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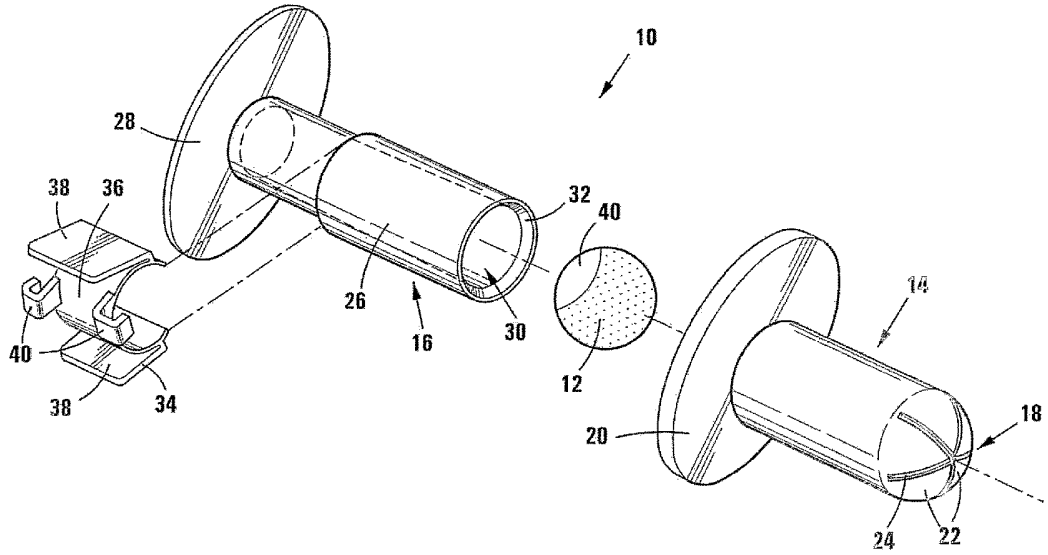
(54) Title: AN ORBITAL IMPLANT APPLICATOR



(57) Abstract: An orbital implant applicator (10) includes a barrel or guide (14) shaped and dimensioned to receive an orbital implant (12). The barrel or guide (14) has an outlet at one end thereof sized to allow an orbital implant (12) to pass therethrough. An ejector or ejection means (16) to eject an orbital implant (12) received in the barrel or guide (14) outwardly through the outlet of the barrel or guide (14) is also provided.

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— *with amended claims*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Description

AN ORBITAL IMPLANT APPLICATOR

[1] THIS INVENTION relates to an orbital implant applicator. It also relates to an orbital implant kit and to a method of inserting an orbital implant into an orbit.

[2] An orbital implant is placed into the orbit or eye socket of a mammal, such as the human, to occupy volume following the loss of an eye. Such a mammal is thus one who has had an ocular enucleation or evisceration, or one who needs an orbital implant replacement. In the case of evisceration, the orbital implant is implanted to replace the contents of the eye. In the case of enucleation, the implant is placed into the eye muscle cone and the eye muscles are attached directly to the implant or, if the implant is covered or wrapped with tissue or artificial material, to the orbital implant wrapping. Instead, the eye muscles can be wrapped around the implant and secured together without direct attachment of the eye muscles to the orbital implant. An anterior surface of the orbital implant is typically covered with tissue including the conjunctiva. Following a healing period, a prosthesis, i.e. an artificial eye, is located in position to obtain an artificial eye with natural appearance.

[3] Such orbital implants may be spherical or they may have more complicated shapes, for example a posterior portion of the implant may be conical with channels to locate eye muscles, and other features to which the eye muscles can be attached. The orbital implant may also be porous or non-porous.

[4] In view of the above, as will be appreciated, when inserting an orbital implant in the eye muscle cone, it may be necessary to achieve deep penetration as well as correctly to orientate the orbital implant. The insertion procedure is complicated by the confined space within which the physician has to work, particularly if it is necessary to achieve correct orientation for orbital implants with more complicated features. In the case of orbital implants which exhibit high surface roughness and porosity, such as implants of the integrated type, tissue adherence due to the hygroscopicity of the orbital implant material also causes problems and may make it difficult to achieve correct orientation of the implant.

[5] The Applicant is aware of a method of inserting an orbital implant, in which two slightly overlapping sheets of a smooth synthetic plastics or polymeric material are inserted over the implant site, with the orbital implant then being placed in position and manually pushed into the orbit. Correctly positioning the orbital implant with this method is difficult. Once inserted, the sheets are removed from behind the orbital implant. During the removal of the sheets, care must be taken that the orientation and position of the orbital implant are not changed.

[6] It is an object of the present invention to at least alleviate the problems currently ex-

perienced when an orbital implant is inserted into an orbit or eye socket.

[7] According to one aspect of the invention, there is provided an orbital implant applicator which includes

[8] a barrel or guide shaped and dimensioned to receive an orbital implant, the barrel or guide having an outlet at one end thereof sized to allow an orbital implant to pass therethrough; and

[9] an ejector or ejection means to eject an orbital implant received in the barrel or guide outwardly through the outlet of the barrel or guide.

[10] The ejector or ejection means may include a plunger slidably received or receivable in the barrel or guide.

[11] The plunger may have a tip which defines a bearing surface or seat for an orbital implant received in the barrel or guide. The bearing surface or seat may be shaped to bear, over the entire surface of the bearing surface or seat, against a spherical surface of predetermined radius. Advantageously, this configuration allows spreading of the load over a larger surface area of an orbital implant when an orbital implant is ejected from the barrel or guide by means of the plunger.

[12] The plunger may define or include an inspection passage, having an outlet in its tip, to allow inspection of an orbital implant received in the barrel or guide. This feature may be important for correct application of orbital implants having to be implanted in a particular orientation in an eye socket or orbit.

[13] Preferably, the inspection passage extends coaxially with the plunger, providing the seat at the tip of the plunger with a central, circular bore.

[14] The orbital implant applicator may include locking means or a lock to lock the plunger releasably in the barrel or guide, thereby to prevent inadvertent ejection of an orbital implant from the barrel or guide.

[15] Preferably, the barrel or guide is shaped and dimensioned snugly, but not tightly, to receive an orbital implant. Typically, the barrel or guide or at least an end portion thereof defines a circular cylindrical interior surface, with an inside diameter ranging between about 18 mm and about 22 mm, e.g. about 20 mm. The barrel typically has a length of between about 30 mm and about 60 mm, e.g. about 55 mm.

[16] The orbital implant applicator may include a closure formation at least partially closing the outlet of the barrel or guide. Advantageously, this would prevent or inhibit contamination or damage to an orbital implant received in the barrel or guide, which is typically located inside the barrel or guide in the vicinity of the outlet but in front of the plunger.

[17] The closure formation may comprise a plurality of petal-like members displaceable between an open condition and a closed condition. Typically, between about 3 and about 7, e.g. 5 petal-like members are included. The petal-like members together may

define a tip for the barrel or guide which is tapered, e.g. a blunt rounded tip, when in their closed condition. Advantageously, this configuration assists in pushing the tip into eye socket tissue during insertion of an orbital implant into an orbit or eye socket.

[18] The petal-like members may be biased towards their closed condition.

[19] In their closed condition, the petal-like members may together define a seat for an orbital implant received in the barrel or guide. The seat may be shaped to correspond with a substantial surface portion of an orbital implant. In one embodiment of the invention, the seat is thus hemispherical, to accommodate or seat a spherical orbital implant. In another embodiment of the invention, the seat is conical, to accommodate or seat an orbital implant having a conical posterior surface.

[20] The petal-like members may be defined by cuts or slits in the tip of the barrel or guide. Typically, these cuts or slits extend longitudinally, rearwardly over the tip of the barrel or guide, and radially outwardly from a centre of the tip. Preferably, the cuts or slits stop short, in a radially outward direction, of a maximum diameter of the barrel or guide, thereby to assist in biasing the petal-like members toward their closed conditions.

[21] The barrel or guide may be of a flexible synthetic plastics or polymeric material, e.g. polyurethane or linear low density polyurethane. The material may have a Shore A hardness of between about Shore A 50 and about Shore A 90, e.g. about Shore A 70, and typically has a smooth external surface to facilitate insertion into eye socket tissue.

[22] The lock or locking means may be configured to lock the plunger in a position where it is bearing with slight force against an orbital implant sandwiched between the plunger and the closure formation. Preferably, the slight force is sufficient to retain the implant with correct orientation (if the implant has a correct orientation) in the barrel, during normal handling of the applicator.

[23] In one embodiment of the invention, the locking means is in the form of a stop formation that can be clamped to the plunger, between an end of the barrel or guide remote from its outlet and a thumb pad of the plunger, preventing depression of the plunger into the barrel or guide.

[24] The applicator may include depth markings to provide to a user thereof information on the depth to which the outlet of the barrel or guide has been inserted into an orbit or eye socket. The depth markings may be provided externally on the barrel or guide, e.g. in the form of a plurality of longitudinally spaced annular marks on the barrel.

[25] According to another aspect of the invention, there is provided an orbital implant kit, the kit including

[26] an orbital implant applicator; and

[27] an orbital implant.

[28] Preferably, both the orbital implant applicator and the orbital implant are sterilized.

The orbital implant is typically matched to the applicator so that it can be inserted into an orbit by means of the applicator. Thus, typically, the implant is shaped and sized to be received or receivable inside the applicator.

[29] The orbital implant applicator may be an applicator as hereinbefore described.

[30] The orbital implant may be located inside the barrel or guide of the applicator. The plunger may be releasably locked in position in the barrel or guide, with the orbital implant seated against the plunger and against the closure formation.

[31] The kit may include a sterilized package within which the applicator and the orbital implant are packaged.

[32] According to a further aspect of the invention, there is provided a method of inserting an orbital implant into an orbit, the method including

[33] inserting an end of a barrel or guide, within which the orbital implant is received, into an orbit; and

[34] guidingly ejecting the orbital implant from the barrel or guide into the orbit.

[35] The orbital implant may be ejected from the barrel or guide by means of a plunger slidably received in the barrel or guide. Typically, the orbital implant is ejected by keeping the plunger stationary and sliding the barrel or guide along the plunger away from the orbit. In this fashion, the orbital implant is inserted at the same depth into the orbit as the depth to which the barrel or guide was inserted into the orbit.

[36] The method may include measuring the depth to which the end of the barrel or guide has been inserted into the orbit, prior to ejecting the orbital implant. Measuring the depth may include using depth markings located on the barrel or guide.

[37] The barrel may form part of an orbital implant applicator as hereinbefore described.

[38] The invention will now be described, by way of example only, with reference to the single accompanying diagrammatic drawing which shows an exploded three-dimensional view of an orbital implant applicator in accordance with the invention, and an orbital implant.

[39] In the drawing, reference numeral 10 generally indicates an orbital implant applicator in accordance with the invention, which is associated with an orbital implant 12.

[40] The applicator 10 includes a barrel 14 and ejection means in the form of a plunger 16 which is slidably receivable in the barrel 14.

[41] The barrel 14 is moulded from polyurethane or LLDPE and has a length of about 55 mm and an internal diameter of about 20 mm. The material of the barrel 14 has a Shore A hardness of about 70.

[42] The barrel 14 is circular cylindrical with a tip 18 defining an outlet at one end thereof and an oval flange 20 at an opposite end thereof. The outlet defined by the tip 18 is closed by a closure formation in the form of five petal-like members 22. The

petal-like members 22 are defined by cuts or slits 24 in the tip 18 of the barrel 14 and are displaceable between an open condition in which they are forced apart and substantially straightened, and a closed condition in which they are curved, as shown in the drawing. The cuts or slits 24 extend longitudinally, rearwardly over the tip 18, and radially outwardly from a centre of the tip 18, as can be clearly seen in the drawing. The cuts or slits 24 stop short, in a radially outward direction, of a maximum diameter of the barrel 14. The Applicant has found that this arrangement assists in biasing the petal-like members 22 toward their closed condition as shown in the drawing.

[43] The plunger 16 includes a shank 26 with an oval thumb pad 28 at one end of the shank 26. The entire plunger 16 is moulded from polyethylene, which is substantially more rigid than the polyurethane or LLDPE from which the barrel 14 is moulded.

[44] The shank 26 is circular cylindrical and is slidably receivable inside the barrel 14 in syringe fashion. An end portion of the shank 26, adjacent the thumb pad 28, is of reduced diameter compared to an end portion thereof remote from the thumb pad 28. An inspection passage 30 extends longitudinally through the shank 26 and opens out in a tip 32 thereof and in the thumb pad 28. As a result of the inspection passage 30 opening out in the tip 32, the tip 32 defines an annular seat to bear against the orbital implant 12. The annular seat defined by the tip 32 is chamfered, as can be clearly seen in the drawing, in use to spread the load over a larger surface area of the orbital implant 12 when the orbital implant 12 is ejected from the barrel 14 by means of the plunger 16.

[45] A lock or locking means, in the form of a stop formation 34 is provided to lock the plunger 16 in a particular longitudinal position in the barrel 14. The stop formation 34 includes a split circular cylindrical body 36 of a rigid plastics material. The body 36 is shaped to clip around and thus to receive the portion of the shank 26 of reduced diameter. Two diverging gripping wings 38 are integrally moulded with the body 36 and extend from diagonally opposite portions of the body 36. The gripping wings 38 allow easy manipulation of the stop formation 34. As will be appreciated, the gripping wings 38 are positioned such that, when they are gripped between a thumb and an index finger with slight force, the body 36 opens up slightly to facilitate clipping of the body 36 onto the shank 26, or removal of the body 36 from the shank 26.

[46] Two spaced hook-like receiving formations 40 are integrally moulded with the body 36. One hook-like receiving formation 40 is shaped and dimensioned to receive a peripheral portion of the flange 20 when the body 36 is clamped onto the shank 26. The other hook-like receiving formation 40 is shaped and dimensioned to receive a peripheral portion of the thumb pad 28 when the body 36 is clamped to the shank 26.

[47] The orbital implant 12 is spherical and has a diameter slightly less that the diameter of the barrel 14, thus allowing the implant 12 to be snugly but not tightly received

inside the barrel 14. Typically, the orbital implant 12 and the applicator 10 are supplied together as a kit in a sterilized package and the invention thus extends to such an orbital implant kit. In the kit, the orbital implant 12 is received inside the barrel 14 and is sandwiched between the tip 32 of the plunger 16 and the tip 18 of the barrel 14, or more specifically, the petal-like members 22. The petal-like members 22 define a hemispherical seat against which the orbital implant 12 is bearing. The plunger 16 is pushing with slight force against the orbital implant 12 so that the petal-like members 22 are only slightly forced apart. The stop formation 34 is clamped by means of the body 36 to the reduced diameter portion of the shank 26 of the plunger 16 and is dimensioned to ensure that the slight force imparted by the plunger 16 on the orbital implant 12 is maintained. As will be appreciated, with the stop formation 34 being clipped to the plunger 16, and being clipped to the thumb pad 28 of the plunger 16 and the flange 20 of the barrel 14, further depression of the plunger 16 into the barrel 14, or retraction of the plunger 16 from the barrel 14, is prevented.

[48] The inspection passage 30 can be used to inspect the orientation of the orbital implant 12 sandwiched between the tip 32 of the shank 26 and the petal-like members 22. Some orbital implants, such as the orbital implant 12 shown in the drawing, must be implanted in a particular orientation in an eye socket or orbit. The orbital implant 12 has an anterior cap 40 and the orbital implant 12 must thus be planted into an orbit such that the anterior cap 40 faces outwardly through the mouth of the orbit. By means of the inspection passage 30, it is possible to inspect the orbital implant 12 inside the barrel 14 to ensure that the anterior cap 40 is fully visible through the inspection passage 30, which would mean a correct orientation, before the orbital implant 12 is inserted into an orbit.

[49] In use, the sterilized package within which the orbital implant 12 and the orbital implant applicator 10 are supplied, is opened only once the orbital implant site has been prepared by the physician. The physician then inspects, if necessary, the orbital implant 12 through the inspection passage 30 to ensure that it is correctly orientated inside the barrel 14 and the rounded tip 18 of the barrel 14 is then pushed into the orbit tissue to the required depth. In order to assist the surgeon to determine when the tip 18 of the barrel 14 has been inserted to the required depth, the barrel 14 may include depth markings, such as longitudinally spaced annular rings. Once the barrel 14 has been inserted to the required depth, the stop formation 34 is removed and the barrel 14 is pulled by means of the flange 20 toward the thumb pad 28 thereby to slide the plunger 16 deeper into the barrel 14 until the orbital implant 12 has been ejected through the outlet in the tip 18. Once the implant 12 has been deposited, the orbital implant applicator 10 is removed leaving the orbital implant 12 correctly positioned in the eye socket tissue.

[50] The Applicant believes that the invention provides a simple but efficient device, and an improved method, for inserting an orbital implant into an orbit.

Claims

[1] An orbital implant applicator which includes
a barrel or guide shaped and dimensioned to receive an orbital implant, the barrel or guide having an outlet at one end thereof sized to allow an orbital implant to pass therethrough; and
an ejector or ejection means to eject an orbital implant received in the barrel or guide outwardly through the outlet of the barrel or guide.

[2] The orbital implant applicator as claimed in claim 1, in which the ejector or ejection means includes a plunger slidably received or receivable in the barrel or guide.

[3] The orbital implant applicator as claimed in claim 2, in which the plunger has a tip which defines a bearing surface or seat for an orbital implant received in the barrel or guide, the bearing surface or seat being shaped to bear, over the entire surface of the bearing surface or seat, against a spherical surface of pre-determined radius.

[4] The orbital implant applicator as claimed in claim 2 or claim 3, in which the plunger defines an inspection passage, having an outlet in its tip, to allow inspection of an orbital implant received in the barrel or guide.

[5] The orbital implant applicator as claimed in any one of claims 2 to 4 inclusive, which includes locking means or a lock to lock the plunger releasably in the barrel or guide, thereby to prevent inadvertent ejection of an orbital implant from the barrel or guide.

[6] The orbital implant applicator as claimed in any one of the preceding claims, in which the barrel or guide is shaped and dimensioned snugly, but not tightly, to receive an orbital implant, the barrel or guide or at least an end portion thereof defining a circular cylindrical interior surface.

[7] The orbital implant applicator as claimed in any one of the preceding claims, which includes a closure formation at least partially closing the outlet of the barrel or guide.

[8] The orbital implant applicator as claimed in claim 7, in which the closure formation comprises a plurality of petal-like members displaceable between an open condition and a closed condition.

[9] The orbital implant applicator as claimed in claim 8, in which the petal-like members together define a tip for the barrel or guide which is tapered, when in their closed condition.

[10] The orbital implant applicator as claimed in claim 8 or claim 9, in which the petal-like members are biased towards their closed condition.

[11] The orbital implant applicator as claimed in any one of claims 8 to 10 inclusive in which, in their closed condition, the petal-like members together define a seat for an orbital implant received in the barrel or guide.

[12] The orbital implant applicator as claimed in claim 5 and claim 7, in which the lock or locking means is configured to lock the plunger in a position where it is bearing with slight force against an orbital implant sandwiched between the plunger and the closure formation.

[13] The orbital implant applicator as claimed in any one of the preceding claims, which includes depth markings to provide to a user thereof information on the depth to which the outlet of the barrel or guide has been inserted into an orbit or eye socket.

[14] An orbital implant kit, the kit including
an orbital implant applicator; and
an orbital implant.

[15] The kit as claimed in claim 14, in which both the orbital implant applicator and the orbital implant are sterilized.

[16] The kit as claimed in claim 14 or claim 15, in which the orbital implant applicator is an applicator as claimed in any one of claims 1 to 13 inclusive.

[17] The kit as claimed in any one of claims 14 to 16 inclusive, in which the orbital implant applicator is an applicator as claimed in any one of claims 7 to 11 inclusive and in which the orbital implant is located inside the barrel or guide of the applicator, with the plunger being releasably locked in position in the barrel or guide, and with the orbital implant seated against the plunger and against the closure formation.

[18] A method of inserting an orbital implant into an orbit, the method including inserting an end of a barrel or guide, within which the orbital implant is received, into an orbit; and
guidingly ejecting the orbital implant from the barrel or guide into the orbit.

[19] The method as claimed in claim 18, in which the orbital implant is ejected from the barrel or guide by means of a plunger slidably received in the barrel or guide.

[20] The method as claimed in claim 18 or claim 19, which includes measuring the depth to which the end of the barrel or guide has been inserted into the orbit, prior to ejecting the orbital implant, measuring the depth including using depth markings located on the barrel or guide.

AMENDED CLAIMS

[received by the International Bureau on 31 August 2004 (31.08.2004);
original claims 1-20 replaced by new claims 1-19 (3 pages)]

CLAIMS:

1. An orbital implant applicator which includes

a barrel or guide shaped and dimensioned to receive an orbital implant, the barrel or guide having an outlet at one end thereof sized to allow an orbital implant to pass therethrough; and

an ejector or ejection means to eject an orbital implant received in the barrel or guide outwardly through the outlet of the barrel or guide.

2. The orbital implant applicator as claimed in claim 1, in which the ejector or ejection means includes a plunger slidably received or receivable in the barrel or guide.

3. The orbital implant applicator as claimed in claim 2, in which the plunger has a tip which defines a bearing surface or seat for an orbital implant received in the barrel or guide, the bearing surface or seat being shaped to bear, over the entire surface of the bearing surface or seat, against a spherical surface of predetermined radius.

4. The orbital implant applicator as claimed in claim 2 or claim 3, in which the plunger defines an inspection passage, having an outlet in its tip, to allow inspection of an orbital implant received in the barrel or guide.

5. The orbital implant applicator as claimed in any one of claims 2 to 4 inclusive, which includes locking means or a lock to lock the plunger releasably in the barrel or guide, thereby to prevent inadvertent ejection of an orbital implant from the barrel or guide.

6. The orbital implant applicator as claimed in any one of the preceding claims, in which the barrel or guide is shaped and dimensioned snugly, but not tightly, to receive an orbital implant, the barrel or guide or at least an end portion thereof defining a circular cylindrical interior surface.

7. The orbital implant applicator as claimed in any one of the preceding claims, which includes a closure formation at least partially closing the outlet of the barrel or guide.

8. The orbital implant applicator as claimed in claim 7, in which the closure formation comprises a plurality of petal-like members displaceable between an open condition and a closed condition.

9. The orbital implant applicator as claimed in claim 8, in which the petal-like members together define a tip for the barrel or guide which is tapered, when in their closed condition.

10. The orbital implant applicator as claimed in claim 8 or claim 9, in which the petal-like members are biased towards their closed condition.

11. The orbital implant applicator as claimed in any one of claims 8 to 10 inclusive in which, in their closed condition, the petal-like members together define a seat for an orbital implant received in the barrel or guide.

12. The orbital implant applicator as claimed in claim 5 and claim 7, in which the lock or locking means is configured to lock the plunger in a position where it is bearing with slight force against an orbital implant sandwiched between the plunger and the closure formation.

13. The orbital implant applicator as claimed in any one of the preceding claims, which includes depth markings to provide to a user thereof information on the depth to which the outlet of the barrel or guide has been inserted into an orbit or eye socket.

14. An orbital implant kit, the kit including

an orbital implant applicator as claimed in any one of claims 1 to 13 inclusive; and

an orbital implant.

15. The kit as claimed in claim 14, in which both the orbital implant applicator and the orbital implant are sterilized.

16. The kit as claimed in claim 14 or claim 15, in which the orbital implant applicator is an applicator as claimed in any one of claims 7 to 11 inclusive and in which the orbital implant is located inside the barrel or guide of the applicator, with the plunger being

releasably locked in position in the barrel or guide, and with the orbital implant seated against the plunger and against the closure formation.

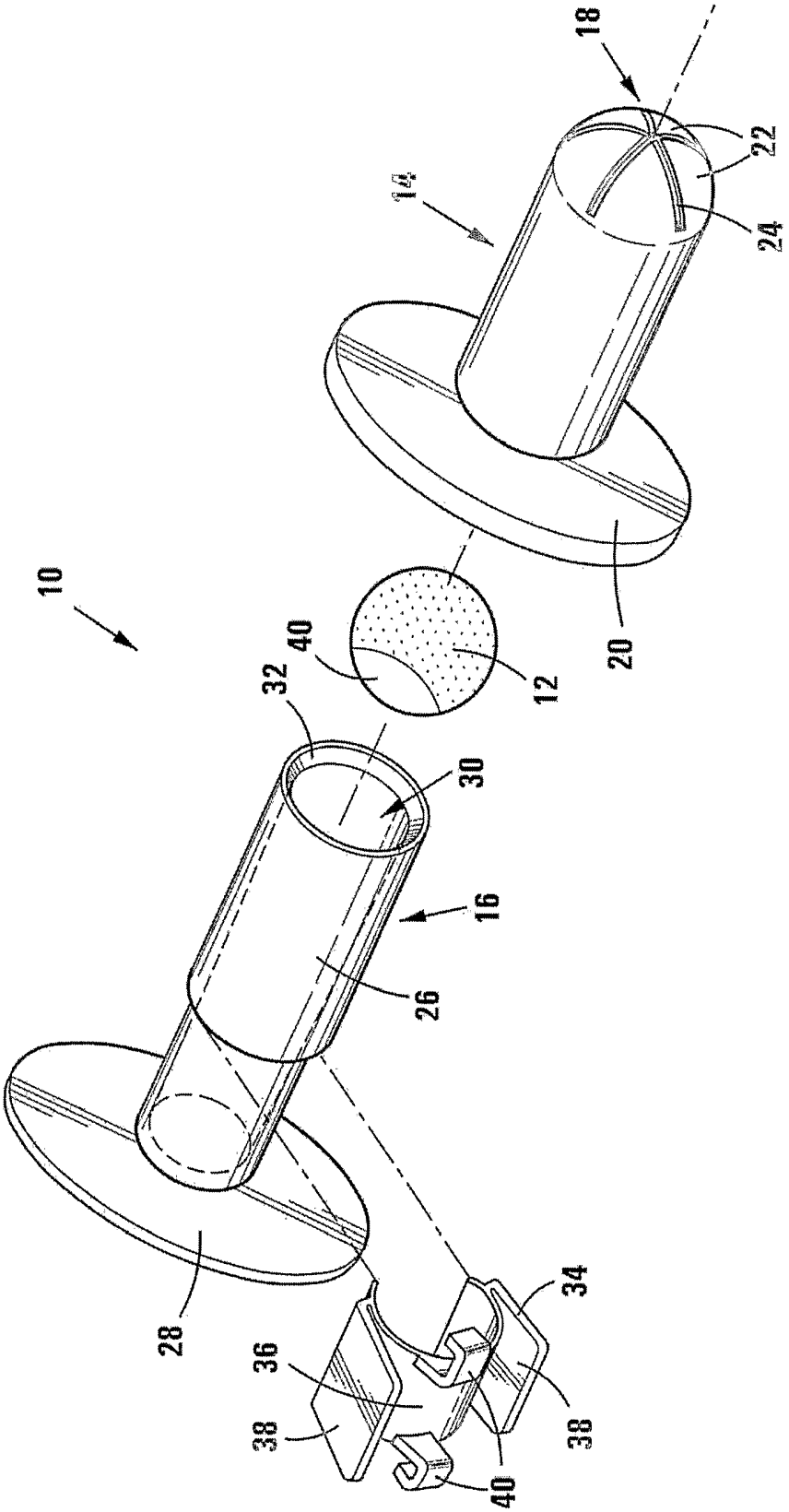
17. A method of inserting an orbital implant into an orbit, the method including

inserting an end of a barrel or guide, within which the orbital implant is received, into an orbit; and

guidingly ejecting the orbital implant from the barrel or guide into the orbit.

18. The method as claimed in claim 17, in which the orbital implant is ejected from the barrel or guide by means of a plunger slidably received in the barrel or guide.

19. The method as claimed in claim 17 or claim 18, which includes measuring the depth to which the end of the barrel or guide has been inserted into the orbit, prior to ejecting the orbital implant, measuring the depth including using depth markings located on the barrel or guide.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INTERNATIONAL SEARCH REPORT

itional Application No
PCT/IB2004/050408

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/14 A61B17/00

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)
IPC 7 A61F 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 A	US 4 147 167 A (HICKMANN HORST R ET AL) 3 April 1979 (1979-04-03) column 6, line 36 - line 66; figure 19	14,15 1-13,16, 17
A	US 6 419 698 B1 (FINGER PAUL T) 16 July 2002 (2002-07-16) the whole document	1-17
A	US 2 570 149 A (NOELLE CONRAD J) 2 October 1951 (1951-10-02) the whole document	1-17

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
27 July 2004	03/08/2004

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, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Daintith, N

INTERNATIONAL SEARCH REPORT

national application No.
PCT/IB2004/050408

Box 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. [X] Claims Nos.: 18-20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal 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 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 fee, this Authority did not invite payment of any additional fee.

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.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

In ational Application No
F../IB2004/050408

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4147167 A	03-04-1979	US 4087867 A	09-05-1978
US 6419698 B1	16-07-2002	NONE	
US 2570149 A	02-10-1951	NONE	