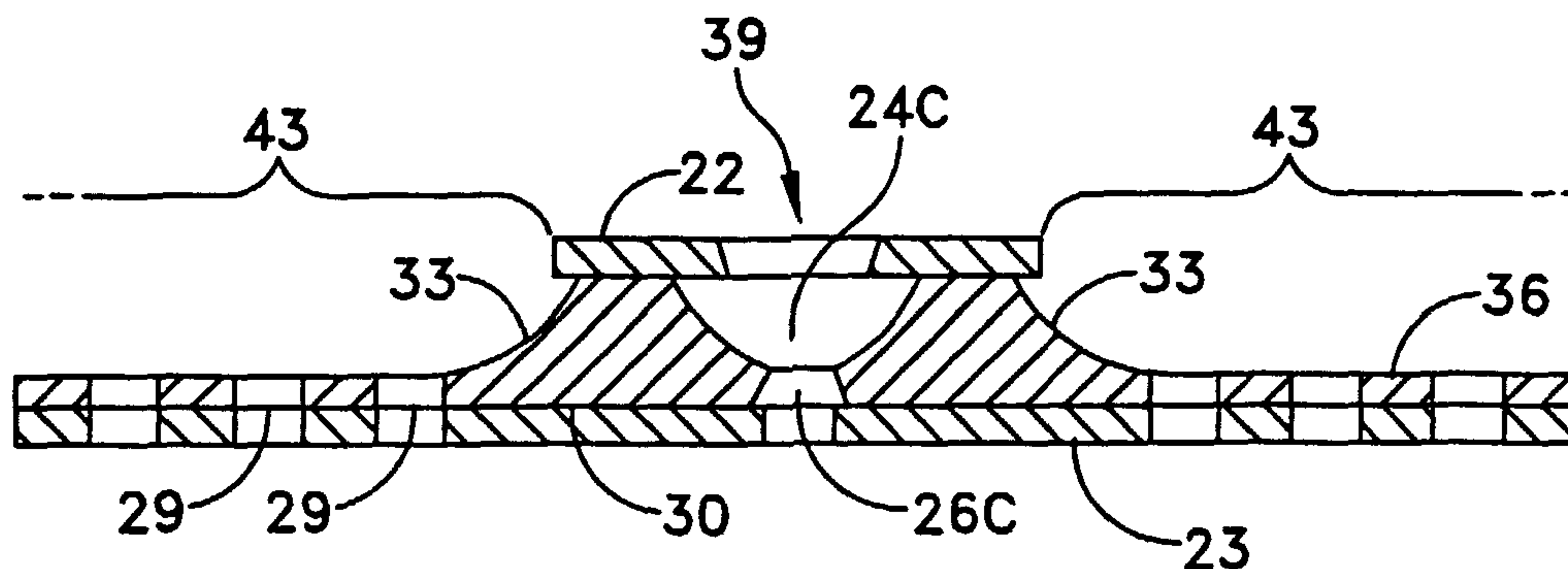




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(54) Titre : PROCEDE DE FABRICATION D'IMPLANTS CHIRURGICAUX A PLAQUE ET MAILLAGE
 (54) Title: METHOD FOR MAKING A MESH-AND-PLATE SURGICAL IMPLANT



(57) **Abrégé/Abstract:**

A mesh-and-plate surgical is manufactured by a method including the steps of applying a mask (22, 23) to first (28) and second (29) faces of a metal sheet (21), selectively ablating the mask on both faces, affixing a first tape (41) to the first face to cover same and maska thereon, but leaving an exposed portion (24A) for a screw hole, affixing a second tape (42) to the second face to cover same and mask thereon, etching the first face screw hole portion to form a crater (24C), removing the first tape, etching the crater and other exposed portions (24B) of the first face, removing the second tape, etching opposite (24C) the crater and other exposed portions of the second face to provide openings in communication with the crater, and other second face openings extending to the first face, and removing remaining mask to provide the implant configured to include a pliable mesh portion (43) and a rigid plate portion (33), and having a screw hole (39) therein.



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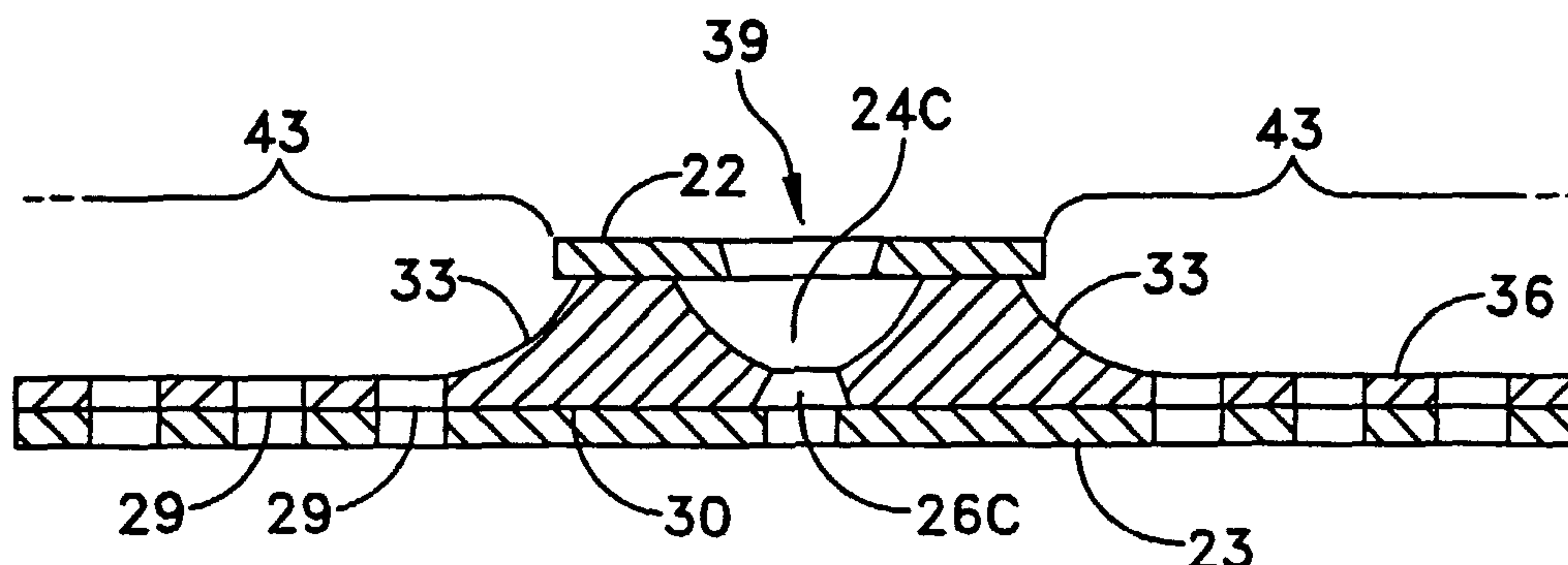
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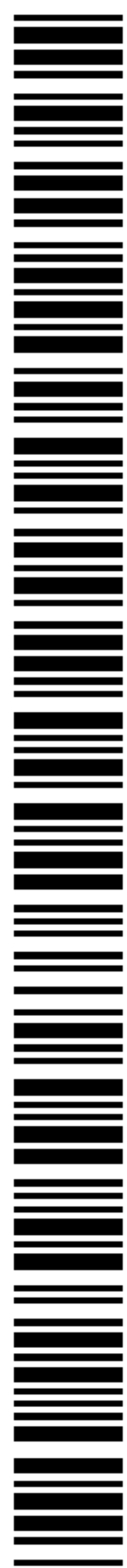
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(57) Abstract: A mesh-and-plate surgical is manufactured by a method including the steps of applying a mask (22, 23) to first (28) and second (29) faces of a metal sheet (21), selectively ablating the mask on both faces, affixing a first tape (41) to the first face to cover same and mask thereon, but leaving an exposed portion (24A) for a screw hole, affixing a second tape (42) to the second face to cover same and mask thereon, etching the first face screw hole portion to form a crater (24C), removing the first tape, etching the crater and other exposed portions (24B) of the first face, removing the second tape, etching opposite (24C) the crater and other exposed portions of the second face to provide openings in communication with the crater, and other second face openings extending to the first face, and removing remaining mask to provide the implant configured to include a pliable mesh portion (43) and a rigid plate portion (33), and having a screw hole (39) therein.



WO 02/092882 A1

1
2 METHOD FOR MAKING A MESH-AND-PLATE SURGICAL IMPLANT

3
4
5 CROSS-REFERENCE TO RELATED APPLICATION

6 This application claims the benefit of U.S. Provisional
7 Patent Application Serial No. 60/291,002, filed May 15, 2001.
8

9 BACKGROUND OF THE INVENTION

10 1. Field of the Invention

11 The invention relates to surgical implants, and is directed
12 more particularly to the making of such implants having relatively
13 rigid plate portions and pliable, textured, mesh portions, either
14 portion being provided with at least one screw hole to facilitate
15 attachment to bone.

16 2. Description of the Prior Art

17 The use of surgical implants is well known. Surgically
18 implantable metal devices generally are formed of plates or sheets
19 of inert metal, such as titanium, compatible with human and animal
20 tissue. When such implants are positioned between bone and soft
21 tissue, a textured, roughened traction surface in contact with the
22 bone promotes ingrowth of the bone, bonding with the traction
23 surface and enhancing the permanent, stable positioning of the
24 implant. Textured bone-contacting surfaces thus enhance the
25 stability of the metal implants after surgery. The desirability

1 of rough, textured, bone-engaging surfaces to assure stable
2 positioning of surgical implants has been recognized and has been
3 discussed in U.S. Patent No. 5,258,098, issued November 2, 1993,
4 in the names of Donald J. Wagner et al, U.S. Patent No. 5,298,115,
5 issued March 29, 1994, in the name of Ian Leonard, U.S. Patent No,
6 5,456,723, issued October 10, 1995, in the names of Samuel G.
7 Steinemann et al, U.S. Patent No. 5,507,815, issued April 16,
8 1996, in the names of Donald J. Wagner et al, U.S. Patent No.
9 5,603,338, issued February 18, 1997, in the name of Keith D.
0 Beaty, U.S. Patent No, 5,853,561, issued December 29, 1998, in the
1 name of Bruce A. Banks, U.S. Patent No. 5,922,029, issued July 13,
2 1999, in the names of Donald J. Wagner et al, and U.S. Patent No.
3 5,965,006, issued October 12, 1999, in the names of Roland Baege
4 et al.

5 Some implants are formed as thin mesh sheets, of extremely
6 light weight and with numerous openings therethrough. In some
7 cases, bendable mesh implants require relatively stiff, unbendable
8 reinforcing plate portions. The formation of perforated thin
9 metallic sheets, or plates, is described in several U.S. patents,
0 including U.S. Patent No. 3,359,192, issued December 19, 1967, in
1 the names of Hans-Joachim Heinrich et al, U.S. Patent No.
2 5,606,589, issued February 25, 1997, in the names of Anthony J.
3 Pellegrino et al, and U.S. Patent No, 5,814,235, issued September
4 29, 1998, in the names of Anthony J. Pellegrino et al. Through-
5 holes penetrating such plate portions are useful for receiving

1 mounting screws, anchoring the mesh-and plate implant in position.
2 However, the manufacture of such implants combining a relatively
3 thin pliable sheet with a thicker unbendable plate, and with
4 mounting screw holes therein, has presented some challenges still
5 lacking feasible and economical solutions.

6
7 SUMMARY OF THE INVENTION

8 An object of the invention is, therefore, to provide a method
9 for making a mesh-and-plate surgical implant including bendable
10 perforated mesh portions adjoining stiff, rigid reinforcing plate
11 portions.

12 A further object is to provide a method for making such
13 implants having therein mounting screw holes which pass
14 therethrough, for receiving mounting screws installed during
15 implantation.

16 With the above and other objects in view, a feature of the
17 present invention is the provision of a method for making a mesh-
18 and-plate surgical implant, the method comprising the steps of
19 applying maskant to first and second faces of a metal sheet,
20 selectively ablating the maskant on both faces, affixing a first
21 protective tape to the first face to cover same and maskant
22 thereon, but leaving exposed a portion for a screw hole, affixing
23 a second protective tape to the second face to cover same and
24 maskant thereon, etching the first face screw hole portion to form
25 a crater, removing the first tape, etching the crater and other

1 exposed portions of the first face, removing the second tape,
2 etching opposite the crater and other exposed portions of the
3 second face to provide an opening in communication with the
4 crater, and to provide other second face openings extending to the
5 first face, and removing remaining maskant to provide the implant
6 configured to include a pliable mesh portion and a rigid plate
7 portion, and having screw holes therein.

8 The above and other features of the invention, including
9 various novel details of construction and combinations of method
10 steps, will now be more particularly described with reference to
11 the accompanying drawings and pointed out in the claims. It will
12 be understood that the particular method embodying the invention
13 is shown and described by way of illustration only and not as a
14 limitation of the invention. The principles and features of this
15 invention may be employed in various and numerous embodiments
16 without departing from the scope of the invention.

17
18 BRIEF DESCRIPTION OF THE DRAWINGS

19 Reference is made to the accompanying drawings in which is
20 shown an illustrative embodiment of the invention, from which its
21 novel features and advantages will be apparent.

22 In the drawings:

23 FIGS. 1 - 10 are diagrammatic cross-sectional views of
24 successive stages in the making of a mesh-and-plate implant in
25 accordance with an embodiment of the invention;

1 FIG. 11 is a top plan view of a mesh-and-plate implant made
2 in accordance with the method illustrated in FIGS. 1-10;

3 FIG. 12 is similar to FIG. 11, but illustrative of an
4 alternative implant; and

5 FIG. 13 is an enlarged illustration of the mesh portions of
6 the implants of FIGS. 11 and 12.

7 8 DESCRIPTION OF THE PREFERRED EMBODIMENT

9 To make a mesh-and-plate surgical implant, there is provided
10 a thin sheet 21 (FIG. 1) of tissue and bone compatible metal, such
11 as titanium.

12 A maskant layer 22 (FIG. 2) is applied to a first face 28 of
13 the sheet 21 and a maskant layer 23 is applied to a second face 30
14 of the sheet 21. The maskant layers 22,23 cover substantially the
15 entirety of the first and second faces 28, 30, respectively. The
16 maskant layers 22, 23 are resistant to chemical attack. It has
17 been found that a photo-chemical resist, such as duPont Riston, or
18 Kodak Thin Film Resist, serve as appropriate materials for the
19 maskant layers 22, 23.

20 The maskant layers 22, 23 are then in part ablated from
21 selected portions of the metal faces 28, 30 (FIG. 3), as by
22 mechanical tools, chemical milling, photo-chemical etching, or by
23 laser eradication, to expose portions 24A, 24B, 26 of the
24 respective metal faces 28, 30 in desired patterns, ready for
25 etching.

1 Referring to FIG. 4, it will be seen that the exposed
2 portions 24B of the first face 28 and the maskant layer 22 on the
3 first face 28 are covered with a protective tape 41, leaving
4 exposed only the region 24A where a central through-hole is
5 desired for acceptance of a mounting screw (not shown).
6 Similarly, the exposed portions 26 of the second face 30 and the
7 maskant layer 23 on the second face 30 are covered with a
8 protective tape 42. The tapes 41, 42 may be 3M Brand Type #1280
9 Platers Tape.

.0 The through-hole region 24A is then subjected to etching, as
.1 by spray or immersion, using an acid bath of a mixture of nitric
.2 and hydrofluoride acid. It is preferred, during the etching
.3 process, to periodically remove the sheet 21 from the etching
.4 process and rinse, dry and bake the sheet to maintain the
.5 integrity of the maskant and allow for in-process inspections.

.6 When the etchant reaching the exposed surface 24A has created
17 a shallow crater 24C (FIG. 5), the protective tape 41 is removed
18 (FIG. 6) and the etching of the crater 24C is resumed, and etching
19 of the exposed portions 24B, constituting the mesh portion of the
20 implant, is undertaken. As etching proceeds, the exposed metal
21 regions 24C and 24B are progressively removed by the etchant (FIG.
22 7). The etching continues until the removal of metal from the
23 first face 28 and crater 24C has reached the predetermined extent
24 desired (FIG. 8).

1 The second tape 42 is then removed, exposing the maskant
2 layer 23 and exposed portions 26 on the second face 30, including
3 an area 26C opposite the crater 24C.

4 Etching of the through-hole area 26C in the sheet face 30
5 breaks through to the crater 24C to effect a counter-sunk through-
6 hole 39 (FIG. 9) and second face openings 29 in communication with
7 the newly etched first face 36.

8 The first and second maskant layers 22, 23 are then removed
9 (FIG. 10), leaving an implant device having the mesh portion 43, a
10 plate portion 33, and at least one through-hole 39 for receiving a
11 mounting screw.

12 In FIG. 11 there is shown, for illustrative purposes, a dog-
13 leg plate portion 33 having one or more through-holes 39 therein,
14 the plate portion 33 being bounded by the mesh portion 43. In
15 FIG. 12 there is shown a divided plate 34 having through-holes 39
16 therein, and bounded by the mesh portion 43.

17 Referring to FIG. 13, it will be seen that through-holes 39
18 may be provided in mesh portions 43, such through-holes preferably
19 being surrounded by rim collars 46 comparable in thickness to a
20 plate portion 33. The through-holes 39 preferably are countersunk
21 to receive mounting screws.

22 In an alternative embodiment, the maskant layers 22, 23 may
23 be exposed to a movable laser beam which is moved in accordance
24 with a path governed by a CAD data file, wherein the beam removes
25 unwanted maskant. After the laser removes the maskant, the sheet

1 21 is exposed to heat and/or ultraviolet light to cure and harden
2 the remaining maskant.

3 The mesh portions 43 preferably are of a thickness of about
4 5 mm and are readily flexed to follow the curvature of a bone.

5 There is thus provided an improved method for making a mesh-
6 and-plate surgical implant including both bendable perforated mesh
7 portions and relatively rigid plate portions, wherein the bendable
8 or comformable perforated portions are integral with and
9 kinematically related to the rigid plate portions. The improved
10 method further provides through-holes for receiving mounting
11 screws during implantation.

12 It will be understood that many additional changes in the
13 details, materials, steps and arrangement of parts, which have
14 been herein described and illustrated in order to explain the
15 nature of the invention, may be made by those skilled in the art
16 within the principles and scope of the invention as expressed in
17 the appended claims.

What is claimed is:

1. A method for making a mesh-and-plate surgical implant, the method comprising the steps of:

applying maskant to first and second faces of a metal sheet;

selectively ablating the maskant on both faces;

affixing a first protective tape to the first face to cover the first face and maskant thereon, but leaving an exposed portion of the first face for a screw hole;

affixing a second protective tape to the second face to cover the second face and maskant thereon;

etching the first face screw hole portion to form a crater;

removing the first tape;

etching the crater and other exposed portions of the first face;

removing the second tape;

etching opposite the crater and other exposed portions of the second face to provide an opening in communication with the crater, and to provide other second face openings extending to the first face; and

removing remaining maskant to provide the implant configured to include a pliable mesh portion and a rigid plate portion having a screw hole therein.

2. The method in accordance with claim 1 wherein the application of maskant to a metal sheet comprises:

providing a metal sheet of substantially uniform thickness throughout; and

applying the maskant as coatings on the first and second faces covering substantially all of the first and second faces.

3. The method in accordance with claim 2 wherein selectively ablating the maskant comprises ablating the maskant on the first and second faces in selected loci to expose underlying portions of the metal sheet first and second faces, to leave maskant in patterns defining configurations of desired plate and

mesh portions, and to further expose an underlying portion of the metal sheet first and second faces defining a disposition of a desired screw hole in the desired plate portion.

4. The method in accordance with claim 3 wherein affixing the first protective tape comprises affixing the first tape so as to cover the exposed underlying portions of the first face and the maskant remaining on the first face, but leaving exposed the underlying portion defining the location of the desired screw hole.

5. The method in accordance with claim 4 wherein the step of etching the first face screw hole portion comprises etching away the portion of the underlying first face defining the location of the desired screw hole to form a crater in the first face.

6. The method in accordance with claim 5 wherein etching the crater and other exposed portions of the first face comprises removing metal from the crater to deepen the crater in the metal sheet, and removing metal from the other exposed portions of the first face to reduce the thickness of the metal sheet in the mesh portion thereof.

7. Method for making a mesh-and-plate surgical implant, the method comprising the steps of:

providing a metal sheet;

applying to first and second faces of the sheet coatings
of maskant resistant to chemical attack;

ablating the maskant on the first and second faces in
selected loci to expose underlying portions of the
metal sheet first and second faces in selected
patterns, to leave the maskant in patterns defining
configurations of desired plate and mesh portions,
and to further expose underlying portions of the
metal sheet first and second faces defining a
location of a of desired screw hole;

affixing a first protective tape to the first face so as
to cover the exposed underlying portions of the first
face and the maskant remaining on the first face, but
leaving exposed the underlying portion defining the
location of the desired screw hole;

affixing a second protective tape to the second face so as
to cover the exposed underlying portions of the
second face and the maskant remaining on the second
face;

etching away the portion of the underlying first face defining the location of the desired screw hole, to form a crater in the first face;

removing the first protective tape;

etching the crater and other exposed portions of the first face to remove metal therefrom;

removing the second protective tape;

etching the second face opposite the crater and etching other exposed portions of the second face to provide an opening in communication with the crater and to provide other second face openings in communication with the first face; and

removing remaining maskant to provide the implant with exposed first and second faces and configured in part as a pliable mesh portion, and in part as at least one rigid plate portion, and having at least one screw hole therein.

8. The method in accordance with claim 7 wherein the metal sheet provided is of substantially uniform thickness throughout,

and the plate portion of the implant is substantially thicker than the mesh portion of the implant.

9. The method in accordance with claim 7 wherein the coatings of maskant applied to the first and second faces are applied to cover substantially all of the first and second faces of the sheet.

10. The method in accordance with claim 7 wherein etching the other exposed portions of the first face reduces the thickness of the sheet in areas of the sheet mesh portion.

11. As an article of manufacture, a surgical implant made in accordance with the method of claim 1.

12. As an article of manufacture, a surgical implant made in accordance with the method of claim 7.

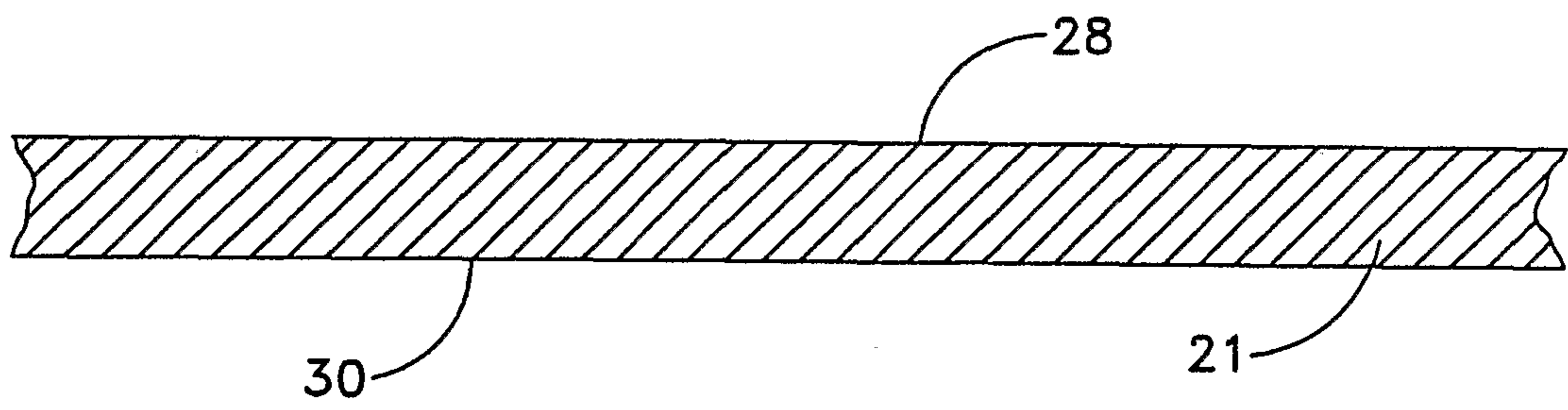


FIG. 1

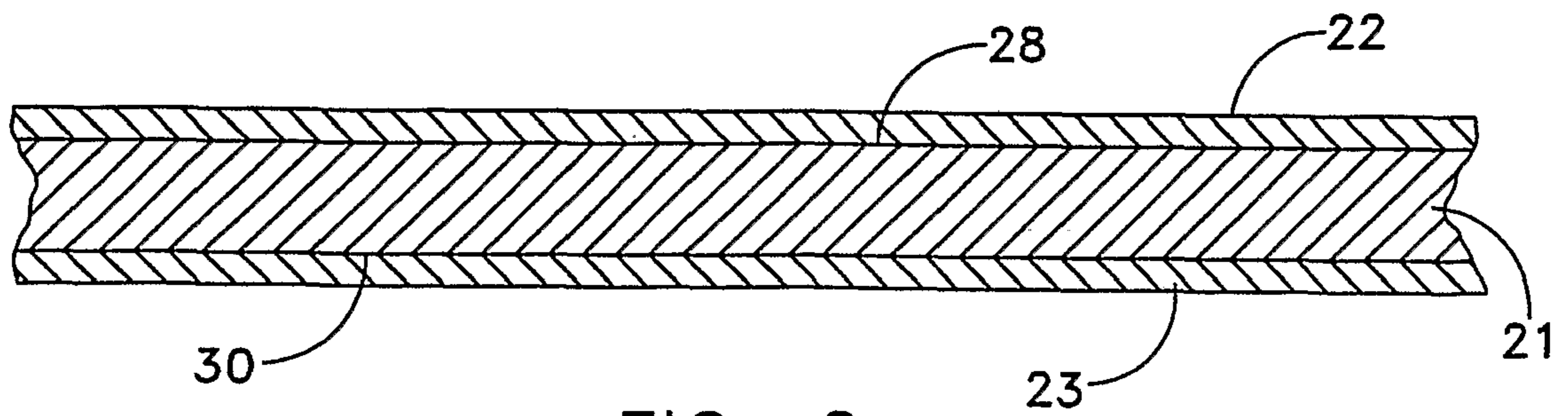


FIG. 2

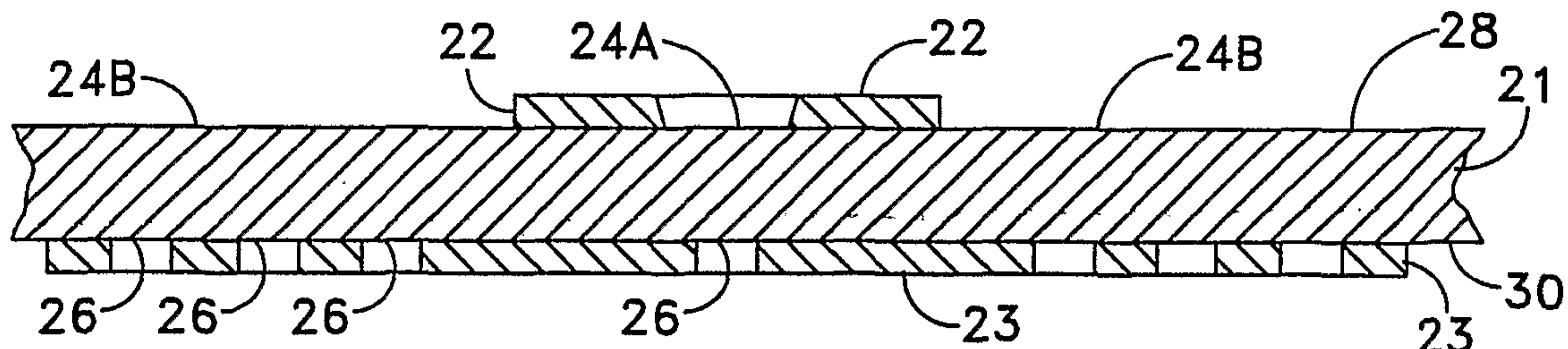


FIG. 3

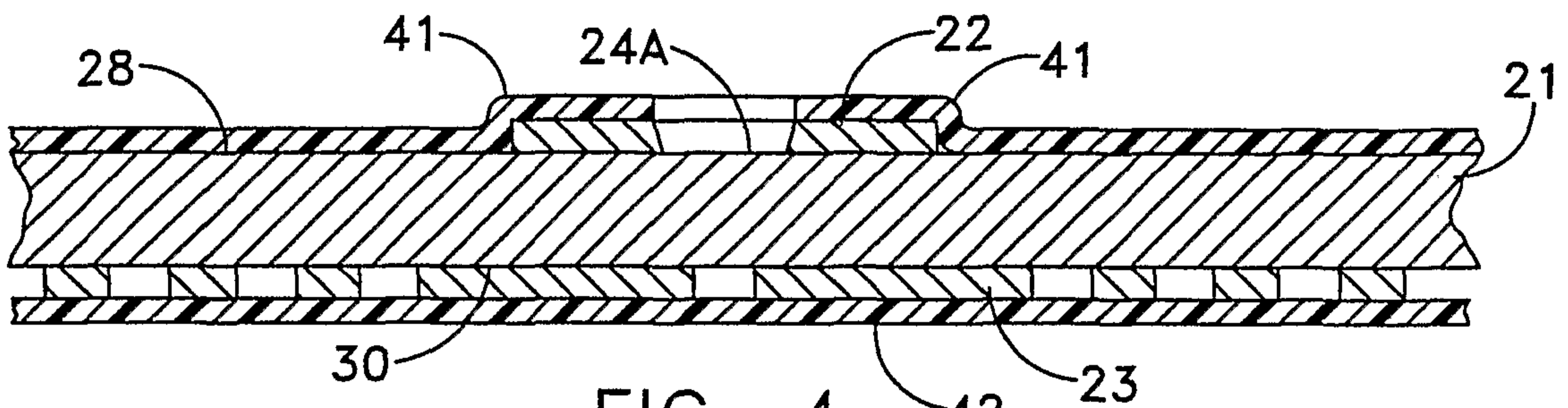


FIG. 4

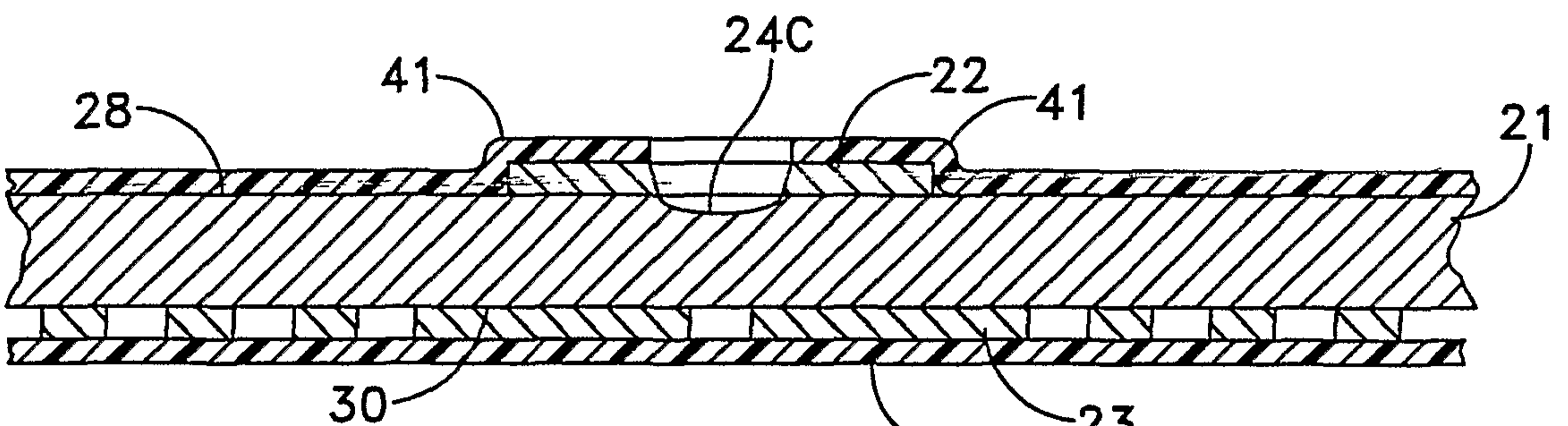


FIG. 5

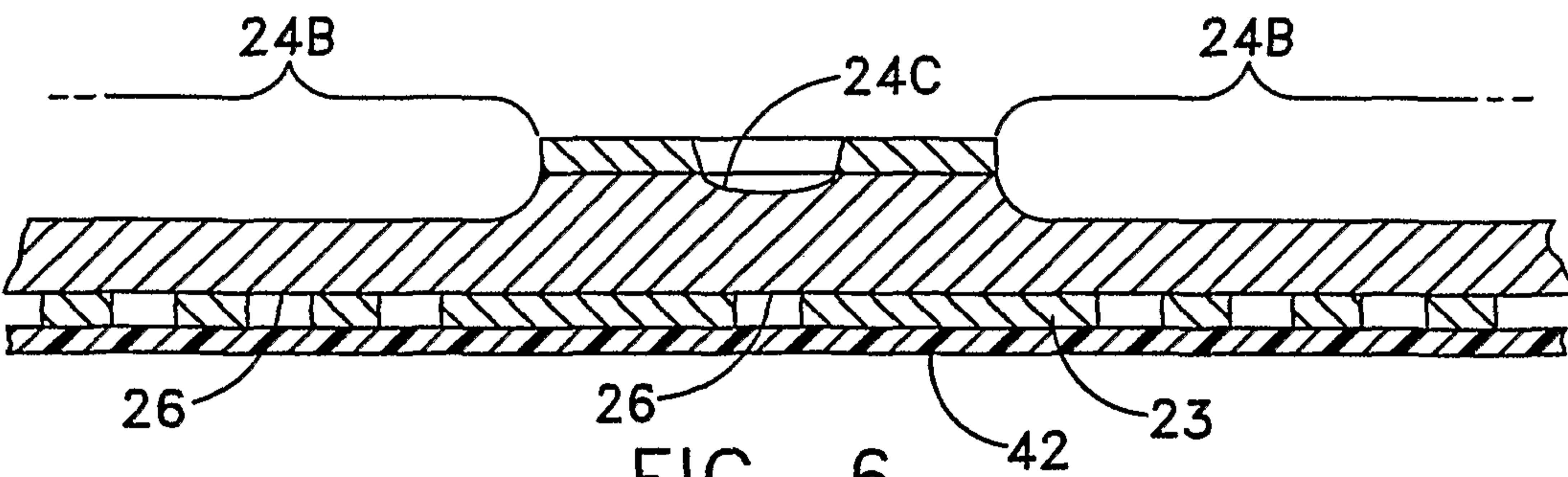


FIG. 6

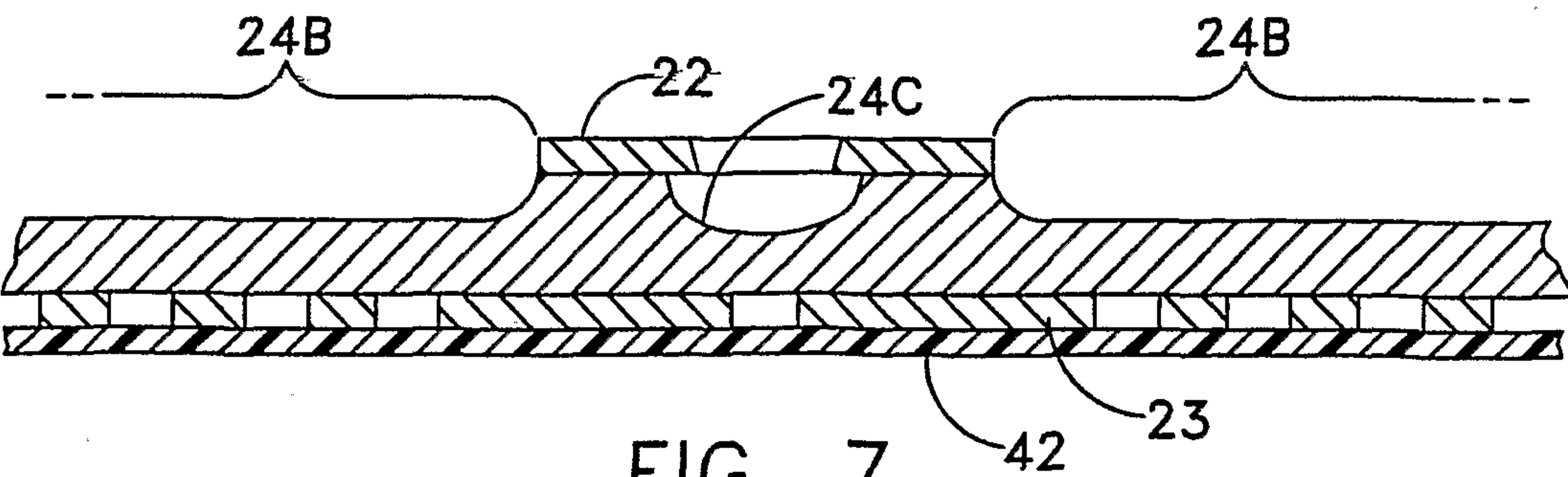


FIG. 7

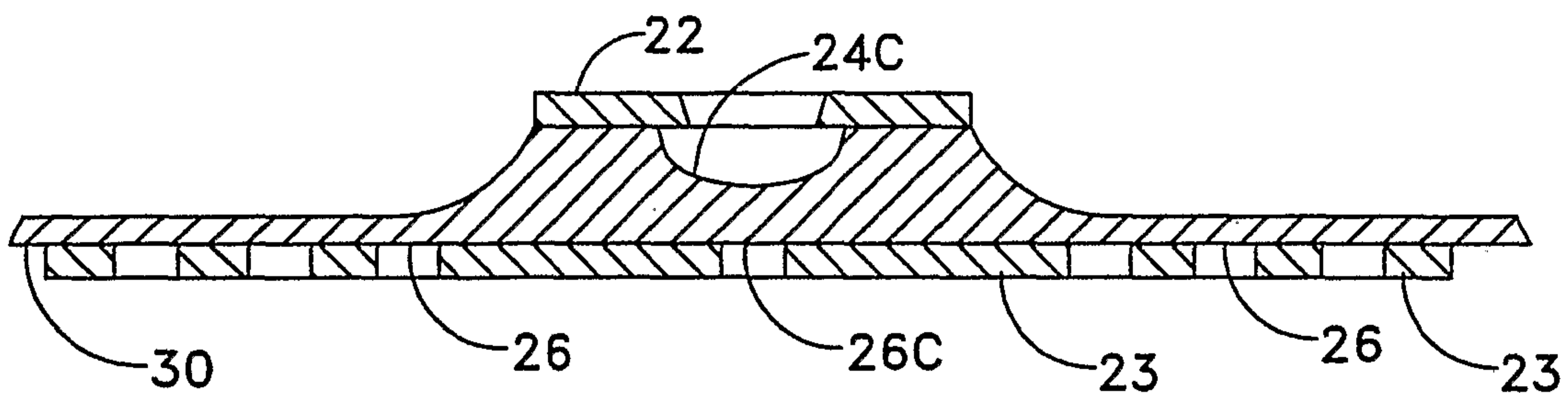


FIG. 8

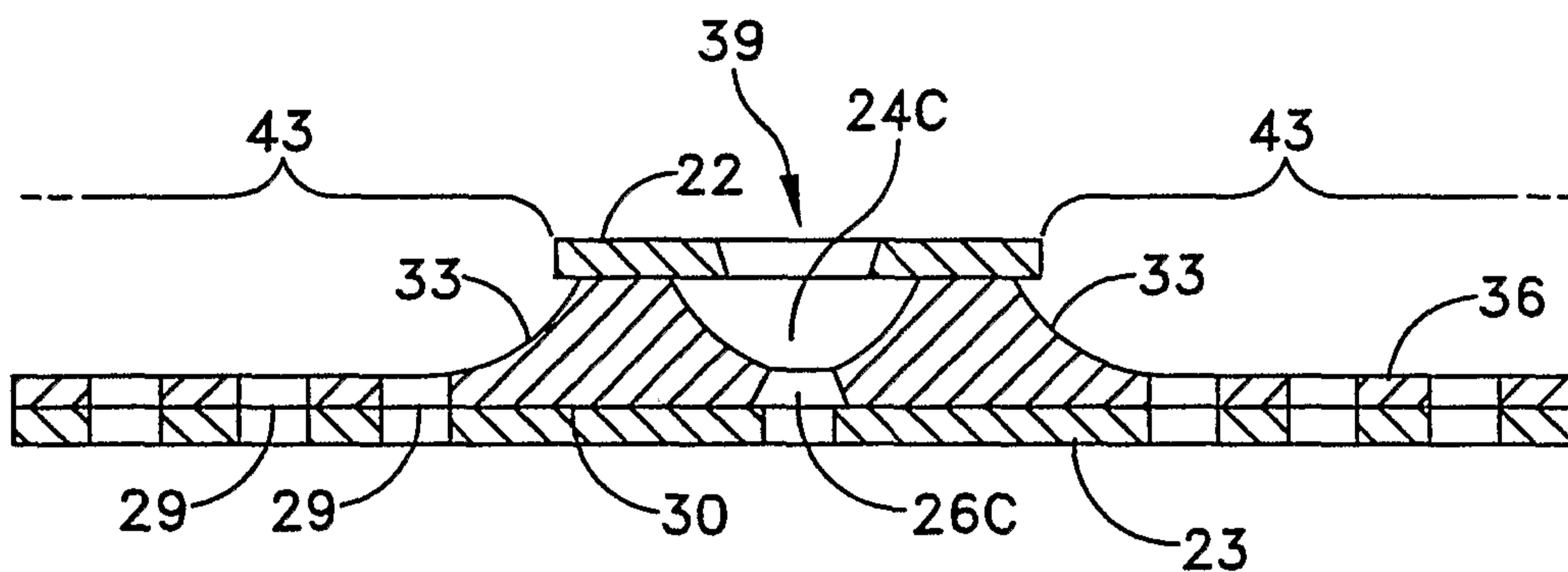


FIG. 9

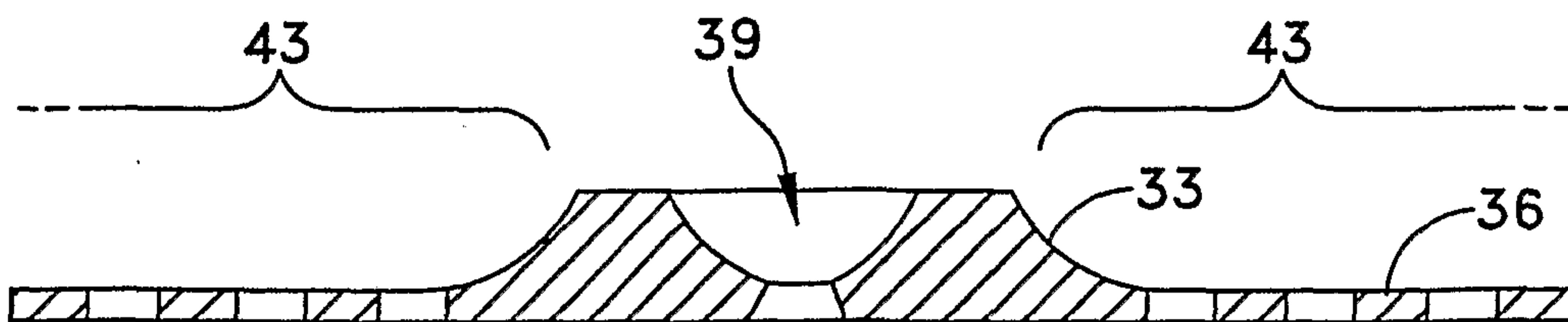


FIG. 10

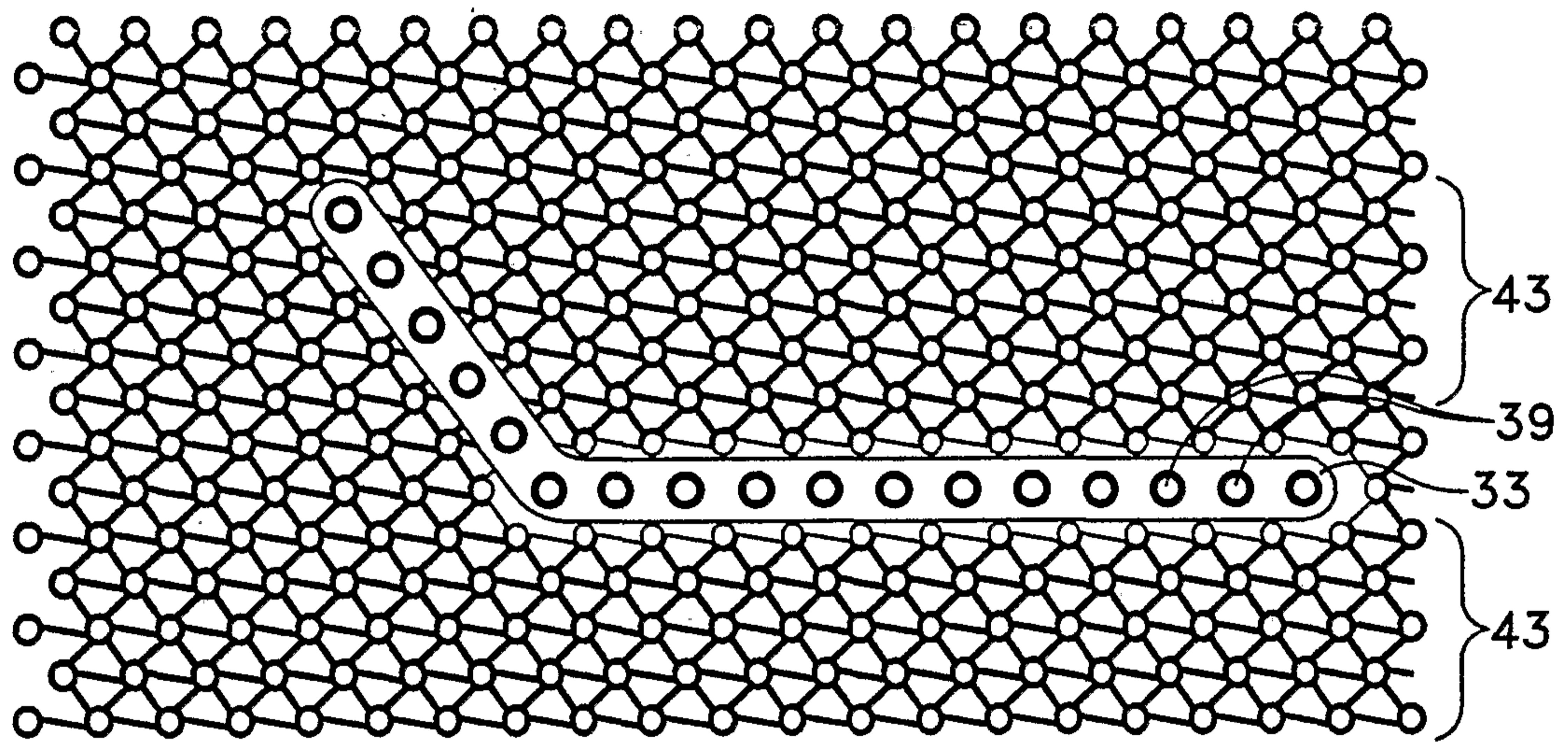


FIG. 11

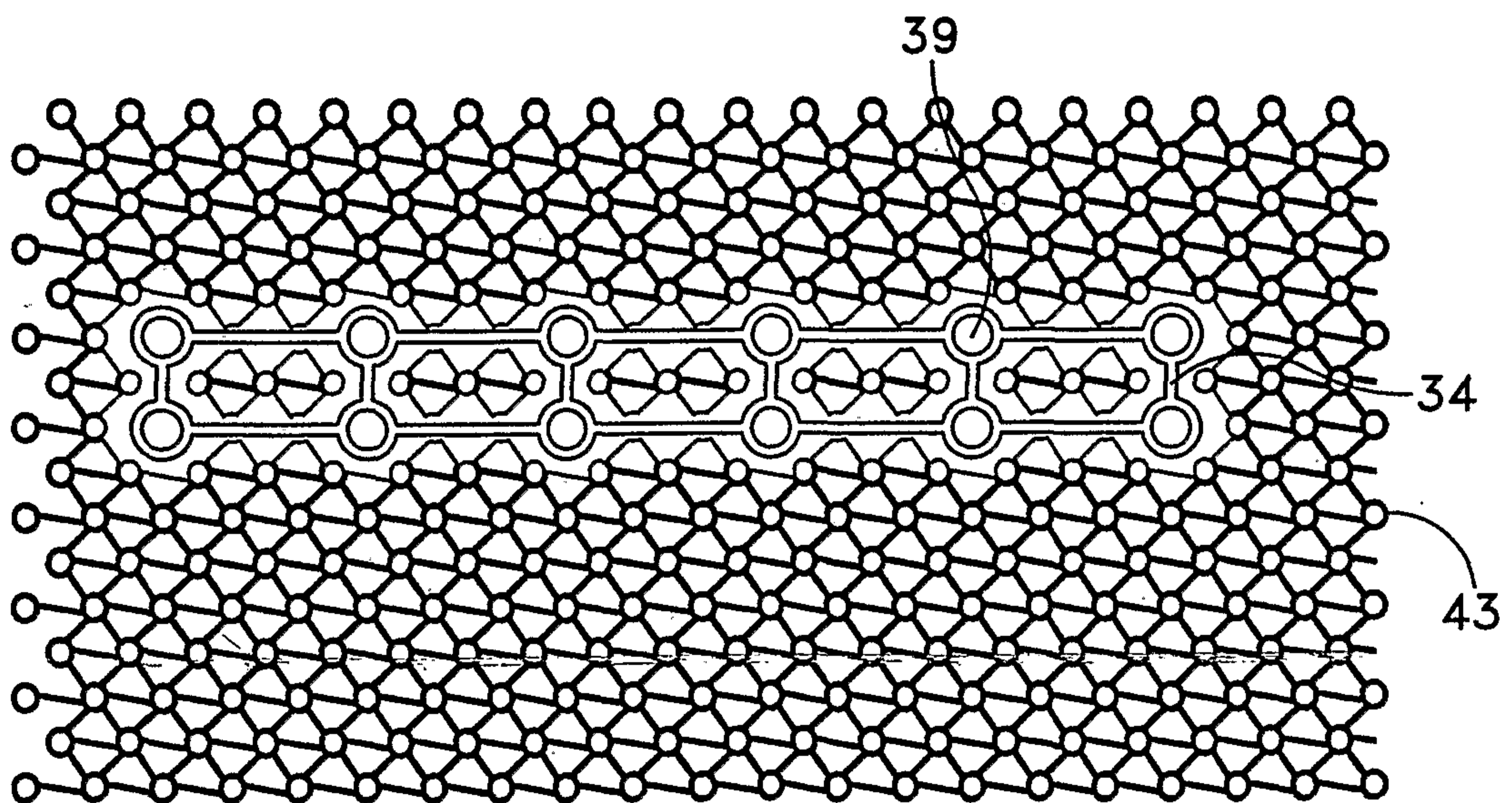


FIG. 12

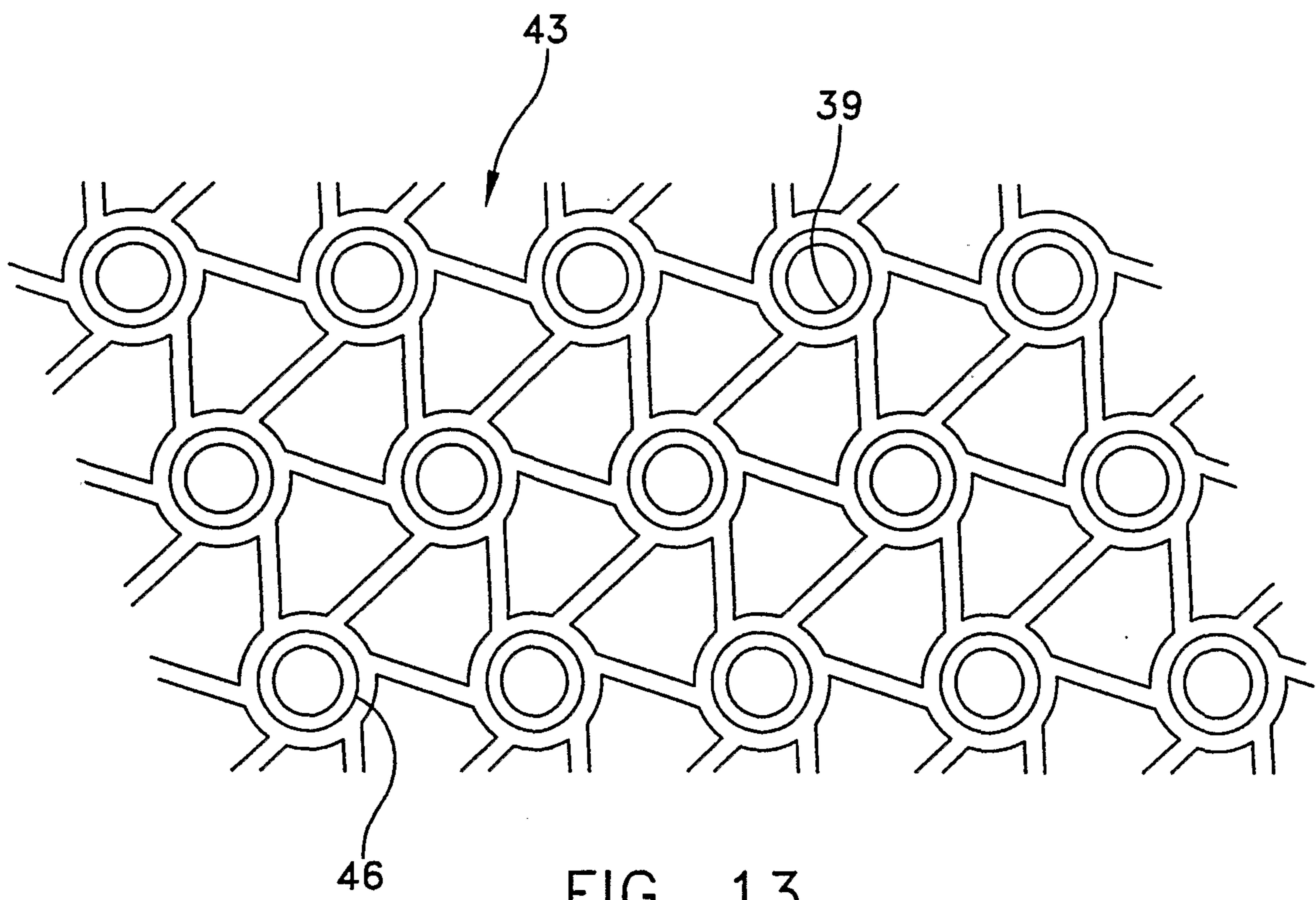


FIG. 13

