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(54) **Title:** BONE AND TISSUE MARKER

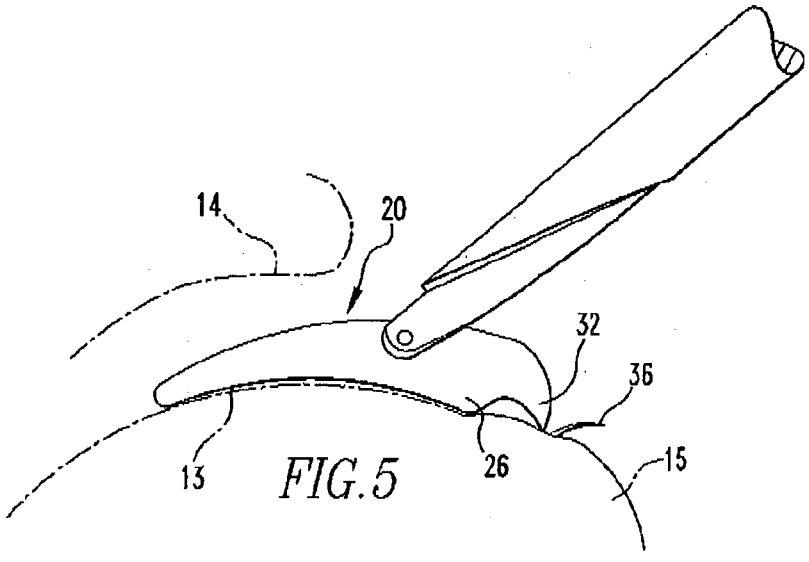

FIG.5

(57) **Abstract:** The present invention concerns a marker for bones, particularly for marking irregularities in the femoral head. There is described a surgical instrument having a shaft including a handle towards a proximal end and an arm towards a distal end. The arm includes a template, and the arm and/or template further includes tissue marking means for marking differences in the curvature of a tissue surface.

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Bone and Tissue Marker

This application is a PCT international Patent Application claiming priority to US Patent Application No. 61/359862, filed June 30, 2010, the disclosure of which is incorporated by reference herein in its entirety.

The present invention concerns a marker for bones, in particular, the present invention relates to a bone marker for marking irregularities In the femoral head.

In many joints, and in particular the hip joint, when the bones forming the joint are operated at the extremes in their range of motion, interference can occur between the bones. In the hip, for example, when the femur is fiexed upwards ft may collide with the rim of the socket or acetabulum, of the pelvis. When this occurs, any soft tissue which is caught between the colliding bones may be damaged and cause pain. The soft tissue that is caught is usually the labrum, which is a ring-like structure formed from cartilage that surrounds the acetabular rim.

The cartilage tissue is generally damaged as **a** result of the high sheer forces that the joint is subjected to through movement at the extreme limits in its mobility. This is particularly damaging to the patient because the cartilage acts as a buffer between adjacent bone surfaces of joints and provides the sliding surfaces which allow the joint to move fluidly. This helps to prevent wear and tear on the joint by stopping the bones of the joint from directly grinding against one another.

Cartilage tissue only has a very limited capacity for repair as it does not contain any blood vessels, and so where damage has occurred the growth of new tissue is extremely slow, if at ail.

interference in the hip joint can be eliminated by removing any bone tissue which interferes with movement of the joint. Typically, interference occurs from naturally occurring **irregularities,** known **as** Cam lesions or **femoral** neck bumps,

on the otherwise generally spherical head of the femur. **These** are commonly removed by surgeons during open hip surgery. During the procedure the surgeon will utilise a generally spherical template by placing it over the generally spherical head of the femur, and then sliding the template around the femora! head until any gaps that occur between the template and the femoral head are observed. These gaps indicate a change in curvature, and any discrepancies or bumps can then be removed by, for example, a chisel or powered burr, to allow the Joint to move without impedance.

Whereas, in the current arthroscopic approach, the surgeon must make an educated guess of where the "bump" is. Due to distortion of the arthroscopic image in the Joint during the procedure, the awkward direction of view of the arthroscope used in hip and the **difficulty** of interoperativeiy moving the femur through its full range of motion, it is a clinical challenge to **arthroscopically** determine where and how much bone should be removed. Typically, a surgeon will remove some of the bump and then flex the hip to see if the joint is still impeded. This is difficult and often impractical as the arthroscopic view becomes occluded by soft tissue with this motion.

A more **convenient** arthroscopic approach could have considerable advantages over open surgical procedures if these obstacles were overcome, in particular, it would lead to a quicker rehabilitation with less chance for iatrogenic damage when dislocating the joint. Accordingly, there exists a need for a fuily integrated arthroscopic approach,

The present invention seeks to overcome the above issues by providing an arthroscopic device which can be used to mark a bone growth or irregularity in the surface of a bone, and any overlying cartilage tissue, so that mechanical devices can be **used** subsequently to remove it arthroscopically.

In a first aspect of the present invention there is provided a surgical instrument comprising a shaft having a handle towards a proximal end and an arm towards a distal end, wherein the arm comprises a template, and the arm and/or

template includes tissue marking means for marking differences in the curvature of a tissue surface.

Preferably, the tissue surface is formed of cartilage or bone,

Suitably, the arm is connected to the distal end of the shaft by a resiliency flexible member. Suitably, the resiliency flexible member is configured to bias the template towards the tissue surface. Suitably, the resiliency flexible member comprises a Nitinol wire, a Nitinol tube, a spring, a live-hinge or a corrugated portion.

Alternatively, the arm is pivotally connected at the distal end of the shaft. Suitably, the arm has proximal and distal ends and is pivotaliy connected therebetween. Preferably, the pivotal connection allows the arm to pivot within a single plane. Optionally, the pivotal connection is a universal joint or a ball-and-socket joint. Suitably, the universal joint or a ball-and-socket joint includes a lock to restrict motion of the joint to a single plane.

The flexibility in the arm, relative to the shaft, allows the template to accurately follow the contours of the tissue surface and enables changes in the curvature of the tissue surface to be identified.

In further alternative embodiments, the arm is connected with and is substantially rigid relative to the shaft.

Suitably, the tempiate includes a tissue engaging surface. Suitably, the tissue engaging surface is curved. Preferably, at least a portion of the *template* directly engages with the tissue surface which Includes tissue to be marked. Alternatively, the template engages with a tissue surface which is complementary to the tissue surface which includes tissue to be marked, in use, the tissue engaging surface of the template allows a surgeon to observe differences in the curvature of a tissue surface by monitoring any deviations in gaps which appear between the template and the tissue surface as the template is moved across the tissue surface.

Suitably, the marking means is a sharpened tip or blade; suitably, located at an end of the arm. Preferably, the marking means is located towards a proximal end of the arm. Alternatively, the marking means is an aperture or channel in the arm comprising a sharpened edge or blade. In this alternative embodiment, the sharpened edge or blade can be used to mark or selectively resect tissue by sequentially passing the instrument over a particular region to shave the tissue. Alternatively, the marking means comprises an ink or dye; suitably India ink.

Alternatively, the marking means is a radio frequency electrode. Preferably, the radio frequency electrode can be selectively energised to mark a region of the tissue surface. Preferably, the surgical instrument comprises control means for the radio frequency electrode. The control means permit the radio frequency electrode to be selectively energised for a fixed period of time, to minimize collateral damage of surrounding tissue. A particular advantage of radio frequency marking means is that marking of the tissue only occurs when the electrode is activated. This means that these instruments are especially accurate, and also allow the surgeon to identify differences in the curvature of a tissue surface and move the template back and forth over the region of difference, before deciding to mark the region. The tissue surface will only be marked when the surgeon energises the electrode, and at all other times the electrode will not be energised, and so damage to tissue will be highly selective.

In alternative instruments employing a radio frequency electrode, the electrode may be activated by suitable sensing means, or automatically through the application of pressure when it comes into contact with a bump.

Preferably, the instrument further comprises deployment means. Suitably, the deployment means is a solid cylindrical member or a hollow tubular member. Suitably, the deployment means is a rod or wire attached to the arm; preferably towards the proximal end of the arm. Preferably, the deployment means is a tubular member coaxially mounted with the instrument shaft. Preferably, the

deployment means includes an opening at a distal end. Suitably, the deployment means is internally mounted within the instrument shaft. Preferably, the deployment means is slidably or rotatably mounted within the shaft and interlocks with the template such that it may be held rigidly.

Alternatively, the tubular member is an outer sheath, mounted on the outer surface of the instrument shaft. Preferably, the outer sheath at least partly surrounds a portion of the outer surface of the shaft, Suitably, the outer sheath is slidably mounted or rotatably mounted on the shaft In embodiments in which the outer sheath is rotatably mounted on the shaft, the rotatable movement arises from a thread and complementary groove arrangement - for example the outer surface of the shaft may include a helical thread.

Preferably, the surgical device includes a lock to prevent the deployment means from impeding movement of the arm when in a deployed position, and for locking the instrument in an arm-stowed position to protect the template in transit. The lock may be any suitable locking means, such as a twist-lock, button or catch.

In use, manipulation of the deployment means moves the arm between a stowed position, in which the arm is aligned substantially with the longitudinal axis of the shaft, and a deployed position, in which the angle between the proximal end of the arm and the shaft is between around 5 degrees and 100 degrees, in particular, distal advancement of outer sheath, relative to the shaft, causes the template arm to align substantially axially with the longitudinal axis of the shaft, and in a stowed position. This is particularly useful for when the instrument is being passed into, and out of, a cannula. Proximal advancement of the outer sheath, relative to the shaft, permits the template arm to pivot relative to the shaft and to deploy.

In alternative embodiments, not shown, the arm will operate in a wider range relative to the shaft. For example, when utilised in other joints or in instances where the surgical instrument is to be introduced into the Joint from unforeseen portal trajectories.

In preferred embodiments, the opening of the outer sheath is axiaiiy elongated between a distal end at the distai end of the outer sheath and a proximal end disposed proximally of the arm, thereby to expose the arm along one side of said outer sheath and define a portion of said outer sheath that provides a hood for an opposite side of the arm. The outer sheath acts to protect the arm of the instrument when it is in a stowed position and being moved to a surgical site.

Preferably, the outer sheath opening is axiaiiy elongated so that *the* proximal end of the opening is disposed adjacent to the proximal end of the arm.

Suitably, the instrument also inciudes a biasing means, to bias the arm and template towards the tissue surface. Suitably, the biasing means may be the deployment means. Alternatively, the biasing means is a rod which is biased to extend the arm dista!ly. Suitably, the rod includes a spring or dampener, In use, the biasing means acts to press the distai end of the arm and template against the tissue surface upon which the instrument is being used. This has the effect that the tissue surface is more accurately tracked when the instrument is passed over it, so that differences in the curvature of, for example, the femorai head can be more accurately Identified and marked,

Opfional!y, the template arm further comprises one or more bearings which assist movement of the template arm over a surface. Suitably, the template arm comprises two, three, four, five or six bearings. Preferably, the template arm comprises two bearings. Preferably, the bearings are located towards distai and proximal ends of the template. The provision of one or more bearings allow the arm and template to move more easily over the tissue surface,

Optionally, the instrument fut her comprises a burr,

in a second aspect of the present invention there is provided a surgical instrument comprising a delivery means and a marking means.

Preferably, the marking means is a paper or **film.** Preferably, the marking means further includes a pressure-sensitive deployable surface. Suitably, the deployable surface comprises an ink or dye; suitably India ink. **Suitably,** the marking means is a carbon paper comprising a carrier sheet and a transferable marking substance. Alternatively, the marking means comprises an ink or cfye; suitably India ink. An advantage of this system is that the marking process is quick, simple and does not cause any damage to the tissue surface being marked.

Suitably, the delivery means is a grasper.

The above and other aspects of **the** invention will now be described with reference to the following drawings in which:

Figure 1 is a partial view of a hip joint;

Figure 2 is an embodiment of an instrument according to the first aspect of the invention, in a retracted position;

Figure 3 is the embodiment of Figure 2 in a deployed position;

Figure 4 is the embodiment of Figure 2 shown *in-situ*;

Figure 5 is a schematic **close-up** view of an embodiment of Figure 4 that incorporates a blade;

Figures 5A &8 are schematic above plan, and sectional side views. **respectively,** of an **alternative** biade arrangement;

Figure 6 is an alternative use of the embodiment of Figure 2;

Figure 7 is schematic Illustration of a method of marking in accordance with the second aspect of the invention, prior to the introduction of marking means into the joint; and

Figure 8 is schematic illustration of a method of marking in accordance with the second aspect of the invention, with marking means located in the joint.

Referring to Figure 1, there is shown a hip, or acetabulofemoral joint 10, formed from the femur 12 and acetabulum of the pelvis 11. Femur 12 includes a substantially spherical head 13, which locates in the cup-like acetabulum of the pelvis 11. The joint is lubricated with synovia! fluid and its surfaces are lined with cartilage to cushion movement and allow it to move freely (not shown). The acetabulum is lined with the acetabular labrum, which is a ring-shaped fibrocartilaginous lip. The labrum extends beyond the acetabulum, forming a tight sliding connection with the femoral head and providing a stable joint,

The purpose of the hip joint is to support the weight of the body in both static and dynamic postures. Huge loads are placed upon the hip Joint and any restrictions within the joint, such as bumps, can lead to significant damage to the surfaces of the joint over time.

In Figures 2 and 3 there is shown a partial view of a surgical instrument 20 in accordance with one embodiment of the present invention. The instrument 20 comprises a shaft 21, the distal end of which is shown in Figures 2 and 3. The shaft includes an arm 22 pivotally connected through pivot 23. The arm 22 is curved, having a lower concave region and an upper convex region, according to the illustration, with the lower concave region defining a template for a femoral head. The arm is suitably dimensioned to allow it to fit between the femoral head and acetabulum without it being necessary to distract the hip joint. In alternative embodiments, not shown, the arm may be shaped appropriately to provide a template for a different joint such as, for example, the ankle.

Arm 22 includes distal and proximal ends, 24 and 25 respectively, either or both of which may incorporate one or more bearings (not shown). These bearings

permit the arm and tempiaie to move more easily over the tissue surface, in this particular case the femoral head, in use.

The lower concave region of the template has a curved profile that broadly matches the curvature of the femoral head. Such curvature allows the template to be mapped over the tissue surface, and where any gaps appear between the curved iower surface of the template and the tissue surfaces this will help to highlight any changes in the curvature of the femoral head (Figure 4). The surgical instrument will have a variety of different sizes so that an appropriate instrument can be selected to suit the particular characteristics of a patient's acetabulofemoral joint.

The template and/or arm 22 also incorporate a marking means in the form of a sharpened tip or blade 32 at, or towards, the proximal end 25 (Figure 5). The sharpened tip or blade 32 is designed to leave one or more marks 36 on the cartilage covering the femoral head when the template is moved in a generally dista! to proximal manner. These marks help to identify changes in the curvature of the femoral head, i.e. where the femoral head "bump" begins, *in* preferred embodiments, the sharpened tip or blade 32 is located on the heal 26 of the arm, or just proximaify thereof, so that marking 36 only occurs with notable changes in the curvature of the femoral head, and not when relatively minor differences are encountered by the template. As can be seen in Figure 5, as the instrument 20 is moved in a generally distal to proximal direction, blade 32 digs into the cartilage which covers a bump, causing it to nick 36 or shave the cartilage in that region. This disturbance in the tissue surface can be used to positiveiy identify the bump and facilitate its subsequent removal. It is possible, where the bump or irregularity is small or slight, to use the blade to remove it by successive shaving, and provide a smooth transition through the cartilage and into the subchondral bone.

In alternative tempiaie arm embodiments, shown in Figures 5A and in section in Figure 5B (only arm shown for clarity), the marking means is an aperture or a channel 27 which passes through arm 22. The aperture or channel 27 has a sharpened distal edge 28, so that when the instrument is drawn distal to

proximal the sharpened edge marks the bump. Repeated drawing over the region of the bump, can be used to shave and reduce, or remove the bump. Alternatively, the aperture or channel has a sharpened proximal edge.

In a further alternative means of marking irregularities in a tissue surface (not shown), an ink or dye suitable for marking a tissue surface is released by, for example, direct injection from a port within the arm or template. The port is suitably located at, or towards, the proximal end of the template or arm. Alternatively, the ink can be delivered from a pen. The pen may be located within, or attached to, the instrument shaft, template or arm. The pen can be retractable, in such embodiments, as the marking means contacts the bump, ink is deposited to thereby mark and identify the irregular shaped region.

In preferred alternative embodiments, not shown, the marking means is a radio frequency electrode. This RF electrode can be electrically energized when a mark is to be made on the bone or cartilage surface. In such embodiments, the lower concave region of the template may be designed with a recess, or so that the concavity is not uniform in order to accommodate the electrode. This allows the electrode to be fitted to the template, leaving a small amount of clearance between the template and femoral head when the template is mapped over regions of 'normal' curvature. When such a template encounters a bump, the electrode comes into contact with the bump and may be automatically activated to mark it as a result of the contact between the electrode and bump, in this manner, the instrument can be used to accurately mark the perimeter of a bump. In alternative embodiments, the electrode may be activated manually by the surgeon who will energise the electrode by pressing a button on the instrument handle or foot pedal. The advantage of this arrangement is that the surgeon can selectively mark the bump, moving the instrument over the site a number of times, and not marking it until they are satisfied that they have correctly identified a bump, so that he or she can be sure of the region being marked.

A further alternative marking means, not as described above, also comprises an ink or dye. This will be discussed in greater detail below in relation to Figures 7 and 8.

in further alternative embodiments, not shown, the arm is connected with and is substantially rigid relative to the shaft, in these embodiments, the substantially spherical shape of the template is incorporated in the side edges of the arm, so that the template is utilised with the arm in a side-on orientation, in this case, rotating the shaft of the surgical instrument allows the arm to roll relative to the tissue surface. This is different to the sliding action utilised in the other described embodiments. The marking means is also wrapped around the edges of the arm so that it may engage with and mark tissue regardless of orientation .

In Figures 2-4, and 6, shaft 21 is partly surrounded by a retractable outer sheath 30. Outer sheath 30 can be moved in an axial direction, and as is shown in greater detail in Figures 2 and 3, in which outer sheath 30 has been retracted in the direction indicated by arrow A, towards a proximal handle (not shown). The outer sheath may be moved by means of an axial thread, slid up and down the shaft, or may include a combination of both - for example, it may be advanced and retracted in a sliding manner and incorporate a twisting or screwing action at or towards the extreme ends of its desired motion in order to lock the sheath in position.

Although Figure 2 illustrates the arm 22 in a deployed position, with the outer sheath retracted, and may freely move about pivot 23, it is shown in the position in which it is held when the outer sheath 30 is distaliy advanced and the arm 22 is said to be in a retracted position. This allows the surgical instrument 20 is be easily passed down a cannula and into a surgical site. The outer sheath also acts to house and protect the delicate template, where the sheath has been advanced distaliy and the arm is in a retracted position. Further, in preferred embodiments, the outer sheath 30 may also act as a deployment means causing the arm and template to move into a stored position.

in a deployed position, the angle Θbetween the proximal end of the arm and the shaft, and thus the operating range, is between around 5 degrees and 100 degrees.

In alternative embodiments, not shown, the deployment means is one or more rods or wires, attached proximally to the arm through aperture 31 (Figure 3). The rods or wires are linked to a mechanism, preferably formed with the instrument handle and are used to deploy the arm and template from a retracted position **to a** deployed position. For example, a pull wire may be fixed to the proximal end of arm 22 **at,** or in the region of, aperture 31 thus inducing rotation of the arm about the pivot when the wire is pushed or putted by the user, **in** embodiments as described above, the template **is** only allowed to pivot in a single plane and so only a single rod or wire is necessary to control and manipulate the arm. However, in **alternative** embodiments (not shown) the template and shaft may be articulated in more than one plane. For example, the pivot may be a universal joint or a ball and socket joint. Such arrangements preferably require a pair of rods or wires as deployment means, In embodiments where the pivot is a universal joint or a ball and socket Joint, the instrument may also include a lock to restrict motion of the joint to a single plane.

In use, the instrument is passed through a cannula and located in the **surgical** site of a joint. The arm is then deployed by retracting the outer sheath, or by suitably manipulating the rod or wire. The instrument can then be **used** to mark any differences in the curvature of a tissue surface which are deemed to impede movement of the joint. After the tissue has been marked, the outer sheath is advanced distalty thereby forcing the arm into a stowed position. The instrument can then be withdrawn, and appropriate surgical instruments used **subsequently** to remove the marked tissue.

An alternative way use of the surgical instrument is illustrated in Figure 6. As shown, the upper and lower surfaces of the **instrument** template are utilised to respectively engage with the corresponding **acetabular** and femoral head surfaces. In this arrangement the concave surface of the acetabular socket is

used to guide the template, rather than the convex femoral head. In an anatogous manner to the marking process using the template described above, marking is carried out by moving the distally to proximally. Accordingiy, the distal upper surface of the template engages with the concave inner surface of the acetabulum, and the proximal lower surface of the template engages with the femoral head. As the template is moved in the distal **to** proximal direction, the template **moves** over the respective surfaces of the acetabulum and femoral head. However, when the portion of the template which is engaged with the femoral head encounters a difference in the curvature, in the form of a bump, it digs in to the bump and thereby marks it

in alternative embodiments, not shown, the instrument also includes a biasing means to bias the arm and template **towards** the tissue surface. The biasing means may be the deployment means, or a separate rod which is biased to extend the arm **distaily.** The rod may include a spring or dampener. In use, the biasing means acts to press the distal end of the arm and template against the tissue surface upon which the instrument is being used. This increases the accuracy of the instrument to **enable** differences in the curvature of a joint surface to be more accurately identified and marked.

As not ail joints are spherical, these concepts may be used to extend to substantially non-spherical joints, such as the ankle joint which is more cylindrical than spherical.

The clinical technique of ail embodiments concerning the first aspect of the invention does not require for the joint to be fully distracted due to the arm of the instrument being suitably dimensioned to slip unimpeded between the femoral head without distraction, where the joint being investigated and treated is the hip. **However,** it may be desirable to partly distract the joint enough to allow the arm of the surgical instrument to have greater **access** to the joint. Referring now to Figures 7 and 8, there is shown a further alternative means of marking irregularities in a tissue surface. According to this method, a paper or film 33 is introduced into the space of a distracted hip joint, between the acetabulum 16 and the **femoral** head **13,** in the region of the rim of the

acetabulum 14. The joint is then allowed to return to its weight bearing, non-distracted, state leaving the paper or film 33 trapped between the femoral head 13 and the rim of the acetabulum 14. The paper or film 33 comprises at least one surface which comprises an ink or dye suitable for marking a tissue surface. This at least one surface is laid facing the surface of the femoral head so that, when the femur is rotated (represented by D), ink or dye will deposit on any surfaces where the movement of the joint is impeded, for example by irregularities in the curvature of the femoral head, such as a bump. In alternative embodiments, not shown, the paper or film 33 has two surfaces, each of which comprises a suitable ink or dye.

Once the appropriate surfaces have been marked, the paper or film 33 can be removed from the surgical site, and then the bump removed subsequently.

The described arthroscopic approaches could provide considerable advantages over traditional, open surgery, methods. In particular, these instruments and techniques could lead to a quicker rehabilitation with less chance for iatrogenic damage when dislocating the joint,

Although specifically described in the context of the femoral head, it will be recognised that the instrument could be used in other suitable joints such as the ankle.

CLAIMS:

1. A surgical instrument comprising a shaft having a handle towards a proximal end and an arm towards a distal end, wherein the arm comprises a template, and the arm and/or template comprises tissue marking means for marking differences in the curvature of a tissue surface.

2. An instrument as claimed in claim 1, wherein the arm is pivotaify connected at the distal end of the shaft.

3. An instrument as claimed in claim 1, wherein the arm comprises proximal and distal ends and is pivotai!y connected at or towards its proximal end with the shaft, or between the proximal and distai ends.

4. An instrument as claimed in claim 1, wherein the pivotal connection allows the arm to pivot within a single plane.

5. An instrument as claimed in claim 1, wherein the pivotai connection comprises a universal joint or a bail-and-socket Joint.

6. An instrument as claimed in claim 1, wherein the arm is connected to the distal end of the shaft by a resHientiy flexible member,

7. An instrument as claimed in claim 6, wherein the resiiientiy flexible member is configured to bias the arm towards the tissue surface.

8. An instrument as claimed in claim 7, wherein the resi!ientiy flexible member comprises a Nitinol wire, a Nitinol tube, a spring, a live-hinge or a corrugated portion.

9. An instrument as claimed in claim 1, wherein the arm is connected with and is substantial ly rigid relative to the shaft

10. An instrument as claimed in claim 1, wherein the arm comprises a curved surface,

11. An instrument as claimed in claim 1, wherein the template is directly engageabie with a tissue surface which includes tissue to be marked.

12. An instrument as claimed in claim 1, wherein the template is engageabie with a tissue surface which is complementary to the tissue surface which includes tissue to be marked.

13. An instrument as claimed in claim 1, wherein the marking means comprises a sharpened tip or blade.

14. An instrument as claimed in claim 13, wherein the marking means is located towards a proximal end of the arm,

15. An instrument as claimed in ciaim 13, wherein the marking means comprises an aperture or channel in the arm which comprises the sharpened edge or blade.

16. An instrument as claimed in claim 1, wherein the marking means comprises a radio frequency electrode.

17. An instrument as claimed in claim 16, wherein the surgicai instrument comprises control means for the radio frequency electrode.

18. An instrument as claimed in ciaim 1, wherein the instrument further comprises deployment means for supporting and protecting the arm and template whilst the instrument is packaged and/or when the instrument is being introduced into a surgicai site.

19. An instrument as claimed in ciaim 18, wherein the deployment means comprises a solid cylindrical member or a hollow tubular member.

20- An instrurrient as claimed in claim 18, wherein the deployment means comprises a rod or wire attached to the arm; preferably towards the proximal end of the arm.

21. An instrument as claimed in claim 18, wherein the deployment means comprises a tubular member coaxially mounted with the shaft and includes an opening at a distal end.

22. An instrument as claimed in claim 21, wherein the deployment means is internally mounted within the shaft, or is an outer sheath mounted on the outer surface of the shaft.

23. An instrument as claimed in claim 22, wherein the deployment means is slidably mounted or rotatably mounted on or within the instrument shaft.

24. An instrument as claimed in claim 23, wherein the surgical instrument comprises a lock for the deployment means.

25. An instrument as claimed in claim 1, wherein the instrument also comprises a biasing means, to bias the arm and template towards the tissue surface.

26. An instrument as claimed in claim 25, wherein the biasing means are deployment means.

27. An instrument as claimed in claim 25, wherein the biasing means is the instrument shaft, or a separate rod, spring, live-hinge or dampener which is biased to extend the arm and template distally.

28. An instrument as claimed in claim 27, wherein the rod includes a spring or dampener.

29, An instrument as claimed in claim 1, wherein the template further comprises one or more bearings which assist movement of the template over a surface,

30. An instrument as claimed in claim 29, wherein the template arm comprises two, three, four, five or six bearings.

31. An instrument as claimed in claim 1, wherein the instrument further comprises a burr.

32. A surgical instrument comprising a delivery means and a marking means.

33. An instrument as claimed in claim 32, wherein the marking means comprises a paper or film.

34. An instrument as claimed in ciaim 32, wherein the marking means further comprise a pressure-sensitive deployable surface.

35. An instrument as claimed in ciaim 34, wherein the deployable surface comprises an ink or dye; suitably India ink.

36. An instrument as claimed in ciaim 32, wherein the marking means comprises a carbon paper comprising a carrier sheet and a transferable marking substance.

37. An instrument as claimed in claim 32, wherein the marking means comprises an ink or dye; suitably India ink.

38. An instrument as claimed in ciaim 37, wherein the delivery means is a grasper.

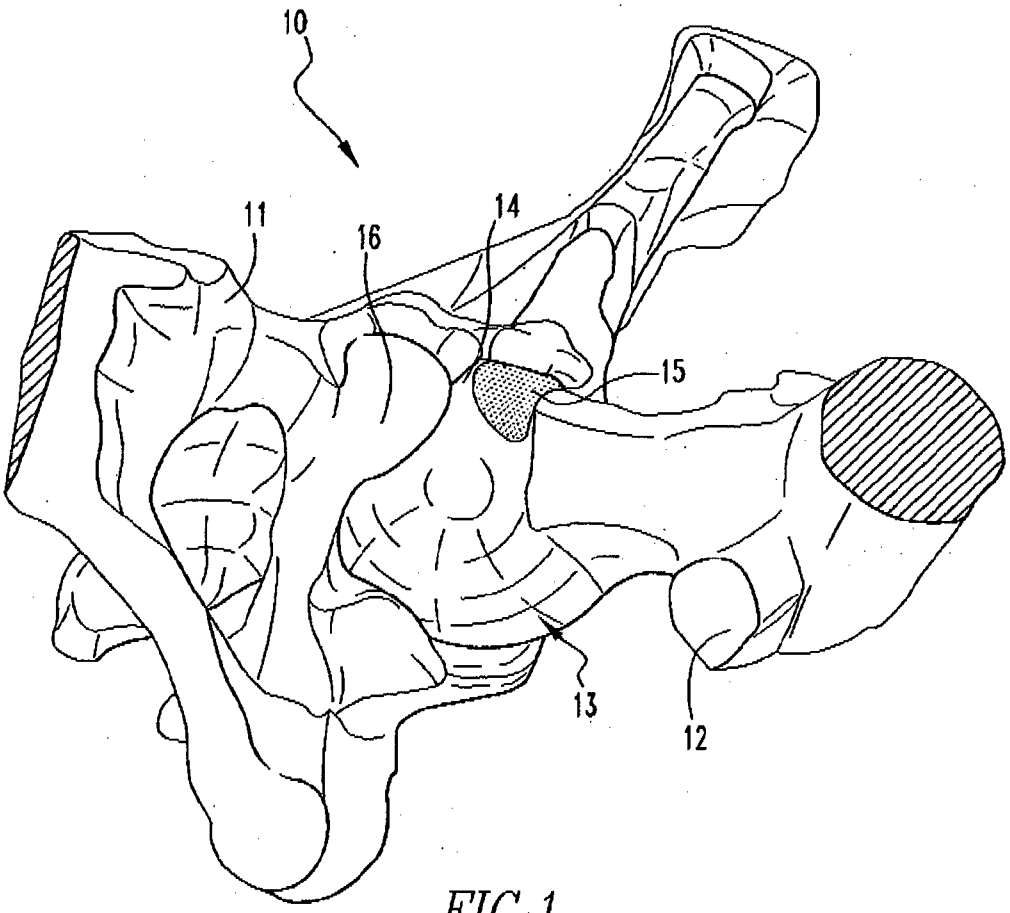


FIG.1

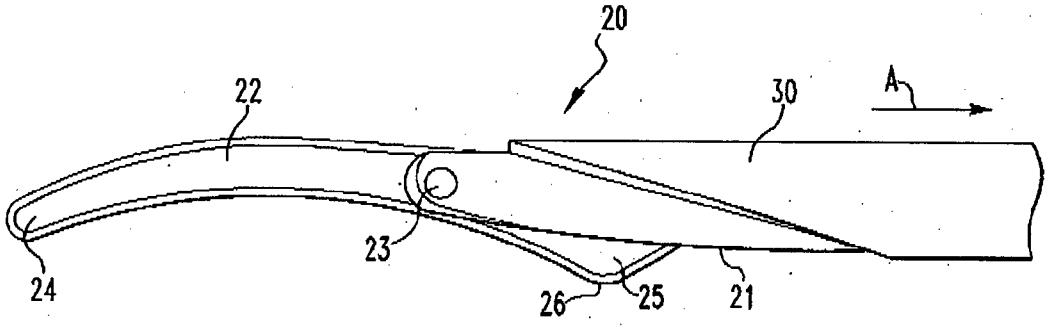


FIG.2

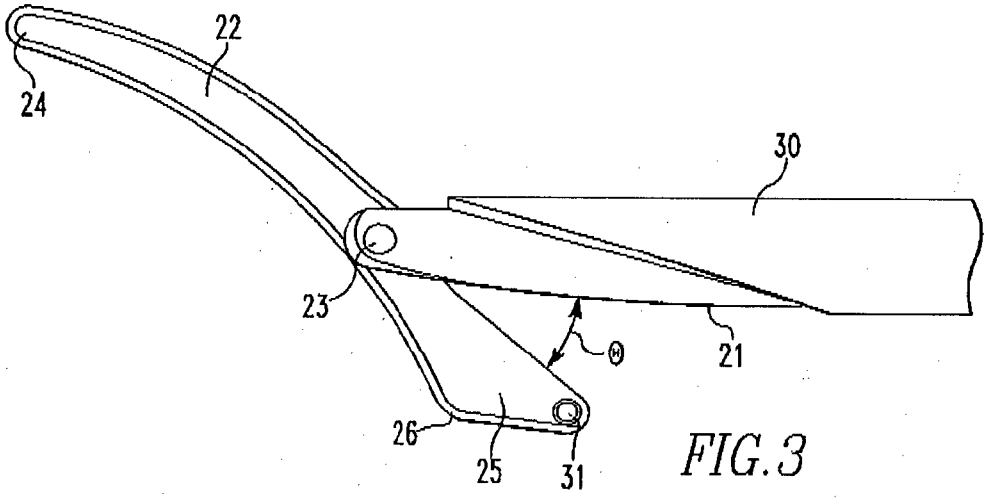
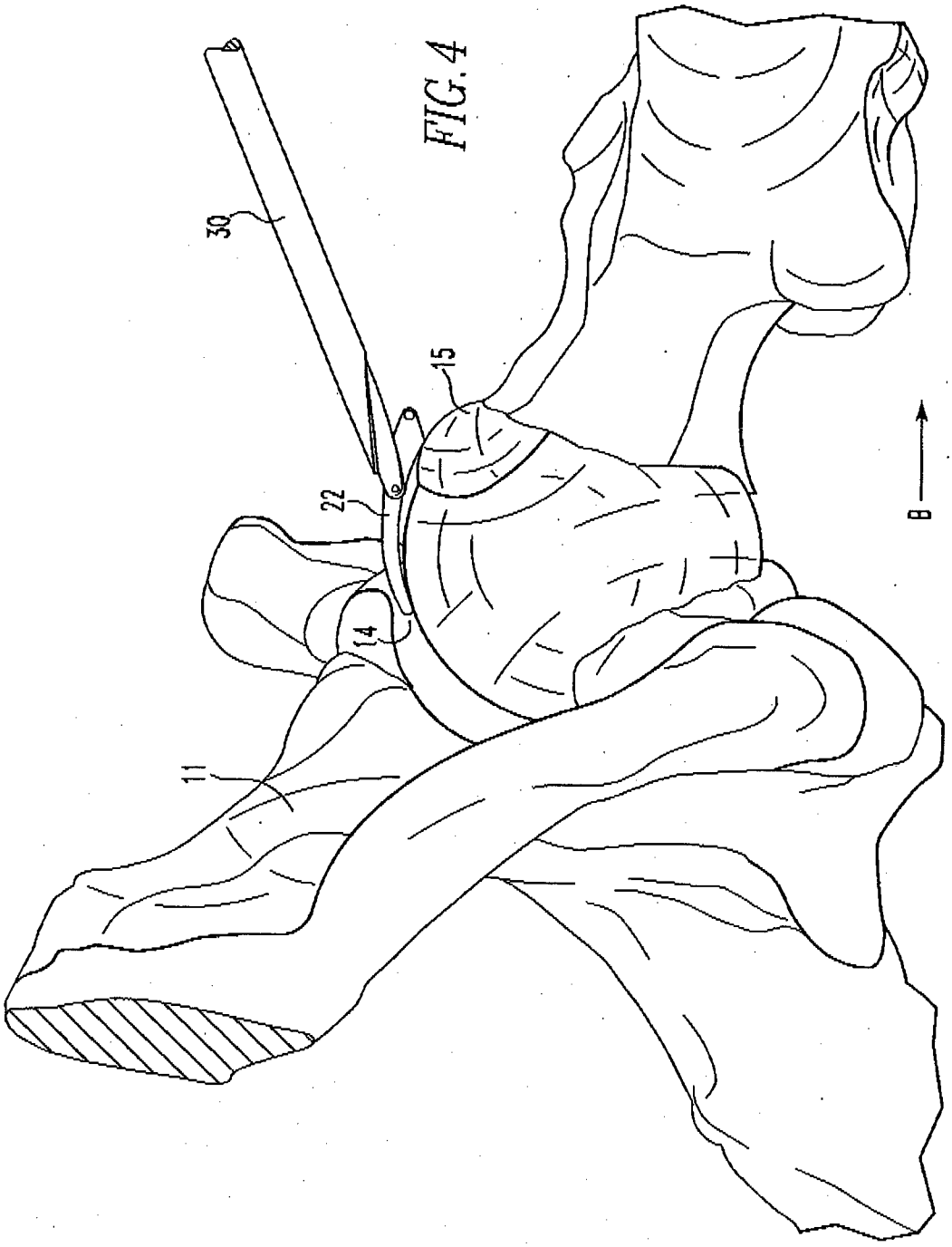


FIG.3

FIG. 4



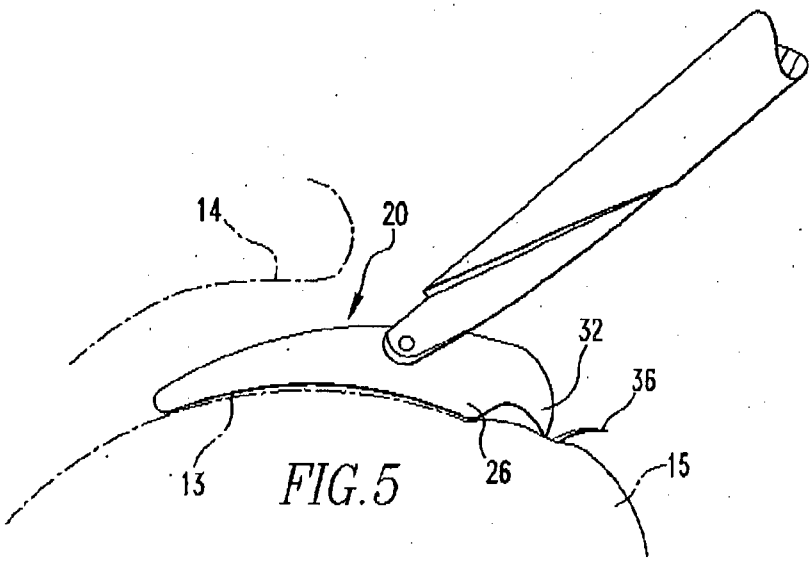


FIG.5

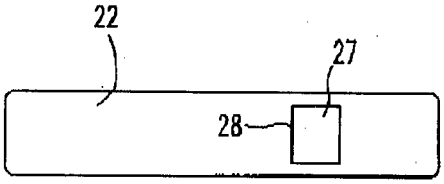


FIG.5A

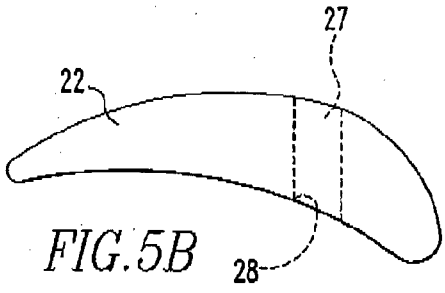


FIG.5B

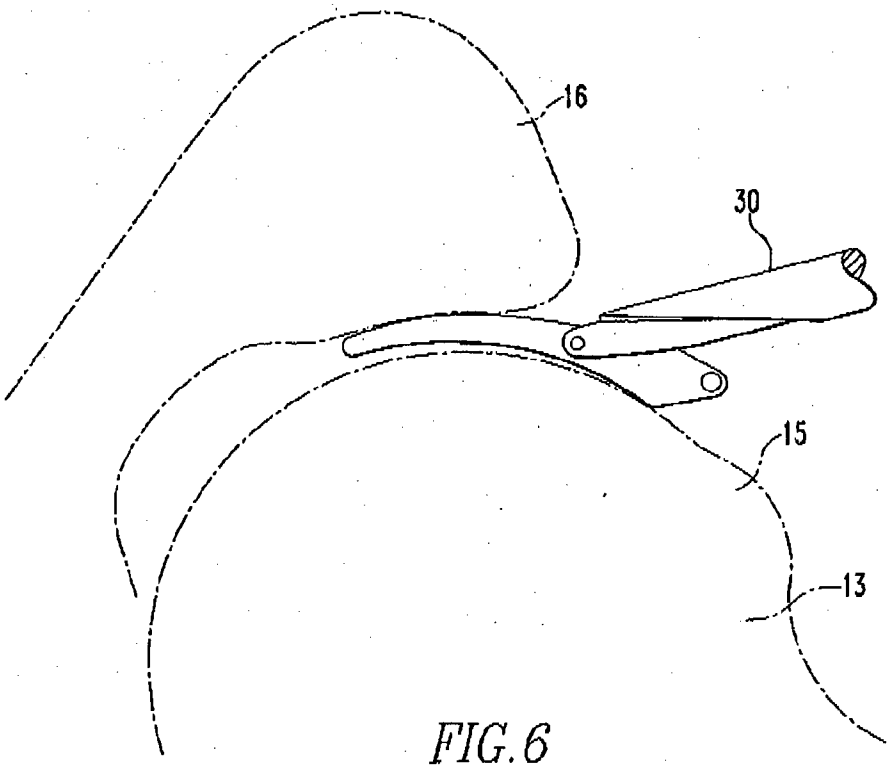


FIG. 6

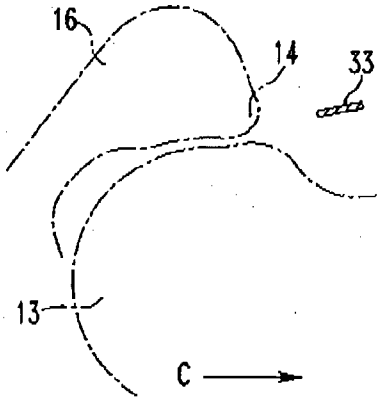


FIG. 7

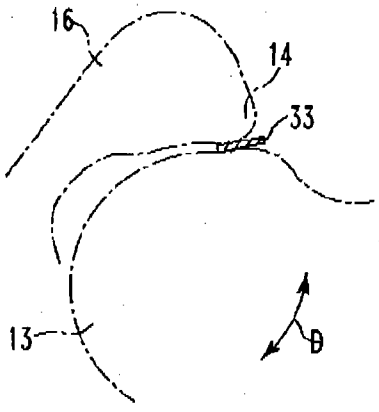


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/042672

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B19/00 A61B17/16
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 319 465 A (SMITH WATSON MFG COMPANY [FR]) 13 November 1902 (1902-11-13) page 1, column 2, paragraph 4; figures 1-3	1,10
X	US 1 722 748 A (HOLDEN JR TIMOTHY N) 30 July 1929 (1929-07-30) figure 4	1,10
X	US 2009/281545 A1 (STUBBS ALLSTON J [US]) 12 November 2009 (2009-11-12) paragraph [0070] - paragraph [0071]; figures 3d-3h	1,10
X	US 2003/130741 A1 (MCMINN DEREK JAMES WALLACE [GB]) 10 July 2003 (2003-07-10) paragraph [0031] - paragraph [0034]; figures 7,8	1,10

-/- .

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 October 2011	08/11/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Barton , Simon

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/042672

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/060039 A1 (CYPRIEN JEAN-MAXWELL [CH]) 17 March 2005 (2005-03-17) figures 8-10	1,10

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/042672

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 319465 A	13-11-1902	NONE	
US 1722748 A	30-07-1929	NONE	
us 2009281545 Al	12-11-2009	NONE	
us 2003130741 Al	10-07-2003	NONE	
us 2005060039 Al	17-03-2005	NONE	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/042672

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ ciaims Nos.: 2-9 , 11-38 (compl etel y) ; 1 (parti al ly)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 2-9, II-38(completely); I(partially)

Claim 1 is not clear as required by Article 6 PCT in combination with Rule 6 PCT, since it seeks to define its subject matter in part in terms of intended use (marking differences in curvature of target tissue not part of the claimed subject matter); and in that the "template" comprised by the "arm" implies no clear technical feature. As a result the subject matter of claim 1 is merely a shaft with a structure that might be gripped at one end and a structure not further defined, other than being capable of marking, at the other end. It is further noted that "marking" could refer to inserting a marker device into tumour tissue as well as superficial marking as here apparently intended. Claims 2-6,9-13 ,16, 18,25 ,29 ,31 are all directly dependent on claim 1. Independent claim 32 is so vague that a marker pen or scalpel would deprive its subject matter of novelty. As a result the number of claims (2-6,9-13 ,16, 18,25 ,29 ,31) directly dependent on a dummy independent claim make it unduly burdensome to determine the matter for which protection is sought. An informal clarification was requested, in preference to making an incomplete search, which would be restricted to claims 1 and 2, or a declaration of no search. The applicant was therefore requested to state which set of claims singly dependent on claim 1 he considers to define the invention in terms of clear technical features thereof, see Rule 6 PCT in combination with Article 6 PCT. In response the applicant elected to direct the search to dependent claim 10. It is further noted that this claim was searched to the extent that it finds support in the description as required by Article 6 PCT, noting that the curved tissue surface and curved arm surface are essentially linked, and the only such surface finding support in the description is the surface of a joint, explicitly the femoral head, but the ankle joint also being mentioned.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.