

SURGICAL INTRODUCER

FIELD OF THE INVENTION

- 5 The present invention relates to a surgical introducer for inserting an implant into the cartilage of a human ear.

BACKGROUND OF THE INVENTION

- 10 Prominent ear deformity is common amongst the human population. An ear which projects more than 20mm from the side of the head is increasingly perceived as prominent as this distance increases. By this estimate, up to 10% of the population may be affected. It is desirable to correct the prominence very early in life when the cartilage is soft and pliable. However, often the prominence is ignored and not treated. Consequently, many children suffer the psychological
15 consequences associated with prominent ears. These consequences can persist into adulthood.

- The ear cartilage is cup-shaped and is formed of the conchal fossa and the antihelical fold which allows the ear to lie flat against the side of the head. Prominence may be the result of abnormal formation of the antihelical fold. Alternatively, it may be the result of a deep conchal fossa. One or
20 both of these abnormalities may need to be addressed when correcting prominence of the ear. However, even for ears with a deep conchal bowl, accentuation of the antihelical fold will make a difference to the perception of prominence. In most cases the prominence is apparent at birth.

- International patent application number PCT/GB2012/000282 discloses an implant formed of shape-memory material in the shape of a horseshoe for reshaping the cartilaginous portion of an ear. The
25 implant is flattened and loaded into an introducer which assists with insertion of the implant into the ear. When the implant is in the desired position it is deployed to reshape the cartilaginous portion of the ear because it reverts to its horseshoe shape when released from the introducer.

- 30 The implant is inserted into the ear using an introducer which holds the implant in its first configuration, and upon insertion the implant adopts its second pre-programmed configuration. The introducer comprises a handle and a slider movable relative to the handle.

- The present invention seeks to provide improvements over the introducer disclosed in
35 PCT/GB2012/000282.

SUMMARY OF THE INVENTION

- Herein disclosed is a surgical introducer for inserting an implant into a human ear, the introducer
40 comprising a handle, a slider movable relative to the handle between a first position and a second position, a retaining means being at least partially defined by the slider, and a releasable locking mechanism biased to lock the slider in said first or second position, wherein, when the slider is in said first position an implant is engaged by the retaining means and when the slider is moved towards said second position the implant is deployed.

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The locking mechanism and the slider are formed from a unitary component.

5 Forming the slider and resilient spring from a unitary component simplifies the construction of the introducer and minimises manufacturing costs.

10 The resilient spring comprises a first portion having a first width received by the channel and a second portion having a second width, greater than the first width engageable with the locking formation of the channel.

The slider may further comprise a visual indicator to assist an operator in identifying when the introducer has been inserted a sufficient distance into the ear of a patient.

15 Provision of a visual indicator provides the surgeon with a visual aid to identify when the introducer has been inserted the correct distance into the patients ear before deployment of the implant.

The visual indicator may be an embossment.

20 The handle may comprise two openings therethrough to each receive a finger of an operator and/or a trigger position to receive a user's index finger.

The surgical introducer for inserting an implant into a human ear may be as described with reference to, and or as shown in, the drawings.

25 The introducer is provided in combination with an implant formed of shape-memory material and having a first configuration when retained by the retaining means of the introducer and a second pre-programmed configuration when deployed into a patient's ear.

According to an aspect of the present invention, there is provided a surgical introducer for inserting an implant into a human ear, the implant comprising engaging members and being formed from a shape memory material which transforms from a first, substantially planar configuration to a second, horseshoe shaped, preprogrammed configuration, wherein the implant is biased in the second, pre-programmed configuration, the introducer comprising: a handle defining a body and a longitudinal channel in the body to house a retaining guide and receive a deployment member; wherein, the retaining guide is configured to hold the implant in the first, substantially planar configuration; wherein, the deployment member is configured to push the implant from the retaining guide to insert the implant into the ear; and a locking mechanism, characterised in that, the handle further comprises a first locking configuration and a second locking configuration in the body of the handle according to a first position and second position of the deployment member respectively and the locking mechanism comprises a resilient spring formed integrally with the deployment member, wherein at least a portion of the resilient spring is wider than the channel such that when the implant is held by the retaining guide and the deployment member is in the first position, the resilient spring engages with the first locking configuration and when the resilient spring is depressed and the deployment member is move to the second position, the resilient spring engages with the second locking formation.

During surgery, precise control over deployment of the implant is critical to the resulting adjustment to prominence of an ear. If deployment were to occur inadvertently in the wrong position the patient's ear would not take the desired shape. The implant would then need to be removed and further implant inserted. Provision of a locking mechanism means that deployment can only occur upon the conscious decision of a surgeon to extend the slider into a second position

The retaining means is further defined by the handle.

The handle comprises a body and a slider support member.

The body of the handle comprises a channel to house the slider support member and receive the slider.

The channel comprises a locking formation having a first locking position and a second locking position according to the first position and second position of the slider respectively.

Provision of a locking formation limits longitudinal movement of the slider to between two fixed positions. This provides certainty to a surgeon that the implant is securely retained by the introducer when the slider is in a first position and that the implant will be deployed when the slider is moved to a second position.

The locking mechanism comprises a resilient spring engageable with the locking formation of the handle.

Use of a resilient spring biases the locking mechanism in the locked position. The slider cannot be extended, and the implant deployed, without a conscious decision by the surgeon to overcome the spring in order to extend the slider.

Given the delicate nature of surgery on a human ear, ergonomic design of the introducer is desirable for the surgeon to have sufficient control over the introducer.

FIGURES

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Specific embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings in which:

10 Figure 1 shows an isometric view of a surgical introducer according to embodiments of the invention.

Figure 2 shows an exploded view of the surgical introducer of Figure 1.

15 Figure 3 shows a further view of the surgical introducer of Figure 1.

Figure 4 shows an implant as used with the introducer of the present invention.

DETAILED SUMMARY OF THE INVENTION

20 Figures 1 to 3 show a surgical introducer 10 for inserting an implant, 22 into the cartilaginous portion of a human ear. The introducer 10 comprises a handle 12 and a slider 14 which is movable relative to the handle 12.

25 The handle 12 comprises a body formed from two mirrored parts 12a, 12b and a slider support 16 extending forwardly of the body 12a, 12b. Each part of the body 12a, 12b includes snap fit connections 12c for joining the two parts of the body 12a, 12b of the handle 12 together. The two parts of the body 12a, 12b define between them a channel 12d within which the slider 14 and slider support 16 are received.

30 The body 12a, 12b has two apertures 12f therethrough which are configured to each receive an operator's finger. The body also has a trigger grip position 12g to provide flexibility in how the introducer 10 is held.

35 The slider support 16 comprises a flat plate 14a which is fixed to the body 12a, 12b of the handle 12. The forward end 16b of the slider support 16 is provided with a longitudinal cut-out 16c for receiving a part of the slider 14 to prevent lateral movement of the slider 14 relative to the handle 12.

40 The slider 14 comprises a substantially flat plate 14a having a distal end 14b and a proximal end 14c. A resilient spring 18 forms an integral part of the slider 14 at its proximal end 14c. The resilient spring is a profiled sprung plate which extends upwardly from the proximal end 14c of the slider 14 and towards the distal end 14b of the slider 14. A portion 18a of the extreme end of the resilient spring 18 is of a greater width than the remainder of the resilient spring 18 and the slider 14.

45 The distal end 14b of the slider 14 defines a retaining lip 14d which partially retains one end of an implant 22. The retaining lip 14d can be up to 0.6mm long but will typically be between 0.45 –

0.5mm long. The lip can be up to 0.5mm thick but will typically be between 0.25 – 0.3mm thick. The distal end 16a of the slider support defines a similar retaining lip (not shown) of substantially similar dimension which partially retains the opposite end of an implant 22.

5 A pin 14e is spot welded to the slider 14 for engagement with the longitudinal cut-out 16b of the slider support 16. An embossment 14f is provided between the retaining lip 14d and pin 14e of the slider to provide visual indication of when the introducer 10 is in the desired position. In the illustrated example, the embossment 14f is disposed centrally between the retaining lip 14d and pin 14e of the slider.

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The slider 14 is received by the channel 12d of the body 12a, 12b and overlays the slider support 16. The slider 14 can move between a first, extended position and a second, retracted position. The range of longitudinal movement of the slider 14 is inhibited by engagement of the wider portion 18a of the resilient spring 18 with respective indents 12e formed in each part of the body 12a, 12b of the handle 12.

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The indents 12e formed in each part of the body 12a, 12b are generally M shaped. The wider portion of the resilient spring 18 has a width corresponding to the maximum distance between the indent 12e of each part of the body 12a, 12b. The range of movement of the slider 14 is thus limited to being equivalent to the distance between the two internal apex of the M-shaped indents 12e.

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A cover 20 overlays the resilient spring 18 to provide comfort and a tactile response to a surgeon. The cover 20 is formed from two mirrored parts 20a, 20b which are snap-fitted together around the resilient spring 18.

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The implant 22, as shown in figures 4 and 5, comprises a nitinol plate 22a which is coated with 24 carat gold. A plurality of tines 22b extend from one side of the plate 22a for engaging with the cartilage of a human ear. The plate 22a includes an opening 22c therethrough to assist with removal of the implant 22 from a human ear once prominent ear deformity has been corrected.

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The implant 22, as shown in figure 4, is biased in a horse shoe shape in its second pre-programmed configuration. When the implant 22 is loaded into the introducer 10 it is flattened (see figure 5) such that it is flattened and retained between the retaining lip 14d of the slider 14 and the retaining lip of the slider support. The slider 14 is in the retracted position when an implant 22 has been loaded into the retaining means. The implant 22 reverts to its biased horseshoe shape when the slider 14 is moved to the extended position and the implant 22 is thus deployed from the introducer 10.

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Before the implant 22 can be implanted into an ear of a patient, the patient needs to be given a local anaesthetic so that an incision can be made through the skin of the ear. The skin is then lifted away from the cartilage to create a tunnel. The slider 14 of the introducer 10 is inserted into the tunnel to position the implant 22 in the desired position. The slider 14 is then extended to increase the distance between the distal end 14b of the slider 14 and the distal end 16a of the slider support 16. The implant 22 is then deployed from the introducer 10 and reverts to its natural horseshoe shape

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around the cartilage of the ear. This has the effect of enhancing the natural shape of the antihelical fold and reducing prominence of the ear.

5 The above description is given by way of example only and is not intended to limit the scope of the invention.

CLAIMS

1. A surgical introducer for inserting an implant into a human ear, the implant comprising
engaging members and being formed from a shape memory material which transforms from a
5 first, substantially planar configuration to a second, horseshoe shaped, preprogrammed
configuration, wherein the implant is biased in the second, pre-programmed configuration,
the introducer comprising: a handle defining a body and a longitudinal channel in the body to
house a retaining guide and receive a deployment member; wherein, the retaining guide is
configured to hold the implant in the first, substantially planar configuration; wherein, the
10 deployment member is configured to push the implant from the retaining guide to insert the
implant into the ear; and a locking mechanism, characterised in that, the handle further
comprises a first locking configuration and a second locking configuration in the body of the
handle according to a first position and second position of the deployment member
respectively and the locking mechanism comprises a resilient spring formed integrally with the
15 deployment member, wherein at least a portion of the resilient spring is wider than the
channel such that when the implant is held by the retaining guide and the deployment
member is in the first position, the resilient spring engages with the first locking configuration
and when the resilient spring is depressed and the deployment member is move to the second
position, the resilient spring engages with the second locking formation.

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2. A surgical introducer for inserting an implant into a human ear according to claim 1 wherein the slider further comprises a visual indicator to assist an operator in identifying when the introducer has been inserted a sufficient distance into the ear of a patient.
- 5 3. A surgical introducer for inserting an implant into a human ear according to claim 2, wherein the visual indicator is an embossment.
4. A surgical introducer for inserting an implant into a human ear according to any preceding claim, wherein the handle comprises two openings therethrough to each receive a finger of an operator.