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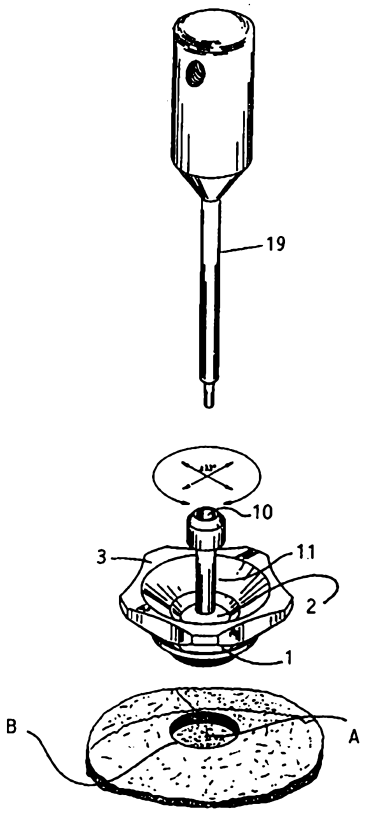
(57) Abstract

The invention concerns a device for adjusting stereotactically and endoscopically located equipment, including pharmaceutical agents, radiation sources and organic material, comprising a holder and a fixing key, where the holder comprises a lower ring (1) with a surface (4) for placing a ball (2) which will form a ball joint, and an upper ring (3) for locking the ball in a specific position, where the ball (2) has a channel for insertion of medical instruments, and where the lower ring (1) has an external threaded surface (8) for direct screwing to an area of a patient's skull. The device is characterized by the fact that the ball's (2) central point, and thereby the ball joint's fulcrum is arranged for positioning on a level with the patient's cranium by means of a groove–like section (20) on the holder which forms an abutment for the ball (2). The invention also concerns a method for adjusting different stereotactically and endoscopically located equipment, including pharmaceutical agents, by means of the device, and application of the method in different contexts.



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DEVICE AND METHOD FOR SETTING STEREOTACTIC AND ENDOSCOPICALLY PLACED EQUIPMENT.

The present invention concerns a device for adjustment of different stereotactically and endoscopically located equipment, including pharmaceutical agents, radiation sources and organic material and a method for adjustment of stereotactically and endoscopically located equipment.

Brain surgery procedures, where precise placement of instruments or other aids is required, are generally performed in several steps:

1. X-rays are taken of the patient.
2. The patient's head is firmly screwed to a frame which is provided with position indicators (stereotactic frame).
3. New X-rays are taken where markers on the frame permit calculations to be performed, thus enabling aids to be inserted into a desired area.
4. The patient is taken to the operating theatre.

An essential condition for the use of all such instrumentation with present day equipment is that the patient's head is fixed to the stereotactic equipment. The frame is usually attached by screws to the skullbone. The head is then fixed by means of arm devices, usually to the operating table.

US-A-4.955.891 concerns a device and a method for performing stereotactic surgery. The method consists in establishing a first, predetermined geometric relationship between a positioning fixture attached both to the skull and to a supporting surface on which the skull is lying. The skull is then scanned in order to provide an image of the target within the skull in relation to the positioning device. This permits the transfer of at least a part of the positioning device to a phantom device and the arrangement of the said part of the positioning device in relation to the phantom device in order to establish a second and predetermined geometric relationship which is identical to the first. The slope of the positioning device which is attached to the skull is doubled in the phantom device. By this means a phantom target can be provided in the phantom device with a location corresponding to the target's position in the skull. This is done by calculating the trajectory and the distance to a medical instrument which extends from the positioning fixture's portion in the skull in the same position in which it was originally attached. The calculation is based on providing a carrier member, arc

member and instrument guide member in the positioning device and inserting the medical instrument through the guide member, whereupon it meets the skull before striking the target area at a specific calculated depth.

In order to implement this method the equipment is passed through a positioning fixture in a trajectory determined by a trajectory ball. The trajectory ball is placed inside a ball holder, which is secured in a skull plate and this in turn is secured to the skull. The ball holder is rotatable relative to the skull plate. This device, however, has several drawbacks: it requires a large operating area; it requires the use of several loose parts (screws for attachment to the skull); and it is expensive to produce, thus having a high retail price. The ball joint's centre is disposed outside the skull's outer surface, resulting in an extremely restricted radius of action (which is restricted only in the path's longitudinal direction) for this medical instrument. This equipment is also impractical due to its large size which makes the use of various instruments more difficult.

US-A-5.263.956 concerns a device for use in neurosurgery. A ball joint is arranged to hold a neurosurgery tool in a predetermined orientation relative to the patient's skull. A plate with sharpened corners is placed against the skull. The plate has a recess in which a ball joint is placed. A bore passes through the ball joint, permitting the introduction of neurosurgery equipment. The ball can be rotated, thus enabling the orientation of the neurosurgery probe to be adjusted relative to the skull. Screws are used to hold the neurosurgery probe stationary relative to the plate. A ball holder ring holds the ball against the plate. The device has several disadvantages in use, including the fact that it comprises several loose parts (including small screws) and the mechanism fixing the ball in position is a screw which grips the ball. This makes the equipment difficult to handle, and the screw can easily be lost. The devices for securing the ring to the skull are not adequate to ensure the absence of relative movements. The main drawback of this device is that the radius of action is severely restricted, since the ball's central point is located outside the area defined by the cranium.

US-A-4.681.103 discloses a guiding device for ultrasound adjustment of surgical instruments. The device consists of an adaptor housing which is securely screwed to the skull and which has a longitudinal opening through which instruments are passed. For screwing purposes the device is provided

with a gripping surface which is held by the fingers. Such an attachment mechanism makes the device difficult to secure on those areas of the head where there is very little room round the adaptor housing (e.g. near shoulders and at the back of the head).

At the same time it is difficult to exercise sufficient force when screwing into the compact outer bone layer of the cranium. The ball's optimal position is an abutment against the surface of the brain, since the closer to the surface of the brain the centre of the ball is located, the smaller the opening in the skull which is necessary to reach a large area of the skull. In the adaptor housing described in US-A-4.681.103 the position of the attachment threads in the housing and the position of the ball in the socket are such that the ball is not located in the said optimal position. In addition to this the ball's diameter is the same size as the longitudinal opening. The combination of these features means that the angular area which is available when using this known device is no greater than 60°. Moreover, several parts are required to lock the ball in a specific position, leading to a reduction in reliability.

It is also known to employ ball joints for securing equipment in a specific position relative to the brain. In this case soft or collapsible balls are employed which, when secured in a specific angular position, clamp the tubes together, thereby securing the tubes' angular position. However, these devices do not permit any further movement of the tubes relative to the ball. Thus they do not permit any advance adjustment of the ball's angular position before the equipment is passed through it.

These and other problems associated with the known solutions are solved by means of the device and method according to the invention. The device according to the invention comprises a holder and a fixing key, wherein the holder comprises a lower ring with a surface for placing a ball which will form a ball joint, and an upper ring for locking the ball in a specific position, where the ball has a channel for insertion of medical instruments, and where the lower ring has an external threaded surface for direct screwing to an area of a patient's skull. The device is characterized in that the ball's central point, and thereby the ball joint's fulcrum is arranged for positioning on a level with the patient's cranium by means of a groove-like section on the holder which forms an abutment for the ball. The invention also concerns a method for adjustment of different stereotactically and endoscopically located

equipment, including pharmaceutical agents, by means of the holder, characterized by:

- localising a point on the skull,
- making a burr hole
- attaching the holder's lower ring to the wall of the formed burr hole by means of the key,
- placing the ball on the lower ring in such a manner that the ball's central point is on a level with the patient's cranium,
- attaching the upper ring to the lower ring without locking the ball,
- passing a stereotactic pointer through the ball in order to adjust direction,
- locking the ball in a specific angular position,
- replacing the stereotactic pointer with implantable equipment, such as a drain, an electrode, etc., or with temporarily introduceable equipment, such as an endoscope, a biopsy needle etc. The invention also concerns the application of the device and the method for:
- biopsy taking,
- puncture of, e.g., cysts, abscesses and other expansive processes,
- puncture of the ventricle system by placing drains and equipment,
- placing of markers, isotopes and biological or other material, such as neuroactive cells,
- placing of electrodes or other equipment for recording/stimulation of the brain.

The holder's lower ring is equipped with grooves for co-operation with protrusions in the fixing key which is employed for screwing the ring's threaded surface on to and off an area of the skull. The use of the fixing key has several advantages including the fact that it permits great force to be exerted, thus securing the ring in the compact outer bone layer of the cranium. In addition to this the use of a key gives access to difficult areas (the key is long and narrow and does not require extra space round the securing ring). The equipment is designed in such a manner that the ball's lower part is on a level with the surface of the dura. This ensures the best possible accessibility for reaching various brain structures through a small burr hole.

The holder's upper ring is equipped with notches on the circumference whose object is to obtain a good grip for securing the upper ring to the lower ring,

thereby facilitating correct positioning. Both the upper and the lower ring are provided with inclined surfaces which permit angular placement of the ball in a large angular area (up to approximately 74°).

The holder according to the invention is simple to use. It does not require complicated instruments to attach it to the skull. The holder consists of only three parts which are easy to assemble and to disinfect.

Since the channel in the ball is unaltered when the ball is locked and unlocked, the holder permits previous adjustment of an angular position, for example by inserting a pointer in the channel, removing the pointer without losing the angular position, and introducing a surgical instrument which will only be restricted in angular position, but which will still be able to rotate in the channel and also be moved in the channel's axial direction.

In a preferred embodiment the ball is equipped with a centrally extending cast-in tube for guiding the instruments through the ball, and the tube's diameter is considerably smaller than the ball's diameter. Together with the rings' inclined planes, this helps to give the instrument a large range of motion in the angular direction. In a preferred embodiment the tube has a lower section with a smaller cross section, which ensures that the orientation equipment (which is used for adjusting the direction) is stopped in the equatorial plane of the ball where the latter abuts against or a few millimetres above the surface of the brain. Where the tube does not have a lower section with a smaller cross section, but has a constant inner cross section, it may be supplied with stoppers on the upper side which will abut against corresponding stoppers in the pointer instruments, thereby restricting the instrument's movement in depth. The tube projects out of the ball towards the environment, thereby increasing the guiding effect on the instruments.

The support for the instruments which is composed of the ball's through-going opening or the tube surrounds the point of the instrument along a major part of the length of the point as close as possible up to the tip of the point.

Since the insertion channel in the casing and through the ball ends right down on the surface of the dura, all instruments which are introduced are ensured support as far as possible up to the brain. The free tip of the instruments is therefore as short as possible. This reduces the risk of navigation error

compared with insertion systems which are located further from the surface of the brain.

During use the holder may, e.g., be further supplied with an adaptor for biopsy needles provided inside the tube, which adaptor is externally adapted to the internal diameter of the insertion sleeve which is connected to the ball and which is internally adapted to the circumference of the instruments which have to be used. Two locks/stoppers are mounted at the correct length along the equipment (e.g. biopsy needles) which have to be inserted into the brain. These locks will abut against a collar on top of the adaptor which is adapted to the individual instrument. By this means equipment is prevented from being inserted deeper into the brain than planned.

In an advantageous embodiment the tube and the adaptor comprise identification means for connecting them to different equipment.

Since it can be sufficient to make a hole in the dura which is exactly as large as the instrument which has to be inserted, optimal sterility is guaranteed. Moreover, larger holes in the dura cause the surface of the brain to collapse slightly. This can be eliminated by the use of the invention.

The equipment is so designed that it is easy to remove after electrodes and other equipment which have to project through the skin have been placed inside the brain. In order to unscrew the bottom ring longer lines or drains may be temporarily inserted and project through a channel drilled in the fixing key (not illustrated in the figures). This means that in a preferred embodiment the method according to the invention comprises the following further steps:

- removal of the holder's upper ring,
- removal of the ball,
- insertion of the implantable/temporarily introduceable equipment in the key through a channel therein,
- removal of the holder's lower ring,
- removal of the implantable/temporarily introduceable equipment from the key, while the equipment remains in place in the patient.

The device according to the invention also permits the ball to be removed in an approximately parallel fashion even though it is in the extreme position of the ball joint's movement.

The device according to the invention has a wide range of applications. It can be used amongst other things for:

a) taking biopsies (e.g. tissue samples from tumours and infected brain tissue);

b) puncture of amongst other things cysts, abscesses (pus formations) and other expansive processes;

c) puncture of the ventricle system with placing of drains and equipment (e.g. endoscope);

d) placing of markers (for any subsequent radiation or surgery), isotopes (for local radiation) and biological or other material (e.g. neuroactive cells for treatment of, e.g., Parkinson's disease);

e) placing of electrodes or other equipment for recording/stimulation in the brain.

The device and the method according to the invention are otherwise characterized by the features presented in the appended patent claims.

The device will now be described in more detail with reference to an example of an application of the holder and to the accompanying figures in which:

figure 1 is a section of the device according to the invention in a dismantled position, illustrating the relative position of the elements and also an adaptor and a stopper for biopsy needles;

figure 2 is a section of the device according to the invention in an assembled position and also of an instrument for use with the holder.

Figure 1 illustrates the device according to the invention in a dismantled position. The device comprises a holder with a lower ring 1 with a surface (groove) 4 for placing a ball 2 and with notches 5 for co-operation with the protrusions 6 in a fixing key 7, and with two external threaded surfaces. The upper part of the first surface 9 is located on ring 1 and will co-operate with an upper ring 3 for locking of a ball 2. The bottom of the second surface 8 is located in the ring, permitting the ring to be attached to the skull. The lower ring 1 is further provided with a groove-like section 21 which forms an abutment for the ball 2.

The ball 2 which will form a ball joint is equipped with a through-going channel 10 for insertion of medical instruments. According to a preferred embodiment the ball is equipped with a cast-in tube 11, which will guide the medical instruments through the ball 2. According to a further preferred embodiment the tube preferably has a lower section 12 with a smaller cross section, which restricts the movements of the instruments which are employed for adjusting the equipment. These instruments will have a part with a larger diameter than the tube's 11 lower section 12 and will therefore be restricted in the longitudinal movement to the area where the tube is wider than they are. This ensures that the adjustment instruments do not touch the brain. The holder's upper ring 3 has a lower edge 13 which surrounds the top of the ball 2 and an internal threaded surface 14 for co-operation with the upper threaded surface 9 in the lower ring 1. The ball 2 can be freely rotated and moved with a conical movement. The upper ring 3 has notches 16 on the circumference, the object of which is to obtain a good grip for attaching the rings 1 and 3 around the ball 2. The ring 3 has an upper conical opening 15 whose object is to ensure the best possible range of movement for the instruments. The figure also illustrates an adaptor 17 and a stopper 18 for biopsy needles.

Figure 2 illustrates the device in an assembled position. The figure shows an opening A in the skull, where the lower threaded surface 8 in the lower ring 1 has to be attached. The figure illustrates the arrangement of the ball 2 in the immediate vicinity of the brain's surface B.

In the method for adjusting equipment by means of the device according to the invention the following steps amongst others are carried out:

- by means of pointing equipment a point is localised on the skull which is selected as an approach to the area which has to be examined;

- a burr hole (opening A, fig. 2) is made with a conventional "ball drill" (Aesculap, diameter = 16 mm);

- the lower ring's 1 surface is screwed into the wall of the formed burr hole A, by means of the fixing key 7 with protrusion 6, the ring's 1 notches 5 being adapted to the protrusions 6, and the fixing key may have a centrally extending channel (not illustrated in the figures);

- the ball 2 is placed inside the groove 4;

- the upper ring 3 and the lower ring 1 which are fixed in the cranium, are screwed together, holding the ball 2 between the lower groove 21 and the upper groove 13 respectively, the ball 2 is attached as far down as possible towards the cranium in order to ensure the best possible stability and range of movement, thus providing the best possible precision and adjustability;

- the tube 11 can be freely manoeuvred and rotated as long as the ball 2 is not locked between the rings 1 and 3. Where the equipment is not cylindrical, the holder permits it to be rotated by means of movement both between the adaptor 17 and the tube 11 and in the ball joint 2, thereby providing the possibility of studying optional cutting planes;

- a stereotactic pointer 19 is inserted into the tube 11 and stopped where the pointer's tip touches the ball's 2 most distal equatorial plane, since the tube's lower section 12 has a smaller diameter than the rest of the tube 11;

- the direction of the tube 11 is adjusted and the depth to the area in which the examination/operation is to be performed is determined;

- the ball 2 is locked by pulling the ring 3 so that the rings 1 and 3 surround the ball 2;

- the pointer 19 is withdrawn and set aside so that all unnecessary equipment - including holders for fixing soft parts aside - is removed before instruments are inserted into the brain (this ensures the best working conditions for further treatment);

- an adaptor 17 which is specially adapted to the equipment which has to be passed down the tube is put in place, the adaptor's end piece 20 preferably being coloured green and projecting, for example, 5 mm above the tube 11;

- the equipment which is passed into the adaptor 17 will be stopped when a ring clamp 18 stops against the adaptor's end piece 20;

- the distance to the target area within the brain is read off;

- the tube's 11 and the adaptor's 17 length (for example 45mm+5mm=50mm) is added;

- the ring clamp 18 is attached to a biopsy needle or another instrument (not shown in the figure) which is thereby stopped at the correct depth.

The biopsy needle's locking system preferably has two hinged ring clamps 18 for maximum security (only one is shown in the figure).

In a preferred embodiment of the invention the top part of the tube 11 is coloured red as a warning against inserting any other equipment than the stereotactic pointer tip 19 therein.

The invention described above represents a universal device which can be employed for many purposes.

In addition to what has been mentioned, the device may also be employed, e.g., as a holder and support for equipment which is moved within the brain. The attachment over the ball joint will ensure the least possible movement of the brain structures under the cranium. In this way care is taken to protect vital brain structures from unnecessary movement, stress and damage. These areas of application are included without departing from the scope of the invention as indicated in the appended patent claims.

PATENT CLAIMS

1. A device for adjusting stereotactically and endoscopically located equipment, including pharmaceutical agents, radiation sources and organic material, comprising a holder and a fixing key, where the holder comprises a lower ring (1) with a surface (4) for placing a ball (2) which will form a ball joint, and an upper ring (3) for locking the ball in a specific position, where the ball (2) has a channel for insertion of medical instruments, and where the lower ring (1) has an external threaded surface (8) for direct screwing to an area of a patient's skull,
characterized in that the ball's (2) central point, and thereby the ball joint's fulcrum is arranged for positioning on a level with the patient's cranium by means of a groove-like section (20) on the holder which forms an abutment for the ball (2).

2. A device according to claim 1,
characterized in that the lower ring (1) has an upper threaded surface (9) for co-operation with a corresponding threaded surface (14) in the upper ring (3).

3. A device according to one of the preceding claims,
characterized in that the lower ring (1) is equipped with grooves (5) for co-operation with protrusions (6) in the fixing key (7) which is employed for screwing the ring's (1) lower threaded surface (8) on to and off an area of the skull.

4. A device according to one of the preceding claims,
characterized in that the upper ring (3) is equipped with notches (16) on the circumference, the object of which is to obtain a good grip in order to secure the upper ring (3) to the lower ring (1).

5. A device according to one of the preceding claims,
characterized in that the upper ring (3) has an upper conical opening (15).

6. A device according to one of the preceding claims,
characterized in that the ball (2) is equipped with a centrally extending cast-in tube (11) for guiding medical instruments through the ball (2), the tube projecting from the ball's surface towards the surroundings.

7. A device according to claim 6,
characterized in that the tube's (11) diameter is considerably smaller than the ball's (2) diameter.

8. A device according to claim 6 or 7,
characterized in that the tube (11) has a lower section (12) with a smaller cross section, for restricting the instruments' range of motion in the longitudinal direction.

9. A device according to one of the claims 6-8,
characterized in that it is further provided with an adaptor (17) for biopsy needles disposed inside the tube (11) and with at least one stopper (18) for biopsy needles disposed on the top of the adaptor.

10. A device according to claim 9,
characterized in that the stopper (18) consists of at least one hinged ring.

11. A device according to claim 9 or 10,
characterized in that the tube (11) and the adaptor (17) comprise identification means for connecting them with different equipment.

12. A device according to one of the preceding claims,
characterized in that the holder and the key (7) which are employed for screwing the holder's lower threaded surface to an area of the skull are designed in such a manner that it is possible to implant equipment which has to project through the skin after the procedure.

13. A device according to one of the preceding claims,
characterized in that the support for the instruments which is composed of the ball's (2) through-going opening or tube (11) surrounds the point of the instrument for a major part of the length of the point as close up to the tip of the point as possible.

14. A device according to one of the preceding claims,
characterized in that the key (7) has a drilled channel to permit removal of the lower ring (1) from the skull while equipment projecting through the ring remains in place.

15. A method for adjusting different stereotactically and endoscopically located equipment, including pharmaceutical agents, by means of the device

according to one of the preceding claims,
characterized in that it comprises:

- localising a point on the skull,
- making a burr hole
- attaching the holder's lower ring (1) to the wall of the formed burr hole by means of the key (7),
- placing the ball (2) on the lower ring (1) in such a manner that the ball's central point is on a level with the patient's cranium,
- attaching the upper ring (3) to the lower ring without locking the ball (2),
- passing a stereotactic pointer through the ball in order to adjust direction,
- locking the ball in a specific angular position,
- replacing the stereotactic pointer with implantable equipment, such as a drain, an electrode, etc., or with temporarily introduceable equipment, such as an endoscope, a biopsy needle etc.

16. A method according to claim 15,
characterized in that it further comprises the following steps after the implantable and/or the temporarily introduceable equipment has been placed in the ball:

- removal of the holder's upper ring (3),
- removal of the ball (2),
- insertion of the implantable/temporarily introduceable equipment in the key (7) through a channel therein,
- removal of the holder's lower ring (1),
- removal of the implantable/temporarily introduceable equipment from the key (7), while the equipment remains in place in the patient.

17. Application of the device according to one of claims 1-14, and the method according to one of claims 15-16 for:
- taking biopsies,
- puncture of amongst other things cysts, abscesses and other expansive processes,
- puncture of the ventricle system with placing of drains and equipment,
- placing of markers, isotopes and biological or other material, such as neuroactive cells,

- placing of electrodes or other equipment for recording/stimulation in the brain.

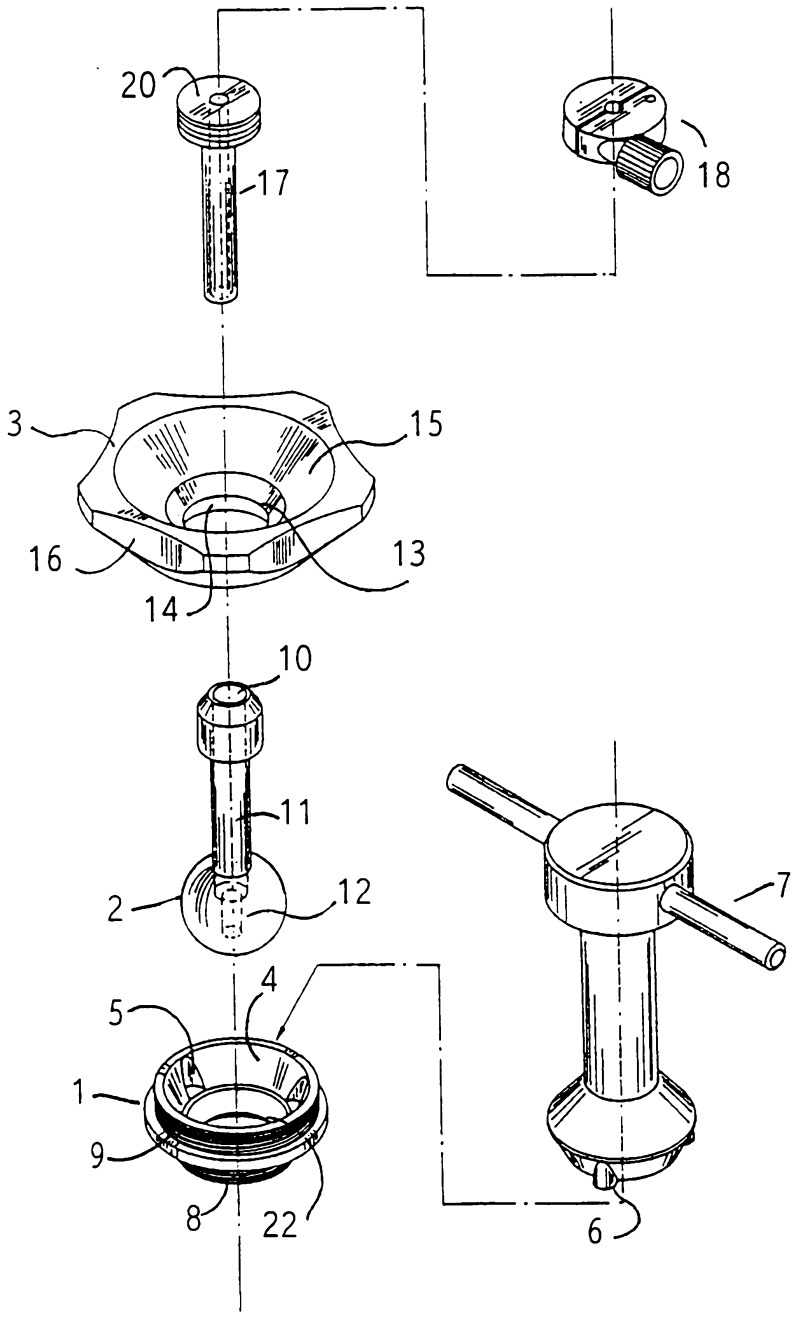

FIG. 1

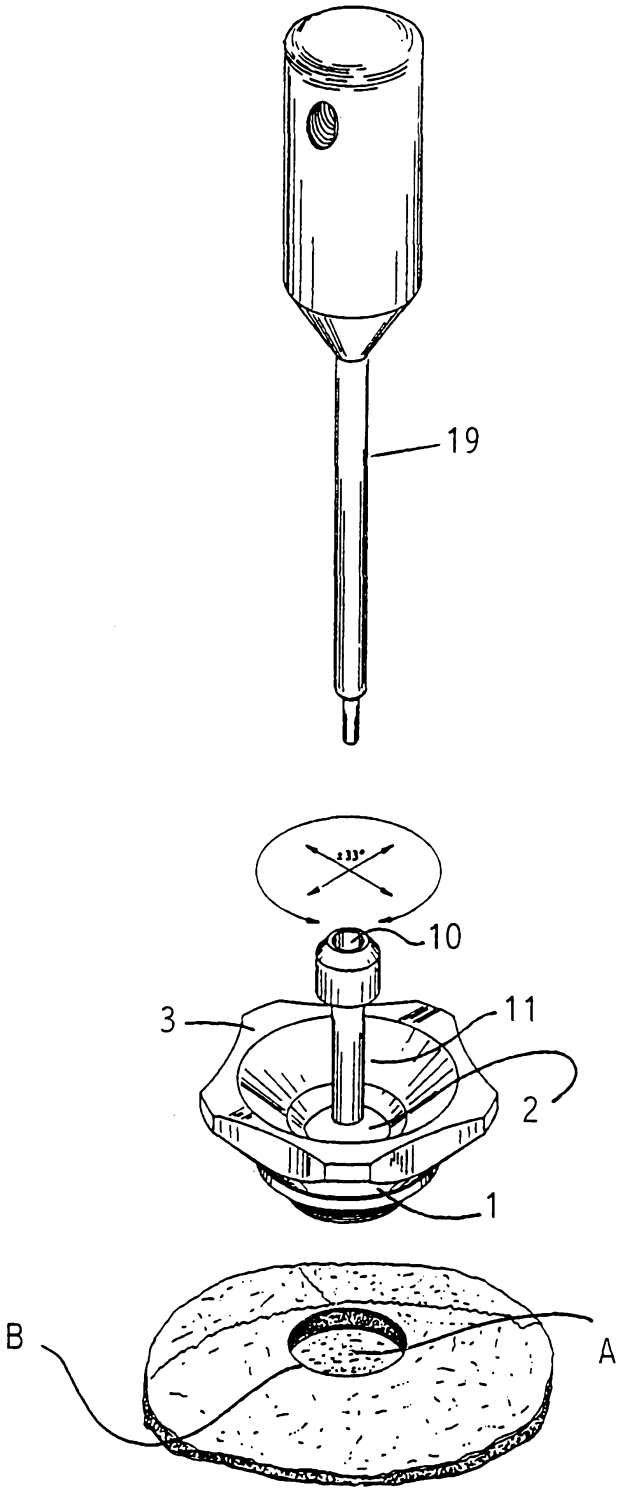

FIG. 2