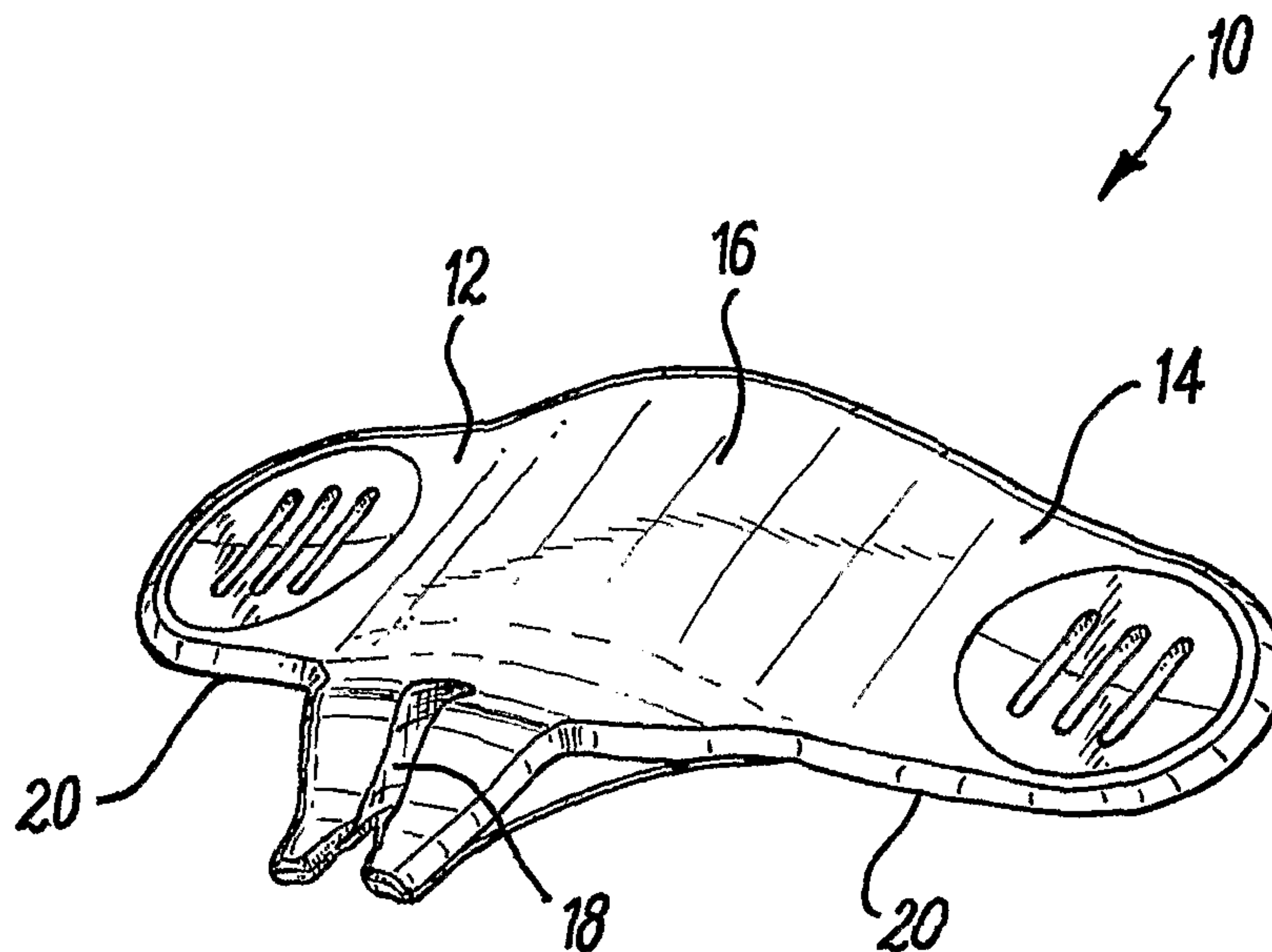




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(54) Titre : APPAREIL DE GUIDAGE D'AIGUILLE  
(54) Title: NEEDLE GUIDANCE APPARATUS



(57) Abrégé/Abstract:

The present invention relates to a needle guidance apparatus. The needle guidance apparatus comprises a needle guide (10) configured for location in relation to a site on the human or animal body. The needle guidance apparatus is also configured to cooperate with a needle such that the needle is moveable at a predetermined angle in relation to the needle guide (10).



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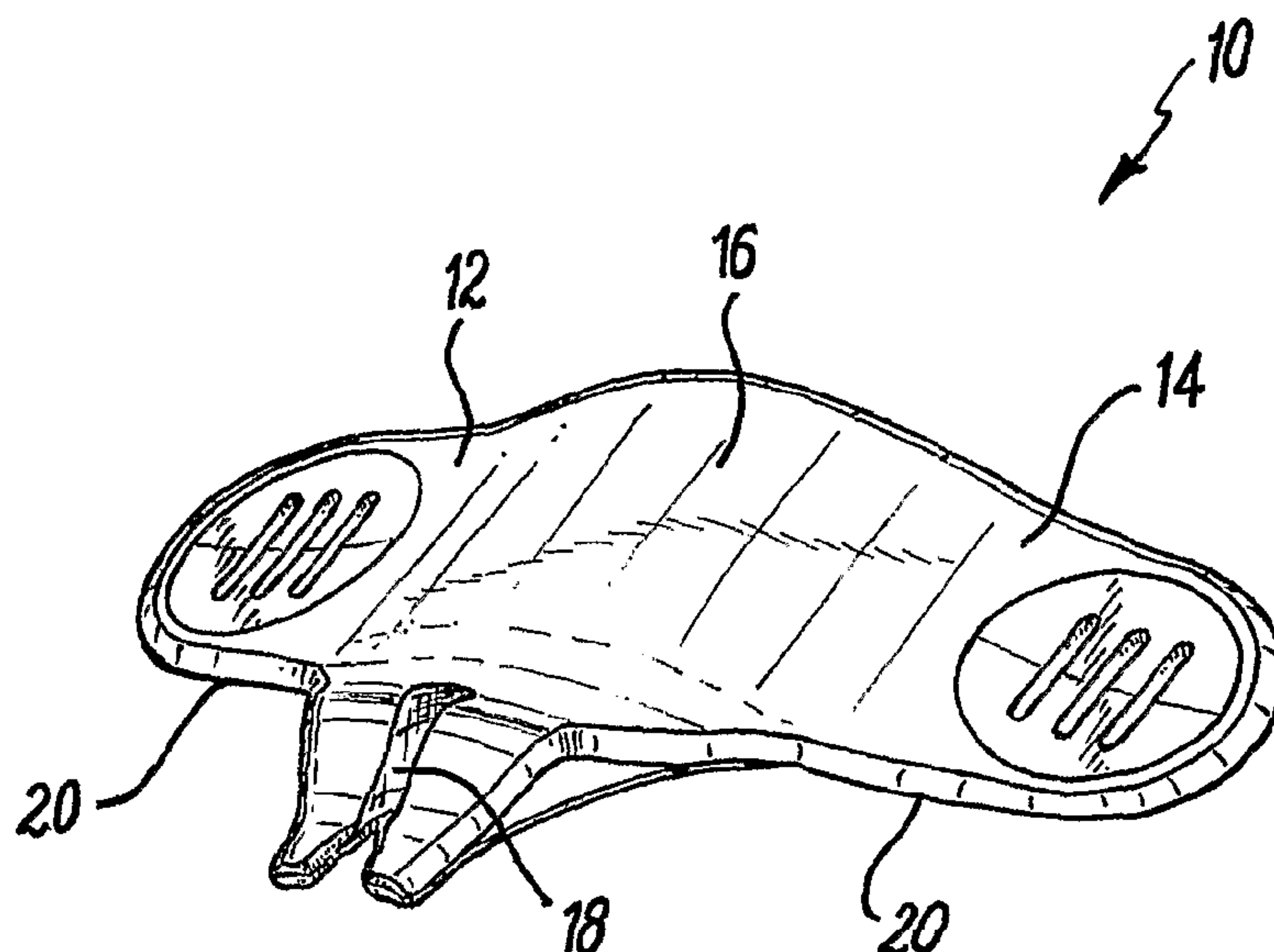
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(54) Title: NEEDLE GUIDANCE APPARATUS



(57) Abstract: The present invention relates to a needle guidance apparatus. The needle guidance apparatus comprises a needle guide (10) configured for location in relation to a site on the human or animal body. The needle guidance apparatus is also configured to cooperate with a needle such that the needle is moveable at a predetermined angle in relation to the needle guide (10).

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1                   **Title: Needle Guidance Apparatus**

2  
3  
4       Field of the invention

5  
6           The present invention relates to needle guidance  
7 apparatus suitable for providing access by a needle to a  
8 site on the human or animal body.

9  
10       Background to the invention

11  
12           Vascular access is required for many medical  
13 procedures, such as haemodialysis, chemotherapy and other  
14 procedures involving intravenous medical administration  
15 and parenteral nutrition. In such medical procedures a  
16 fistula may be created in the body, e.g. on the underside  
17 of the forearm for haemodialysis, to provide a conduit  
18 that is capable of carrying a high blood flow. The  
19 fistula often needs to be capable of tolerating repeated  
20 needling. Alternatively, a vascular prosthetic graft may  
21 be surgically attached between an artery and a vein.  
22 Access to a fistula is normally gained by inserting two  
23 needles into the fistula at spaced apart locations. The  
24 inserted needles are then held in place whilst the



1 medical procedure, e.g. dialysis, is performed.  
2 Likewise, a graft is brought into use by insertion of a  
3 needle into the graft. A rate of repetition of use of  
4 the fistula or graft depends on the medical procedure  
5 being performed. For example, dialysis is typically  
6 performed three times per week.

7 There are three methods of locating the spaced apart  
8 insertion points on a fistula. The three methods are the  
9 rotation method, the same area method and the exact-site  
10 method.

11 The rotation method has the advantage of allowing  
12 areas around the fistula to rest. However, the method  
13 has the disadvantage of a relatively high occurrence of  
14 bad sticks (i.e. where the needle misses the fistula),  
15 which increases the likelihood of complications, such as  
16 haematoma.

17 The same area method provides for ease of access to  
18 a fistula. However, use of the method often results in a  
19 weakening of the fistula wall and enlargement of the  
20 fistula in the area of the insertion points. This can  
21 increase the rate of complications, such as thrombosis,  
22 stenosis and false aneurysm formation, leading to loss of  
23 access to the fistula in addition to the attendant  
24 morbidity.

25 Use of the same site method provides for development  
26 of a track that can be accessed repeatedly. This  
27 technique also has been called the 'constant-site' method  
28 as described in Twardowski, Pol. Arch. Med. Wewn. 57:205-  
29 214, 1977 or the 'exact-site' or 'buttonholing' method.  
30 This method is preferred over the other methods because  
31 it is less likely to weaken the fistula wall, it is less  
32 painful, it reduces likelihood of haematoma formation, it  
33 increases the patency of the fistula, and it greatly

1 reduces the need for reinsertion of needles as a result  
2 of 'bad sticks'.

3 Of the above three methods the 'exact-site' method  
4 is preferred from a clinical perspective. However, it  
5 can be a difficult method to perform. More specifically,  
6 the fistula needs to be needled at the same site on at  
7 least six occasions to ensure that the track develops  
8 properly. Therefore, it is recommended that the same  
9 experienced member of staff should perform the procedure  
10 until the track develops properly to increase the  
11 likelihood that the needle is inserted repeatedly at the  
12 same site. As a result a patient is allocated a  
13 particular clinician or nurse to perform the procedure  
14 and this often presents difficulties because it is rare  
15 that the same member of staff will be available at each  
16 of the six required patient visits. In summary, there is  
17 a general reluctance to use the 'exact-site' method  
18 because of a lack of confidence on the part of staff and  
19 the complexity of managing duty rosters.

20 Where a graft is used, the angle of entry of a  
21 needle to the graft can have an impact on the  
22 complication rate. For example, if the angle of entry is  
23 too small the graft may be damaged by shearing; and if  
24 the angle of entry is too great there may be an increased  
25 likelihood of the back wall of the graft being punctured.

26 It is therefore an aim of the present invention to  
27 provide an apparatus that addresses the above noted  
28 problems. More specifically, it is an aim of the present  
29 invention to provide an apparatus that provides for  
30 access by a needle to site on the human or animal body  
31 without the need for experienced staff to perform the  
32 procedure.

33



1 Statement of Invention

2

3       The present invention has been devised in the light  
4 of the above noted problems and thus according to a first  
5 aspect of the present invention there is provided a  
6 needle guidance apparatus comprising a needle guide  
7 configured for location in relation to a site on the  
8 human or animal body and being further configured to  
9 cooperate with a needle such that the needle is moveable  
10 at a predetermined angle in relation to the needle guide.

11       In use, the needle guide is located in relation to a  
12 site on the human or animal body, e.g. a vascular  
13 prosthetic graft or an arteriovenous fistula in a  
14 patient, and a needle brought into cooperation with and  
15 moved in relation to the needle guide so as to gain  
16 access to the site by the needle.

17       Configuring the needle guide such that the needle is  
18 movable in relation to the needle guide at a  
19 predetermined angle may, for example, provide for proper  
20 entry of a needle to a graft. For example, if insertion  
21 of a needle into a graft is attempted when an angle  
22 between the needle and the body is too shallow the needle  
23 may tear the graft. On the other hand, if the angle is  
24 too obtuse there can be an increased likelihood of the  
25 needle passing through the graft. Thus, configuring the  
26 needle guide such that a needle moves at a predetermined  
27 angle in relation to the needle guide can provide a means  
28 to set an appropriate angle of movement of a needle in  
29 relation to the body and, hence, the graft or fistula in  
30 the body.

31       More specifically, the needle guide may be  
32 configured such that the predetermined angle is between  
33 substantially 40 degrees and substantially 50 degrees.

1 More specifically, the needle guide may be  
2 configured such that the predetermined angle is  
3 substantially 45 degrees. An angle of 45 degrees has  
4 been found to be appropriate for gaining entry to a  
5 graft.

6 Alternatively or in addition, the needle guide may  
7 be configured such that the predetermined angle is  
8 between substantially 20 degrees and substantially 40  
9 degrees.

10 More specifically, the needle guide may be  
11 configured such that the predetermined angle is  
12 substantially 30 degrees. An angle of 30 degrees has  
13 been found to be appropriate for gaining entry to a  
14 fistula.

15 Alternatively or in addition, the needle guide may  
16 have a needle guiding profile configured to cooperate  
17 with a needle and to guide movement of the needle in  
18 relation to the needle guide.

19 More specifically, the needle guiding profile may  
20 define a channel constructed to receive a needle. The  
21 channel may be constructed to restrict movement of the  
22 needle in relation to the needle guide radially of the  
23 channel.

24 More specifically, the channel may be substantially  
25 semi-circular in cross-section.

26 Alternatively or in addition, the channel may be  
27 substantially "U" shaped in cross-section. In use, the  
28 opposing of the channel may be spaced apart from each  
29 other to an extent that is greater than a width of a  
30 needle to reduce the likelihood of the needle slipping  
31 out of the needle guide.

32 Alternatively the channel may define a near complete  
33 circle in cross-section along at least part of its



1 length. Thus the channel may have a gap which allows for  
2 removal of a needle from the channel when the needle has  
3 been inserted into the human or animal body where the  
4 needle is of a kind that tapers away from the inserted  
5 end of the needle.

6 Alternatively the channel may define a complete  
7 circle in cross-section along at least part of its  
8 length.

9 More specifically, the needle guide may comprise at  
10 least one channel closing component configured to be  
11 moved in relation to the channel from a first position in  
12 which the channel defines a complete circle along at  
13 least part of its length and to a second position in  
14 which the needle can be removed from the channel. Thus,  
15 in use, the channel closing component can be in the first  
16 position during movement of the needle in relation to the  
17 needle guide during insertion of the needle into the  
18 human or animal body and then can be moved to the second  
19 position to allow for removal of the needle from the  
20 channel of the needle guide when the needle is properly  
21 inserted into the human or animal body.

22 More specifically, the channel closing component may  
23 be frangible.

24 Alternatively or in addition, the channel closing  
25 component may be hingedly attached to the needle guide.

26 Alternatively or in addition, the needle guide may  
27 comprise a body engaging component configured to engage  
28 with the human or animal body.

29 More specifically, the body engaging component may  
30 be configured and the needle guiding profile disposed in  
31 relation to the body engaging component to provide for at  
32 least one predetermined attitude of the needle guiding  
33 profile in relation to the body engaging component. In



1 use, this may provide for at least one predetermined  
2 attitude of the needle guiding profile in relation to the  
3 body.

4 More specifically, the needle guiding profile may be  
5 configured to provide for a plurality of predetermined  
6 attitudes of the needle guiding profile in relation to  
7 the body engaging component.

8 Alternatively or in addition, the needle guiding  
9 profile may be configured to receive needles of different  
10 gauges. Thus, the needle guiding profile may define a  
11 plurality of channels of different diameters.

12 Alternatively or in addition, the needle guide may  
13 comprise a plurality of channels of different diameters.  
14 The plurality of channels may be spaced apart from each  
15 other laterally of a direction of movement of a needle in  
16 a channel. Alternatively or in addition, the plurality  
17 of channels may be disposed substantially co-axially of  
18 each other.

19 Alternatively or in addition, the needle guide may  
20 be configured so as to permit alteration of the at least  
21 one predetermined attitude of the needle guiding profile  
22 in relation to the body. Thus, an angle between the  
23 needle guide and the body may be changed. For example,  
24 having an obtuse angle between the needle guide and the  
25 body initially may provide for ease of gaining access to  
26 the fistula by the needle; when the needle has entered  
27 the fistula the angle may be reduced so that the needle  
28 is substantially in line with the skin of the body.

29 More specifically, the needle guiding profile may be  
30 movable in relation to the body engaging component.

31 More specifically, the needle guiding profile may be  
32 rotatable in relation to the body engaging component.

1       More specifically, the needle guide may comprise a  
2 hinge configured to provide for rotation of the needle  
3 guiding profile in relation to the body engaging  
4 component.

5       Alternatively or in addition, the needle guide may  
6 be configured so as to permit stepwise alteration of the  
7 at least one predetermined attitude of the needle guiding  
8 profile in relation to the body.

9       Alternatively or in addition, the needle guide may  
10 be configured to resist an unintended reduction of a  
11 predetermined attitude of the needle guiding profile  
12 whilst permitting an intended increase in the  
13 predetermined attitude.

14       More specifically, the needle guide may comprise a  
15 ratchet arrangement.

16       More specifically, the ratchet arrangement may be  
17 configured to be releasable to provide for a reduction in  
18 the predetermined attitude of the needle guiding profile.

19       Alternatively or in addition, the body engaging  
20 component may be configured and the needle guiding  
21 profile may be disposed in relation to the body engaging  
22 component to provide for at least one predetermined limit  
23 to the extent to which a needle can be advanced through  
24 the needle guiding profile. Thus, in use, an extent to  
25 which the needle can be inserted into the human or animal  
26 body can be limited.

27       More specifically, the needle guiding profile may be  
28 configured to provide for a plurality of predetermined  
29 limits to the extent to which a needle can be advanced  
30 through the needle guiding profile and hence, in use,  
31 inserted into the human or animal body. For example, the  
32 needle guiding profile may be configured for use with a  
33 needle that is about 50 mm long, such as a 16 gauge



1 needle. A 16 gauge needle is a typical arterial/venous  
2 fistula needle that is suitable for the majority of  
3 patients attending for kidney dialysis.

4 At a later stage, e.g. during the next patient  
5 visit, another needle is brought into cooperation with  
6 the needle guide apparatus so as to gain access to the  
7 said site. Thus, the needle guidance apparatus can be  
8 used to gain repeated access to the same site and thus  
9 provide for ease of use of the same site method.

10 Accordingly, the needle guide may be configured for  
11 temporary location on the human or animal body and may  
12 further comprise a registration profile for locating the  
13 needle guide in registration with the site on the human  
14 or animal body. This may provide for an improvement in  
15 the accuracy of the location of a point of insertion of a  
16 needle, whereby the risk of bad sticks may be reduced.  
17 Improved precision of location of the point of insertion  
18 may provide for repeated access to the same site as is  
19 required of the 'exact site' method. Thus, the needle  
20 guide can be removed from the human or animal body  
21 between uses of the needle guidance apparatus.  
22 Configuration of the needle guide for temporary location  
23 on the human or animal body and the provision of the  
24 registration profile can provide for removal of the  
25 needle guide from the body and replacement at a later  
26 stage whilst providing for repeated access to the site by  
27 a needle.

28 More specifically, the needle guide may comprise a  
29 registration component comprising said registration  
30 profile, the registration component being configured for  
31 cooperation with the human or animal body so as to  
32 provide for registration of the registration profile with  
33 a location on the human or animal body. For example, the

1 registration profile may comprise an edge of the needle  
2 guide that is configured to rest on or near the skin of  
3 the human or animal body and that can be brought into  
4 registration with a mark made on the skin, such as a mark  
5 made by indelible marker pen.

6 Alternatively or in addition, the needle guidance  
7 apparatus may comprise a main body, which is configured  
8 to cooperate with the needle, and at least one  
9 registration component having a registration profile.

10 More specifically, the at least one registration  
11 component may extend from the main body.

12 More specifically, the needle guidance apparatus may  
13 comprise two registration components extending in  
14 opposite directions from the main body.

15 Where the needle guide comprises a body engaging  
16 component configured to engage with the human or animal  
17 body, the body engaging component may comprise a body  
18 engaging surface configured to be brought into contact  
19 with the skin of the human or animal body.

20 More specifically, the body engaging component may  
21 have a profile configured to permit positioning of the  
22 needle guide over a raised part of the skin of the human  
23 or animal body. For example, the raised part of the skin  
24 may be raised because of a fistula under the skin.

25 More specifically, the body engaging component may  
26 comprise an arcuate portion.

27 Alternatively or in addition, the body engaging  
28 component may be configured for use with differently  
29 shaped parts of the human or animal body.

30 Alternatively or in addition, the body engaging  
31 component may be pliable. Thus, the body engaging  
32 component may for example be more readily used with  
33 different parts of the human or animal body or with



1 differently sized parts of the human or animal body. For  
2 example, where the body engaging component comprises a  
3 body engaging surface the body engaging surface can be  
4 shaped to conform to differently shaped forearms.

5 Alternatively or in addition, the body engaging  
6 component may be comprised at least in part of a plastics  
7 material.

8 Alternatively or in addition, the body engaging  
9 component may comprise hinged components configured to  
10 conform to differently shaped human or animal bodies.  
11 More specifically, a main body of the needle guide may be  
12 less pliable than the hinged components. Thus, the main  
13 body of the needle guide may provide for a needle to  
14 follow a fixed track as the needle advances into a  
15 fistula or graft.

16 Alternatively or in addition, the body engaging  
17 component may comprise at least in part a material that  
18 provides for friction between the body engaging component  
19 and the skin of the human or animal body. This can  
20 reduce the likelihood of the needle guide slipping on the  
21 human or animal body during use. More specifically, the  
22 body engaging component may comprise at least in part at  
23 least one of polypropylene (PP), polyphenylene sulphide  
24 (PPS) and polymethylpentane (PMP).

25 Alternatively or in addition, the body engaging  
26 component may comprise at least in part a material that  
27 provides for biocompatibility with the human or animal  
28 body. More specifically, the body engaging component may  
29 comprise at least in part at least one of polypropylene  
30 (PP), polyphenylene sulphide (PPS) and polymethylpentane  
31 (PMP).

32 Alternatively or in addition, the needle guide may  
33 be comprised at least in part of a plastics material.

1       Alternatively or in addition, the needle guide may  
2 be a unitary body.

3       The needle guidance apparatus may be configured for  
4 attachment to a tourniquet or similar such device.

5       In a form, the needle guidance apparatus may further  
6 comprise at least one needle configured to cooperate with  
7 the needle guide.

8       More specifically, the at least one needle may have  
9 a plurality of graduations spaced apart along the needle.  
10 The graduations may be spaced apart along a body of the  
11 needle. In use, the graduations can be used, e.g. by a  
12 clinician, to provide for determination of an extent to  
13 which the needle has been inserted into the human or  
14 animal body. Thus, the graduations may be discernible by  
15 a human.

16       More specifically, the plurality of graduations may  
17 comprise at least one of a coloured mark, engraved  
18 feature, a protrusion and other such visible feature.

19       Alternatively or in addition, the plurality of  
20 graduations may be spaced apart from one another by less  
21 than or equal to substantially 5mm.

22       More specifically, the plurality of graduations may  
23 be spaced apart from one another by less than or equal to  
24 substantially 4mm. Reduced spacing of the graduations  
25 may provide for improved resolution on the one hand but  
26 may be less readily perceived by the naked eye on the  
27 other hand.

28       More specifically, the plurality of graduations may  
29 be spaced apart from one another by less than or equal to  
30 substantially 3mm.

31       Alternatively or in addition, the needle may  
32 comprise a bevelled aperture and at least one of the  
33 plurality of graduations may be disposed on at least one



1 of a hilt of the needle and the needle itself so as to  
2 indicate an orientation of the bevelled aperture. A hilt  
3 of the needle may, for example, be formed of a plastics  
4 material.

5 Alternatively or in addition, the at least one  
6 needle may comprise an aperture (e.g. an eye) formed in a  
7 rear part of the needle. In use, the aperture may let  
8 part of the blood flow pass through the needle and thus,  
9 for example, through a graft during dialysis to thereby  
10 divert some of the blood flow into the dialysis unit.

11 Alternatively or in addition, the needle may  
12 comprise at least one member extending radially of the  
13 needle.

14 More specifically, the at least one member may  
15 comprise two members spaced apart circumferentially round  
16 the needle.

17 Alternatively or in addition, the at least one  
18 member may be formed of a plastics material.

19 Alternatively or in addition, the at least one  
20 member may be movable in relation to the needle.

21 More specifically, the at least one member may move  
22 circumferentially about the needle.

23 More specifically, the at least one member may be  
24 rotatable about the needle.

25 Alternatively or in addition, the at least one  
26 member may be attached to the needle such that the at  
27 least one member may be moved in relation to the needle.  
28 For example, the at least one member may be attached to  
29 the needle to provide for rotation of the at least one  
30 member about the needle.

31 In use, the at least one member may be held such  
32 that it extends away from the body as the needle is being  
33 moved in the needle guide. Thus, the at least one member

1 can be used to provide for increased control of the  
2 needle, for example, as it is being inserted into a graft  
3 or fistula. Furthermore, the at least one member may be  
4 moved when the needle is in position in the body. For  
5 example, the at least one member may be moved to be in  
6 line with the skin of the body. In this disposition the  
7 at least one member may be used to hold the needle in  
8 position, e.g. by means of adhesive tape.

9 Alternatively or in addition, the at least one  
10 needle may be at least about 50mm in length.

11 More specifically, the at least one needle may be  
12 about 60mm in length.

13 Alternatively or in addition, the at least one  
14 needle may taper away from an inserted end of the needle.

15 Alternatively or in addition, a diameter of the at  
16 least one needle at a location spaced apart from an  
17 inserted end of the needle may be less than a diameter of  
18 the needle at a location towards the inserted end of the  
19 needle.

20 Alternatively or in addition, a first needle may  
21 have a tip configured to break the skin of the human or  
22 animal body. For example, the tip may be sharp. In use,  
23 the first needle can be used upon first use of the needle  
24 guidance apparatus when breaking the skin and perhaps  
25 also during formation of a fistula track, e.g. during the  
26 subsequent five, or more, uses of the needle guidance  
27 apparatus.

28 Alternatively or in addition, the first needle may  
29 have a surface configured to promote scarring of tissue  
30 at the site of insertion of the needle on the human or  
31 animal body. In use, this helps development of a fistula  
32 track suitable for subsequent repeated use.



1       Alternatively or in addition, at least a portion of  
2 the surface of the first needle may be rough. For  
3 example, a surface of the first needle at or towards an  
4 end configured to break the skin may be rough.

5       Alternatively or in addition, the needle guidance  
6 apparatus may further comprise a second needle configured  
7 to cooperate with the needle guide.

8       More specifically, the second needle may have a tip  
9 configured to reduce the likelihood of the tip breaking  
10 the skin of the human or animal body. For example, the  
11 tip of the second needle may be blunt. This can have the  
12 advantage of reducing the likelihood of pushing the  
13 needle through the back wall of the fistula, of needle-  
14 stick injury to the clinician, and of damaging the track  
15 between the skin and the fistula or the fistula itself.

16       Alternatively or in addition, the second needle may  
17 have a substantially smooth surface.

18       Alternatively or in addition, the second needle may  
19 have a diameter less than a diameter of the first needle.  
20 In use, this can provide for ease of insertion of the  
21 second needle into the human or animal body and can  
22 reduce damage to the fistula track.

23       Alternatively, the second needle may have diameter  
24 greater than a diameter of the first needle. In use, the  
25 second needle can provide for an increase in blood flow.  
26 Therefore, for example, more blood can be dialysed to  
27 thereby reduce the time required for dialysis treatment.

28       According to a second aspect of the present  
29 invention there is provided a kit of parts comprising: a  
30 needle guide configured for location in relation to a  
31 site on the human or animal body and being further  
32 configured to cooperate with a needle such that the

1 needle is moveable at a predetermined angle in relation  
2 to the needle guide; and at least one needle.

3 More specifically, the kit of parts may comprise a  
4 first needle having a sharp tip, i.e. a tip configured to  
5 break the skin of the human or animal body.

6 Alternatively or in addition, the kit of parts may  
7 comprise a second needle having a blunt tip, i.e. a tip  
8 configured to reduce the likelihood of the tip breaking  
9 the skin of the human or animal body.

10 Further embodiments of the second aspect of the  
11 present invention may comprise one or more features of  
12 the first aspect of the present invention.

13 According to a third aspect of the present invention  
14 there is provided dialysis apparatus comprising needle  
15 guidance apparatus according to the first aspect of the  
16 present invention.

17 Embodiments of the third aspect of the present  
18 invention may comprise one or more features of the first  
19 aspect of the present invention.

20 According to a fourth aspect of the present  
21 invention, there is provided a needle configured to be  
22 inserted into the human or animal body, the needle  
23 comprising a body, a tip portion configured to be  
24 received in the body first upon insertion of the needle,  
25 and an aperture formed in the tip portion, in which a  
26 plurality of spaced apart graduations, which are  
27 discernible by a human, are disposed along a part of the  
28 body of the needle, the part of the body being spaced  
29 apart from the tip portion.

30 More specifically, further graduations may be  
31 disposed on the body of the needle between the part of  
32 the body bearing the plurality of graduations and the tip  
33 portion.



1 More specifically, the further graduations may be  
2 disposed on the tip portion.

3 Alternatively or in addition, the plurality of  
4 graduations may comprise at least one of a coloured mark,  
5 engraved feature, a protrusion and other such humanly  
6 discernible feature.

7 Alternatively or in addition, the plurality of  
8 graduations may be spaced apart from one another by less  
9 than or equal to substantially 5mm.

10 Alternatively or in addition, the needle may be at  
11 least about 50mm in length.

12 More specifically, the needle may be about 60mm in  
13 length.

14 Alternatively or in addition, the needle may have a  
15 sharp tip portion, i.e. a tip portion configured to break  
16 the skin of the human or animal body.

17 Alternatively, the needle may have a blunt tip  
18 portion, i.e. a tip portion configured to reduce the  
19 likelihood of the tip portion breaking the skin of the  
20 human or animal body.

21 Alternatively or in addition, at least a part of a  
22 surface of the needle may be configured to promote  
23 scarring of tissue at the site of insertion of the needle  
24 on the human or animal body. In use, this helps  
25 development of a fistula track suitable for subsequent  
26 repeated use.

27 More specifically, at least a portion of the surface  
28 of the needle may be rough.

29 Alternatively, the needle may have a substantially  
30 smooth surface.

31 Further embodiments of the fourth aspect of the  
32 present invention may include at least one feature of the  
33 first to third aspects of the present invention.

1 According to a further aspect of the present  
2 invention there is provided a method of gaining access to  
3 a site on a human or animal body by a needle, the method  
4 comprising the steps of: locating a needle guide of a  
5 needle guidance apparatus in relation to a site on the  
6 human or animal body; bringing a needle into cooperation  
7 with the needle guide; and moving the needle at a  
8 predetermined angle in relation to the needle guide to  
9 gain access to the said site, in which the needle guide  
10 is configured for said method steps.

11 Embodiments of the further aspect of the present  
12 invention may comprise one or more features of the  
13 previous aspects of the present invention.

14

15 Brief description of drawings

16

17 Further features and advantages of the present  
18 invention will become apparent from the following  
19 specific description, which is given by way of example  
20 only and with reference to the accompanying drawings, in  
21 which:

22 Figure 1 is a perspective view of the needle guide  
23 of the present invention;

24 Figure 2 is a plan view of the needle guide shown in  
25 Figure 1;

26 Figure 3 is an end view of the needle guide of  
27 Figure 1;

28 Figure 4 is a side view of the needle guide of  
29 Figure 1;

30 Figures 5A to 5C are cross-sectional views through  
31 different embodiments of a channel of the needle guide of  
32 Figures 1 to 4;



1        Figure 6 is a perspective view of a needle of the  
2 needle guidance apparatus of the present invention; and

3        Figure 7 is a schematic of a hinge used in an  
4 embodiment of the needle guide of the present invention.

5

6        Specific description

7

8        A needle guide 10 of needle guidance apparatus  
9 according to the present invention is shown in Figure 1.  
10 The needle guide has two wing-shaped flaps 12, 14  
11 extending laterally of a main body 16 that defines a  
12 channel 18 (which constitutes a needle guiding profile).  
13 The two flaps 12, 14 and main body 16 together constitute  
14 a body engaging component. The underside of the body  
15 engaging component (not shown in Figure 1) defines a body  
16 engaging surface. Also, the two flaps 12, 14 constitute  
17 registration components and the leading edges 20 of the  
18 two flaps 12, 14 constitute registration profiles. As  
19 will become apparent from the description of use of the  
20 apparatus, which can be found below, other parts (e.g.  
21 the trailing edges) of the two flaps 12, 14 can  
22 constitute registration profiles.

23        The needle guide 10 is a unitary body made of a  
24 plastics material that provides for friction between the  
25 needle guide and the skin of a human or animal subject.  
26 Also, the plastics material is of a kind that is  
27 biocompatible with the skin of the human or animal  
28 subject.

29        Figures 2 to 4 provide plan, end and side views of  
30 the needle guide 10 shown in Figure 1. The needle guide  
31 of Figures 2 to 4 has components identified above with  
32 reference to Figure 1 and thus the reader's attention is  
33 directed to the immediately preceding two paragraphs for

1 a description of components common to Figure 1 and to  
2 Figures 2 to 4. Components of Figures 2 and 3 not  
3 already described with reference to Figure 1 will now be  
4 described with reference to each of Figures 2 and 3 in  
5 turn.

6 Figure 2 shows the needle guide in plan view. A  
7 finger pad 22 is provided distally of each of the two  
8 flaps 12, 14. Each finger pad has ridges 24, which  
9 provide a grip for a finger of a user, e.g. the  
10 clinician, during use of the needle guide.

11 Figure 3 shows an end view of the needle guide 10.  
12 As can be seen from Figure 3 the two flaps 12, 14 and  
13 main body 16 comprise an arcuate portion 26. In use, the  
14 arcuate portion 26 provides for the spacing apart of the  
15 main body 16 from the skin of the human or animal  
16 subject. This can be useful where the needle guide 10 is  
17 being located over a raised part of the skin of the human  
18 or animal subject, such as a raised part created by a  
19 fistula located under the skin. The wing shaped flaps  
20 12, 14 are pliable. This enables the needle guide to be  
21 used with differently shaped parts of a human or animal  
22 body, such as the forearm or leg, or indeed with  
23 differently sized parts of different human or animal  
24 bodies, such as forearms of different shape or size. In  
25 an un-illustrated embodiment, each of the two flaps 12,  
26 14 is hinged in relation to the main body 16. The hinge  
27 may be formed by a conventional hinge mechanism or by  
28 means of a thin connecting member between each flap and  
29 the main body, with the thin connecting member being  
30 capable of repeated bending.

31 As can be seen from Figures 1 to 3, the main body 16  
32 of the needle guide 10 defines a straight channel 18,  
33 which defines a predetermined angle in relation to the



1 underside of the main body 16. Normally, the straight  
2 channel 18 defines an angle of 45 degrees, where access  
3 is to be gained to a graft, and 30 degrees, where access  
4 is to be gained to a fistula. Thus, the channel 18 is  
5 used to insert a needle at a 45 degree angle or a 30  
6 degree angle, as appropriate, into the skin of the human  
7 or animal body. However, if a fistula is superficial or  
8 if the shape of the human or animal body so requires it,  
9 the straight channel 18 may define an angle of 25 degrees  
10 or less. In un-illustrated embodiments of the needle  
11 guide the main body 16 defines two or more channels,  
12 which are of different lengths, diameters or of different  
13 angles in relation to the underside of the main body.  
14 Channels of different lengths provide for different  
15 depths of penetration of the human or animal body by  
16 needles used in cooperation with the needle guide.  
17 Channels of different diameters provide for use of  
18 needles of different gauges in cooperation with the  
19 needle guide. Channels of different angles provide for  
20 the insertion of needles at different angles into the  
21 human or animal subject.

22 Figures 5A to 5C provide cross-sectional views  
23 through different embodiments of channel 18 of the needle  
24 guide of Figures 1 to 4.

25 As shown in Figure 5A the channel 18 is of semi-  
26 circular cross-section.

27 In an alternative embodiment shown in Figure 5B the  
28 channel 18 defines a near complete circle in cross-  
29 section to provide a gap 30. The gap 30 allows for  
30 removal of a needle from the channel 18 where the needle  
31 is of a kind having a diameter that is just less than the  
32 diameter of the channel towards the inserted end of the  
33 needle and less than the width of the gap away from the

1 inserted end of needle. For example, the needle may be  
2 of a kind that tapers away from its inserted end.

3 In a further alternative embodiment shown in Figure  
4 5C the channel 18 defines a complete circle in cross-  
5 section. The channel is enclosed by frangible components  
6 32, 34, which can be broken away from main body 16 to  
7 allow for removal of a needle from the channel 18.  
8 Alternatively hinged components 32, 34 can be provided  
9 instead of the frangible components. The hinged  
10 components 32, 34 hinge at the point where they join the  
11 main body 16 to provide for their re-use.

12 Figure 6 provides a perspective view of a needle  
13 arrangement 50 of the needle guidance apparatus of the  
14 present invention. The needle arrangement 50 comprises a  
15 conduit 52, used for example during dialysis, a pair of  
16 flaps 54 and a needle 56. When the needle 56 has been  
17 properly inserted into the human or animal subject the  
18 flaps 54 are rotated apart from each other and used to  
19 hold the needle arrangement in place on the subject, e.g.  
20 by means of surgical tape bridging each flap 54 and the  
21 skin of the subject or similar such means of keeping the  
22 device in place. The needle 56 shown in Figure 6 has a  
23 sharp tip 58, which is used to break the skin of the  
24 subject upon first use and during fistula development.  
25 The needle 56 also has a number of spaced apart ridges 60  
26 towards the sharp tip 58. The ridges 60 provide a rough  
27 surface to the needle that promotes scarring of the  
28 tissue of the subject, which helps to develop formation  
29 of the fistula track. The ridges are also spaced apart  
30 from each other by a predetermined amount and are colour  
31 coded or incrementally numbered to provide visual  
32 feedback to the user, e.g. the clinician, of the extent



1 to which the needle is inserted into the human or animal  
2 body.

3 When a fistula track has developed, a second (un-  
4 illustrated) needle is used. The second needle is the  
5 same as the needle shown in Figure 6, with the exceptions  
6 that it has a blunt tip instead of a sharp tip 58 and a  
7 number of spaced apart coloured marks instead of ridges  
8 60 such that the needle lacks a rough surface. Thus, the  
9 surface of the second needle is substantially smooth. A  
10 sharp tip and surface roughness are not needed on a  
11 needle after a fistula track has been developed. The  
12 second needle is of a smaller gauge than the first needle  
13 to provide for ease of insertion of the second needle  
14 into a developed fistula track.

15 The first 56 and second needles are about 50mm in  
16 length.

17 Use of the needle guide and the needle arrangement  
18 will now be described with reference to Figures 1 to 6.  
19 The needle guide 10 is placed over the fistula present in  
20 the human or animal subject making use of the arcuate  
21 portion 26 where the fistula raises part of the skin of  
22 the subject. The pliability of the two flaps 12, 14  
23 enables the user, e.g. a clinician, to conform the flaps  
24 to the shape of the part of the subject, e.g. forearm,  
25 bearing the fistula. Using an indelible marker pen  
26 reference marks are drawn on the skin of the subject  
27 using the leading edges 20 of the two flaps 12, 14 as a  
28 guide for the pen. The reference marks on the skin  
29 enable the needle guide to be removed and subsequently  
30 replaced on the subject in the same location ready for  
31 re-use. The needle 56 of a sharp tipped needle  
32 arrangement 50 is introduced into the upper end of the  
33 channel 18 of the needle guide 10 and the needle 50 moved

1 through the channel until it breaks the skin. The needle  
2 is inserted into the subject to the required depth as  
3 indicated by the ridges 60 and the depth noted for  
4 subsequent use. The needle 56 is disengaged from the  
5 needle guide 10 as described above with reference to  
6 Figures 5A to 5C and the needle guide is removed from the  
7 subject. The needle 56 is then held in place on the  
8 subject by means of the flaps 54 as described above.

9 During subsequent uses of the needle guidance  
10 apparatus sufficient to develop the fistula track, the  
11 needle guide is located on the subject using the  
12 reference marks on the subject's skin and the needle  
13 arrangement 50 used as described in the immediately  
14 preceding paragraph. When the fistula track is properly  
15 developed the needle guidance apparatus can be used when  
16 required by making use of the needle guide 10 and the  
17 version of needle arrangement comprising the second  
18 needle, which has the blunt tip and the substantially  
19 smooth surface.

20 An embodiment of the present invention is shown in  
21 part in Figure 7. The embodiment provides for movement  
22 of the channel 18 of the embodiment shown in Figures 1 to  
23 3 in relation to the main body 16 of the embodiment of  
24 Figures 1 to 3. As shown in Figure 7, the embodiment  
25 comprises a hinge arrangement 80 having a hinge 82 that  
26 provides for relative rotational movement of first and  
27 second parts 84, 86. The first part 84 forms part of the  
28 main body 16 and the second part 86 supports the channel  
29 18. The hinge arrangement 80 also comprises an arm 88  
30 that is rotatably connected at one end to the second part  
31 86 distally of the hinge 82. The opposing free end 89 of  
32 the arm 88 is shaped to engage with a series of spaced  
33 apart teeth 90 that are mounted on the first part 84 so



1 as to define an upwardly sloping stepwise progression of  
2 teeth. In use, the free end 89 engages with a particular  
3 tooth and sets the angle of the channel 18 with the main  
4 body 16. The teeth are shaped to resist an unintended  
5 reduction in the angle as might be caused by a clinician  
6 applying pressure accidentally to the channel 18 or the  
7 second part 86, which bears the channel 18. The angle  
8 between the channel 18 and the main body 16 can be  
9 increased by pushing the arm 88 such that the free end 89  
10 engages with the next tooth in the upward slope. The  
11 angle between the channel 18 and the main body 16 can be  
12 deliberately reduced by rotating the second part 86 away  
13 from the first part 84 such that the free end 89  
14 disengages from the teeth, whereby the first and second  
15 parts 84, 86 can then be moved together again whilst  
16 positioning the arm 88 such that it engages with a tooth  
17 90 further down the slope defined by the teeth.

18 The embodiment of Figure 7 enables the clinician to  
19 set an acute angle between the channel 18 and the main  
20 body 16 while the needle guide 10 is moved into position  
21 on a patient's body. The setting of an acute angle  
22 reduces the likelihood of a needle held in the channel 18  
23 inadvertently breaking the patient's skin. When the  
24 needle guide 10 is in position the angle between the  
25 channel 18 and the main body can be increased as  
26 described above and as desired by the clinician before  
27 the needle is used to access a fistula under the  
28 patient's skin.

29 Aside from the above description of the first and  
30 second needles and their use with fistulae, needles  
31 having graduations disposed along their bodies have wider  
32 application as will now be described. The graduations  
33 are spaced from one another by about 5mm. Four types of

1 needle find use with grafts and fistulae. In all four  
2 types of needle the graduations are configured to  
3 indicate the orientation of the bevelled aperture of the  
4 needle. Also, all four types of needle have an eye in  
5 the back of the needle that provides for a flow of blood  
6 through the needle and thus through a fistula or graft,  
7 e.g. during dialysis. Furthermore, all four types of  
8 needle comprise a pair of flaps 54 as described above  
9 with reference to Figure 6.

10 The first type of needle has a smooth surface, a  
11 sharp tip and is of a length of about 50mm. This type of  
12 needle is used to access a graft using the above  
13 described needle guide 10 or to access deep grafts  
14 without the needle guide. More specifically, graduations  
15 are provided along the body of the needle as coloured  
16 marks such that they form no protrusions or concavities  
17 in the surface of the needle. The smooth surface  
18 minimises damage to the graft during needle entry. The  
19 sharp tip provides for a small size of puncture to the  
20 graft. In use, ultrasound is used to determine the depth  
21 of the graft below the surface of the skin. When the  
22 needle is inserted, the extent to which the needle is  
23 received in the body is monitored by means of the  
24 graduations vis-à-vis the depth of the graft to which  
25 access is being gained by the needle. If the needle has  
26 been advanced to the depth determined by ultrasound but  
27 the graft has not been penetrated, then there is a  
28 problem with the procedure and a risk presented of  
29 causing damage to the tissue. Thus, the needle should be  
30 withdrawn and the procedure repeated at another location.

31 The second type of needle has a rough surface, a  
32 sharp tip and is of a length of about 50mm. The second  
33 type of needle is used along with the needle guide 10 to



1 access fistulae and create buttonholes or without the  
2 needle guide to access deep fistulae. The graduations  
3 are etched into the surface of the needle such that they  
4 present a rough surface to the tissue upon insertion of  
5 the needle. The rough surface provided by the  
6 graduations and a lack of coating over the needle surface  
7 causes scarring of the tissue, which aids track  
8 development. The graduations enable the needle to be  
9 inserted to the same depth on each use. This aids  
10 development of the track along its entire length and  
11 reduces tapering of the track towards the fistula.

12 The third type of needle has a smooth surface, a  
13 blunt tip and is of a length of about 50mm. This type of  
14 needle is used to access buttonholes using the needle  
15 guide 10 or to access deep fistulae without the needle  
16 guide. The blunt tip minimises damage to the track as  
17 the needle moves along the track to the fistula. The  
18 graduations provide the means to determine that the  
19 needle is inserted to the correct depth. The smooth  
20 surface of the needle and the formation of the  
21 graduations such that they form no protrusions or  
22 concavities in the surface of the needle minimises damage  
23 to the fistula during needle entry.

24 The fourth type of needle has a smooth surface, a  
25 blunt tip and is of a length of about 25mm. The fourth  
26 type of needle is used to access buttonholes without the  
27 needle guide 10. The fourth type of needle is as per the  
28 third type of needle, with the exception that the needle  
29 has a shorter length of about 25mm.

30  
31  
32  
33

## 1 CLAIMS:

2

3 1. A needle guidance apparatus comprising a needle  
4 guide configured for location in relation to a site on  
5 the human or animal body and being further configured to  
6 cooperate with a needle such that the needle is moveable  
7 at a predetermined angle in relation to the needle guide.

8

9 2. Apparatus according to claim 1, in which the needle  
10 guide is configured such that the predetermined angle is  
11 between substantially 40 degrees and substantially 50  
12 degrees.

13

14 3. Apparatus according to claim 2, in which the needle  
15 guide is configured such that the predetermined angle is  
16 substantially 45 degrees.

17

18 4. Apparatus according to any preceding claim, in which  
19 the needle guide is configured such that the  
20 predetermined angle is between substantially 20 degrees  
21 and substantially 40 degrees.

22

23 5. Apparatus according to claim 4, in which the needle  
24 guide is configured such that the predetermined angle is  
25 substantially 30 degrees.

26

27 6. Apparatus according to any preceding claim, in which  
28 the needle guide has a needle guiding profile configured  
29 to cooperate with a needle and to guide movement of the  
30 needle in relation to the needle guide.

31



1 7. Apparatus according to claim 6, in which the needle  
2 guiding profile defines a channel configured to receive a  
3 needle.

4

5 8. Apparatus according to claim 7, in which the channel  
6 is substantially semi-circular in cross-section.

7

8 9. Apparatus according to claim 7 or 8, in which the  
9 channel is substantially "U" shaped in cross-section.

10

11 10. Apparatus according to any of claims 7 to 9, in  
12 which the channel defines a near complete circle in  
13 cross-section along at least part of its length.

14

15 11. Apparatus according to any of claims 7 to 10, in  
16 which the channel defines a complete circle in cross-  
17 section along at least part of its length.

18

19 12. Apparatus according to claim 11, in which the needle  
20 guide comprises at least one channel closing component  
21 configured to be moved in relation to the channel from a  
22 first position in which the channel defines a complete  
23 circle along at least part of its length to a second  
24 position in which the needle can be removed from the  
25 channel.

26

27 13. Apparatus according to claim 12, in which the  
28 channel closing component is frangible.

29

30 14. Apparatus according to claim 12 or 13, in which the  
31 channel closing component is hingedly attached to the  
32 needle guide.

33

1 15. Apparatus according to any preceding claim, in which  
2 the needle guide comprises a body engaging component  
3 configured to engage with the human or animal body.  
4

5 16. Apparatus according to claim 15, when depending from  
6 any one of claims 6 to 15, in which the body engaging  
7 component is configured and the needle guiding profile  
8 disposed in relation to the body engaging component to  
9 provide for at least one predetermined attitude of the  
10 needle guiding profile in relation to the body engaging  
11 component.  
12

13 17. Apparatus according to claim 16, in which the needle  
14 guiding profile is configured to provide for a plurality  
15 of predetermined attitudes of the needle guiding profile  
16 in relation to the body engaging component.  
17

18 18. Apparatus according to any one of claims 6 to 17, in  
19 which the needle guiding profile is configured to receive  
20 needles of different gauges.  
21

22 19. Apparatus according to claim 18, in which the needle  
23 guiding profile defines a plurality of channels of  
24 different diameters.  
25

26 20. Apparatus according to claim 18 or 19, in which the  
27 needle guide comprises a plurality of channels of  
28 different diameters.  
29

30 21. Apparatus according to claim 20, in which the  
31 channels are at least one of: spaced apart from each  
32 other laterally of a direction of movement of a needle in



1 a channel; and disposed substantially co-axially of each  
2 other.

3

4 22. Apparatus according to any of claims 16 to 21, in  
5 which the needle guide is configured so as to permit  
6 alteration of the at least one predetermined attitude of  
7 the needle guiding profile in relation to the body  
8 engaging component.

9

10 23. Apparatus according to claim 22, in which the needle  
11 guiding profile is movable in relation to the body  
12 engaging component.

13

14 24. Apparatus according to claim 23, in which the needle  
15 guiding profile is rotatable in relation to the body  
16 engaging component.

17

18 25. Apparatus according to claim 24, in which the needle  
19 guide comprises a hinge configured to provide for  
20 rotation of the needle guiding profile in relation to the  
21 body engaging component.

22

23 26. Apparatus according to any one of claims 22 to 25,  
24 in which the needle guide is configured so as to permit  
25 stepwise alteration of the at least one predetermined  
26 attitude of the needle guiding profile in relation to the  
27 body engaging component.

28

29 27. Apparatus according to any one of claims 22 to 26,  
30 in which the needle guide is configured to resist an  
31 unintended reduction of a predetermined attitude of the  
32 needle guiding profile whilst permitting an intended  
33 increase in the predetermined attitude.

1

2 28. Apparatus according to claim 27, in which the needle  
3 guide comprises a ratchet arrangement.

4

5 29. Apparatus according to claim 28, in which the  
6 ratchet arrangement is configured to be releasable to  
7 provide for a reduction in the predetermined attitude of  
8 the needle guiding profile.

9

10 30. Apparatus according to any one of claims 15 to 29  
11 when depending from any one of claims 6 to 14, in which  
12 the body engaging component is configured and the needle  
13 guiding profile is disposed in relation to the body  
14 engaging component to provide for at least one  
15 predetermined limit to the extent to which a needle can  
16 be advanced through the needle guiding profile.

17

18 31. Apparatus according to claim 30, in which the needle  
19 guiding profile is configured to provide for a plurality  
20 of predetermined limits to the extent to which a needle  
21 can be advanced through the needle guiding profile.

22

23 32. Apparatus according to any preceding claim, in which  
24 the needle guide is suitable for temporary location on  
25 the human or animal body and further comprises a  
26 registration profile configured for locating the needle  
27 guide in registration with the site on the human or  
28 animal body.

29

30 33. Apparatus according to claim 32, in which the needle  
31 guide comprises a registration component comprising said  
32 registration profile, the registration component being  
33 configured for cooperation with the human or animal body



1 so as to provide for registration of the registration  
2 profile with a location on the human or animal body.

3

4 34. Apparatus according to claim 32 or 33, in which the  
5 needle guidance apparatus comprises a main body, which is  
6 configured to cooperate with the needle, and at least one  
7 registration component having a registration profile.

8

9 35. Apparatus according to claim 34, in which the at  
10 least one registration component extends from the main  
11 body.

12

13 36. Apparatus according to claim 35, in which the needle  
14 guidance apparatus comprises two registration components  
15 extending in opposite directions from the main body.

16

17 37. Apparatus according to any preceding claim, in  
18 which, where the needle guide comprises a body engaging  
19 component suitable for engaging with the human or animal  
20 body, the body engaging component comprises a body  
21 engaging surface configured to be brought into contact  
22 with the skin of the human or animal body.

23

24 38. Apparatus according to claim 37, in which the body  
25 engaging component has a profile configured to permit  
26 positioning of the needle guide over a raised part of the  
27 skin of the human or animal body.

28

29 39. Apparatus according to claim 38, in which the body  
30 engaging component comprises an arcuate portion.

31

32 40. Apparatus according to any of claims 37 to 39, in  
33 which the body engaging component is configured for use

1 with differently shaped parts of the human or animal  
2 body.

3

4 41. Apparatus according to any of claims 37 to 40, in  
5 which the body engaging component is pliable.

6

7 42. Apparatus according to any of claims 37 to 41, in  
8 which the body engaging component is comprised at least  
9 in part of a plastics material.

10

11 43. Apparatus according to any of claims 37 to 42, in  
12 which the body engaging component comprises hinged  
13 components configured to conform to differently shaped  
14 human or animal bodies.

15

16 44. Apparatus according to claim 43, in which a main  
17 body of the needle guide is less pliable than the hinged  
18 components.

19

20 45. Apparatus according to any of claims 37 to 43, in  
21 which the body engaging component comprises at least in  
22 part at least one of polypropylene (PP), polyphenylene  
23 sulphide (PPS) and polymethylpentane (PMP).

24

25 46. Apparatus according to any preceding claim, in which  
26 the needle guide is comprised at least in part of a  
27 plastics material.

28

29 47. Apparatus according to any preceding claim, in which  
30 the needle guide is a unitary body.

31



1 48. Apparatus according to any preceding claim, in which  
2 the apparatus is configured for attachment to a  
3 tourniquet.  
4

5 49. Apparatus according to any preceding claim, in which  
6 the needle guidance apparatus further comprises at least  
7 one needle configured to cooperate with the needle guide.  
8

9 50. Apparatus according to claim 49, in which the at  
10 least one needle has a plurality of graduations spaced  
11 apart along the needle.  
12

13 51. Apparatus according to claim 50, in which the  
14 plurality of graduations comprises at least one of a  
15 coloured mark, engraved feature, a protrusion and other  
16 such visible feature.  
17

18 52. Apparatus according claim 50 or 51, in which the  
19 plurality of graduations are spaced apart from one  
20 another by less than or equal to substantially 5mm.  
21

22 53. Apparatus according to any of claims 49 to 52, in  
23 which the needle comprises a bevelled aperture and at  
24 least one of the plurality of graduations is disposed on  
25 at least one of a hilt of the needle and the needle  
26 itself so as to indicate an orientation of the bevelled  
27 aperture.  
28

29 54. Apparatus according to any of claims 49 to 53, in  
30 which the at least one needle comprises an aperture  
31 formed in a rear part of the needle.  
32

1 55. Apparatus according to any of claims 49 to 54, in  
2 which the needle comprises at least one member extending  
3 radially of the needle.

4

5 56. Apparatus according to claim 55, in which the at  
6 least one member comprises two members spaced apart  
7 circumferentially round the needle.

8

9 57. Apparatus according to claim 55 or 56, in which the  
10 at least one member is formed of a plastics material.

11

12 58. Apparatus according to any of claims 55 to 58, in  
13 which the at least one member is movable in relation to  
14 the needle.

15

16 59. Apparatus according to claims 58, in which the at  
17 least one member is moveable circumferentially about the  
18 needle.

19

20 60. Apparatus according to claim 59, in which the at  
21 least one member is rotatable about the needle.

22

23 61. Apparatus according to any of claims 55 to 60, in  
24 which the at least one member is attached to the needle  
25 such that the at least one member is moveable in relation  
26 to the needle.

27

28 62. Apparatus according to any of claims 49 to 61, in  
29 which the at least one needle is at least about 50mm in  
30 length.

31



1 63. Apparatus according to any of claims 49 to 62, in  
2 which the at least one needle tapers away from an  
3 insertable end of the needle.

4

5 64. Apparatus according to any of claims 49 to 63, in  
6 which a diameter of the at least one needle at a location  
7 spaced apart from an insertable end of the needle is less  
8 than a diameter of the needle at a location towards the  
9 insertable end of the needle.

10

11 65. Apparatus according to any of claims 49 to 64, in  
12 which a first needle has a tip configured to break the  
13 skin of the human or animal body.

14

15 66. Apparatus according to any of claims 49 to 65, in  
16 which at least a portion of a surface of a first needle  
17 is rough.

18

19 67. Apparatus according to any of claims 49 to 66, in  
20 which the needle guidance apparatus further comprises a  
21 second needle configured to cooperate with the needle  
22 guide.

23

24 68. Apparatus according to claim 67, in which the second  
25 needle has a tip configured to reduce the likelihood of  
26 the tip breaking the skin of the human or animal body.

27

28 69. Apparatus according to claim 67 or 68, in which the  
29 second needle has a substantially smooth surface.

30

31 70. Apparatus according to any of claims 67 to 69, in  
32 which the second needle has a diameter greater than a  
33 diameter of a first needle.

1

2 71. A kit of parts comprising: a needle guide configured  
3 for location in relation to a site on the human or animal  
4 body and being further configured to cooperate with a  
5 needle such that the needle is moveable at a  
6 predetermined angle in relation to the needle guide; and  
7 at least one needle.

8

9 72. Apparatus according to claim 71, in which the kit of  
10 parts comprises a first needle having a sharp tip.

11

12 73. Apparatus according to claim 71 or 72, in which the  
13 kit of parts comprises a second needle having a blunt  
14 tip.

15

16 74. Dialysis apparatus comprising needle guidance  
17 apparatus according to any preceding claim.

18

19 75. A needle suitable for insertion into the human or  
20 animal body, the needle comprising a body, a tip portion  
21 configured to be received in the body first upon  
22 insertion of the needle, and an aperture formed in the  
23 tip portion, in which a plurality of spaced apart  
24 graduations, which are discernible by a human, are  
25 disposed along a part of the body of the needle, the part  
26 of the body being spaced apart from the tip portion.

27

28 76. Apparatus according claim 75, in which further  
29 graduations are disposed on the body of the needle  
30 between the part of the body bearing the plurality of  
31 graduations and the tip portion.

32



1 77. Apparatus according to claim 76, in which the  
2 further graduations are disposed on the tip portion.  
3

4 78. Apparatus according to any of claims 75 to 77, in  
5 which the plurality of graduations comprise at least one  
6 of a coloured mark, engraved feature, a protrusion and  
7 other such humanly discernible feature.  
8

9 79. Apparatus according to any of claims 75 to 78, in  
10 which the plurality of graduations are spaced apart from  
11 one another by less than or equal to substantially 5mm.  
12

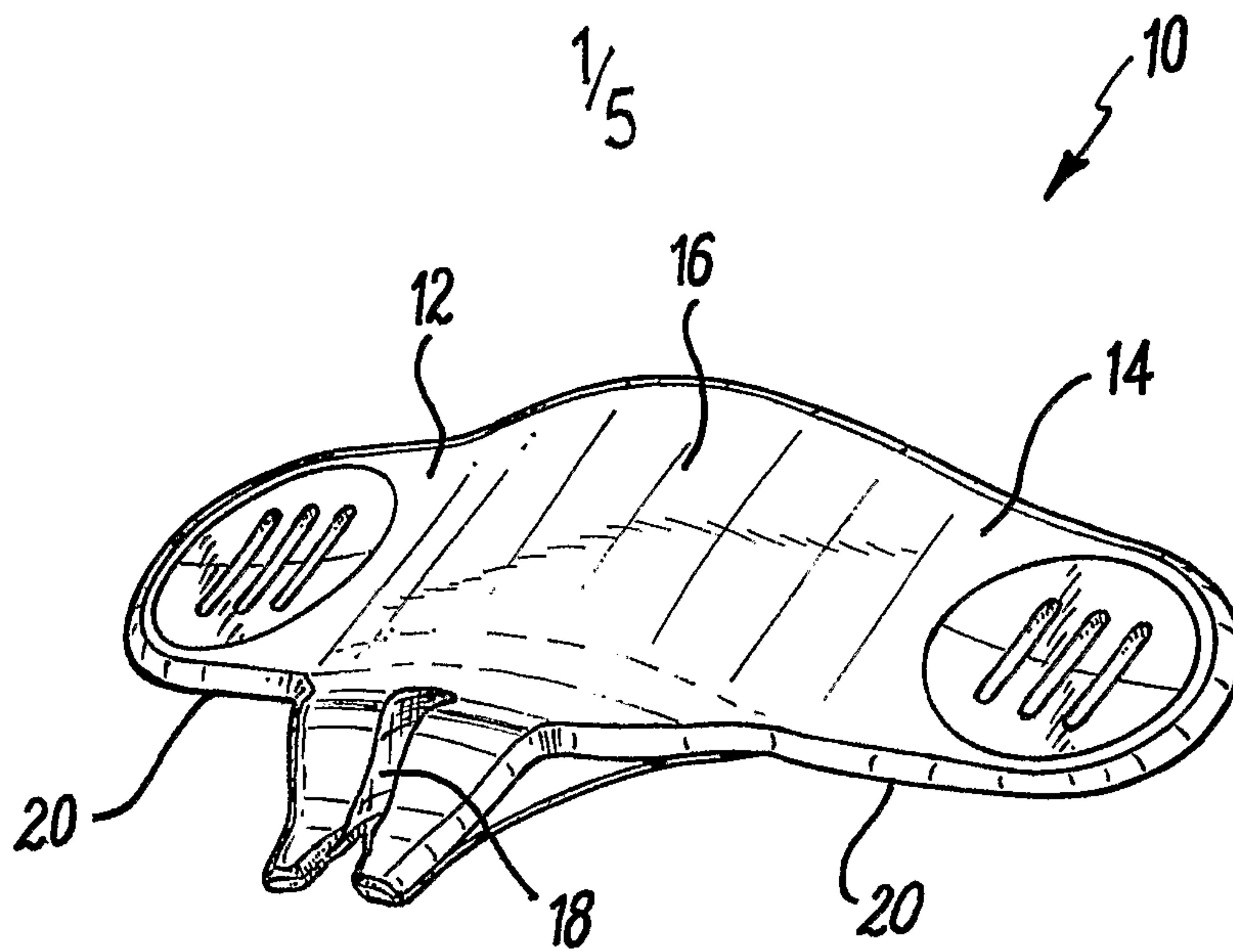
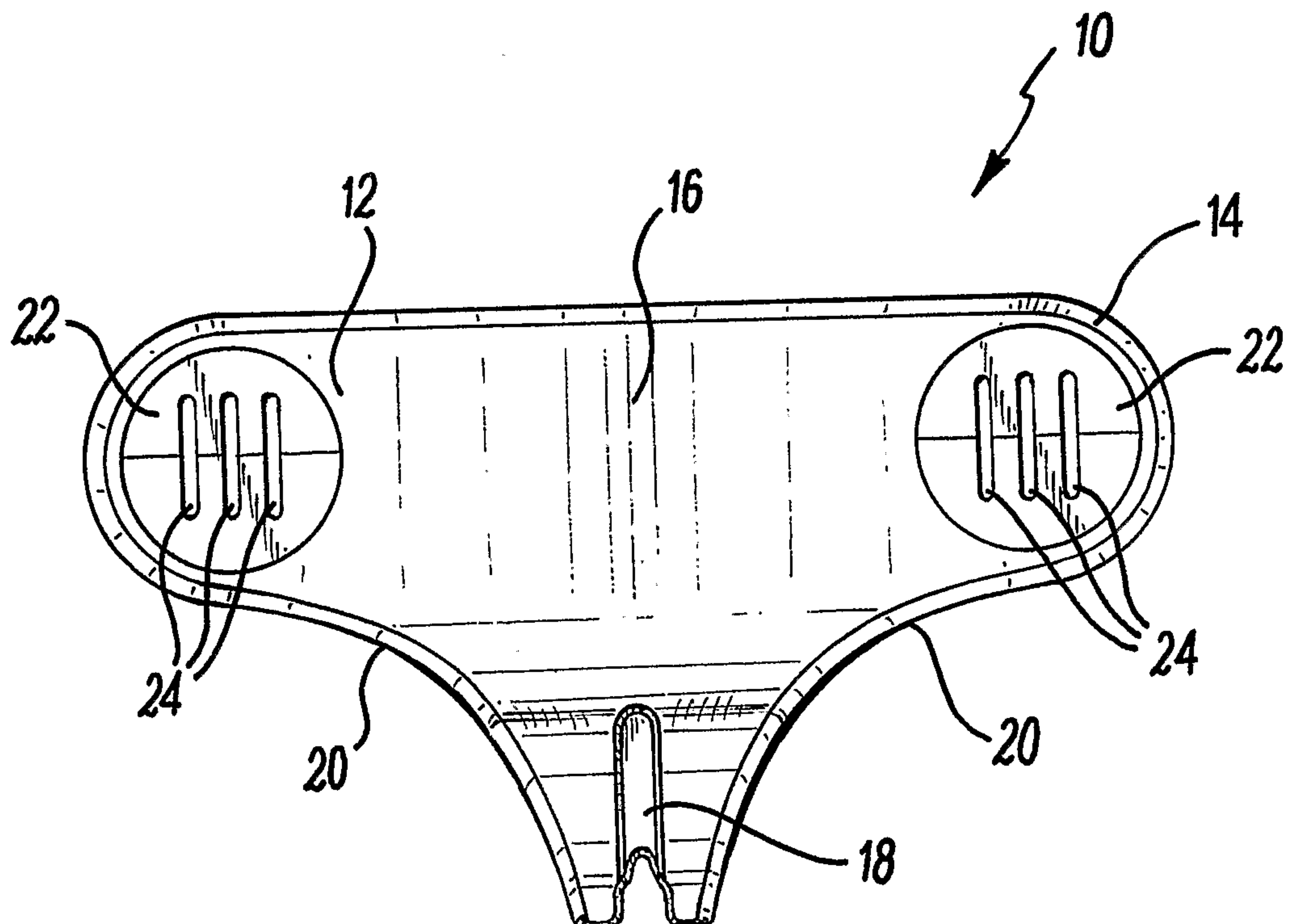
13 80. Apparatus according to any of claims 75 to 79, in  
14 which the needle is at least about 50mm in length.  
15

16 81. Apparatus according to any of claims 75 to 80, in  
17 which the needle has a sharp tip portion.  
18

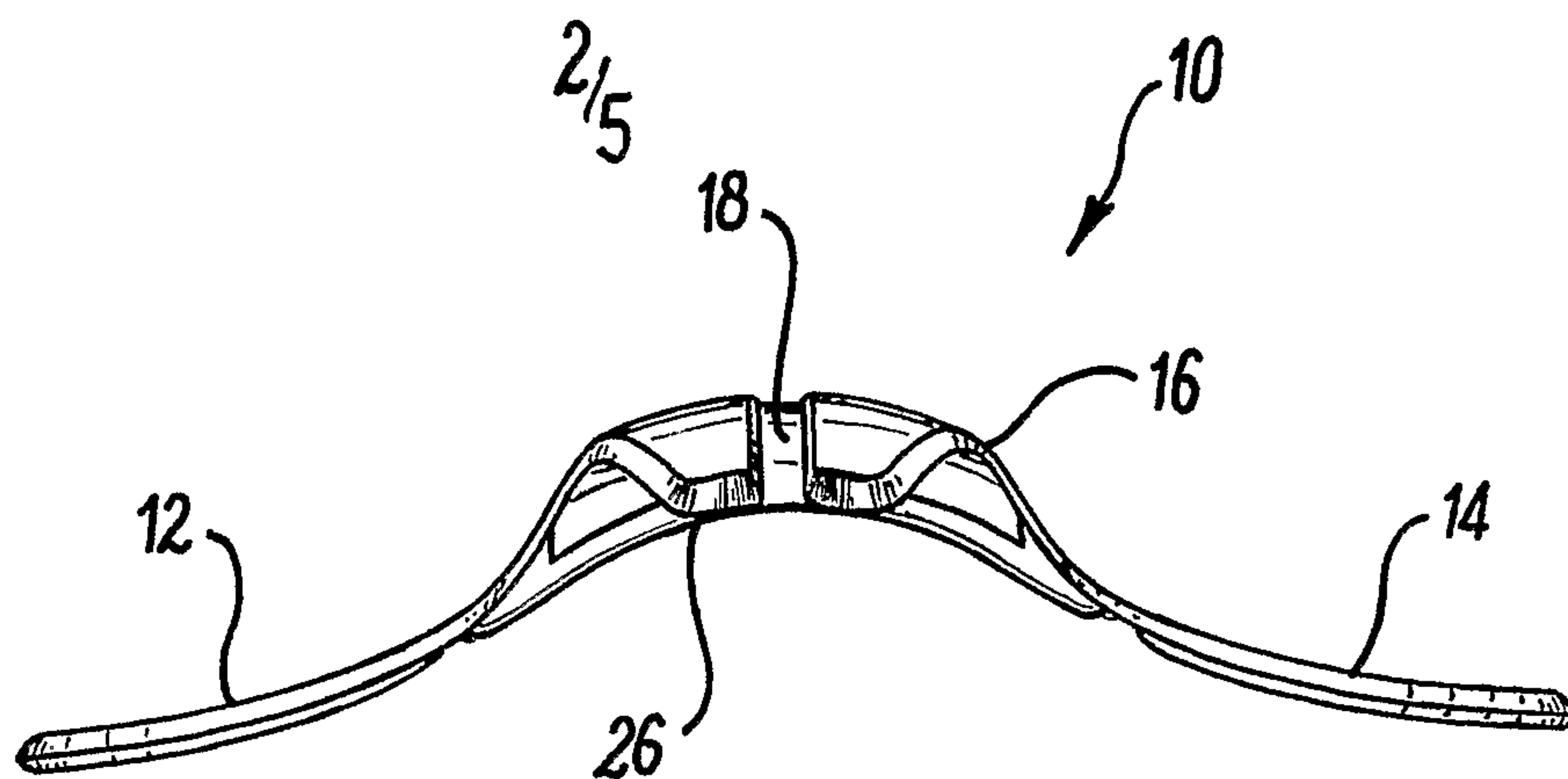
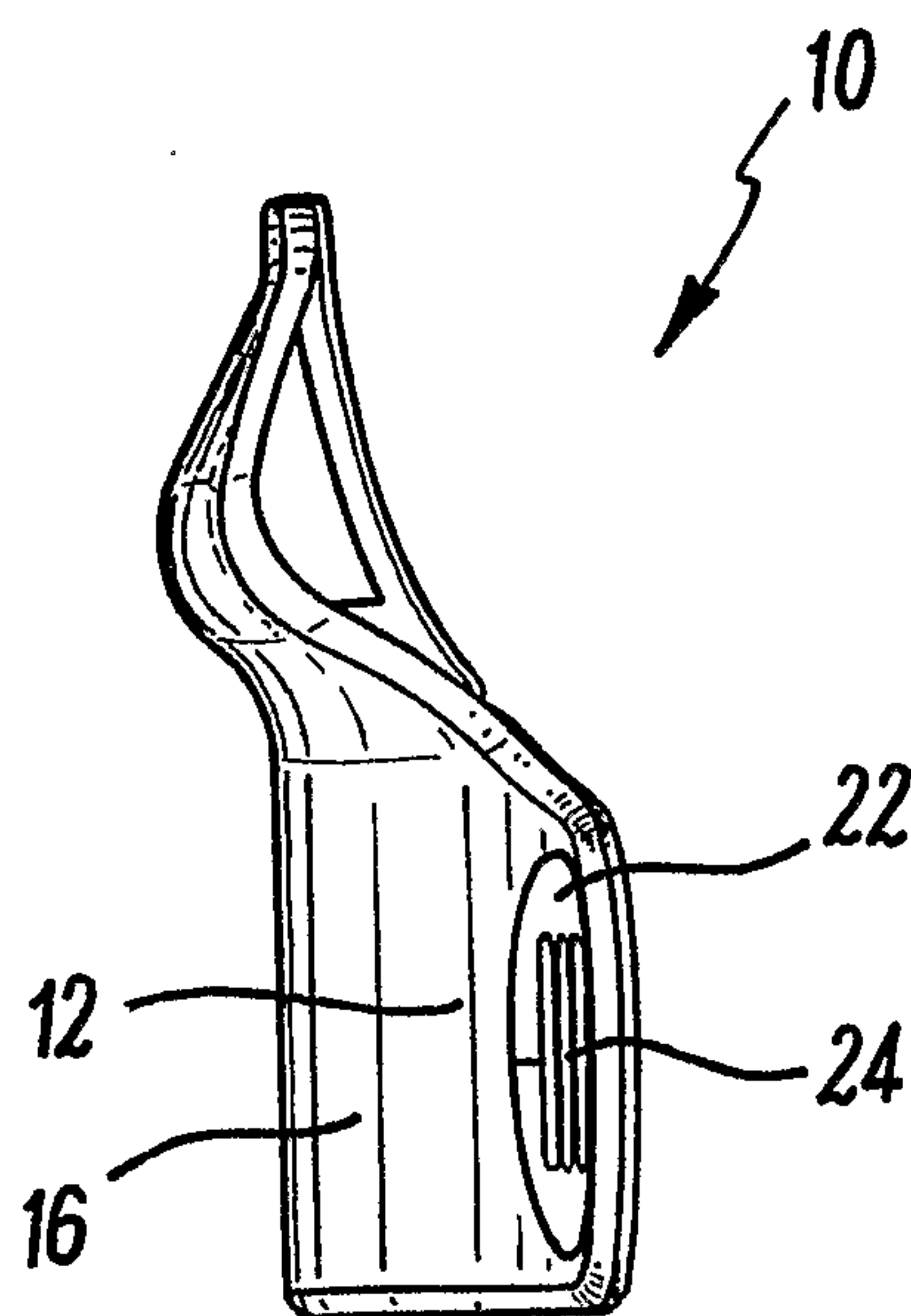
19 82. Apparatus according to any of claims 75 to 81, in  
20 which the needle has a blunt tip portion.  
21

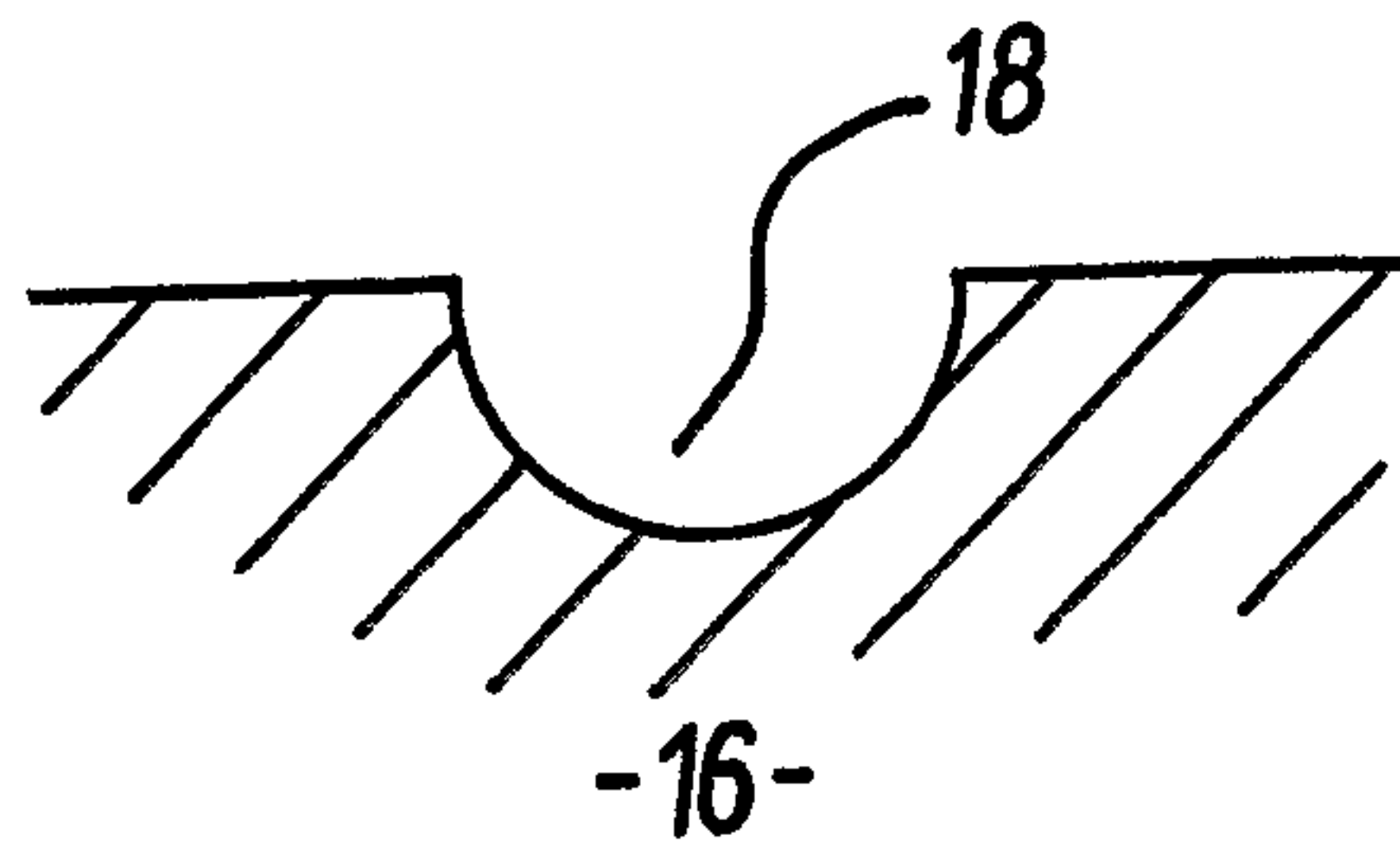
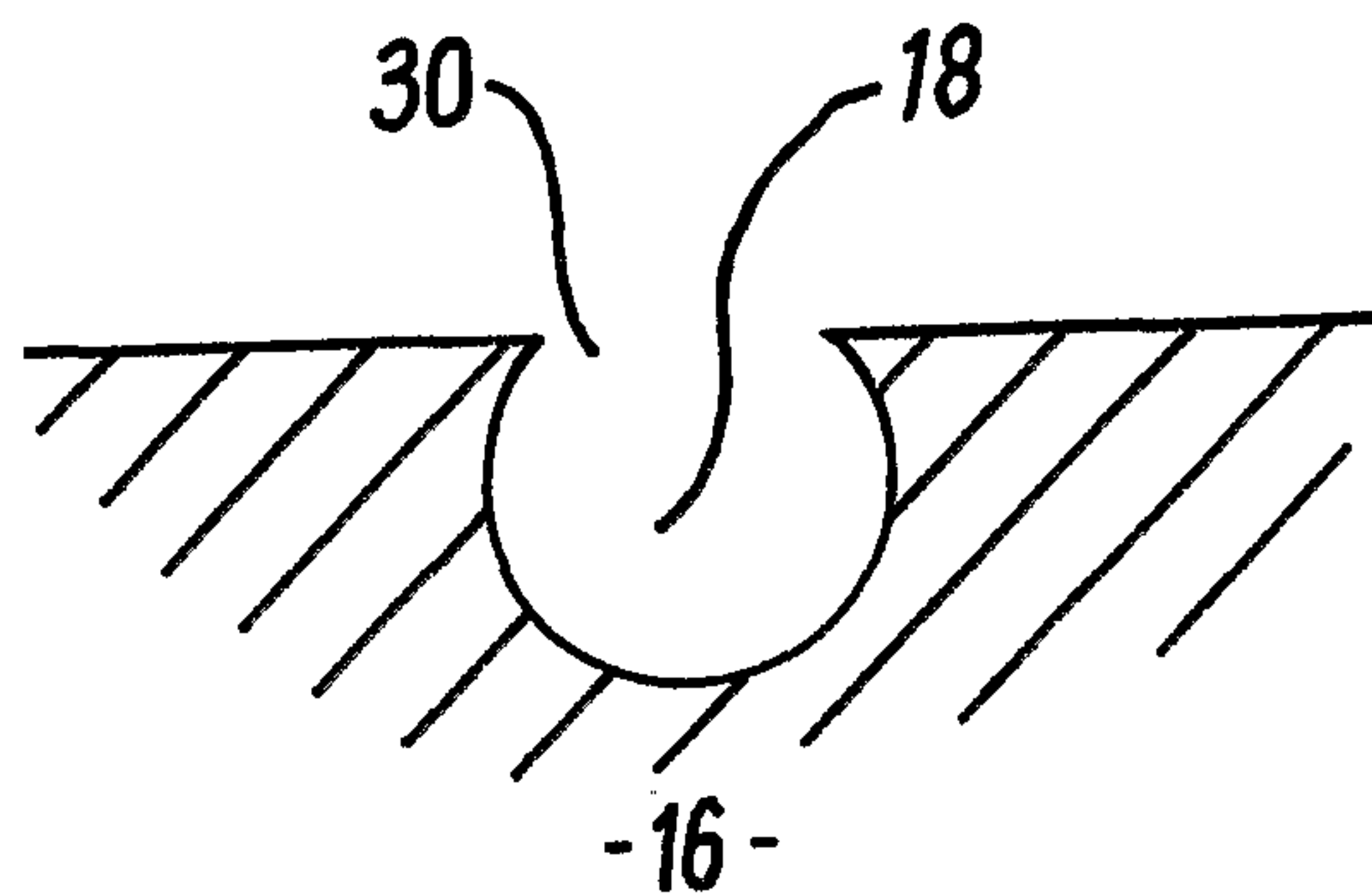
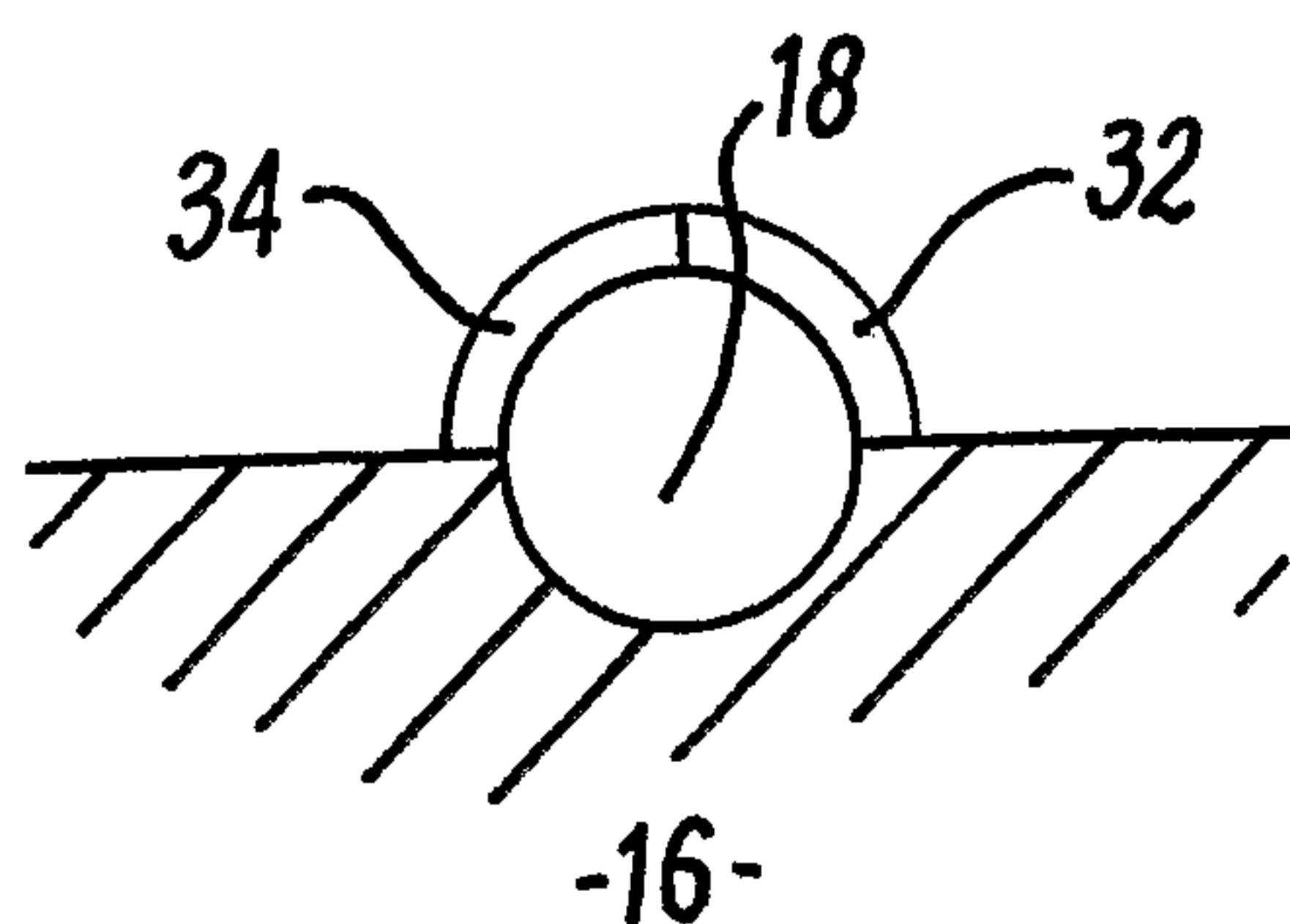
22 83. Apparatus according to any of claims 75 to 82, in  
23 which at least a portion of a surface of the needle is  
24 rough.  
25

26 84. Apparatus according to any of claims 75 to 82, in  
27 which the needle has a substantially smooth surface.  
28  
29  
30  
31  
32  
33

**FIG. 1****FIG. 2**

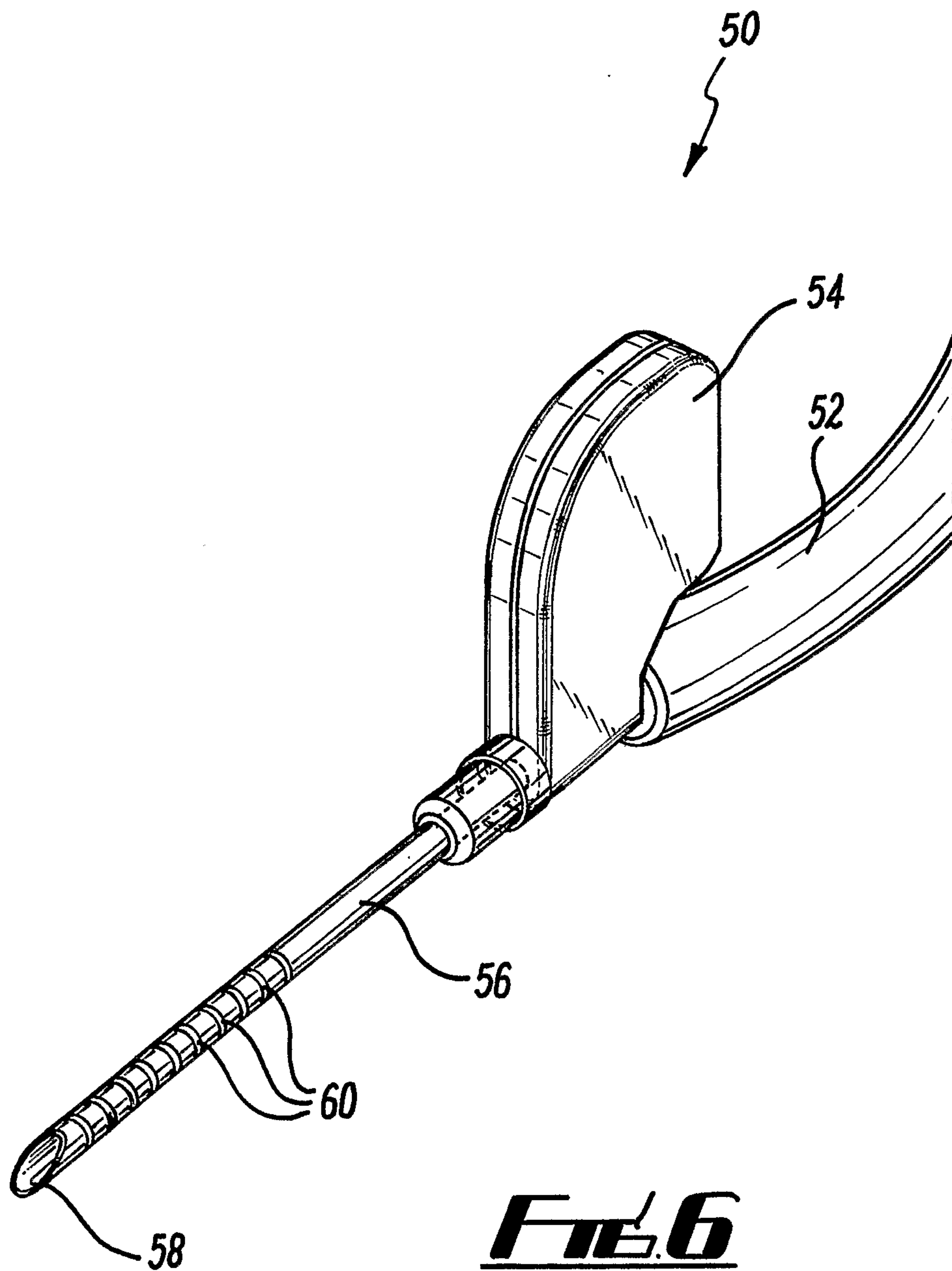


**FIG. 3****FIG. 4**

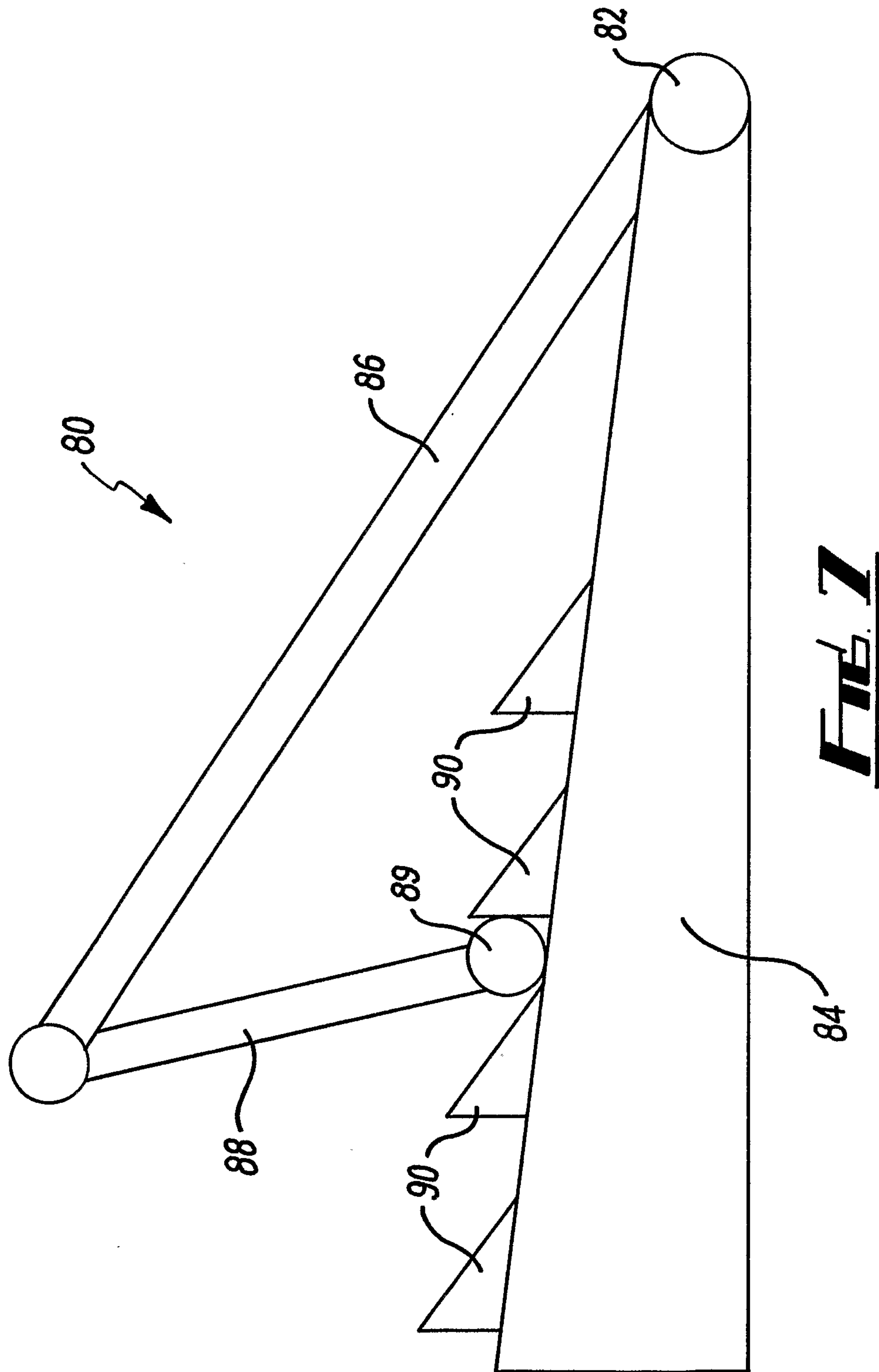
$\frac{3}{5}$ **FIG. 5A****FIG. 5B****FIG. 5C**



4/5



5/5



**Fig. 1**



