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(54) Title: DRILL GUIDE

(57) Abstract: The present invention relates to a drill guide for use in drilling an acetabular tunnel. The drill guide comprises a cannulated shaft having a handle towards a proximal end, and an offset arm towards a distal end. The arm is flexible or pivotable and has a distal tip for engaging the articular surface of the acetabulum, and is offset from a projected path of the shaft cannulation.



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Drill Guide

The present invention relates to a drill guide. In particular, the present invention relates to a drill guide for use in hip arthroscopy.

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

- 15 The labrum improves stability of the hip joint by effectively deepening the hip socket to provide extra structural support to the joint. It also helps to create a negative intra-articular pressure which partially seals the joint and acts to prevent it from being distracted. In addition, the cartilage tissue of the labrum acts as a buffer between adjacent bone surfaces of the hip joint and provides
20 an articular surface which permits 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.

- The acetabular labrum has an irregular shape and comprises essentially three
25 parts. The first connects the labrum to the acetabular rim. The second is an extension of the articular surface of the acetabulum, and provides an internal articular surface, and the third is an external surface where the hip joint capsule attaches.

- 30 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 all.

Due to advances in arthroscopic surgical procedures on the hip, the number of labral tears being identified has markedly increased. Such tears can be caused by injury through a specific trauma or repetitive movements, or by degeneration. Femoral acetabular impingement, interference caused by naturally occurring irregularities on the generally spherical head of the femur with the rim of the acetabulum, can also lead to such tears. Often, an individual will be completely unaware of a tear in their labrum and will not display any symptoms. Such cases will not generally require treatment. However, in more severe cases an affected individual may experience pain and stiffness, or limited range of motion in their hip joint or groin. They may also notice a locking, clicking or catching sensation in the affected hip.

Arthroscopic repair of a torn hip labrum can be approached in several ways, depending on the severity of the tear. The damaged tissue may be removed by debridement to relieve pain for flap tears. Where the tear is more severe, bioabsorbable suture can be utilised to hold the tear together whilst the cartilage tissue heals. This is generally only successful in regions where there is a good blood supply. Where the damage is severe and the labrum has become detached from the acetabular rim, reattachment is often necessary and this typically requires the use of one or more bone anchors.

In surgical repairs where suture anchors are required in the reattachment of a torn labrum back to the bony rim of the acetabulum, it is necessary to drill bone tunnels within the acetabulum. Due to the inherent anatomy of the hip, and the restriction on the arthroscopic trajectories which are available to a surgeon, the procedure for drilling bone tunnels to accommodate the suture anchors is challenging. Placement and pitch of the tunnels relative to the acetabular rim is critical in order to avoid a 'blow-out' of the acetabular cartilage, or the back of the acetabulum itself

Previously, this issue has typically been dealt with in one of two ways. The surgeon may force a drill guide into what is deemed to be the correct trajectory by using brute force, and then visually determine whether the projected drill path would cause the a blow-out of the acetabulum or acetabular cartilage.

Alternatively, a curved drill guide can be used to enable standard portals and trajectories to be used. Using a curved guide allows the drill to bend and enter the acetabulum at an angle which minimises any potential blow-out.

- 5 However, during surgery and in the aqueous environment of the joint space, both of these approaches suffer from lens distortion with the wide angled arthroscope necessary for performing hip arthroscopy, and the high angle (70°) of the direction of view to the camera axis. Operating under these conditions, it is extremely difficult to mentally project a straight drill path through the bone
10 with any accuracy.

A more convenient arthroscopic approach could have considerable advantages over open surgical procedures if these obstacles were overcome. In particular, it would help to reduce the number of instances acetabular blow-out.

- 15 Accordingly, there exists a need for a better arthroscopic approach.

- The present invention seeks to address at least some of these problems by providing a drill guide which allows bone tunnels to be drilled in the acetabulum, whilst reducing the risk of a blow-out of the acetabulum or acetabular cartilage
20 occurring.

In its broadest sense the present invention provides a drill guide having a flexible or pivotable offset arm.

- 25 According to the present invention there is provided a drill guide for use in drilling an acetabular tunnel, comprising a cannulated shaft having a handle towards a proximal end, and an offset arm towards a distal end, wherein the arm is flexible or pivotable and comprises a distal tip for engaging the articular surface of the acetabulum, and which is offset from a projected path of the
30 shaft cannulation.

Suitably, the arm is resiliently flexible. Suitably, the arm is formed from a Nitinol wire or plate, a Nitinol tube, or a plastics material.

Alternatively, the arm is rigid and is pivotally connected at or near the distal end of the shaft. Suitably, the pivotal connection is a hinge. Suitably, the pivotal connection is a living hinge. Preferably, the pivotal connection includes biasing means. Suitably, the biasing means is a spring. All of these arrangements

5 allow the arm to bend, flex or pivot within a single plane if a surgeon chooses a trajectory other than the default provided by the natural state of the arm.

Preferably, the drill guide includes an obturator for supporting and protecting the offset arm whilst the instrument is packaged and/or when the instrument is

10 being introduced into a surgical site. Suitably, the obturator is a curved or flattened member, or a hollow tubular member. Preferably, the obturator is a tubular member, or at least partially tubular, coaxially mounted with the shaft. Suitably, the obturator includes an opening at a distal end. Preferably, the obturator is slidably or rotatably mounted within the shaft and interlocks with the

15 offset arm such that it may be held substantially rigidly.

Alternatively, the obturator is an outer sheath, mounted on the outer surface of the 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

20 rotatably mounted on the shaft, or is removable. 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.

25 Preferably, the drill guide includes a lock. The lock helps locking the obturator when it is engaged with the offset arm and in a position for transit. The lock may be any suitable locking means, such as a twist-lock, button or catch.

Preferably, the distal end of shaft includes bone engaging means. Suitably, the

30 bone engaging means are one or more teeth or spikes which, in use, act to prevent the distal end of the shaft from slipping when engaged with a bone surface.

Preferably, the proximal end of the shaft, or handle, includes a depth stop to prevent over-drilling of the bone tunnels. This feature helps to prevent over-drilling of the bone tunnels, by ensuring that the bone tunnels are only drilled to a depth required for the particular anchor which is being used. Suitably, the depth stop is adjustable. An adjustable depth stop allows anchors of different sizes to be used in conjunction with the drill guide - the depth stop being set according to the particular anchor size being used in the procedure.

Preferably, the offset arm includes one or more marks to define a preferred region of contact of the offset arm with the acetabular surface, during use of the instrument. Suitably, the one or more marks are at or towards the distal end of the offset arm. The mark or markings assist the surgeon in the correct usage of the instrument.

Suitably, the offset arm includes one or more bends. Bends may advantageously be incorporated into the offset arm so that only a preferred region of the arm comes into contact with tissue during use of the instrument. Alternatively, the arm may be curved, or be straight and include one or more hinges. This helps to minimise the extent of contact of the instrument with the labral tissue, to prevent damage to the tissue.

Another general aspect of the invention features a method for positioning a bone tunnel in the acetabulum using the guide discussed above. In use, the bone engaging means at the distal end of the instrument shaft are located against a surface of the acetabular rim, and the pitch of the instrument relative to the acetabulum is adjusted, and thus the trajectory of the guide, until the offset arm comes into contact with the acetabular surface. Next, a drill bit is inserted through the drill guide and the bone drilled to a depth stop. A suture anchor is then delivered down the guide and into the previously drilled bone hole. The guide is subsequently removed from the patient. Among other advantages, the invention provides an efficient and accurate way of positioning a bone tunnel, and helps to prevent a blow-out of the acetabulum or acetabular cartilage.

The current invention provides an arthroscopic instrument that uses the curved surface of the acetabular socket to guide a drill for placement of anchor tunnels in procedure for reattaching the labrum to the acetabulum. The instrument provides an offset position which allows a safe drill trajectory to be chosen
5 before drilling takes place.

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

- 10 Figure 1 is a partial view of a distracted hip joint including a first embodiment of an instrument according to the invention;
- Figure 2 is a side-view of the distal end of the instrument of Figure 1;
- 15 Figure 3 is a close-up side-view of the distal end of the instrument of Figure 1, with the hip joint shown in a partial sectional view;
- Figure 4 is a close-up side-view of the distal end of the instrument of Figure 1, in which a blow-out has occurred.;
- 20 Figure 5 is a surgical view illustrating a blow-out of the acetabulum;
- Figures 6A & B are, respectively, side views of the embodiment of Figure 1 in which the offset arm is flexible and bent; and rigid and hinged.
- 25 Figure 7 is a perspective view from the side and below of the distal end of an alternative embodiment, in which the offset arm has an alternative mounting arrangement;
- 30 Figure 8 is a sectional view of the embodiment of Figure 7;
- Figure 9 is a partial sectional view, from below, of the embodiment of Figure 7; and
-

Figure 10 is a perspective view from the side and above of the distal end of the instrument of Figure 1 which includes an internal obturator.

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Referring to Figure 1, there is shown a partially distracted 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 synovial 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. Also shown is a drill guide 14 for assisting a surgeon when conducting drilling procedures of the acetabulum.

The drill guide comprises a shaft 15, having a handle 20 towards a proximal end, and an offset arm 21 towards a distal end. The shaft 15 is cannulated to allow the passage of a drill (not shown) during a drilling procedure. The drill guide assists a surgeon in judging where to drill the acetabulum and helps to keep the drill piece steady during the drilling process.

As shown in Figures 2 and 3, the offset arm 21 helps to maintain a minimum wall thickness of bone between a bone tunnel and the articular surface of the acetabular cartilage 23, when the arm 21 remains in contact with the acetabulum during the drilling process. In the preferred embodiment of Figure 2, the distal end or tip 22 of the offset arm 21 is shorter in length than the tunnel to be drilled. According to this illustration, the position of the anchor 19 is intended to depict its final position once it has been inserted within the drilled tunnel, and relative to the positioning of the drill guide. In alternative embodiments (not shown), the distal end or tip of the offset arm is intended to roughly correlate with the bottom of the tunnel to be drilled. To this end, a depth stop (not shown) for preventing over-drilling of the bone tunnel is provided. The depth stop may be any suitable means and can be a shoulder

within the cannulated shaft or a similar such feature at the point of entry of the drill piece to the cannulated shaft, to serve the purpose of preventing over-advancement of the drill piece. Accordingly, the risk of a drill passing directly through the acetabulum and out the medial side is reduced.

5

The offset arm can be designed with any offset desired, and to some extent will be determined by the anatomy of a particular patient, with a larger offset resulting in a thicker the bone wall between tunnel and acetabular cartilage.

- 10 In Figure 3, with the tip 22 of the offset arm 21 held against the acetabular cartilage 23, a bone tunnel 24 resulting from drilling using the guide is shown with hashed lines. As can be seen, the drill guide provides for a minimal bone thickness between the tunnel and acetabular cartilage 23, helping to prevent a blow-out of the acetabular cartilage.

15

If the drill guide is not correctly aligned, and the tip 22 of the offset arm 21 is not abutted against the surface of the acetabular cartilage 23 of the acetabular socket during drilling, or lifts away, as shown in Figure 4, the thickness of bone between the subsequently drilled hole and the socket or cartilage will be

- 20 reduced, and a blow-out of the acetabulum may occur.

An actual blow-out of the acetabular cartilage is shown in Figure 5, where the distal tip of the offset-arm is not in contact with the articular surface of the acetabular cartilage. As a result, the drill has passed through the bone and
25 cartilage of the acetabulum and into the joint space of the socket.

A key feature of the offset arm is that it is designed to pivot, flex or bend if the surgeon chooses a trajectory other than the minimum indicated by the arm.

- 30 Typically in this condition, the offset arm is curved or bent, as depicted in Figure 6A. The arm is also resiliently flexible, and preferably formed from a material having memory properties, such as Nitinol or a suitable plastics material. In the illustrated embodiment, the offset arm is made of Nitinol that allows it to be bent

yet return to its original position once the force is removed. The Nitinol arm can be screwed, pinned, riveted or welded to the cannulated shaft.

Alternatively, as shown in Figure 6B, the offset arm may be rigid and include a pivot 'A' in a region where offset arm connects or couples with the shaft of the drill guide. The pivot can be a hinge. In such embodiments, the drill guide may include a biasing means (not shown), for example a spring, to bias the offset arm in a minimal bone thickness indicating position. The provision of a pivot permits the arm to bend only within a single plane. This is advantageous if a surgeon chooses a trajectory other than the minimum provided by the arm.

It is known to be difficult to weld Nitinol directly to stainless steel. In the embodiments of Figures 1 to 4, a Nitinol offset arm is attached to the cannulated shaft of the drill guide by means of a screw or pin. However, stress concentrations at the point of attachment, and the precision required in fixing the arm to the shaft mean that it can be difficult to manufacture drill guides in this manner. Figures 7 to 9 illustrate an alternative means of attaching the Nitinol arm to the cannulated shaft. In this alternative embodiment, the drill guide has a Nitinol offset arm which is formed with and trapped within a stainless steel cap. According to this construction, the stainless steel cap is welded to the cannulated shaft, which itself is preferably also formed from stainless steel. The offset arm is cantilevered relative to the shaft and steel cap. As a result, some of the difficulties of manufacture may be alleviated.

Figure 7 shows the distal end of a drill guide 14' having an offset arm 21' formed from a resiliently flexible Nitinol finger and cap 30. In this embodiment the cap is formed from stainless steel and is welded to the cannulated shaft 15', which is also formed from stainless steel. In alternative embodiments, the cap is formed from other suitable materials.

Additionally, the distal end of cannulated shaft 15' features bone engaging means 31 to help prevent slippage of the guide once it has been placed for, and during, drilling.

As is more clearly shown in Figures 8 to 10, cap 30 includes various supports 32, 32' and lip 34 for fixing the Nitinol finger within a channel of the cap, and preventing it from moving. In addition, one or more 'bumps' or projections 33 are provided on cap 30 to prevent the Nitinol finger from translating out of
5 channel.

The distal region of the offset arm 21 also includes one or more marks 35 which define a preferred region of contact for the offset arm with the acetabular surface. The mark or marks help the surgeon to correctly position the drill
10 guide and assist its usage of the instrument.

An obturator may also be used with the drill guide to protect the offset arm. This prevents tissue catching on the offset arm, particularly during the introduction of the drill guide into the body and joint region, and can stabilize
15 the offset arm during insertion.

In the embodiment shown in Figure 10, drill guide 14 includes an obturator 25 which projects from the distal end of shaft 15. The obturator may be a generally tubular member coaxially mounted with the shaft which supports and
20 protects the offset arm 21 whilst the instrument is packaged and/or when the instrument is being introduced into a surgical site. In the embodiment shown, the obturator is retractable and moveable between a deployed position, in which the offset arm is engaged for storage or insertion into a surgical site, and a retracted position in which the obturator is housed within the shaft of the drill
25 guide. In such embodiments, the drill guide is formed of an inner tube and an outer tube. The inner tube provides the channel through which a drill may be guided, and the region between the inner and outer tubes houses the obturator. In alternative embodiments, not shown, the obturator may simply be removed once the instrument has been inserted into the surgical site.

30 The obturator may be slidably or rotatably attached to the instrument, or may be removable.

In alternative embodiments, not shown, the obturator is a sheath mounted on the outer surface of the shaft of the drill guide. The sheath includes an opening at a distal end and can be moved in an axial direction for deployment or retraction. The outer sheath may be advanced and retracted by means of
5 complementary axial threads on the outer surface of the shaft and inner surface of outer sheath. Alternatively, the outer sheath may be 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 that incorporates a twisting or screwing action at or towards the extreme ends of its desired motion in order to lock the sheath
10 in position.

The surgical instrument may also include a lock (not shown) for locking the instrument in the stowed position for storage or passage into, or out of, the body. The lock may be any suitable locking means, such as a twist-lock, button
15 or catch.

The drill guide also includes a depth stop (not shown). The depth-stop can be set, by suitable means, to a depth required to safely deploy a bone anchor, and acts to prevent a drill from being inserted too deeply, which would result in over-
20 drilling of the acetabulum. For example, the depth stop may be an internal shoulder in the cannulated shaft of the drill guide or a portion of the handle. The depth stop may also be adjustable to account for bone anchors of differing sizes, or alternatively, to allow a surgeon to drill shallower/deeper bone tunnels where deemed appropriate.

25 The described drill guide provides an advantage over standard known straight guides because a safe drill trajectory may be chosen before drilling of an anchor hole, and also because, the estimation of a safe trajectory is eliminated. Further, it provides an advantage over existing curved guides since it eliminates
30 any unseen trajectory changes within the joint which are sometimes difficult to comprehend when viewed through an endoscope, for the reasons mentioned previously.

CLAIMS:

1. A drill guide for use in drilling an acetabular tunnel, comprising a
cannulated shaft having a handle towards a proximal end, and an offset
5 arm towards a distal end, wherein the arm is flexible or pivotable and
comprises a distal tip for engaging the articular surface of the
acetabulum, and which is offset from a projected path of the shaft
cannulation.
- 10 2. A drill guide according to claim 1, wherein the arm is resiliently flexible.
3. A drill guide according to claim 2, wherein the arm is formed from a
Nitinol wire or plate, a Nitinol tube, or a plastics material.
- 15 4. A drill guide according to claim 1, wherein the arm is rigid and is pivotally
connected at or near the distal end of the cannulated shaft.
5. A drill guide according to claim 4, wherein the pivotal connection is a
hinge.
- 20 6. A drill guide according to claim 4 or claim 5, wherein the pivotal
connection includes biasing means.
7. A drill guide according to claim 6, wherein the biasing means is a spring.
- 25 8. A drill guide according to claim 1, wherein the drill guide includes an
obturator.
9. A drill guide according to claim 8, wherein the obturator is a curved or
30 flattened member, or a hollow tubular member.
10. A drill guide according to claim 9, wherein the obturator is a tubular
member, or at least partially tubular, coaxially mounted with the shaft.
- 35 11. A drill guide according to claim 8, wherein the obturator is slidably or
rotatably mounted within the shaft and interlocks with the offset arm.

12. A drill guide according to claim 8, wherein the obturator is an outer sheath, mounted on the outer surface of the shaft.
13. A drill guide according to claim 12, wherein the outer sheath at least partly surrounds a portion of the outer surface of the shaft.
14. A drill guide according to claim 12, wherein the outer sheath is slidably mounted or rotatably mounted on the shaft, or is removable.
15. A drill guide according to claim 8, further comprising a lock.
16. A drill guide according to claim 1, wherein the distal end of shaft includes bone engaging means.
17. A drill guide according to claim 16, wherein the bone engaging means comprise one or more teeth or spikes which, in use, act to prevent the distal end of the shaft from slipping when engaged with a bone surface.
18. A drill guide according to claim 1, wherein the proximal end of the shaft, or handle, comprises a depth stop to prevent over-drilling of the bone tunnels.
19. A drill guide according to claim 18, wherein the depth stop is adjustable.
20. A drill guide according to claim 1, wherein the offset arm includes one or more marks to define a preferred region for contacting the acetabular surface.
21. A drill guide according to claim 1, wherein the offset arm is curved or includes one or more bends.
22. A method for positioning and drilling a bone tunnel in the acetabulum, using a drill guide according to claim 1 comprising the steps of: locating the bone engaging means at the distal end of the drill guide against a surface of the acetabulum; adjusting the pitch of the drill guide relative to the acetabulum until the offset arm comes into contact with the acetabular surface; inserting a drill bit into the drill guide; drilling into the

bone to a desirable depth; delivering a suture anchor into the drilled hole, removing the drill guide, leaving the suture anchor in place.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/059216

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/17
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	US 5 601 550 A (ESSER RENE D [US]) 11 February 1997 (1997-02-11) figures 13-16	1-3,8-21
X	US 2010/016984 A1 (TRABISH HARUTARO [US]) 21 January 2010 (2010-01-21) figure 4	1
X	US 2006/106398 A1 (LAURYSSSEN CARL [US] ET AL) 18 May 2006 (2006-05-18) figure 1A	1
X	US 2010/049200 A1 (RE PAUL [US]) 25 February 2010 (2010-02-25) figure 14	1,4-7
X	US 2004/015170 A1 (TALLARIDA STEVEN J [US] ET AL) 22 January 2004 (2004-01-22) paragraph [0165]; figure 9a	1,4-7



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

2 February 2012

Date of mailing of the international search report

14/02/2012

Name and mailing address of the ISA/

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Authorized officer

Fernández Arillo, J

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/059216

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.: 22
because they relate to subject matter not required to be searched by this Authority, namely:
Pursuant to Rule 39.1(iv) PCT, the subject-matter of claim 22 has not been searched, since it is directed to a method for treatment of the human body by surgery.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2011/059216

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