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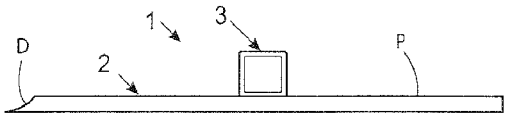
(54) Title: INSERTER FOR TUBULAR MEDICAL IMPLANT DEVICES

FIG. 1



(57) Abstract: An inserter is provided for inserting a tubular medical implant device into tissue. The inserter includes a rigid rod extending along a longitudinal axis. The rod has a distal portion that defines an open slot. The open slot extends diametrically through the rod along the longitudinal axis to a base. The open slot is configured to receive and release the tubular medical implant device.

2014278364 08 Jun 2018

WHAT IS CLAIMED IS:

1. An inserter system for inserting a tubular ocular shunt into an eye tissue, the system comprising:

a tubular ocular shunt having an elongated, compressible body defining a central lumen; and

an elongated rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends through the rod along the longitudinal axis from an open end to a base, and extends diametrically through the rod along a first transverse axis that is transverse to the longitudinal axis, wherein the open slot is dimensioned to receive and retain a portion of the tubular ocular shunt in a compressed state and with the lumen of the retained portion of the shunt being aligned with the first transverse axis and extending diametrically completely across the slot and through the rod, and wherein a distal end of the rod is configured for insertion through a tissue tract leading into the eye together with the portion of the tubular ocular shunt that is received and retained in the compressed state by the open slot of the rod.

2. The inserter system according to claim 1, wherein:

the open slot is defined by two opposed fingers that extend from the base distally parallel to the longitudinal axis to distal ends of the fingers at the distal end of the rod.

3. The inserter system according to claim 2, wherein each finger has a planar inner surface that extends parallel with the longitudinal axis from a proximal end of the finger at the base to the distal end of the finger, and wherein the planar inner surfaces of the fingers are parallel to each other, and wherein the distal ends of the two opposed fingers define an opening that leads into the slot.

4. The inserter system according to claim 3, wherein each finger has a curved outer surface opposite the planar inner surface.

2014278364 08 Jun 2018

5. The inserter system according to claim 4, wherein for each finger, the distal end of the finger is defined by a curved edge between the inner planar surface and the curved outer surface.

6. The inserter system according to claim 5, wherein the curved edge is curved about a first transverse axis that is transverse to the longitudinal axis, wherein the first transverse axis and the longitudinal axis define a plane that extends parallel to the plane of the inner surface.

7. The inserter system according to claim 6, wherein each finger is curved at its distal end about a second transverse axis that is transverse to the longitudinal axis and the first transverse axis.

8. The inserter system according to claim 7, wherein the width of the finger, measured along the first transverse axis, is less at the distal end of the finger than at the proximal end of the finger.

9. The inserter system according to claim 8, wherein the slot is constructed to receive the portion of the tubular ocular shunt oriented longitudinally along the first transverse axis.

10. The inserter system according to any one of claims 2 to 9, wherein the base of the slot is defined by a diametrically extending circular bore extending along the first transverse axis where the first transverse axis and the transverse axis define a plane that extends parallel to a plane defined by the slot.

11. The inserter system according to claim 10, wherein the diameter of the circular bore is larger than the distance between opposed, planar inner surfaces of the fingers.

12. The inserter system according to claim 11, wherein the distance between the planar inner surfaces of the fingers is less than the outer diameter of the tubular body of the ocular shunt when the shunt is in a relaxed state.

13. The inserter system according to any one of claims 10 to 12, wherein each finger has a curved outer surface opposite the planar inner surfaces of the fingers.

2014278364 08 Jun 2018

14. The inserter system according to claim 13, wherein for each finger, the distal end of the finger is defined by a curved edge between the inner planar surface and the curved outer surface.

15. The inserter system according to claim 14, wherein the curved edge is curved about the first transverse axis.

16. The inserter system according to claim 15, wherein each finger is curved at its distal end about a second transverse axis orthogonal to both the longitudinal axis and the first transverse axis.

17. The inserter system according to claim 16, wherein the width of the finger, measured along the first transverse axis, is less at the distal end of the finger than at its proximal end.

18. The inserter system according to claim 17, wherein the slot is constructed to receive the portion of the tubular ocular shunt oriented longitudinally along the first transverse axis.

19. The inserter system according to any one of claims 1 to 18, further comprising a handle having a distal portion and a proximal portion, the distal portion of the handle attached to the rod, the proximal portion of the handle being offset from the longitudinal axis of the rod.

20. An implant kit comprising:

the system according to any one of claims 1 to 19, wherein the portion of the tubular ocular shunt is retained in the open slot in a compressed state with the lumen of the retained portion of the shunt being aligned with the first transverse axis and extending diametrically completely across the slot and through the rod.

21. A method of inserting a tubular ocular shunt into an eye, the tubular ocular shunt having an elongated, compressible body defining a central lumen, the method comprising:

providing an inserter for inserting the tubular ocular shunt into the eye, the inserter comprising:

an elongated rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends through the rod along the

2014278364 08 Jun 2018

longitudinal axis from an open end to a base, and extends diametrically through the rod along a first transverse axis that is transverse to the longitudinal axis, wherein the open slot is dimensioned to receive and retain a portion of the tubular ocular shunt in a compressed state and with the lumen of the retained portion of the shunt being aligned with the first transverse axis and extending diametrically completely across the slot and through the rod, and wherein a distal end of the rod is configured for insertion through a tissue tract leading into the eye together with the portion of the tubular ocular shunt that is received and retained in the compressed state by the open slot of the rod;

disposing the portion of the tubular ocular shunt in the slot, wherein the disposed portion is retained in the slot in a compressed state; and

inserting the distal portion of the rod and the tubular ocular shunt in a first direction into the tissue tract.

22. The method according to Claim 21, further comprising moving the rod in a second direction different from the first direction to remove the tube from the slot to deposit the tubular ocular shunt in the eye.

23. The method according to Claim 22, wherein the second direction is opposite the first direction.

24. The method according to any one of Claims 21 to 23, further comprising removing the rod from the eye to remove the tube from the slot to deposit the tubular ocular shunt in the eye.

25. The method according to any one of Claims 21 to 24, wherein a distal portion of the tubular ocular shunt is introduced into the slot.

26. The method according to any one of Claims 21 to 25, wherein the rod and tubular ocular shunt are inserted through a tract formed in the eye.

27. A method of inserting a tubular ocular shunt into an eye, the tubular ocular shunt having an elongated, compressible body defining a central lumen, the method comprising:

providing an inserter for inserting the tubular ocular shunt into the eye, the inserter comprising:

2014278364 08 Jun 2018

an elongated rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends through the rod along the longitudinal axis from an open end to a base, and extends diametrically through the rod along a first transverse axis that is transverse to the longitudinal axis, wherein the open slot is dimensioned to receive and retain a portion of the tubular ocular shunt in a compressed state and with the lumen of the retained portion of the shunt being aligned with the first transverse axis and extending diametrically completely across the slot and through the rod, and wherein a distal end of the rod is configured for insertion through a tissue tract leading into the eye together with the portion of the tubular ocular shunt that is received and retained in the compressed state by the open slot of the rod, wherein the tubular implant device is disposed in the slot in the compressed state; and

inserting the distal portion of the rod and the tubular ocular shunt in a first direction into the tissue tract.

28. The method according to Claim 27 or claim 28, further comprising moving the rod in a second direction different from the first direction to remove the tube from the slot to deposit the tubular ocular shunt in the eye.

29. The method according to Claim 27, wherein the rod and tubular ocular shunt are inserted through a tract formed in the eye.

WHAT IS CLAIMED IS:

1. An inserter for inserting a tubular medical implant device into tissue, the inserter comprising:

a rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends diametrically through the rod along the longitudinal axis to a base, wherein the open slot is configured to receive the tubular medical implant device.

2. The inserter according to claim 1, wherein:

the rod has a distal end, and the open slot is defined by two opposed fingers that extend from the base distally parallel to the longitudinal axis to distal ends of the fingers at the distal end of the rod.

3. The inserter according to claim 2, wherein each finger has a planar inner surface that extends parallel with the longitudinal axis from a proximal end of the finger at the base to the distal end of the finger, and wherein the planar inner surfaces of the fingers are parallel to each other, and wherein the distal ends of the two opposed fingers define an opening that leads into the slot.

4. The inserter according to claim 3, wherein each finger has a curved outer surface opposite the planar inner surface.

5. The inserter according to claim 4, wherein for each finger, the distal end of the finger is defined by a curved edge between the inner planar surface and the curved outer surface.

6. The inserter according to claim 5, wherein the curved edge is curved about a first transverse axis that is transverse to the longitudinal axis, wherein the first transverse axis and the longitudinal axis define a plane that extends parallel to the plane of the inner surface.

7. The inserter according to claim 6, wherein each finger is curved at its distal end about a second transverse axis that is transverse to the longitudinal axis and the first transverse axis.

8. The inserter according to claim 7, wherein the width of the finger, measured along the first transverse axis, is less at the distal end of the finger than at the proximal end of the finger.

9. The inserter according to claim 8, wherein the slot is constructed to receive the implant device oriented longitudinally along the first transverse axis.

10. The inserter according to claim 2, wherein the base of the slot is defined by a diametrically extending circular bore extending along a first transverse axis orthogonal to the longitudinal axis of the rod where the first transverse axis and the transverse axis define a plane that extends parallel to a plane defined by the slot.

11. The inserter according to claim 10, wherein the diameter of the circular bore is larger than the distance between opposed, planar inner surfaces of the fingers.

12. The inserter according to claim 11, wherein the distance between the planar inner surfaces of the fingers is less than the outer diameter of the tubular body of the implant when the implant is in a relaxed state.

13. The inserter according to claim 10, wherein each finger has a curved outer surface opposite the planar inner surfaces of the fingers.

14. The inserter according to claim 13, wherein for each finger, the distal end of the finger is defined by a curved edge between the inner planar surface and the curved outer surface.

15. The inserter according to claim 14, wherein the curved edge is curved about the first transverse axis.

16. The inserter according to claim 15, wherein each finger is curved at its distal end about a second transverse axis orthogonal to both the longitudinal axis and the first transverse axis.

17. The inserter according to claim 16, wherein the width of the finger, measured along the first transverse axis, is less at the distal end of the finger than at its proximal end.

18. The inserter according to claim 17, wherein the slot is constructed to receive the implant device oriented longitudinally along the first transverse axis.

19. The inserter according to claim 1, further comprising a handle having a distal portion and a proximal portion, the distal portion of the handle attached to the rod, the proximal portion of the handle being offset from the longitudinal axis of the rod.

20. An implant kit comprising:
the inserter according to claim 1; and
a tubular implant disposed in the slot.

21. A method of inserting a tubular implant device into tissue, the method comprising:
providing an inserter for inserting the tubular medical implant device into tissue, the inserter comprising:
a rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends diametrically through the rod along the longitudinal axis to a base, wherein the open slot is configured to receive the tubular medical implant device;
disposing the tubular implant device in the slot;
inserting the distal portion of the rod and the tubular implant in a first direction into the tissue.

22. The method according to Claim 21, further comprising moving the rod in a second direction different from the first direction to remove the tube from the slot to deposit the tubular implant device in the tissue.

23. The method according to Claim 22, wherein the second direction is opposite the first direction.

24. The method according to Claim 21, further comprising removing the rod from the tissue to remove the tube from the slot to deposit the tubular implant device in the tissue.

25. The method according to Claim 21, wherein a distal portion of the tubular implant device is introduced into the slot.

26. The method according to Claim 21, wherein the rod and tubular implant device are inserted through a tract formed in the tissue.

27. A method of inserting a tubular implant device into tissue, the method comprising:

providing an inserter for inserting the tubular medical implant device into tissue, the inserter comprising:

a rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends diametrically through the rod along the longitudinal axis to a base, wherein the open slot is configured to receive the tubular medical implant device, wherein the tubular implant device is disposed in the slot;

inserting the distal portion of the rod and the tubular implant in a first direction into the tissue.

28. The method according to Claim 27, further comprising moving the rod in a second direction different from the first direction to remove the tube from the slot to deposit the tubular implant device in the tissue.

29. The method according to Claim 27, wherein the rod and tubular implant device are inserted through a tract formed in the tissue.

AMENDED CLAIMS
received by the International Bureau on 17 November 2014 (17.11.2014)

In the Claims:

1. (original) An inserter for inserting a tubular medical implant device into tissue, the inserter comprising:

a rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends diametrically through the rod along the longitudinal axis to a base, wherein the open slot is configured to receive the tubular medical implant device.

2. (original) The inserter according to claim 1, wherein:

the rod has a distal end, and the open slot is defined by two opposed fingers that extend from the base distally parallel to the longitudinal axis to distal ends of the fingers at the distal end of the rod.

3. (original) The inserter according to claim 2, wherein each finger has a planar inner surface that extends parallel with the longitudinal axis from a proximal end of the finger at the base to the distal end of the finger, and wherein the planar inner surfaces of the fingers are parallel to each other, and wherein the distal ends of the two opposed fingers define an opening that leads into the slot.

4. (original) The inserter according to claim 3, wherein each finger has a curved outer surface opposite the planar inner surface.

5. (original) The inserter according to claim 4, wherein for each finger, the distal end of the finger is defined by a curved edge between the inner planar surface and the curved outer surface.

6. (original) The inserter according to claim 5, wherein the curved edge is curved about a first transverse axis that is transverse to the longitudinal axis, wherein the first transverse axis and the longitudinal axis define a plane that extends parallel to the plane of the inner surface.

7. (original) The inserter according to claim 6, wherein each finger is curved at its distal end about a second transverse axis that is transverse to the longitudinal axis and the first transverse axis.

8. (original) The inserter according to claim 7, wherein the width of the finger, measured along the first transverse axis, is less at the distal end of the finger than at the proximal end of the finger.

9. (original) The inserter according to claim 8, wherein the slot is constructed to receive the implant device oriented longitudinally along the first transverse axis.

10. (original) The inserter according to claim 2, wherein the base of the slot is defined by a diametrically extending circular bore extending along a first transverse axis

orthogonal to the longitudinal axis of the rod where the first transverse axis and the transverse axis define a plane that extends parallel to a plane defined by the slot.

11. (original) The inserter according to claim 10, wherein the diameter of the circular bore is larger than the distance between opposed, planar inner surfaces of the fingers.

12. (original) The inserter according to claim 11, wherein the distance between the planar inner surfaces of the fingers is less than the outer diameter of the tubular body of the implant when the implant is in a relaxed state.

13. (original) The inserter according to claim 10, wherein each finger has a curved outer surface opposite the planar inner surfaces of the fingers.

14. (original) The inserter according to claim 13, wherein for each finger, the distal end of the finger is defined by a curved edge between the inner planar surface and the curved outer surface.

15. (original) The inserter according to claim 14, wherein the curved edge is curved about the first transverse axis.

16. (original) The inserter according to claim 15, wherein each finger is curved at its distal end about a second transverse axis orthogonal to both the longitudinal axis and the first transverse axis.

17. (original) The inserter according to claim 16, wherein the width of the finger, measured along the first transverse axis, is less at the distal end of the finger than at its proximal end.

18. (original) The inserter according to claim 17, wherein the slot is constructed to receive the implant device oriented longitudinally along the first transverse axis.

19. (original) The inserter according to claim 1, further comprising a handle having a distal portion and a proximal portion, the distal portion of the handle attached to the rod, the proximal portion of the handle being offset from the longitudinal axis of the rod.

20. (original) An implant kit comprising:

the inserter according to claim 1; and

a tubular implant disposed in the slot.

21. (original) A method of inserting a tubular implant device into tissue, the method comprising:

providing an inserter for inserting the tubular medical implant device into tissue, the inserter comprising:

a rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends diametrically through the

rod along the longitudinal axis to a base, wherein the open slot is configured to receive the tubular medical implant device;

disposing the tubular implant device in the slot;

inserting the distal portion of the rod and the tubular implant in a first direction into the tissue.

22. (original) The method according to Claim 21, further comprising moving the rod in a second direction different from the first direction to remove the tube from the slot to deposit the tubular implant device in the tissue.

23. (original) The method according to Claim 22, wherein the second direction is opposite the first direction.

24. (original) The method according to Claim 21, further comprising removing the rod from the tissue to remove the tube from the slot to deposit the tubular implant device in the tissue.

25. (original) The method according to Claim 21, wherein a distal portion of the tubular implant device is introduced into the slot.

26. (original) The method according to Claim 21, wherein the rod and tubular implant device are inserted through a tract formed in the tissue.

27. (original) A method of inserting a tubular implant device into tissue, the method comprising:

providing an inserter for inserting the tubular medical implant device into tissue, the inserter comprising:

a rigid rod extending along a longitudinal axis, the rod having a distal portion that defines an open slot, wherein the open slot extends diametrically through the rod along the longitudinal axis to a base, wherein the open slot is configured to receive the tubular medical implant device, wherein the tubular implant device is disposed in the slot;

inserting the distal portion of the rod and the tubular implant in a first direction into the tissue.

28. (original) The method according to Claim 27, further comprising moving the rod in a second direction different from the first direction to remove the tube from the slot to deposit the tubular implant device in the tissue.

29. (original) The method according to Claim 27, wherein the rod and tubular implant device are inserted through a tract formed in the tissue.

30. (new) The inserter according to Claim 2, wherein the rod extends outwardly transverse to the longitudinal direction and the two opposed fingers extend outwardly transverse to the longitudinal direction up to the extent of the rod.

31. (new) The inserter according to Claim 30, wherein the two opposed fingers extend outwardly fully within the extent of the rod.

32. (new) The inserter according to Claim 1, wherein the rod has an outer diameter and wherein the two opposed fingers extend outwardly a distance in a direction transverse to the longitudinal direction wherein the distance is less than or equal to the outer diameter of the rod.

FIG. 1

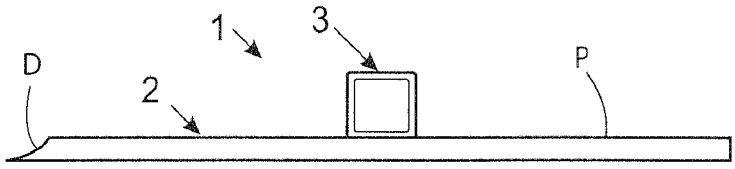


FIG. 2

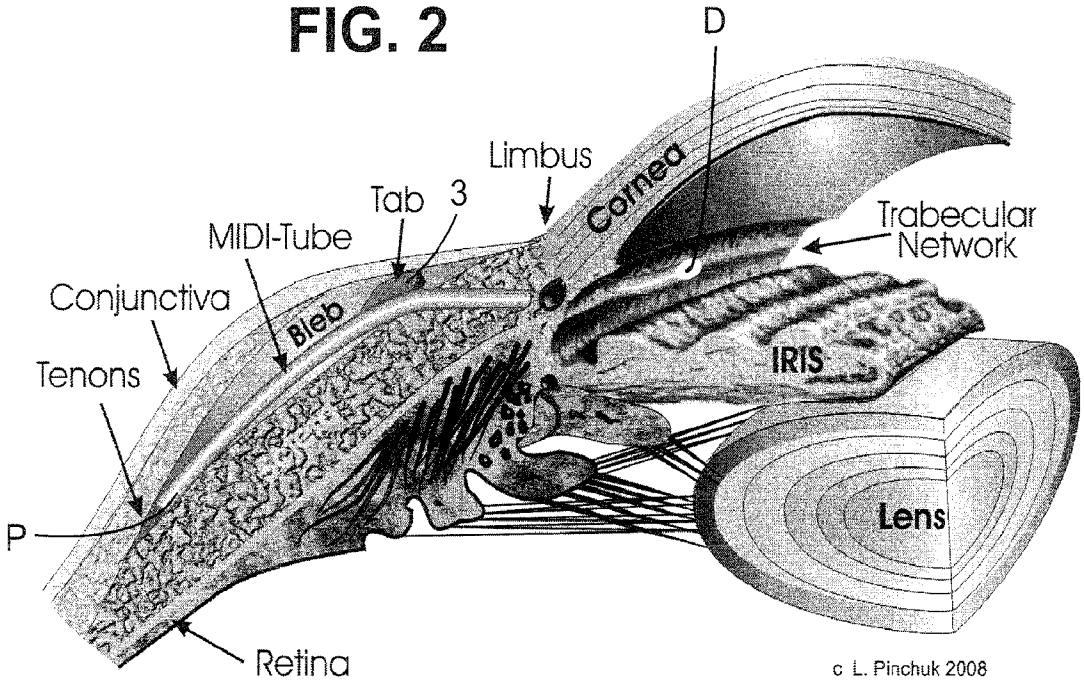


FIG. 3A

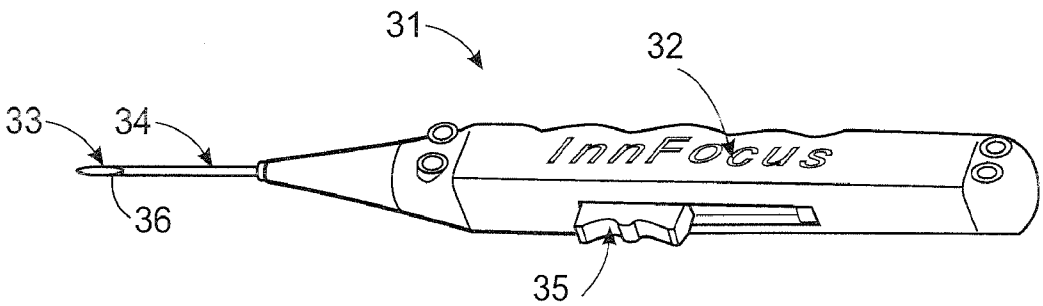


FIG. 3B

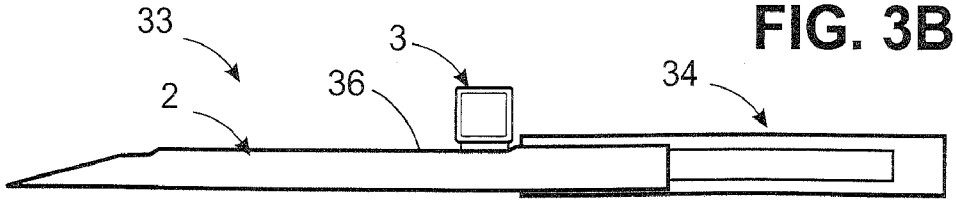


FIG. 4

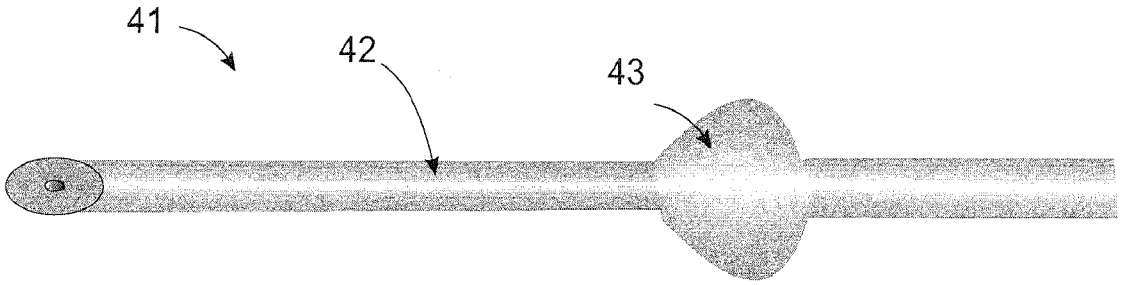


FIG. 5

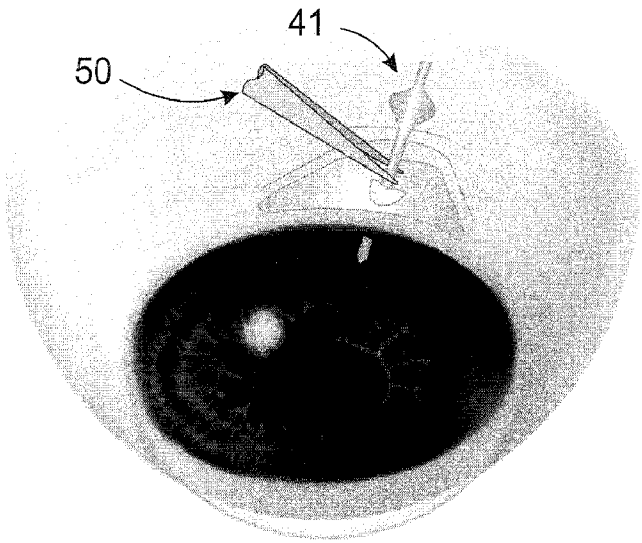
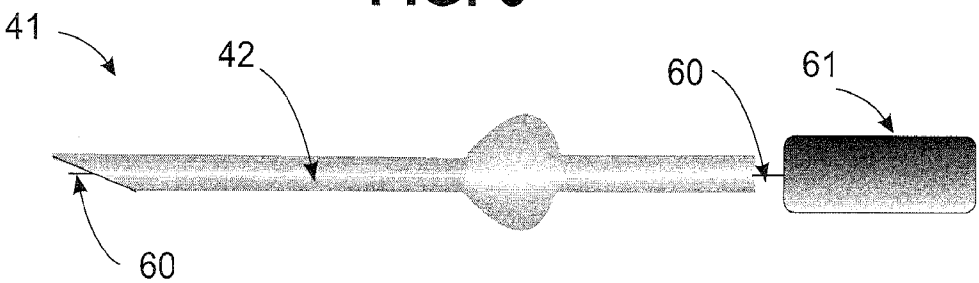


FIG. 6



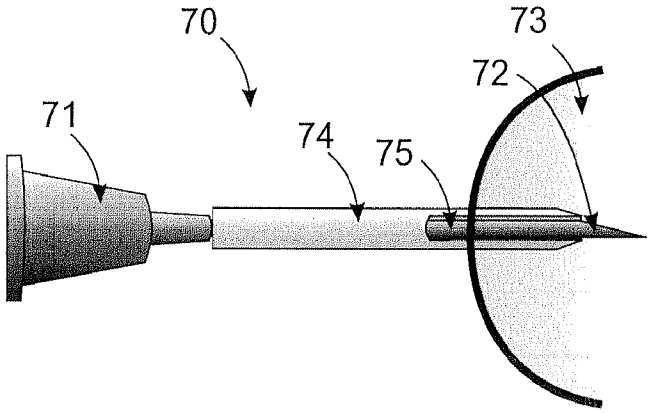


FIG. 7A

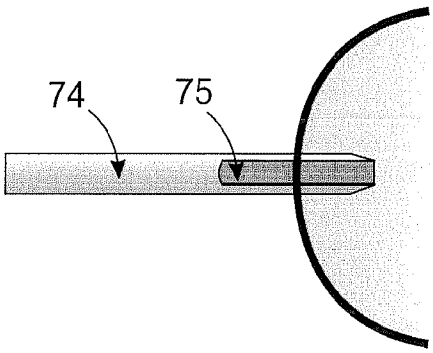


FIG. 7B

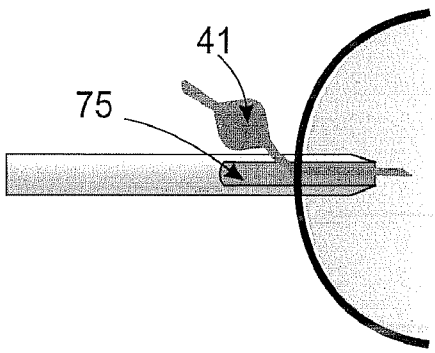


FIG. 7C

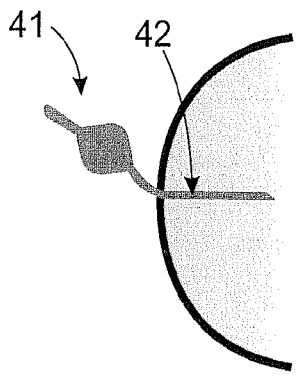


FIG. 7D

FIG. 8A

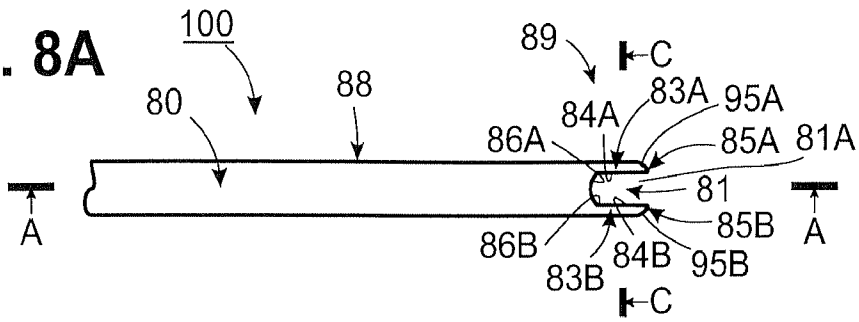


FIG. 8B

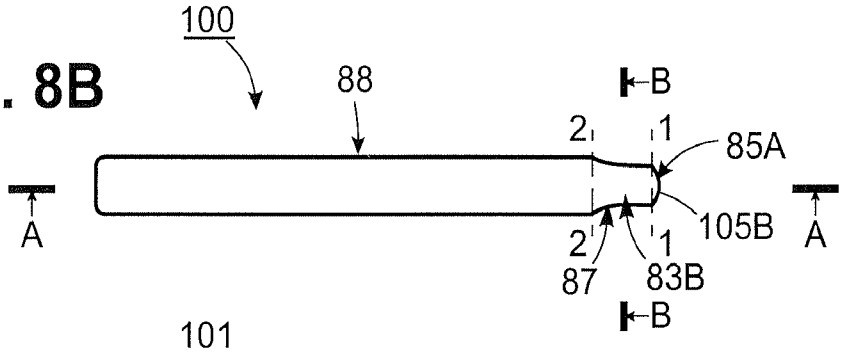


FIG. 9

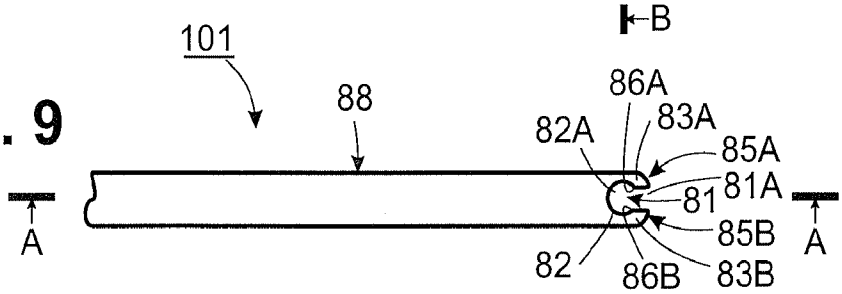


FIG. 10

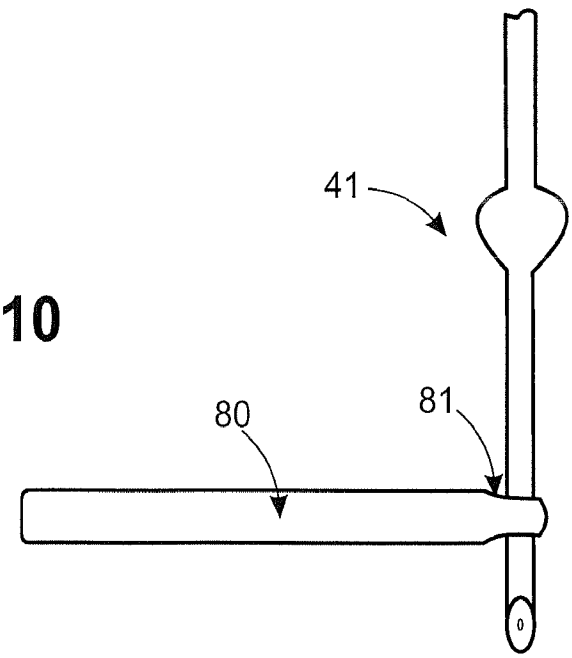


FIG. 11A

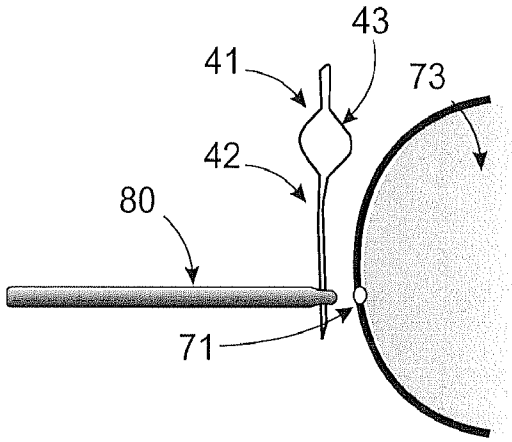


FIG. 11B

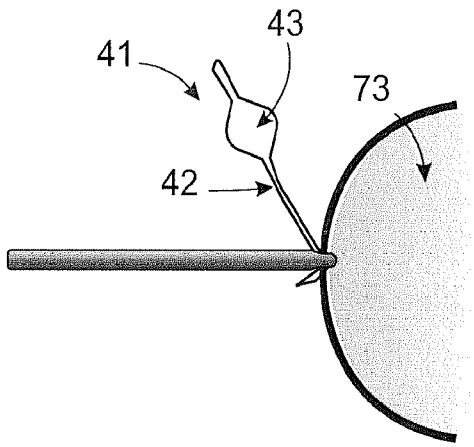


FIG. 11C

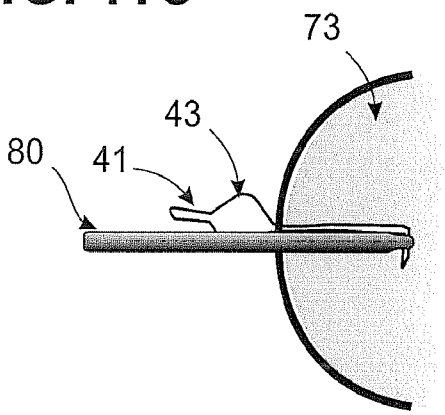
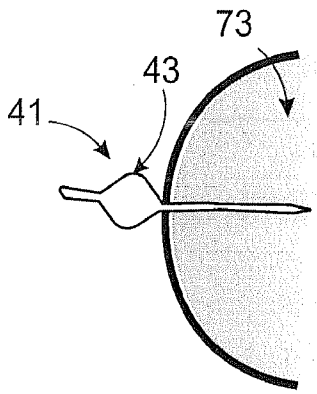


FIG. 11D



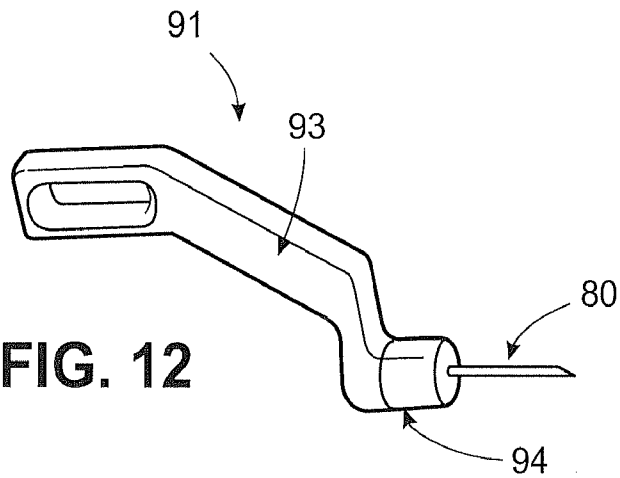


FIG. 12