SYSTEMS, DEVICES, AND METHOD FOR TREATING A SINUS CONDITION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 61/785,939, filed on March 14, 2013, and titled "SYSTEMS, DEVICES, AND METHOD FOR TREATING A SINUS CONDITION," the content of which is hereby incorporated in its entirety.

FIELD

[0002] The invention is generally related to expandable implants, devices for delivering and/or crimping implants, and methods of using them.

BACKGROUND

[0003] There is a movement toward using minimally-invasive approaches to treat conditions or diseases associated with bodily structures such as the nasal passageways, sinus cavities, or the like. For example, individuals suffering from nasal polyposis may have obstructed airways or sinus ostia, and may experience symptoms such as difficulty breathing, headaches, sneezing, snoring, and general discomfort. Expandable implants may be useful in maintaining, opening, or dilating bodily structures such as nasal passageways, paranasal sinus cavities, or the like. Given the variety of benefits that these devices may provide, additional expandable devices may be desirable, as well as systems for crimping and/or delivering such implants.

BRIEF SUMMARY

[0004] Described here are devices, systems, and methods for treating one or more sinus or nasal conditions. Also described here are devices and methods for crimping an implant. In one aspect, there is provided an expandable implant for placement in a sinus or nasal cavity comprising: a hub, the hub comprising a plurality of apertures extending through the hub, each of said plurality of apertures comprising a first aperture segment and a second aperture segment separated by a hollow interior of the hub; and a plurality of filaments, wherein each filament of the plurality of filaments is positioned in a corresponding aperture of the plurality of apertures such that a portion of the filament extends through each of the first aperture segment, the second aperture segment, and the hollow interior of the hub~~to extend through the hub~~ to define a first leg on a first side of the hub and a second leg on the second side of the hub. In some variations, the devices may comprise an expandable implant comprising a hub and plurality of filaments. The hub may comprise a plurality of apertures extending through the hub, and each filament of the plurality of filaments may be positioned in a corresponding aperture to extend through the hub. In these variations, placement of a filament in a corresponding aperture may define a first leg on a first side of the hub and a second leg on the second side of the hub. In some variations, the filament may comprise a first straight segment, a second straight segment, and a curved segment positioned between the first straight segment and the second straight segment. In some of these variations, the curved segment of each filament may be positioned in

the corresponding aperture to position the first straight segment on the first side of the hub and the second straight segment on the second side of the hub. In some variations, each filament may be an extruded polymer filament. In some variations, the hub and the plurality of filaments may be formed from one or more biodegradable materials. In some variations, the implant may comprise a drug-releasing coating. The implants described here may be delivered to any suitable location, such as a sinus or nasal cavity. In some variations, the methods described here may comprise advancing an implant to a location in a sinus cavity, sinus ostium, or nasal passageway, delivering the implant, and expanding the implant from a low-profile configuration to an expanded configuration.

[0005] Described here are methods for crimping an implant. ~~In another aspect, there is provided a device for crimping an implant comprising: a housing, the housing comprising a recess; and a crimping member comprising a plurality of arms radially extending from a stem portion wherein movement of the stem portion into the recess rotates the plurality of arms relative to the stem portion.~~ In some variations, the device may comprise a housing and a crimping member. The crimping member may comprise a plurality of arms radially extending from a stem portion, and the housing may comprise a recess, such that movement of the stem portion into the recess may rotate the plurality of arms relative to the stem portion. In some variations, the recess may comprise a central recess and a plurality of channels radially extending from the central recess. In some of these variations, each arm of the plurality of arms may be at least partially positioned within a corresponding channel of the plurality of channels. In some variations, the device may further comprise a spring positioned between the stem portion and the recess. Additionally or alternatively, each arm of the plurality of arms may comprise at least one holder having a channel. In some variations the stem portion may comprise a recess configured to receive a portion of the implant.

[0006] Also described here are systems for treating a patient comprising an implant and a crimping device. ~~In another aspect, there is provided a system for treating one or more conditions comprising: an implant comprising a plurality of legs; and a crimping device comprising a housing and a crimping member, wherein the housing comprises a recess and a crimping member comprising a plurality of arms radially extending from a stem portion, and wherein movement of the stem portion into the recess rotates the plurality of arms relative to the stem portion.~~ The implant may comprise a plurality of legs, and in some instances may further comprise a hub attaching the plurality of legs. The crimping device may comprise a crimping member, which may be configured to engage the plurality of legs and move the implant to a low-profile configuration. In some instances, each leg of an implant may be engaged by a correspond arm of a crimping member of the crimping device. The crimping member may be moved into a recess of a housing of the crimping member to rotate the plurality of arms relative to a stem portion of the crimping device. This rotation of the arms may rotate the corresponding legs of the implant to move the implant to a low-profile configuration. ~~In another aspect, there is provided a method for crimping an implant comprising a plurality of legs comprising using a crimping device comprising a housing having a recess and a crimping member comprising a plurality of arms radially extending from a stem portion, comprising engaging each leg of the implant with a corresponding arm of the crimping member, and moving the crimping member into the recess of the housing to rotate each arm relative to the stem portion, wherein rotation of each arm rotates a corresponding leg of the implant to move the implant to a low-profile configuration.~~ In some variations, a delivery device may be used to push the crimping member into the recess of

the housing. In some of these variations, a portion of the delivery device may be advanced to hold the implant in a low-profile configuration.

[0007] ~~In another aspect, there is provided a system comprising a device for crimping an implant comprising: a housing, the housing defining a crimping chamber having a proximal end and distal end, the crimping chamber having a proximal opening at the proximal end of the crimping chamber; and a plurality of ribs located within the crimping chamber, wherein the plurality of ribs define a plurality of channels between adjacent ribs of the plurality of ribs.~~ In some variations, a crimping device may comprise a housing, the housing defining a crimping chamber having a proximal end and distal end, the crimping chamber having a proximal opening at the proximal end of the crimping chamber. The crimping device may further comprise a plurality of ribs located within the crimping chamber, wherein the plurality of ribs defines a plurality of channels between adjacent ribs of the plurality of ribs. The crimping chamber may comprise a first segment and a second segment, wherein the first segment extends from the proximal opening to a proximal end of the second segment. In some of these variations, the first segment may have an outer diameter which tapers from a first diameter at a proximal end of the first segment to a second diameter at a distal end of the first segment, wherein the first diameter is larger than the second diameter. In some of these variations, the second segment may have an outer diameter equal to the second diameter.

[0008] In some variations, the crimping chamber may further comprise a third segment, wherein the second segment extends distally from a distal end of the second segment. In some of these variations, the third segment may have an outer diameter equal to an outer diameter of the second segment. Additionally or alternatively, the inner diameter of the second segment is equal to an outer diameter of the second segment. Additionally or alternatively, the third segment has an inner diameter smaller than an inner diameter of the second segment. In some variations the system may further comprise a delivery device having an inner shaft and an outer sheath. In some of these variations, an outer diameter of a distal end of the outer sheath may be less than or equal to the inner diameter of the second segment and greater than the inner diameter of the third segment.

[0009] In some variations, the plurality of ribs and plurality of channels extend at least partially through each of the first, second, and third segments. In other variations, the plurality of ribs and the plurality of channels may comprise a first plurality of ribs and a first plurality of channels extending at least partially through first segment and a second plurality of ribs extends and a second plurality of channels extending at least partially along the third segment. In some variations, the system may further comprise an implant, wherein the implant comprises a hub and a plurality of legs extending from the hub and wherein the implant is moveable from an expanded configuration to a low-profile configuration. The first segment and second segment

CLAIMS

We claim:

1. An expandable implant for placement in a sinus or nasal cavity comprising:

   a hub, the hub comprising a plurality of apertures extending through the hub; and

   a plurality of filaments, wherein each filament of the plurality of filaments is positioned in a corresponding aperture of the plurality of apertures to extend through the hub to define a first leg on a first side of the hub and a second leg on the second side of the hub.

2. The implant of claim 1 wherein each filament comprises a first straight segment, a second straight segment, and a curved segment positioned between the first straight segment and the second straight segment.

3. The implant of claim 2 wherein the curved segment of each filament is positioned in the corresponding aperture to position the first straight segment on the first side of the hub and the second straight segment on the second side of the hub.

4. The implant of claim 1 wherein each filament is an extruded polymer filament.

5. The implant of claim 1 wherein the hub and the plurality of filaments are formed from one or more biodegradable materials.

6. The implant of claim 1 further comprising a drug-releasing coating.

7. A device for crimping an implant comprising:

a housing, the housing comprising a recess; and

a crimping member comprising a plurality of arms radially extending from a stem portion,

wherein movement of the stem portion into the recess rotates the plurality of arms relative to the stem portion.

8. The device of claim 7 wherein the recess comprises a central recess and a plurality of channels radially extending from the central recess, and wherein each arm of the plurality of arms is at least partially positioned within a corresponding channel of the plurality of channels.

9. The device of claim 7 further comprising a spring positioned between the stem portion and the recess.

10. The device of claim 7 wherein each arm of the plurality of arms comprises at least one holder having a channel.

11. The device of claim 7 wherein the stem portion comprises a recess configured to receive a portion of the implant.

12. A system for treating one or more conditions comprising:

an implant comprising a plurality of legs; and

a crimping device comprising a housing and a crimping member, wherein the housing comprises a recess and a crimping member comprising a plurality of arms radially extending from a stem portion, and wherein movement of the stem portion into the recess rotates the plurality of arms relative to the stem portion.

13. The system of claim 12 wherein the implant further comprises a hub, wherein the each leg of the plurality of legs is attached to the hub.

14. The system of claim 13 wherein the stem portion comprises a recess configured to receive a portion of the hub.

15. The system of claim 12 wherein the recess comprises a central recess and a plurality of channels radially extending from the central recess, and wherein each arm of the plurality of arms is at least partially positioned within a corresponding channel of the plurality of channels.

16. The device of claim 12 further comprising a delivery device configured to releasably couple to the implant.

17. A method for crimping an implant comprising a plurality of legs comprising using a crimping device comprising a housing having a recess and a crimping member comprising a plurality of arms radially extending from a stem portion, comprising

engaging each leg of the implant with a corresponding arm of the crimping member, and

moving the crimping member into the recess of the housing to rotate each arm relative to the stem portion, wherein rotation of each arm rotates a corresponding leg of the implant to move the implant to a low-profile configuration.

18. The method of claim 17 wherein moving the crimping member into the recess comprises pushing the implant against the stem portion to move the crimping member.

19. The method of claim 18 further comprising advancing a distal cup of the delivery device relative to the plurality of legs to hold the implant in the low-profile configuration.

20. A system comprising:

a device for crimping an implant comprising:

a housing, the housing defining a crimping chamber having a proximal end and distal end, the crimping chamber having a proximal opening at the proximal end of the crimping chamber; and

a plurality of ribs located within the crimping chamber, wherein the plurality of ribs define a plurality of channels between adjacent ribs of the plurality of ribs.

21. The system of claim 20 wherein the crimping chamber comprises a first segment and a second segment, wherein the first segment extends from the proximal opening to a proximal end of the second segment.

22. The system of claim 21, wherein the first segment has an outer diameter which tapers from a first diameter at a proximal end of the first segment to a second diameter at a distal end of the first

segment, wherein the first diameter is larger than the second diameter.

23. The system of claim 22 wherein the second segment has an outer diameter equal to the second diameter.

24. The system of claim 21 wherein the crimping chamber further comprises a third segment, wherein the second segment extends distally from a distal end of the second segment.

25. The system of claim 24 wherein the third segment has an outer diameter equal to an outer diameter of the second segment.

26. The system of claim 24 wherein the third segment has an inner diameter smaller than an inner diameter of the second segment.

27. The system of claim 26 further comprising a delivery device having an inner shaft and an outer sheath.

28. The system of claim 26 wherein an outer diameter of a distal end of the outer sheath is less than or equal to the inner diameter of the second segment and greater than the inner diameter of the third segment.

29. The system of claim 24 wherein the inner diameter of the second segment is equal to an outer diameter of the second segment.

30. The system of claim 24 wherein the plurality of ribs and plurality of channels extend at least partially through each of the first, second, and third segments.

31. The system of claim 24 wherein the plurality of ribs and the plurality of channels comprises a first plurality of ribs and a first plurality of channels extending at least partially through first segment and a second plurality of ribs extends and a second

plurality of channels extending at least partially along the third segment.

32. The system of claim 21 further comprising an implant, wherein the implant comprises a hub and a plurality of legs extending from the hub, the implant moveable from an expanded configuration to a low-profile configuration.

33. The system of claim 32 wherein the first segment and second segment are sized such that advancement of the hub from the first segment into the second segment crimps the implant from the expanded configuration to the low-profile configuration.

34. The system of claim 20 wherein the crimping device comprises a cap removably connected to the housing.

35. The system of claim 20 wherein the housing further comprises a base.

CLAIMS

We claim:

1. An expandable implant for placement in a sinus or nasal cavity comprising:

   a hub, the hub comprising a plurality of apertures extending through the hub, each of said plurality of apertures comprising a first aperture segment and a second aperture segment separated by a hollow interior of the hub; and

   a plurality of filaments, wherein each filament of the plurality of filaments is positioned in a corresponding aperture of the plurality of apertures such that a portion of the filament extends through each of the first aperture segment, the second aperture segment, and the hollow interior of the hub to define a first leg on a first side of the hub and a second leg on the second side of the hub.

2. The implant of claim 1 wherein each filament comprises a first straight segment, a second straight segment, and a curved segment positioned between the first straight segment and the second straight segment.

3. The implant of claim 2 wherein the curved segment of each filament is positioned in the corresponding aperture to position the first straight segment on the first side of the hub and the second straight segment on the second side of the hub.

4. The implant of claim 1 wherein each filament is an extruded polymer filament.

5. The implant of claim 1 wherein the hub and the plurality of filaments are formed from one or more biodegradable materials.

6. The implant of claim 1 further comprising a drug-releasing coating.