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(71) Applicant *(for all designated States except US)*: **EVEXAR MEDICAL LIMITED** [GB/GB]; Broadway House, 3 High Street, Bromley, Kent BR1 1LF (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **BARKER, Stephen, George, Edward** [GB/GB]; Evexar Medical Limited, Broadway House, 3 High Street, Bromley, Kent BR1 1LF (GB).

(74) Agents: **PRICE, Nigel, John, King** et al.; J.A. Kemp & Co., 14 South Square, Gray's Inn, London WC1R 5JJ (GB).

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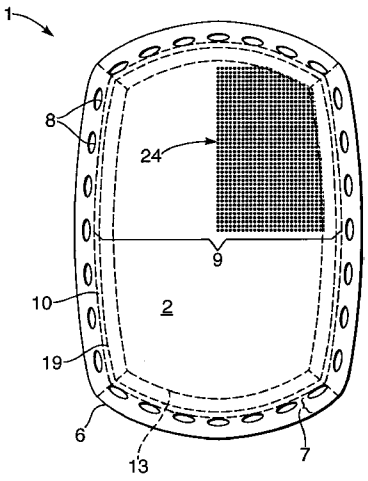


(57) **Abstract:** An implantable prosthesis (1) is provided for repairing a defect or opening, such as a hernia, in a muscle or tissue wall. The prosthesis comprises a pliable sheet (2) of barrier material having first and second opposed surfaces (4, 5), a peripheral edge (6), a peripheral region (7) inwardly of the peripheral edge (6) and a central region (9) inwardly of the peripheral region (7). It also comprises a sheet (11) of structural material attached to and covering at least part of the central region (9) of said surface (4) of said sheet (2) of barrier material, the sheet (11) of barrier material having a peripheral edge (12) and the peripheral region (9) of the sheet (2) of barrier material lying beyond the peripheral edge (12) of the sheet (11) of structural material. A plurality of openings (8) are provided in said peripheral region (9) and are intended for use in attaching the prosthesis (1) to the muscle or tissue wall. The barrier material is constructed and arranged to discourage the formation of post-operative adhesions and the structural material is constructed and arranged to encouraged tissue ingrowth.

WO 2008/023164 A1

IMPROVEMENTS IN AND RELATING TO IMPLANTABLE PROSTHESES

This invention relates to improvements in and relating to implantable prostheses, such as those used to repair a defect or opening in muscle or tissue walls, such as ventral hernias, incisional hernias, large paraumbilical hernias and laparascopically repaired hernias.

Various implantable prostheses have previously been proposed, and used with success, in repairing openings in muscle or tissue walls. These prostheses commonly take the form a prosthetic mesh material which can be used to close the opening, for example in an abdominal wall, and to reinforce the wall in the region of the closed opening. Post-operative ingrowth of tissue into the mesh contributes to this reinforcement.

In certain procedures, the prosthetic mesh can come into direct with the sensitive abdominal viscera, leading to undesirable post-operative adhesions between the mesh and the viscera.

In order to address the complication of unwanted post-operative adhesions, it has previously been proposed to provide a composite prosthesis comprising a mesh of fabric and a barrier on one side of the mesh. The purpose of the barrier is to prevent exposure of the mesh fabric to areas of potential adhesion, such as the abdominal viscera. The mesh fabric is, however, not covered by the barrier on the other side and the uncovered mesh is exposed to the abdominal wall tissue. The interstices of the uncovered mesh fabric are, over time, infiltrated by tissue which assists in securing the prosthesis in place and in reinforcement of the defect being repaired. The prosthesis is positioned in the body with the barrier facing the region of potential adhesion, such as the abdominal viscera. Exemplary prostheses of this general sort are disclosed in US Patent No. 5,593,441 and in International Patent Publication No. WO 98/49967.

Once a prosthesis is in place, if the barrier covers the surface of the prosthesis facing the area of potential adhesion, adhesion should not take place on that surface. There is, however, a danger that the barrier may have become slightly folded back during placement of the prosthesis and/or that the exposed extreme peripheral edge of the mesh fabric may come into unwanted contact with an area of potential adhesion. To try to minimise this risk it has been proposed (for example in International Patent Publication No. WO 02/22047) to extend

the barrier material about the outer peripheral edge of the mesh fabric so as to shield the peripheral edge of the mesh fabric from unwanted contact with regions of potential adhesion.

The disclosures of these three earlier publications are incorporated herein by way of reference.

Prostheses of this sort can be difficult to position and then to secure in position during the surgical procedure. Conventionally, the surgeon would like to tack the prosthesis in place, and only to effect more permanent attachment once he or she is satisfied that the prosthesis is correctly located in position. Placement and tacking of the prosthesis can be a problem in both open and laparoscopic surgical procedures. In open surgical procedures the effect of gravity on the prosthesis is such as to cause the prosthesis to "fall away" from the interior of the abdominal wall to which the surgeon is trying to tack the prosthesis. In a laparoscopic procedure, the procedure is further hampered by the lack of access.

There is, thus, a need for a composite prosthesis which limits the opportunities for unwanted post operative adhesion and which may more readily be manipulated by a surgeon during the course of positioning and tacking the prosthesis in place.

According to a first aspect of the present invention there is provided an implantable prosthesis for repairing a defect or opening in a muscle or tissue wall.

The prosthesis of the first aspect may comprise a pliable sheet of barrier material having first and second opposed surfaces, a peripheral edge, a peripheral region inwardly of the peripheral edge and a central region inwardly of the peripheral region. It may further comprise a sheet of structural material attached to and covering at least part of the central region of said first surface of said sheet of barrier material, the sheet of structural material having a peripheral edge and the peripheral region of the sheet of barrier material lying beyond the peripheral edge of the sheet of structural material. In a preferred arrangement a plurality of openings are provided in said peripheral region and for use in attaching the prosthesis to the muscle or tissue wall and the barrier material is constructed and arranged to discourage the formation of post-operative adhesions and the structural material is constructed and arranged to encourage tissue ingrowth.

Alternatively, the prosthesis of the first aspect may comprise a sheet of biocompatible material having first and second opposed surfaces, a peripheral edge, a peripheral region inwardly of the peripheral edge and a central region inwardly of the peripheral region and a

plurality of openings provided in said peripheral region and for use in attaching the prosthesis to the muscle or tissue wall. In this alternative prosthesis the second surface of the sheet and the first surface of the peripheral region of the sheet may have the property of discouraging the formation of post-operative adhesions when placed in contact with viscera. The first surface of at least part of the central region of the sheet may have the property of encouraging tissue ingrowth when placed in contact with the muscle or tissue wall. In addition, the pliability of the sheet may be such as to enable, in use, the first surface of the peripheral region of the sheet to be folded back towards the first surface of the central region of the sheet so as to enable the peripheral region of the sheet to be attached to the muscle or tissue wall with the second surface of the peripheral region of the sheet and the first surface of the central region of the sheet contacting the muscle or tissue wall.

The prosthesis has a thickness and the openings may comprise through holes extending fully through the thickness of the prosthesis.

The openings may comprise through holes extending between the first and second surfaces of the sheet of barrier material. The openings are preferably at least 1 mm inwardly of the peripheral edge of the sheet of barrier material and/or are at least 2 mm across. Advantageously the openings are generally elongate in plan view, with the longer dimension of the hole being generally parallel to the closest portion of the peripheral edge of the sheet of barrier material. The openings may be generally oval in shape and have a major axis and a minor axis, the major axis being said longer dimension.

The peripheral region of the sheet of barrier material advantageously extends around the complete peripheral edge of the sheet of structural material. The sheet of barrier material may comprise expanded PTFE (ePTFE). The structural material may comprises polypropylene, for example in the form of a woven mesh or a non-woven sheet.

The sheet of structural material may attached to the sheet of barrier material by stitching. This stitching may comprise a thread material which is arranged to discourage the formation of post-operative adhesions, such as PTFE or Prolene (Trade Mark) or the like.

The sheet of barrier material may have at least a double-thickness in at least its peripheral region, which peripheral region may be formed by folding back, around a fold line, the periphery of a larger piece of barrier material. The peripheral edge of the sheet of barrier material may be formed by the fold line. The folded back periphery of the larger piece of

barrier material may overlap the peripheral edge of the sheet of structural material. The peripheral edge of the sheet of structural material may be sandwiched between the first surface of the sheet of barrier material and the folded back periphery of the larger piece of barrier material. The folded back periphery of the larger piece of barrier material may be secured in its folded back position by stitching. This stitching may extend through the folded back periphery of the larger sheet of barrier material, the overlapped peripheral edge of the sheet of structural material and the central region of the sheet of barrier material.

In the preferred arrangements the sheet of structural material is arranged, in use, to be placed over and facing the opening in the muscle or tissue wall, with at least the central region of the second surface of the sheet of barrier material facing away from that opening. In these arrangements the pliability of the sheet of barrier material is such as to enable, in use, the peripheral region of the sheet of barrier material to be folded back towards the sheet of structural material so as to enable said peripheral region to be attached to the muscle or tissue wall with the second surface of the peripheral region contacting the muscle or tissue wall. Where the defect is an abdominal wall defect the peripheral edge of the sheet of structural material may be shielded by the folded back peripheral region of the sheet of barrier material from contact with the viscera facing the abdominal wall.

The sheet of barrier material may be provided across at least its central region with an array of micro-openings to allow fluid transfer across the prosthesis in use, which micro-openings may be less than 1 mm across their widest point.

According to a second aspect of the present invention there is provided a method of repairing a defect or opening in a muscle or tissue wall, the method comprising the initial steps of providing the prosthesis of one of the above first aspects of the present invention and positioning the prosthesis adjacent the opening with the second surface of the sheet of barrier material facing generally away from the opening.

In the method of the second aspect the peripheral region of the sheet of barrier material may then be folded back in the region of a said through hole, to place the second surface of said folded back peripheral region of the sheet of barrier material in contact with the muscle or tissue wall adjacent the opening. Finally, said folded back peripheral region of the sheet of barrier material may be attached to the muscle or tissue wall using said opening through hole.

The method may be an open surgical procedure. Advantageously said folding back and attaching steps are repeated around the peripheral region of the sheet of barrier material, using other said openings, to attach the prosthesis to the muscle or tissue wall around the opening so as to result in the sheet of structural material facing the opening, the central region of the second surface of the sheet of barrier material facing away from the opening and the second surface of the folded back peripheral region of the sheet of barrier material in contact with the muscle or tissue wall around the opening.

Alternatively, the method of the second aspect may simply further comprise attaching the peripheral region of the sheet of barrier material to the muscle or tissue wall using said openings.

This method may be a laparoscopic surgical procedure. Advantageously said attaching step is repeated around the peripheral region of the sheet of barrier material, using a plurality of said openings, to attach the prosthesis to the muscle or tissue wall around the opening so as to result in the sheet of structural material facing the opening, the second surface of the sheet of barrier material facing away from the opening and the peripheral region of the first surface of the sheet of barrier material in contact with the muscle or tissue wall around the opening.

Either method may further comprise subsequently attaching the prosthesis to the muscle or tissue wall by a series of further attachments. The further attachments may pass through the central region of the sheet of barrier material into the muscle or tissue wall closer to the opening than the attachments through the openings in the sheet of barrier material.

Embodiments of apparatus in accordance with the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Fig. 1a is a top plan view of a first embodiment of implantable prosthesis, viewing the prosthesis from the side of the second surface of a sheet of barrier material with Figs. 1b and 1c as side and end elevations respectively;

Fig. 2 is a perspective view of the prosthesis of Fig. 1, showing the opposite first surface of the sheet of barrier material with a sheet of structural material attached thereto;

Fig. 3 is an enlarged close-up of the top left-hand corner of the prosthesis illustrated in Fig. 2;

Fig. 4 is a top plan view of a larger piece of barrier material capable of being used to

form the smaller pliable sheet of barrier material used in the prosthesis of Fig. 1;

Fig. 5 is a top plan view of the larger piece of barrier material of Fig. 4, showing its periphery folded back to form the smaller sheet of barrier material used in the prosthesis of Fig. 1;

Fig. 6 is a schematic lateral section through the prosthesis of Fig. 1 in the early stages of being tacked in place during a laparoscopic surgical procedure to repair a defect in an abdominal wall; and

Fig. 7 is a schematic lateral section through the prosthesis of Fig. 1 in the early stages of being tacked in place during an open surgical procedure to repair a defect in an abdominal wall.

Fig 1a illustrates, in top plan view, a first embodiment of implantable prosthesis 1 for use in repairing an opening in a muscle or tissue wall. As will be described in more detail below, the opening in question might be a hernia defect.

The prosthesis 1 comprises a pliable sheet 2 of barrier material and a sheet 11 of structural material, obscured from view in Fig 1a below the sheet 2 of barrier material. The sheet 2 of barrier material has first and second opposed surfaces 4, 5, of which the second surface 5 is uppermost and visible in Fig 1a. The downward facing first surface 4 is not visible in Fig. 1a. The sheet 2 of barrier material has a peripheral edge 6, inwardly of which lies a peripheral region 7. Provided around the peripheral region 7 of the sheet 2 of barrier material are a plurality of fixing elements for use in attaching the prosthesis to a muscle or tissue wall in use. The fixing elements may, as shown, comprise openings in the form of through holes 8 extending between the first and second surfaces 4, 5 of the sheet 2 of barrier material. The sheet 2 of barrier material also has a central region 9 inwardly of the peripheral region 7. In the illustrated embodiment, the notional boundary between the peripheral region 7 and the central region 9 is in the region of the broken line 10 in Fig. 1a. The material properties of the sheet 2 of barrier material are chosen so that at least its second surface 5 will discourage the formation of post-operative adhesions when exposed to, for example, the abdominal viscera. A preferred choice for the sheet 2 of barrier material is biocompatible expanded PTFE (ePTFE) having a thickness of no less than 0.05 mm, preferably about 0.5mm thick. ePTFE sheets for use in prostheses are well known and are used currently in a wide

range of hernia repair products. Other materials that will discourage the formation of post-operative adhesions when exposed to, for example, the abdominal viscera may alternatively be used for the sheet 2 of barrier material.

Attached to and covering the central region 9 of the first surface 4 of the sheet 2 of barrier material is a sheet 11 of structural material. Because this sheet 11 of structural material is attached to the first surface 4 of the sheet 2 of barrier material it is not visible in Fig 1a , but can be seen in Figs. 1b, 1c, 2 and 3. The sheet 11 of structural material is advantageously a sheet of biocompatible polypropylene mesh, such as Prolene (Trade Mark) mesh manufactured by Ethicon, Inc. Polypropylene mesh is good at encouraging tissue ingrowth. Other materials that will encourage tissue ingrowth may alternatively be used, such as non-woven polypropylene sheet. The sheet 11 of structural material has a peripheral edge 12 which, in the illustrated embodiment, is generally coincident with the broken line 10 at the boundary between the central region 9 and peripheral region 7 of the sheet 2 of barrier material. As a result, in the illustrated embodiment the peripheral region 7 of the sheet 2 of barrier material lies beyond the peripheral edge 12 of the sheet 11 of structural material - this is most readily seen in Figs. 1b, 1c and 3. It will be noted that the plurality of through holes 8 are provided in the peripheral region 7 of the sheet 2 of barrier material, and thus are not also formed through the sheet 11 of structural material. The through holes 8 extend fully through the thickness of the prosthesis 1, from one side of the prosthesis to the other.

The peripheral edge 12 of the sheet 11 of structural material is spaced inwardly from the peripheral edge 6 of the sheet 2 of barrier material, by a distance x, so as to leave the peripheral region 7 of the sheet 2 of barrier material uncovered by structural material. As a result, the prosthesis 1 has a border (consisting of the peripheral region 7 of the sheet 2 of barrier material) that is more flexible than the central portion of the prosthesis (consisting of the central region 9 of the sheet 2 of barrier material and the superposed sheet 11 of structural material). This distance x is substantially greater than the thickness of the sheet 2 of barrier material. Consequently, if the sheet of barrier material has a thickness of approximately 0.5 mm, the distance x would be substantially greater than 0.5 mm, for example at least 1 mm. Advantageously, the distance x would be greater than that, for example at least 2 mm, and more preferably at least 4 mm or 6 mm. Distance x could even be greater than 8 mm. For example, if the holes 8 were (as described below and as shown in Fig. 3) to be approximately

2 mm wide in the radial direction of the prosthesis 1, it would be appropriate for the peripheral region 7 of the sheet 2 of barrier material to have a radial dimension (distance x) of approximately 8 mm. It will though be appreciated that other values of x and/or size of holes 8 would be appropriate, as long as there was no significant risk of a fixing element (such as a suture) extending through a hole tearing the barrier material in which the hole is formed.

The sheet 2 of barrier material and sheet 11 of structural material are, in the illustrated embodiment, attached to one another by stitching, for example in the region of the broken line 19 shown just inwardly of the peripheral edge 12 of the sheet 11 of structural material represented by the broken line 10 in Fig 1a. Advantageously, the stitching utilizes a biocompatible thread containing material which is arranged to discourage the formation of post-operative adhesions, such as PTFE or Prolene (Trade Mark).

As will be explained in more detail below, the purpose of the through holes 8 is to enable the surgeon to attach the prosthesis 1 to the muscle or tissue wall. Such attachment may take the form of tacking using sutures or staples. To minimise the risk of the prosthesis tearing in the region of the holes 8, it may be desirable for the sheet 2 of barrier material to have a double thickness in its peripheral region 7. In order to achieve this the sheet 2 of barrier material may be formed from a larger piece 21 of barrier material, as shown in Fig 4. In Fig 4 an appropriately shaped larger piece 21 of barrier material is cut out having the outline referenced 22. Marked in dotted lines 23 are a series of fold lines. By folding back the periphery of the larger piece 21 of barrier material around the fold lines 23 there may be formed the sheet 2 of barrier material shown in Fig 5, with the peripheral edge 6 of the sheet 2 of barrier material being formed by the fold lines 23 in Fig 4. Heat and/or pressure may be used to assist in the folding operation. In this way, there may easily be provided a double thickness of barrier material in at least the peripheral region 7 of the sheet 2 of barrier material. The through holes 8 may then be formed in the double thickness layer, either before or after attachment of the sheet 2 to the sheet 11 of structural material.

As can be seen from Fig 5, the extent of the folded back edges of the larger piece 21 of barrier material is advantageously such that the double thickness layer of material will extend inwardly of the junction between the peripheral region 7 and central region 9 of the sheet 2 of barrier material, i.e. inwardly of the broken line 10 and inwardly of the peripheral edge of the sheet 2 of barrier material in Fig. 1a. As illustrated, the folded back edges of the larger piece

21 of barrier material terminate at broken line 13, inwardly of the stitch line 19. In this way, the folded back periphery of the larger piece 21 of barrier material can be made, as shown in Fig 1, to overlap the peripheral edge 12 of the sheet 11 of structural material and the two layers of barrier material and the edge of the sheet 11 of structural material secured together around their peripheries by a single row of stitching.

Advantageously, in order to protect the peripheral edge 12 of the sheet 11 of structural material from unwanted contact with tissue, the peripheral edge 12 of the sheet 11 of structural material may be sandwiched between the outer ring of the central region 9 of the sheet 2 of barrier material and the folded back periphery of the larger piece 21 of barrier material.

As is most apparent from Fig. 3, in the illustrated embodiment the through holes 8 are generally elongate in plan view, with the longer dimension being generally parallel to the closest portion of the peripheral edge 6 of the sheet 2 of barrier material. Where, as shown, the through holes are generally oval in shape, and have a major axis and a minor axis, exemplary dimensions for oval-shaped through holes 8 would be approximately 6 mm for the major axis and 2 mm for the minor axis.

The sheet 2 of barrier material may optionally be provided, at least in its central region 9, with a plurality of micro-openings 24 to allow fluid to transfer across the prosthesis in use. For reasons of clarity these micro-openings 24 are shown only in a small area of the prosthesis 1, but it is envisaged that they could extend across the majority or totality of the area of the prosthesis. They are most readily visible in Fig. 1a in the top right-hand quadrant of the prosthesis, but can also be seen to the right-hand side of Fig. 3. Where provided the micro-openings 24 would be substantially smaller in size than the through holes 8, for example having a diameter of only 0.3 mm Equally well, the micro-openings 24 may be omitted entirely.

Rather than being provided as a discrete field of micro-openings, the effect of the omitted openings may be achieved by the sheet 2 of barrier material and the sheet 11 of structural material being sewn together in the cental region 9 by a zig-zag arrangement of stitches (not shown). By using a slightly oversize needle, so that the stitch holes are larger than the threads of the stitching passing therethrough, the prosthesis my be rendered permeable across its central region so as to allow the transfer of fluid across the prosthesis in

use.

It is envisaged that the illustrated embodiment of prosthesis would be suitable for use in repairing an opening in a muscle or tissue wall via both open surgery and laparoscopic surgery. The technique used in these two types of surgery would, however, likely differ, due to the differing constraints applied on the surgeon as regards access to the opening.

In both types of procedure the prosthesis 1 would be arranged with the sheet 11 of structural material placed over and facing the opening in the muscle or tissue wall, with at least the central region 9 of the second surface 5 of the sheet 2 of barrier material facing away from the opening. The difference between the envisaged surgical procedures is how the prosthesis is initially tacked in place and the orientation of the peripheral region 7 of the sheet 2 of barrier material.

To illustrate this point, a method of repairing an opening in a muscle or tissue wall will be described, firstly using a laparoscopic procedure (Fig 6) and secondly using an open surgical procedure (Fig 7) using the prosthesis of Figs 1-3. The drawings are highly schematic and the thicknesses of the sheets 2, 11 of the prosthesis 1 are exaggerated for clarity.

In the laparoscopic procedure, illustrated by way of reference to Fig 6, the muscle or tissue wall 30 has a defect to be repaired, in this case an opening 31 to be closed. In the case of a hernia the defect 31 may not be an opening but might simply be a localised weakening of the abdominal wall 30. In Fig 6 the viscera are shown schematically as 32. The prosthesis 1 is introduced into the abdominal cavity 33 on the same side of the abdominal wall 30 as the viscera 32. Using appropriate laparoscopic instruments, the prosthesis 1 is unrolled after its passage down a laparoscopic trocar (not shown) and the surgeon uses forceps (not shown) to position the prosthesis 1 with the sheet 11 of structural material facing the opening of defect 31 and with the second surface 5 of the sheet 2 of barrier material facing the viscera 32. The direction of access of the forceps is denoted by arrow 34. The first surface of the sheet 2 of barrier material in the peripheral region 7 is placed in contact with the abdominal wall 30 (as shown) and the prosthesis 1 is tacked in place using either staples or sutures 35 passing through the through holes 8. By repeating this tacking process around the full extent of the peripheral region 7 of the sheet 2 of barrier material the prosthesis 1 may be tacked in place, prior to being attached more permanently to the abdominal wall 30 by a series of further

attachments (not shown) passing through the central region 9 of the sheet 2 of barrier material, in a conventional manner. As will be appreciated from Fig 6, the sheet 11 of structural material, which is constructed and arranged to encourage tissue ingrowth, will in the final event be in contact with the abdominal wall 30, but will be prevented from contact with the viscera 32 by the sheet 2 of barrier material, thereby avoiding unwanted post-operation adhesions between the prosthesis and the viscera 32.

In the open procedure illustrated schematically in Fig. 7, access to the underside of the abdominal wall 30 may be gained through the opening 31. By passing forceps (not shown) through the opening 31 the surgeon is able to fold back the peripheral region 7 of the sheet 2 of barrier material so as to place the second surface 5 of the folded back peripheral region 7 of the sheet 2 of barrier material in contact with the abdominal wall 31, prior to tacking it in place through the through hole 8 using a suture or staple 35. Once again the direction of access of the forceps is denoted by arrow 34. By being able to fold back the peripheral region 7 of the sheet 2 of barrier material by grasping it using forceps, the surgeon is able to position and tack in place the prosthesis 1 much more easily than with a conventional sheet of prosthetic repair fabric, whose peripheral region is not intended to be folded over. By tacking the prosthesis 1 in place using a similar technique through different through holes 8 around the periphery of the prosthesis 1, the prosthesis 1 may be suspended or hung like a curtain from a series of tacks around its periphery. Once the surgeon is satisfied with the positioning of the prosthesis 1, the prosthesis may be attached to the abdominal wall 30 by a series of further attachments (not shown) in a conventional manner. In the final event the sheet 11 of structural material is pressed by the viscera 32 into contact with the abdominal wall 30, and the sheet 11 of structural material encourages tissue ingrowth into the prosthesis from the abdominal wall so as to strengthen the repair. The sheet 11 of structural material is, however, shielded from contact with the viscera 32 by the sheet 2 of barrier material.

As mentioned above, the preferred construction for the prosthesis 1 results in the prosthesis having a border (largely or exclusively consisting of the peripheral region 7 of the sheet 2 of barrier material) that is more flexible than the central portion of the prosthesis (consisting of the central region 9 of the sheet of barrier material and the superposed sheet 11 of structural material). Even if the barrier material in the peripheral region 7 that forms the border of the prosthesis is double thickness, as a result of being bent back on itself for

example, the border consisting solely of barrier material is likely to be significantly more flexible than the central portion of the prosthesis, due to structural material generally being quite stiff. In the open procedure illustrated schematically in Fig. 7, the increased flexibility of the border of the prosthesis 1, relative to the central portion of the prosthesis, assists the surgeon in being able to fold back the peripheral region 7 of the sheet 2 of barrier material so as to be able to place the second surface 5 of the folded back peripheral region 7 of the sheet 2 of barrier material in contact with the abdominal wall 31.

Although in the illustrated embodiment the fixing element for use in attaching the prosthesis to the muscle or tissue wall comprise through holes 8, they may take other forms, such as D-shaped loops or rings, or may simply be areas of the peripheral region with no particular distinction from their surroundings but which may be stapled or sutured through.

In the drawings, the dimensions shown in millimetres and degrees are exemplary and are not intended to be limiting.

CLAIMS

1. An implantable prosthesis for repairing a defect or opening in a muscle or tissue wall, the prosthesis comprising:

a pliable sheet of barrier material having first and second opposed surfaces, a peripheral edge, a peripheral region inwardly of the peripheral edge and a central region inwardly of the peripheral region;

a sheet of structural material attached to and covering at least part of the central region of said first surface of said sheet of barrier material, the sheet of structural material having a peripheral edge and the peripheral region of the sheet of barrier material lying beyond the peripheral edge of the sheet of structural material; and

a plurality of openings provided in said peripheral region and for use in attaching the prosthesis to the muscle or tissue wall;

wherein the barrier material is constructed and arranged to discourage the formation of post-operative adhesions and the structural material is constructed and arranged to encourage tissue ingrowth.

2. A prosthesis as claimed in claim 1, wherein the prosthesis has a thickness and said openings comprise through holes extending fully through the thickness of the prosthesis.

3. A prosthesis as claimed in claim 2, wherein said openings comprise through holes extend between the first and second surfaces of the sheet of barrier material.

4. A prosthesis as claimed in any one of the preceding claims, wherein the peripheral edge of the structural material is spaced inwardly from the peripheral edge of the barrier material, to form said peripheral region of the sheet of barrier material, by a distance x.

5. A prosthesis as claimed in claim 4, wherein said distance x is substantially greater than the thickness of the sheet of barrier material.

6. A prosthesis as claimed in claim 4 or claim 5, wherein said distance x is at least twice the thickness of the sheet of barrier material.

7. A prosthesis as claimed in any one of claims 4 to 6, wherein said distance x is least 2 mm.

8. A prosthesis as claimed in any one of claims 4 to 7, wherein said distance x is least 4 mm.

9. A prosthesis as claimed in any one of claims 4 to 8, wherein said distance x is least 6 mm.

10. A prosthesis as claimed in any one of claims 4 to 9, wherein said distance x is least 8 mm.

11. A prosthesis as claimed in any one of the preceding claims, wherein the peripheral region of the sheet of barrier material extends around the complete peripheral edge of the sheet of structural material.

12. A prosthesis as claimed in any one of the preceding claims, wherein the sheet of structural material is attached to the sheet of barrier material by stitching.

13. A prosthesis as claimed in claim 12, wherein the stitching comprises a thread material which is arranged to discourage the formation of post-operative adhesions.

14. A prosthesis as claimed in claim 13, wherein the thread material comprises PTFE or Prolene (Trade Mark) or similar..

15. A prosthesis as claimed in any one of the preceding claims, wherein the sheet of barrier material has at least a double-thickness in at least its peripheral region.

16. A prosthesis as claimed in claim 15, wherein said multi-thickness peripheral region is formed by folding back, around a fold line, the periphery of a larger piece of barrier material.

17. A prosthesis as claimed in claim 16, wherein the peripheral edge of the sheet of barrier material is formed by the fold line.

18. A prosthesis as claimed in claim 16 or claim 17, wherein the folded back periphery of the larger piece of barrier material overlaps the peripheral edge of the sheet of structural material.

19. A prosthesis as claimed in claim 18, wherein the peripheral edge of the sheet of structural material is sandwiched between the first surface of the sheet of barrier material and the folded back periphery of the larger piece of barrier material.

20. A prosthesis as claimed in any one of claims 16 to 19, wherein the folded back periphery of the larger piece of barrier material is secured in its folded back position by stitching.

21. A prosthesis as claimed in claim 20, wherein the stitching extends through the folded back periphery of the larger sheet of barrier material, the overlapped peripheral edge of the sheet of structural material and the central region of the sheet of barrier material.

22. A prosthesis as claimed in any one of the preceding claims, wherein the openings are at least 1 mm inwardly of the peripheral edge of the sheet of barrier material.

23. A prosthesis as claimed in any one of the preceding claims, wherein the openings are at least 2 mm across.

24. A prosthesis as claimed in any one of the preceding claims, wherein the openings are generally elongate in plan view, with the longer dimension of the hole being generally parallel to the closest portion of the peripheral edge of the sheet of barrier material.

25. A prosthesis as claimed in claim 24, wherein the openings are generally oval in shape and have a major axis and a minor axis, the major axis being said longer dimension.

26. A prosthesis as claimed in any one of the preceding claims, wherein said sheet of structural material is arranged, in use, to be placed over and facing the opening in the muscle or tissue wall, with at least the central region of the second surface of the sheet of barrier material facing away from that opening.

27. A prosthesis as claimed in claim 26, wherein the pliability of the sheet of barrier material is such as to enable, in use, the peripheral region of the sheet of barrier material to be folded back towards the sheet of structural material so as to enable said peripheral region to be attached to the muscle or tissue wall with the second surface of the peripheral region contacting the muscle or tissue wall.

28. A prosthesis as claimed in claim 27, wherein said folded back peripheral region of the sheet of barrier material is arranged to be attached to the muscle or tissue wall, with the second surface of the peripheral region contacting the muscle or tissue wall, by passing a fixing element through the opening into the muscle or tissue wall.

29. A prosthesis as claimed in claim 27 or claim 28, wherein the opening in the muscle or tissue wall is an abdominal wall defect and, in use, the peripheral edge of the sheet of structural material is shielded by the folded back peripheral region of the sheet of barrier material from contact with the viscera facing the abdominal wall.

30. A prosthesis as claimed in any one of the preceding claims, wherein the barrier material comprises expanded PTFE (ePTFE).

31. A prosthesis as claimed in any one of the preceding claims, wherein the sheet of barrier material is provided across at least its central region with an array of micro-openings to allow fluid transfer across the prosthesis in use.

32. A prosthesis as claimed in claim 31, wherein said micro-openings are less than 1 mm across their widest point.

33. A prosthesis as claimed in any one of the preceding claims, wherein the structural material comprises polypropylene.

34. A prosthesis as claimed in claim 33, wherein the polypropylene is in the form of a woven mesh.

35. A prosthesis as claimed in claim 33, wherein the polypropylene is in the form of a non-woven sheet.

36. An implantable prosthesis for repairing a defect or opening in a muscle or tissue wall, the prosthesis comprising:

a sheet of biocompatible material having first and second opposed surfaces, a peripheral edge, a peripheral region inwardly of the peripheral edge and a central region inwardly of the peripheral region; and

a plurality of openings provided in said peripheral region and for use in attaching the prosthesis to the muscle or tissue wall;

wherein the second surface of the sheet and the first surface of the peripheral region of the sheet have the property of discouraging the formation of post-operative adhesions when placed in contact with viscera;

wherein the first surface of at least part of the central region of the sheet has the property of encouraging tissue ingrowth when placed in contact with the muscle or tissue wall; and

wherein the pliability of the sheet is such as to enable, in use, the first surface of the peripheral region of the sheet to be folded back towards the first surface of the central region of the sheet so as to enable the peripheral region of the sheet to be attached to the muscle or tissue wall with the second surface of the peripheral region of the sheet and the first surface of the central region of the sheet contacting the muscle or tissue wall.

37. A prosthesis as claimed in claim 36, wherein the prosthesis has a thickness and said openings comprise through holes extending fully through the thickness of the prosthesis.

38. A prosthesis as claimed in claim 36 or 37, wherein the sheet is homogeneous.

39. A method of repairing a defect or opening in a muscle or tissue wall, the method comprising the steps of:

providing a prosthesis as claimed in any one of the preceding claims;

positioning the prosthesis adjacent the opening with the second surface of the sheet of barrier material facing generally away from the opening;

folding back the peripheral region of the sheet of barrier material in the region of a said through hole, to place the second surface of said folded back peripheral region of the sheet of barrier material in contact with the muscle or tissue wall adjacent the opening; and

attaching said folded back peripheral region of the sheet of barrier material to the muscle or tissue wall using said through hole.

40. A method as claimed in claim 39, wherein said folding back and attaching steps are repeated around the peripheral region of the sheet of barrier material, using other said openings, to attach the prosthesis to the muscle or tissue wall around the opening so as to result in the sheet of structural material facing the opening, the central region of the second surface of the sheet of barrier material facing away from the opening and the second surface of the folded back peripheral region of the sheet of barrier material in contact with the muscle or tissue wall around the opening.

41. A method as claimed in claim 39 or claim 40, wherein said method is an open surgical procedure.

42. A method of repairing a defect or opening in a muscle or tissue wall, the method comprising the steps of:

providing a prosthesis as claimed in any one of claims 1 to 38;

positioning the prosthesis adjacent to the opening with the second surface of the sheet

of barrier material facing generally away from the opening; and

attaching the peripheral region of the sheet of barrier material to the muscle or tissue wall using said openings.

43. A method as claimed in claim 42, wherein said attaching step is repeated around the peripheral region of the sheet of barrier material, using a plurality of said openings, to attach the prosthesis to the muscle or tissue wall around the opening so as to result in the sheet of structural material facing the opening, the second surface of the sheet of barrier material facing away from the opening and the peripheral region of the first surface of the sheet of barrier material in contact with the muscle or tissue wall around the opening.

44. A method as claimed in claim 42 or claim 43, wherein said method is a laparoscopic surgical procedure.

45. A method as claimed in claim 40 or claim 42, further comprising subsequently attaching the prosthesis to the muscle or tissue wall by a series of further attachments.

46. A method as claimed in claim 45, wherein said further attachments pass through the central region of the sheet of barrier material into the muscle or tissue wall closer to the opening than the attachments through the openings in the sheet of barrier material.

Fig.1a.

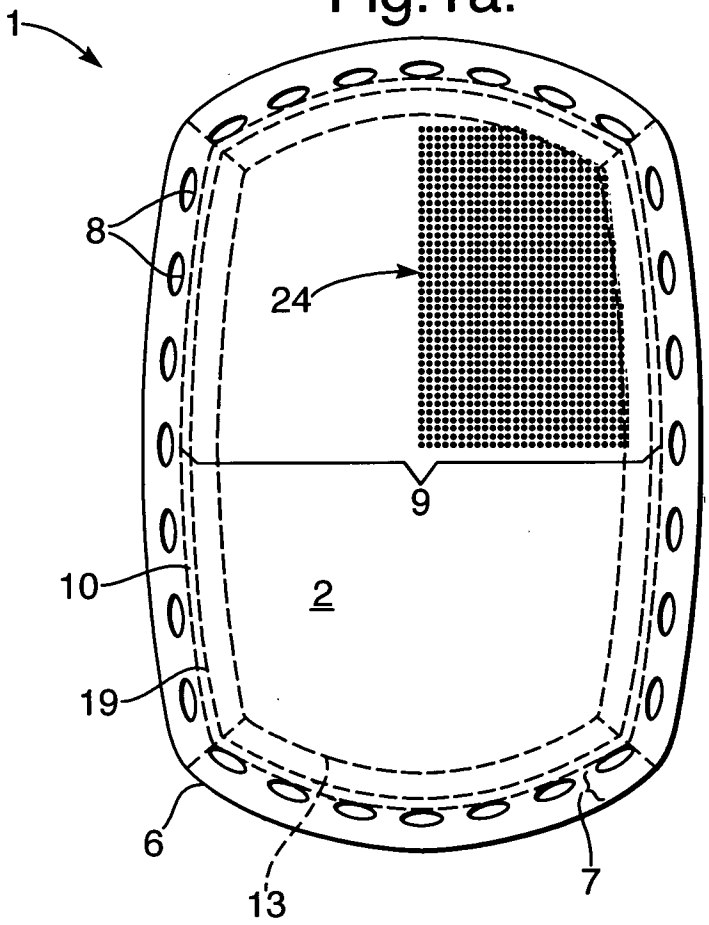


Fig.1b.

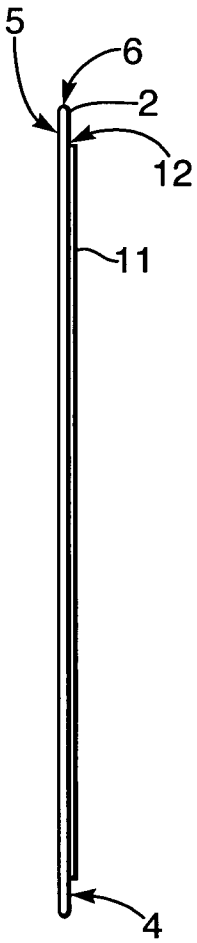


Fig.1c.

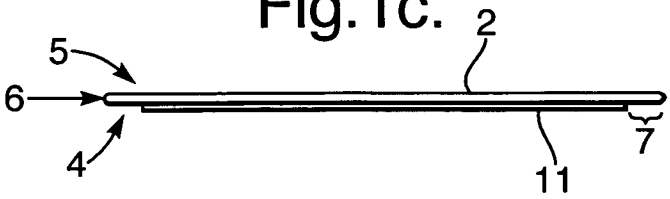


Fig.2.

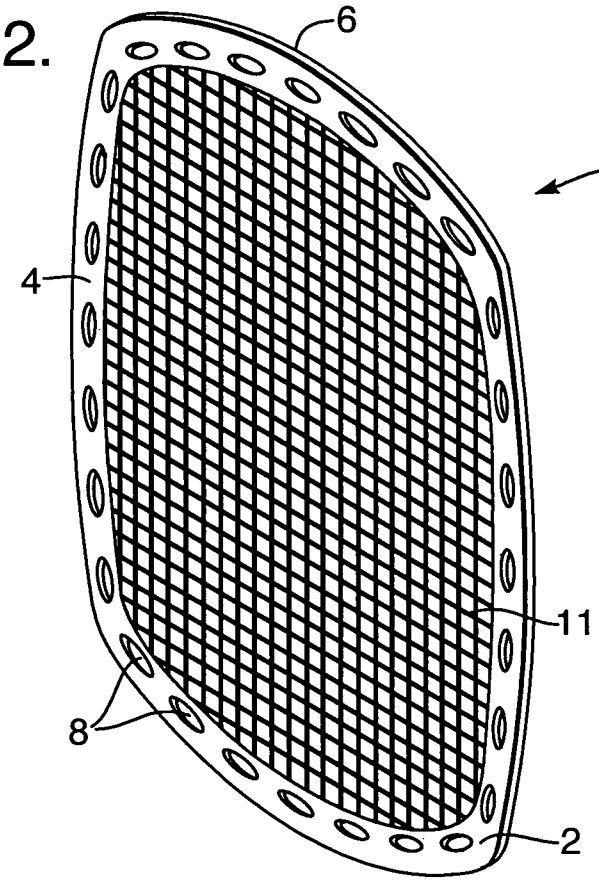


Fig.3.

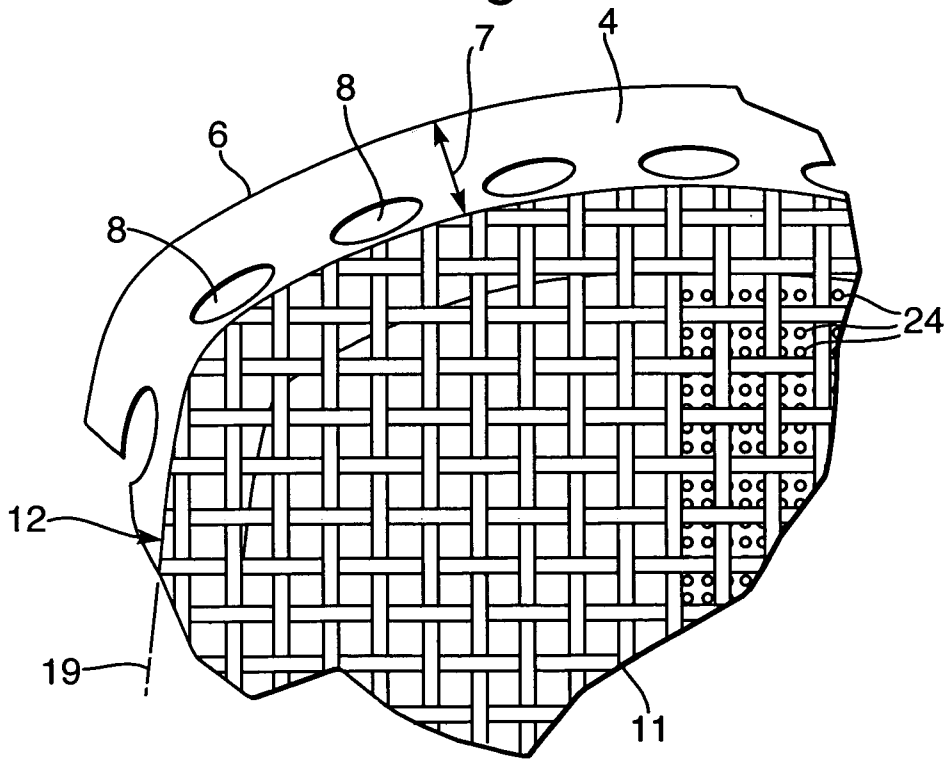


Fig.4.

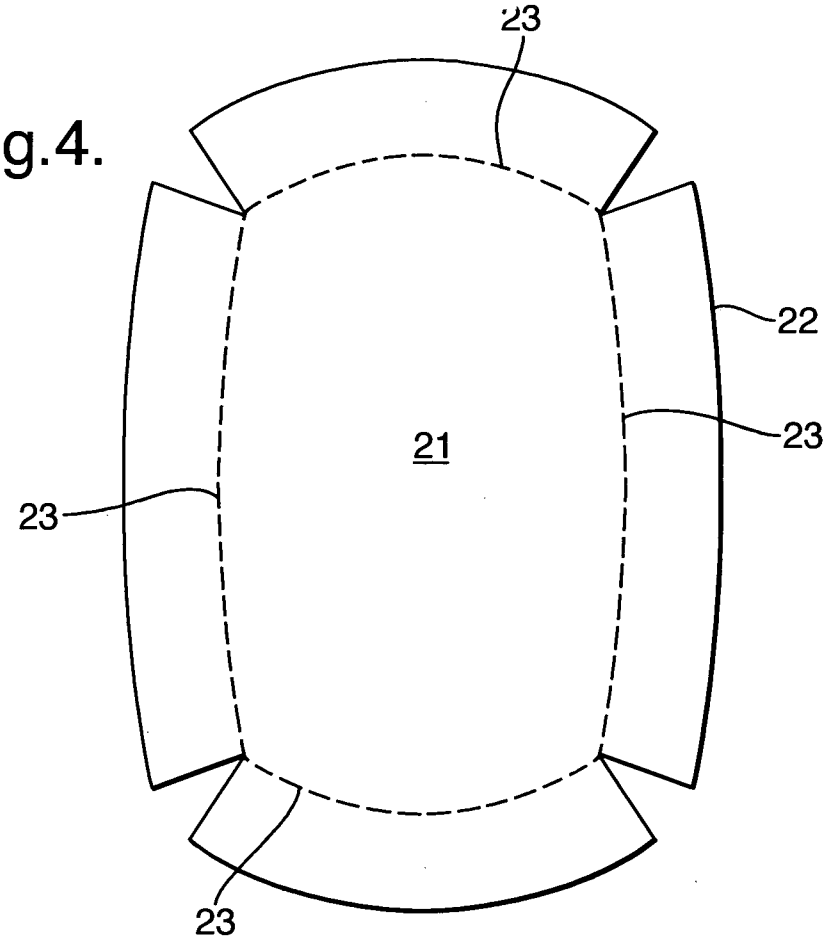


Fig.5.

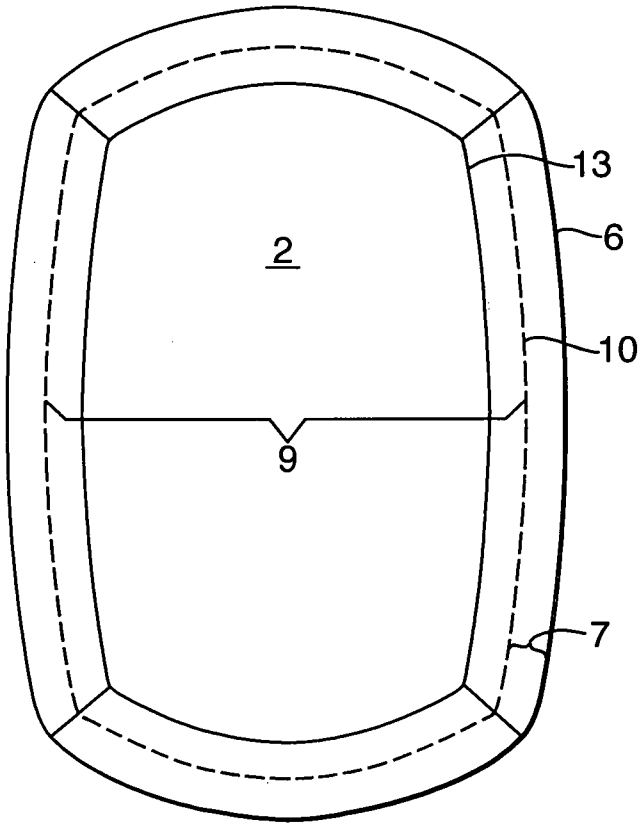


Fig.6.

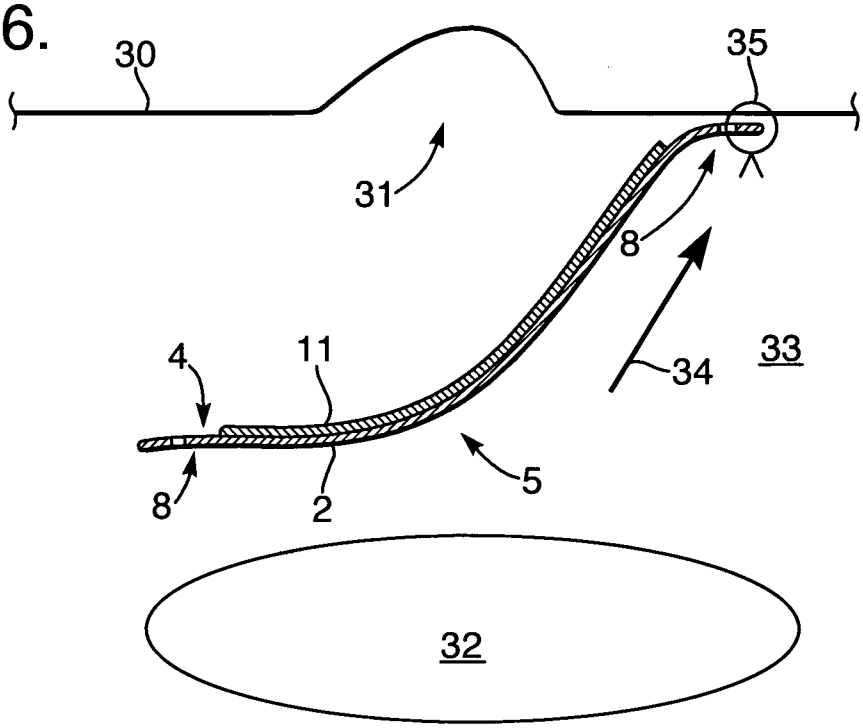
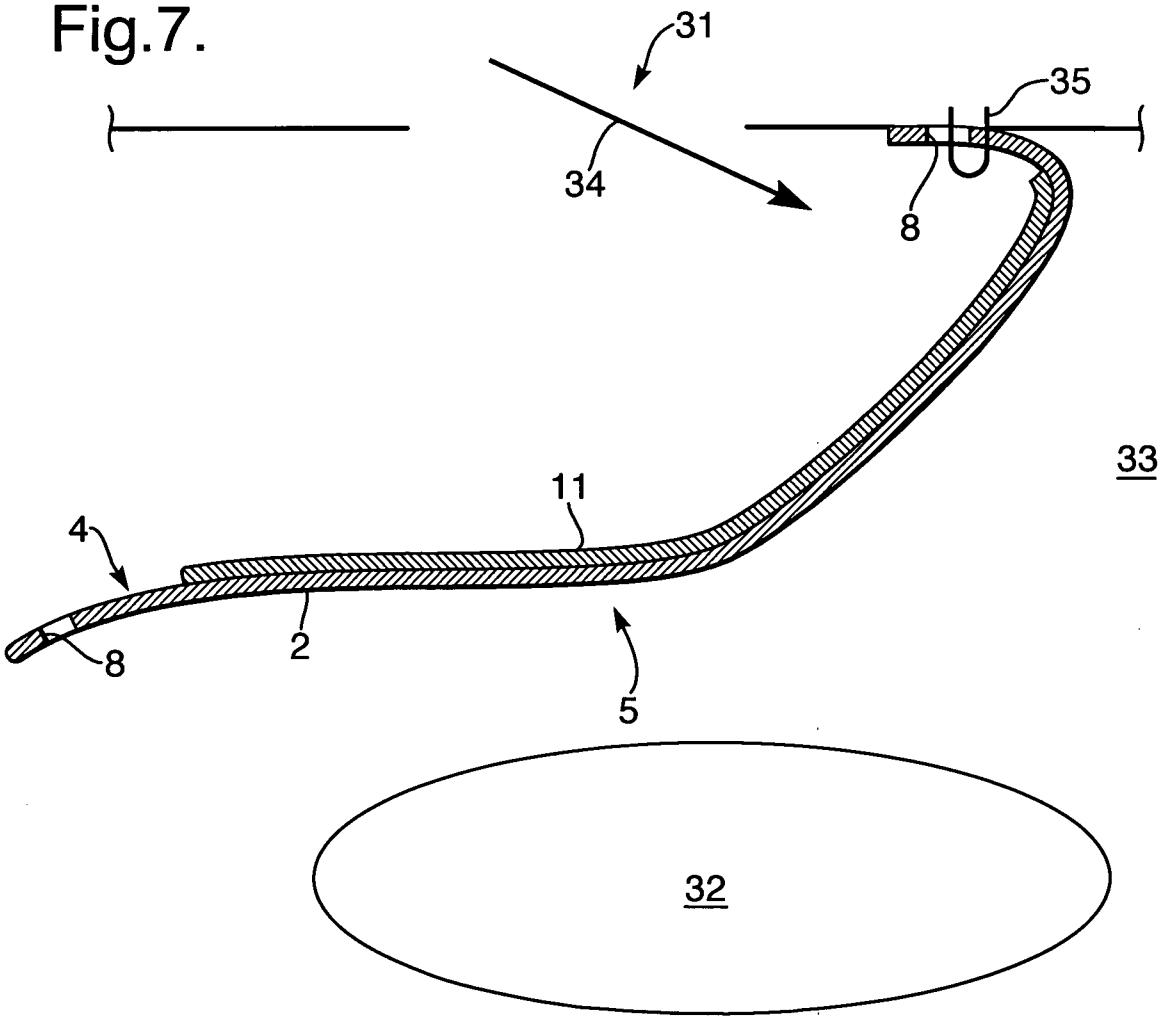


Fig.7.



INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/003186

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02/22047 A (BARD INC C R [US]) 21 March 2002 (2002-03-21) page 4 - page 10; claims; figures	1-38
Y	EP 0 009 072 A (SIGRI ELEKTROGRAPHIT GMBH [DE]) 2 April 1980 (1980-04-02) page 3	1-38
Y	US 5 290 217 A (CAMPOS LUIS I [US]) 1 March 1994 (1994-03-01) the whole document	1-38
Y	US 6 290 708 B1 (KUGEL ROBERT D [US] ET AL) 18 September 2001 (2001-09-18) abstract; claims; figures	1-38

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 November 2007	30/11/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	SERRA I VERDAGUER, J

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/003186

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/049638 A1 (MANDELBAUM JON A [US]) 3 March 2005 (2005-03-03) abstract	1-38
A	WO 94/17747 A (MEDPROD INC [US]) 18 August 1994 (1994-08-18) abstract	1-38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2007/003186

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 39-46
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III *Observations where unity of invention is lacking* (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Continuation of Box II.1

Claims Nos.: 39-46

The subject-matter of claims 39 to 46, discloses a method for repairing a defect in a muscle or tissue wall. The method comprises the step of positioning an implant. The International preliminary searching authority is not required to establish an opinion with regard to novelty, inventive step and industrial applicability on methods for treatment of the human body by surgery or therapy (Rule 39.1(iv)).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2007/003186

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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