

SUMMARY

[0005] Embodiments of the present invention provide methods, systems and devices for filling implants with drug and for holding the implantable device during insertion of the device into the patient. In many embodiments, the methods, systems and devices provide for injection of a therapeutic agent into an implantable device prior to insertion. Embodiments of the implantable device can be manufactured and provided to a clinic without a therapeutic agent, such that the therapeutic agent can be placed in the implantable device in the clinic prior to insertion.

[0006] Disclosed herein is an ocular implant system having an ocular implant having a retention structure and a reservoir sized and shaped to be inserted at least partially into an eye such that the implant can deliver a drug from the reservoir into the eye. The system has a carrier member with a shell having a central channel extending at least partially through the shell from a proximal end towards a distal end of the shell; and a guide sleeve removably attached within at least a first region of the central channel of the shell, the guide sleeve defining a proximal port into the central channel that is accessible from the proximal end of the shell. The system includes an implant holder removably attached within at least a second region of the central channel of the shell adjacent to a distal end of the guide sleeve. The implant holder has a pair of graspers adapted to releasably secure the implant at a distal end of the implant holder.

[0007] The system can further include a fill syringe sized and shaped to be inserted through the port into the central channel through the guide sleeve to fill the implant with one or more therapeutic agents. The guide sleeve can simultaneously detach from the shell and attach to the fill syringe when the fill syringe is inserted into the central channel. The guide sleeve can have at least one guide sleeve slot sized and shaped to receive a corresponding tab of the shell

can include an actuator element, a spring-held slider member, and a pair of arms. The actuator element can have a projection extending from a lower surface and have a ramped surface. Movement of the actuator element towards the upper surface of the handle can cause the ramped surface to slide against a corresponding ramped surface of the slider member urging the slider member in a proximal direction relative to the pair of arms. The slider member can have a forked region interfaced with the pair of arms such that proximal movement of the slider member causes the pair of arms to open in a scissor-like movement. Opening the pair of arms can urge the pair of graspers away from one another releasing the implant held therebetween.

[0012] The central channel can terminate at a window extending through a distal end region of the shell. The pair of graspers can secure the implant within the window. The implant can have an elongate axis extending through a center of the implant from a proximal end to the distal end of the implant. The elongate axis of the implant can be concentric with an elongate axis of the central channel. A proximal end of the guide sleeve can be relatively flush with the proximal end of the shell. A proximal end of the guide sleeve can extend a distance beyond the proximal end of the shell. The proximal end of the guide sleeve can incorporate a gripping element. The gripping element can have an ergonomic size and shape that facilitates grasping by a user. The guide sleeve can have a generally cylindrical shape. The guide sleeve can have a c-shaped cross section such that a first side of the guide sleeve is cylindrical and a second side of the guide sleeve is discontinuous. The discontinuous second side of the guide sleeve can align with the first side of the shell and the central channel.

[0013]

According to a first aspect of the present invention, there is provided an ocular implant handling system, comprising: a carrier member comprising: a shell having a central channel extending at least partially through the shell from a proximal end towards a distal end of the shell; a guide sleeve removably attached within at least a first region of the central channel of the shell, the guide sleeve defining a proximal port into the central channel that is accessible from the proximal end of the shell; and an implant holder removably attached within at least a second region of the central channel of the shell adjacent to a distal end of the guide sleeve, the implant holder having a pair of graspers adapted to releasably secure an implant at a distal end of the implant holder.

[0014] The handle member can be usable for inserting an implant into an eye. The system can further include an ocular implant having a retention structure and a reservoir sized and shaped to be inserted at least partially into an eye such that the implant can deliver a drug from the reservoir into the eye.

[0015] The system can further include a fill syringe sized and shaped to be inserted through the port into the central channel through the guide sleeve. The guide sleeve can simultaneously detach from the shell and attach to the fill syringe when the fill syringe is inserted into the central channel. The guide sleeve can have at least one guide sleeve slot sized and shaped to receive a corresponding tab of the shell that projects into the at least one guide sleeve slot when the guide sleeve is positioned within the central channel. An edge of the guide sleeve slot can abut a distal end of the shell tab when in a locked first state. The fill syringe can have a needle assembly having an outer surface. Insertion of the fill syringe through the guide sleeve positioned within the central channel can cause contact between the outer surface of the needle assembly and an inner surface of the shell tab urging the shell tab to flex outward away from the guide sleeve slot into an unlocked second state wherein the edge of the guide sleeve slot no longer abuts the distal end of the shell tab. A region of the guide sleeve can have a u-shaped slot

to the distal end of the implant. The elongate axis of the implant can be concentric with an elongate axis of the central channel. A proximal end of the guide sleeve can be relatively flush with the proximal end of the shell. A proximal end of the guide sleeve can extend a distance beyond the proximal end of the shell. The proximal end of the guide sleeve can incorporate a gripping element. The gripping element can have an ergonomic size and shape that facilitates grasping by a user. The guide sleeve can have a generally cylindrical shape. The guide sleeve can have a c-shaped cross section such that a first side of the guide sleeve is cylindrical and a second side of the guide sleeve is discontinuous. The discontinuous second side of the guide sleeve can align with the first side of the shell and the central channel.

[0021] Disclosed herein is an ocular implant handling and delivery system. The system includes a handle member usable for inserting an ocular implant into an eye having an elongated proximal portion and a distal attachment portion. The system includes a carrier member having a shell having a central channel extending at least partially through the shell from a proximal end towards a distal end of the shell; and a guide sleeve removably attached within at least a first region of the central channel of the shell. The guide sleeve defines a proximal port into the central channel that is accessible from the proximal end of the shell. The system includes an implant holder removably attached within at least a second region of the central channel of the shell adjacent to a distal end of the guide sleeve. The implant holder has a pair of graspers adapted to releasably secure the ocular implant at a distal end of the implant holder. The implant holder is configured to interchangeably couple with the carrier member and the handle member.

[0022] The system can further include the ocular implant. The ocular implant can include a retention structure and a reservoir sized and can be shaped to be inserted at least

partially into an eye such that the ocular implant can deliver a drug from the reservoir into the eye.

[0023] Disclosed herein is an ocular implant handling and filling system. The system includes a carrier member having a shell having a central channel extending at least partially through the shell from a proximal end towards a distal end of the shell; and a guide sleeve removably attached within at least a first region of the central channel of the shell. The guide sleeve defines a proximal port into the central channel that is accessible from the proximal end of the shell. The system includes an implant holder removably attached within at least a second region of the central channel of the shell adjacent to a distal end of the guide sleeve. The implant holder has a pair of graspers adapted to releasably secure an ocular implant at a distal end of the implant holder. The system includes a fill syringe sized and shaped to be inserted through the port into the central channel through the guide sleeve.

[0024] The system can further includes the ocular implant having a retention structure and a reservoir sized and shaped to be inserted at least partially into an eye such that the implant can deliver a drug from the reservoir into the eye. The system can further include a handle member usable for inserting an ocular implant into an eye. The handle member can include an elongated proximal portion and a distal attachment portion. The implant holder can be configured to interchangeably couple with the carrier member and the handle member.

[0025] Disclosed herein is a handling and filling system having a carrier member. The carrier member includes a shell having a central channel extending at least partially through the shell from a proximal end towards a distal end of the shell. The carrier member includes a guide sleeve removably attached within at least a first region of the central channel of the shell. The guide sleeve defines a proximal port into the central channel that is

accessible from the proximal end of the shell. The system includes an implant holder removably attached within at least a second region of the central channel of the shell adjacent to a distal end of the guide sleeve. The implant holder has a pair of graspers adapted to releasably secure an implant at a distal end of the implant holder. The system includes a fill syringe sized and shaped to be inserted through the port into the central channel through the guide sleeve. The system includes a handle member usable for inserting the implant into an eye. The handle member includes an elongated proximal portion and a distal attachment portion. The implant holder is configured to interchangeably couple with the carrier member and the handle member.

[0026] The system can further include the ocular implant. The ocular implant can include a retention structure and a reservoir sized and shaped to be inserted at least partially into an eye such that the ocular implant can deliver a drug from the reservoir into the eye.

[0027]

According to a second aspect of the present invention, there is provided a fill syringe sized and shaped to insert through a region of a carrier member holding an ocular implant, the fill syringe configured to inject one or more therapeutic agents from the fill syringe into a reservoir of the ocular implant.

[0028] The carrier member can include a shell having a central channel extending at least partially through the shell from a proximal end towards a distal end of the shell. The carrier member can include a guide sleeve removably attached within at least a first region of the central channel of the shell. The guide sleeve can define a proximal port into the central channel that is accessible from the proximal end of the shell. A portion of the fill syringe can lock with a portion of the guide sleeve when the fill syringe is inserted through the central channel of the shell. Withdrawal of the fill syringe from the carrier member can remove the guide sleeve from the shell. The fill syringe can be pre-filled with the one or more therapeutic agents.

WHAT IS CLAIMED:

1. An ocular implant handling system, comprising:
a carrier member comprising:
a shell having a central channel extending at least partially through the shell from a proximal end towards a distal end of the shell;
a guide sleeve removably attached within at least a first region of the central channel of the shell, the guide sleeve defining a proximal port into the central channel that is accessible from the proximal end of the shell; and
an implant holder removably attached within at least a second region of the central channel of the shell adjacent to a distal end of the guide sleeve, the implant holder having a pair of graspers adapted to releasably secure an implant at a distal end of the implant holder.
2. The system of claim 1, further comprising a handle member usable for inserting an implant into an eye.
3. The system of claim 1 or 2, further comprising an ocular implant comprising a retention structure and a reservoir sized and shaped to be inserted at least partially into an eye such that the implant can deliver a drug from the reservoir into the eye.
4. The system of any of claims 1-3, further comprising a fill syringe sized and shaped to be inserted through the port into the central channel through the guide sleeve.
5. The system of claim 4, wherein the guide sleeve simultaneously detaches from the shell and attaches to the fill syringe when the fill syringe is inserted into the central channel.

6. The system of any of claims 1-5, wherein the guide sleeve has at least one guide sleeve slot sized and shaped to receive a corresponding tab of the shell that projects into the at least one guide sleeve slot when the guide sleeve is positioned within the central channel.

7. The system of claim 6, wherein an edge of the guide sleeve slot abuts a distal end of the shell tab when in a locked first state.

8. The system of any of claims 4-7, wherein the fill syringe has a needle assembly having an outer surface.

9. The system of claim 8, wherein insertion of the fill syringe through the guide sleeve positioned within the central channel causes contact between the outer surface of the needle assembly and an inner surface of the shell tab urging the shell tab to flex outward away from the guide sleeve slot into an unlocked second state wherein the edge of the guide sleeve slot no longer abuts the distal end of the shell tab.

10. The system of any of claims 1-9, wherein a region of the guide sleeve has a u-shaped slot forming a guide sleeve tab.

11. The system of claim 10, wherein the guide sleeve tab has a free end that projects inwards towards a longitudinal axis of the guide sleeve positioned within the central channel.

12. The system of any of claims 4-11, wherein the fill syringe has a first portion having a first outer diameter and a second portion having a second outer diameter, wherein the first portion is located distal to the second portion and the first outer diameter is larger than the second outer diameter.

13. The system of claim 12, wherein distal advancement of the fill syringe through the guide sleeve causes the first portion of the fill syringe to abut against the free end of the

guide sleeve tab and urges the guide sleeve tab outward away from the longitudinal axis of the guide sleeve.

14. The system of claim 13, wherein further distal advancement of the fill syringe through the guide sleeve advances the first portion distal to the free end of the guide sleeve tab such that the free end flexes back inward toward the longitudinal axis and towards the smaller diameter second portion located proximal to the first portion.

15. The system of any of claims 11-14, wherein the free end of the guide sleeve tab abuts a proximal ledge of the first portion locking the guide sleeve to the fill syringe.

16. The system of any of claims 8-15, wherein the implant holder has an interior configured to receive at least a portion of the needle assembly of the fill syringe.

17. The system of claim 16, wherein the pair of graspers extend substantially around the retention structure of the implant such that a fill port of the implant is available from within the interior of the implant holder.

18. The system of claim 17, wherein a first grasper of the pair of graspers has a first protrusion and a second grasper of the pair of graspers has a second protrusion, wherein the first and second protrusions are configured to be received within an indentation distal to the retention structure of the implant such that the retention structure is held within the interior of the implant holder and the reservoir extends distal to the implant holder.

19. The system of any of claims 2-18, wherein the handle member comprises an elongated proximal portion and a distal attachment portion.

20. The system of claim 19, wherein the distal attachment portion releasably attaches to the implant holder.

21. The system of claim 19 or 20, wherein the distal attachment portion of the handle member is sized and shaped to be inserted through the central channel after the fill syringe and guide sleeve coupled to the fill syringe are removed from the shell.

22. The system of any of claims 19-21, wherein the distal attachment portion comprises a first arm and a second arm.

23. The system of any claims 3-22, wherein a proximal end region of the implant holder has a pair of tabs formed by a pair of u-shaped slots.

24. The system of claim 23, wherein each of the pair of tabs has a projection on its inner surface.

25. The system of any of claims 22-24, wherein the first arm and the second arm each have a recess on its outer surface;

26. The system of claim 25, wherein each of the recesses are configured to receive the projections when the first and second arms are inserted through the interior of the implant holder.

27. The system of any of claims 2-26, wherein the handle member further comprises an actuator configured to detach the implant from the implant holder.

28. The system of claim 27, wherein when the actuator is in a first state, the graspers are positioned adjacent one another and surround the implant.

29. The system of claim 27 or 28, wherein when the actuator is in a second state, the pair of graspers are urged away from one another and release the implant.

30. The system of any of claims 27-29, wherein the actuator comprises an actuator element, a spring-held slider member, and a pair of arms.

31. The system of claim 30, wherein the actuator element has a projection extending from a lower surface and having a ramped surface.

32. The system of claim 31, wherein movement of the actuator element towards the upper surface of the handle causes the ramped surface to slide against a corresponding ramped surface of the slider member urging the slider member in a proximal direction relative to the pair of arms.

33. The system of claim 32, wherein the slider member has a forked region interfaced with the pair of arms such that proximal movement of the slider member causes the pair of arms to open in a scissor-like movement.

34. The system of claim 33, wherein opening the pair of arms urges the pair of graspers away from one another releasing an implant held therebetween.

35. The system of any of claims 1-34, wherein the central channel terminates at a window extending through a distal end region of the shell, and wherein the pair of graspers secure an implant within the window.

36. The system of any of claims 3-35, wherein the ocular implant has an elongate axis extending through a center of the implant from a proximal end to the distal end of the implant, wherein the elongate axis of the implant is concentric with an elongate axis of the central channel.

37. The system of any of claims 1-36, wherein a proximal end of the guide sleeve is relatively flush with the proximal end of the shell.

38. The system of any of claims 1-37, wherein a proximal end of the guide sleeve extends a distance beyond the proximal end of the shell.

39. The system of claim 38, wherein the proximal end of the guide sleeve incorporates a gripping element.

40. The system of claim 39, wherein the gripping element has an ergonomic size and shape that facilitates grasping by a user.

41. The system of any of claims 1-40, wherein the guide sleeve has a generally cylindrical shape.

42. The system of any of claims 1-41, wherein the guide sleeve has a c-shaped cross section such that a first side of the guide sleeve is cylindrical and a second side of the guide sleeve is discontinuous.

43. The system of claim 42, wherein the discontinuous second side of the guide sleeve aligns with the first side of the shell and the central channel.

44. A fill syringe sized and shaped to insert through a region of a carrier member holding an ocular implant, the fill syringe configured to inject one or more therapeutic agents from the fill syringe into a reservoir of the ocular implant.

45. The fill syringe of claim 44, wherein the carrier member comprises a shell having a central channel extending at least partially through the shell from a proximal end towards a distal end of the shell; and a guide sleeve removably attached within at least a first region of the central channel of the shell, the guide sleeve defining a proximal port into the central channel that is accessible from the proximal end of the shell.

46. The fill syringe of claim 45, wherein a portion of the fill syringe locks with a portion of the guide sleeve when the fill syringe is inserted through the central channel of the shell.

47. The fill syringe of claim 45 or 46, wherein withdrawal of the fill syringe from the carrier member removes the guide sleeve from the shell.

48. The fill syringe of any of claims 44-47, wherein the fill syringe is pre-filled with the one or more therapeutic agents.