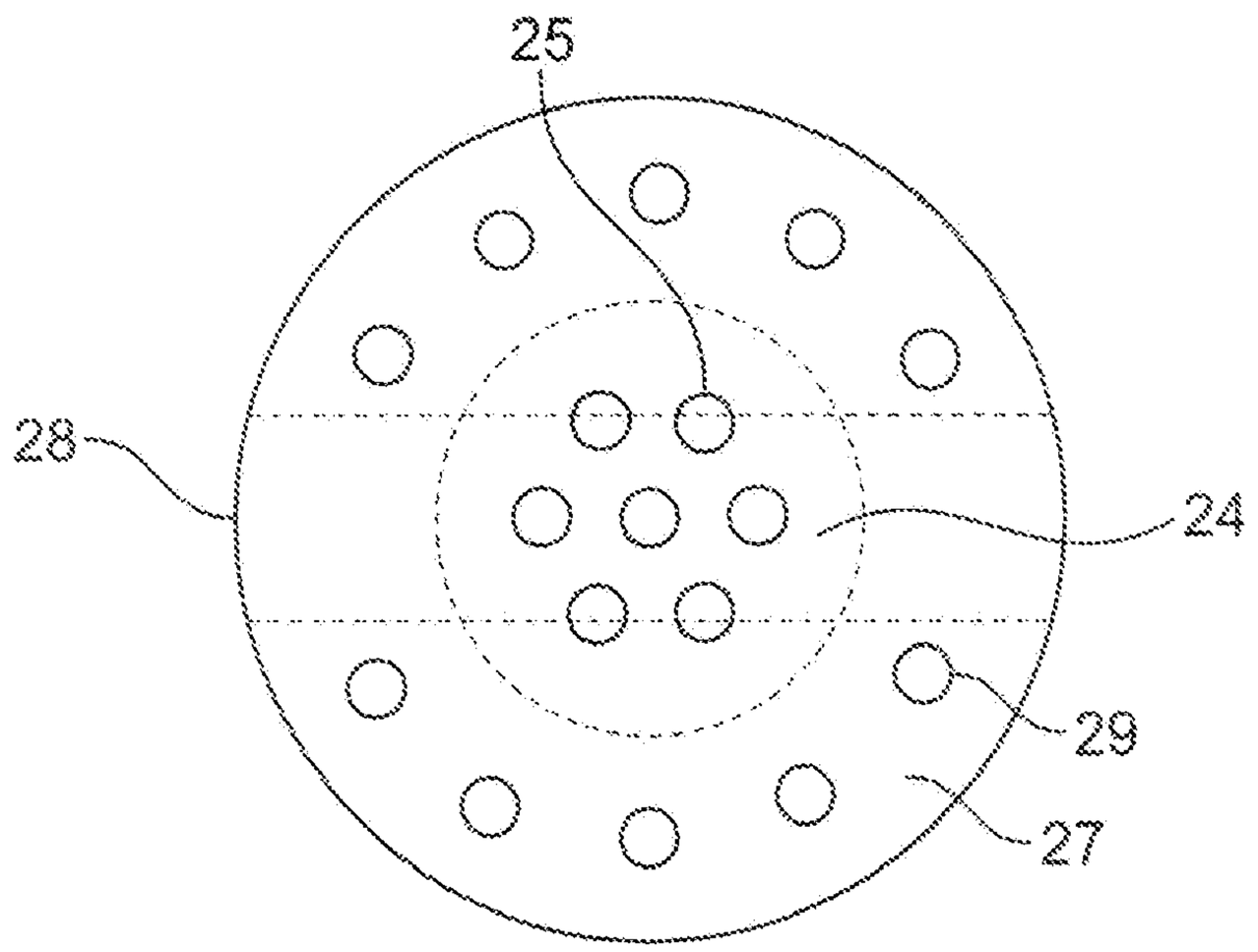

Fig. 4

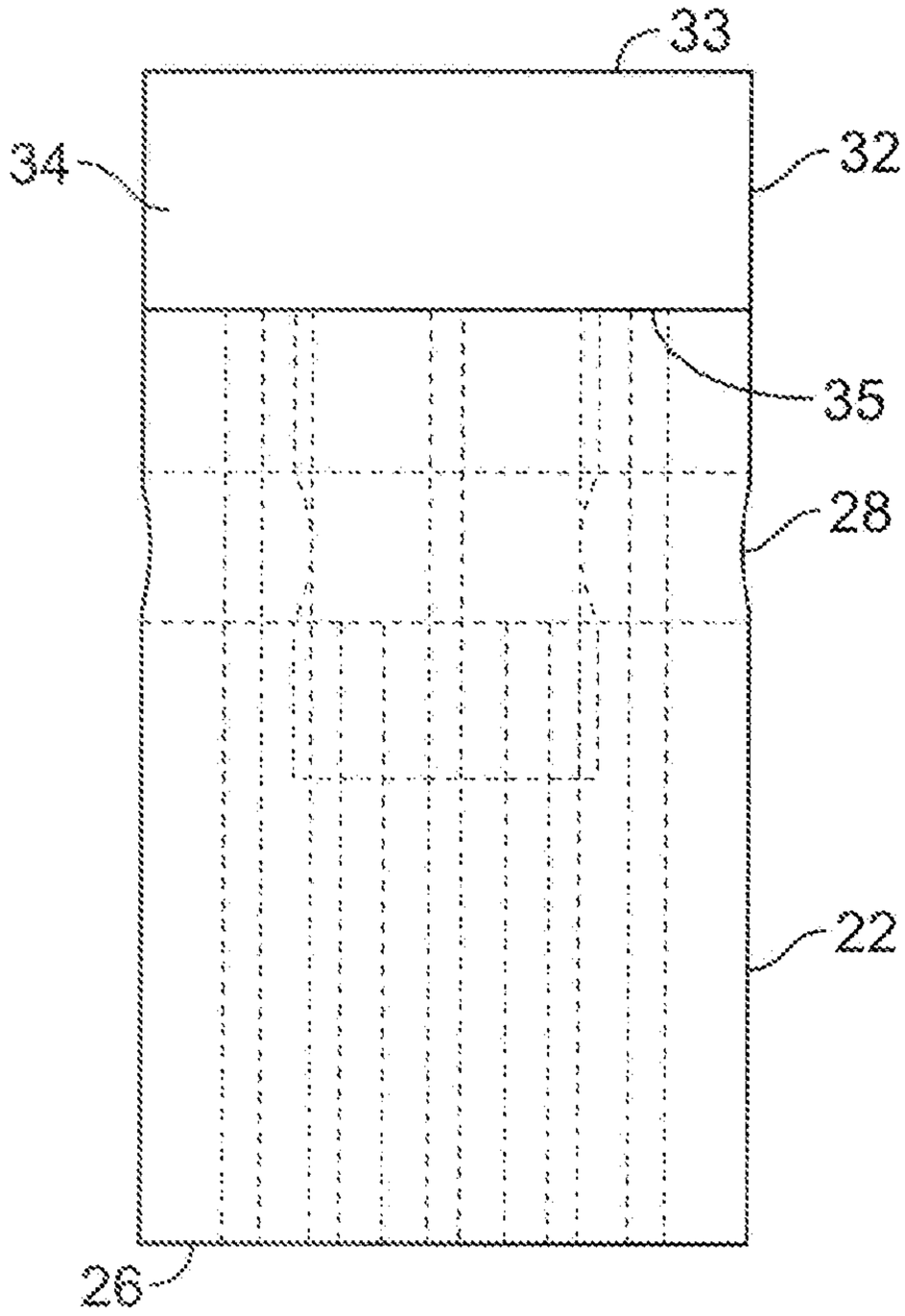

Fig. 5

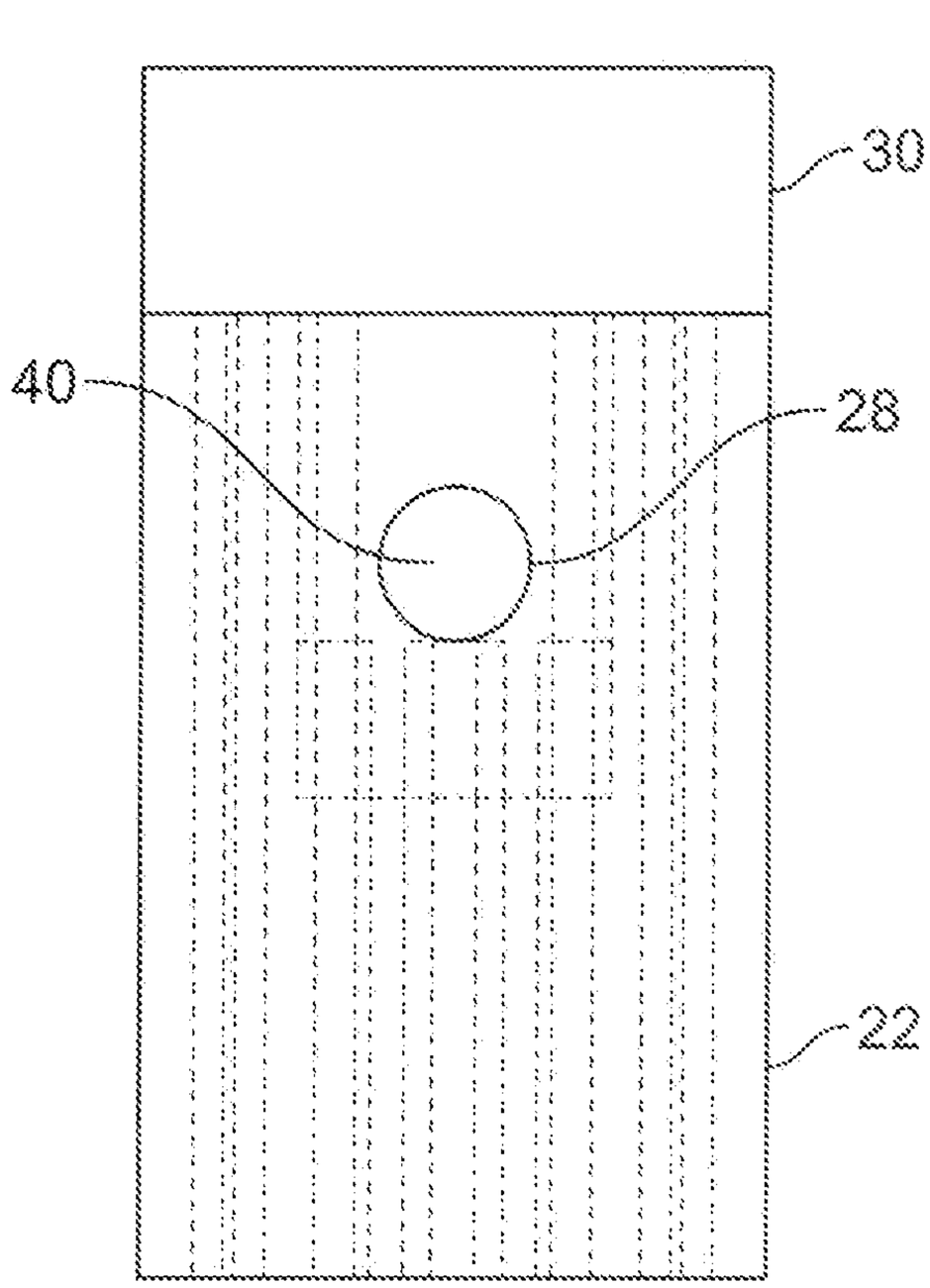

Fig. 6

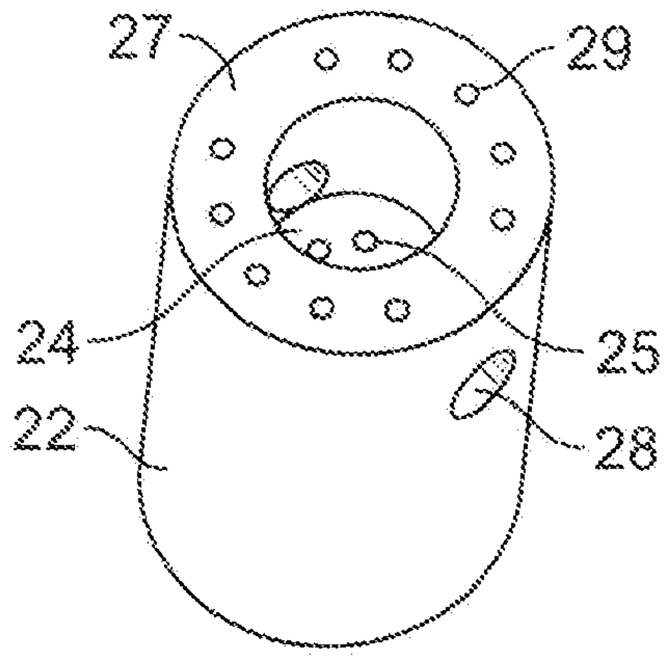

Fig. 7

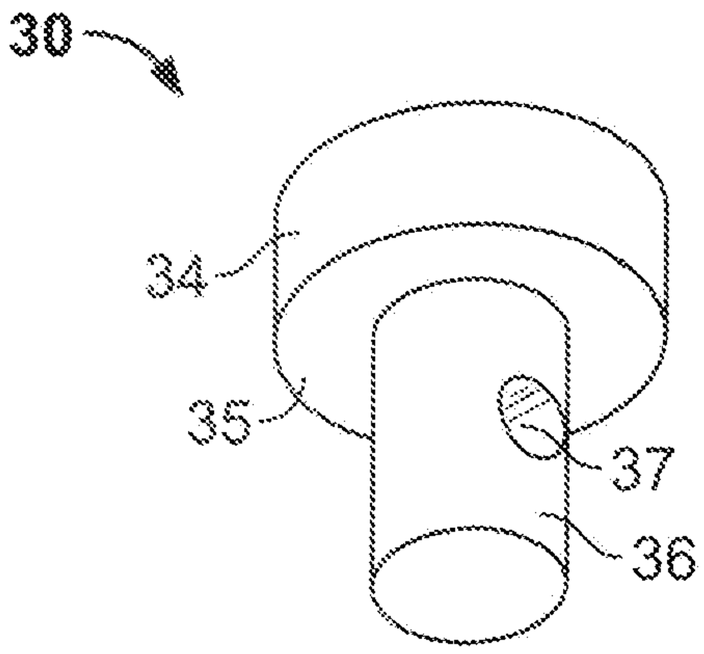

Fig. 8

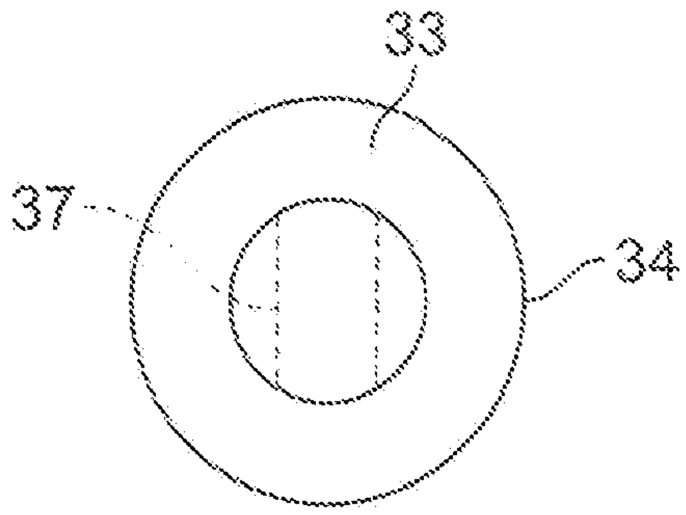

Fig. 9

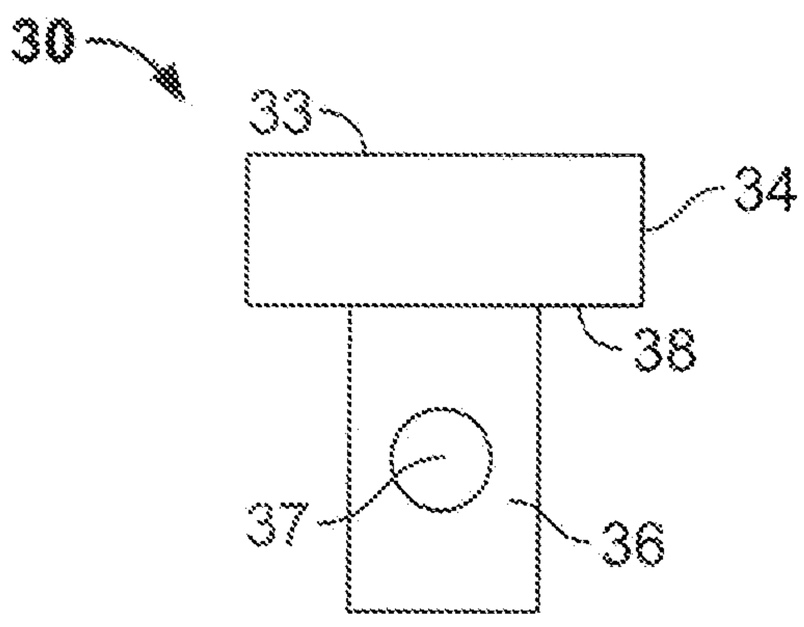

Fig. 10

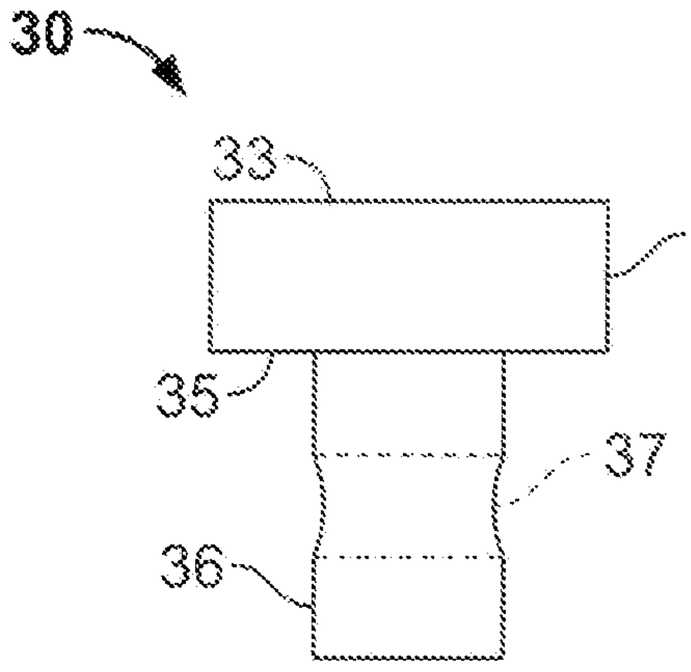

Fig. 11

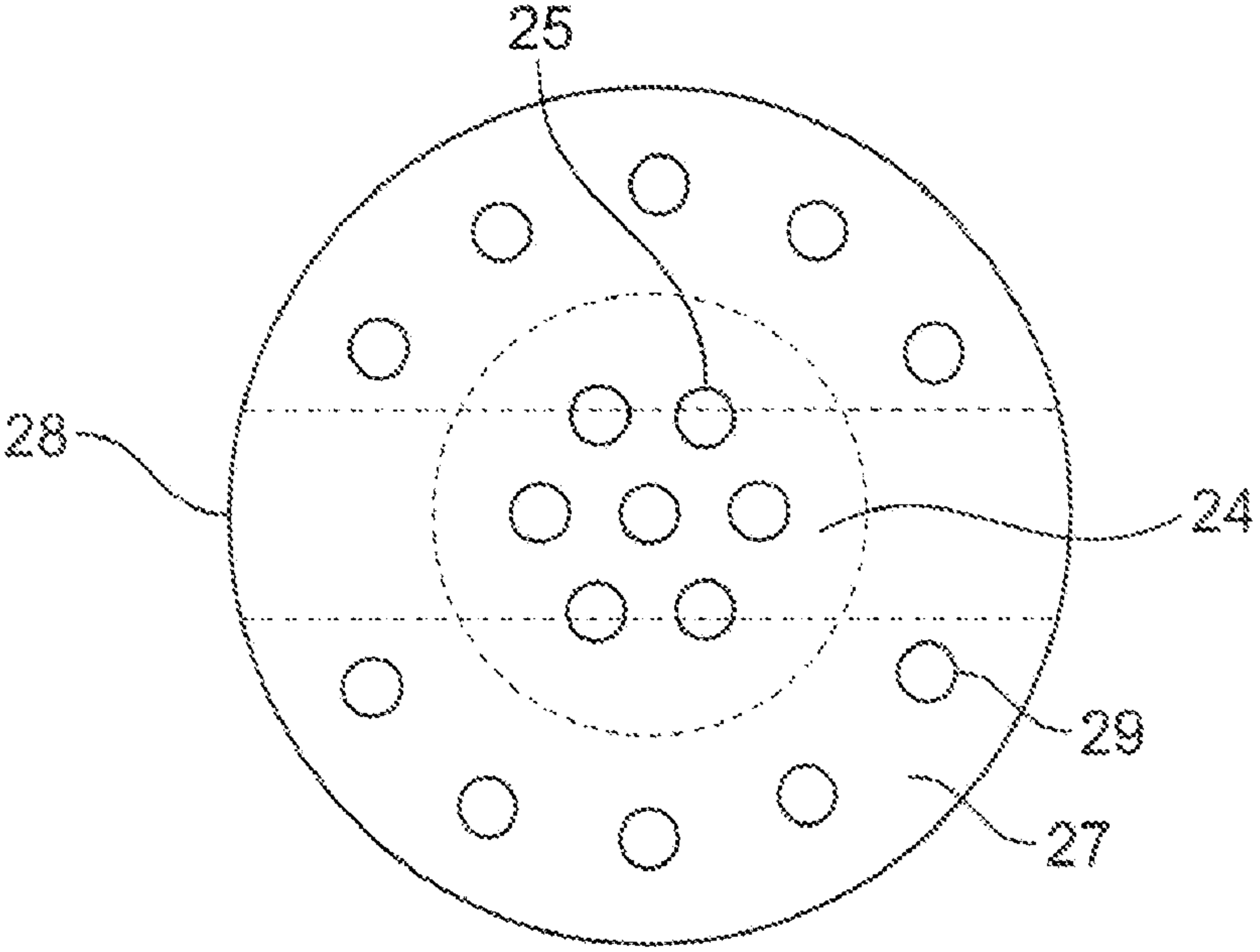

Fig. 4