(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 May 2024 (30.05.2024)

WIPO | PCT

(10) International Publication Number
WO 2024/112657 A2

(51) International Patent Classification:
A61B 17/84 (2006.01)

(21) International Application Number:
PCT/US2023/080517

(22) International Filing Date:
20 November 2023 (20.11.2023)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/427,278 22 November 2022 (22.11.2022) US

(71) Applicants: **SMITH & NEPHEW, INC.** [US/US]; 1450 Brooks Road, Memphis, Tennessee 38116 (US). **SMITH & NEPHEW ORTHOPAEDICS AG** [CH/CH]; Theilerstrasse 1A, 6300 Zug (CH). **SMITH & NEPHEW ASIA PACIFIC PTE. LIMITED** [SG/SG]; 29 Media Circle, #06-05, Alice@Mediapolis, Singapore 138565 (SG).

(72) Inventors: **MIRANDA CRUZ, Luis Alejandro**; ArthroCare Costa Rica S.R.L., Coyol, 223-3006 (CR). **KRASNIAK, Carolyn M.**; 150 Minuteman Road, Andover, Massachusetts 01810 (US). **YEUNG, David A.**; 150 Minuteman Road, Andover, Massachusetts 01810 (US). **JABLONSKI, Brendan**; 150 Minuteman Road, Andover, Massachusetts 01810 (US). **KEEN, Rachel S.**; 31 Chipman Street, Medford, Massachusetts 02155 (US). **FALCO, Kevin M.**; 150 Minuteman Road, Andover, Massachusetts 01810 (US). **PIERCE, Cori G.**; 150 Minuteman Road, Andover, Massachusetts 01810 (US). **SIBANI MORA, Elias Milad**; ArthroCare Costa Rica S.R.L., Coyol Free Zone, Coyol, 223-3006 (CR).

(74) Agent: **BURGMAIER, Jason W.**; 100 South 5th Street, Suite 600, Minneapolis, Minnesota 55402 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ,

(54) Title: SYSTEMS AND METHODS FOR TREATING SOFT TISSUE

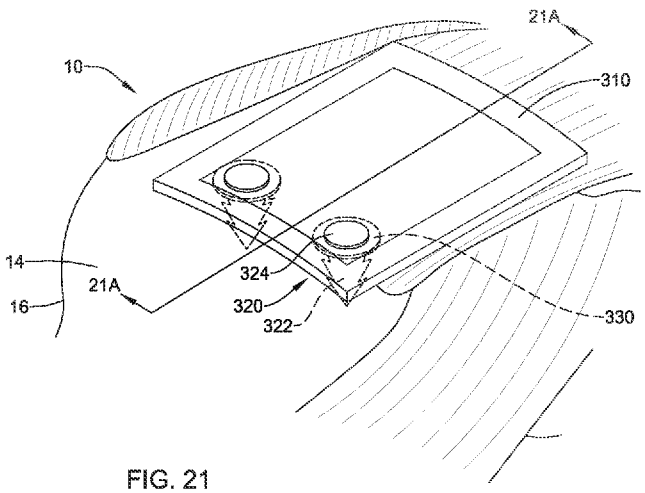

FIG. 21

(57) Abstract: Systems and methods for securing a sheet-like implant to bone and/or tissue at a treatment site are disclosed. Some systems and methods may include an annular bone anchor. Some systems and methods may include a bone anchor having an anchor hook configured to engage a loop on the sheet-like implant, wherein tension may be applied to the loop. Some systems and methods may include a bone anchor rotatably attached to the sheet-like implant. Some systems and methods may include a bone anchor having a body and a cap attachable to the body to secure the sheet-like implant. Some systems and methods may include a suture anchor having at least one suture extending from the suture anchor and configure to secure the sheet-like implant.

WO 2024/112657 A2

[Continued on next page]

DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

SYSTEMS AND METHODS FOR TREATING SOFT TISSUE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Patent Application Serial No. 63/427,278 filed on November 22, 2022, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

The present disclosure pertains generally to medical devices and methods of using medical devices. More particularly, the present disclosure relates to medical devices and/or systems, and methods of using the same, for arthroscopic placement of a sheet-like implant over or in the area of a full or partial thickness tear of a tendon, such as the supraspinatus tendon of the shoulder

BACKGROUND

With its complexity, range of motion and extensive use, a common soft tissue injury is damage to the rotator cuff or rotator cuff tendons. Damage to the rotator cuff is a potentially serious medical condition that may occur during hyperextension, from an acute traumatic tear, or from overuse of the joint. There is an ongoing need to deliver, position, and secure medical implants to soft tissue during an arthroscopic procedure in order to treat injuries to the rotator cuff, rotator cuff tendons, or other soft tissue or tendon injuries throughout a body.

SUMMARY

In one example, a system for deploying a bone anchor in bone may comprise an elongate shaft including a distal tip configured for insertion into the bone, and an annular bone anchor positioned proximate a distal end of the elongate shaft proximal of the distal tip. The annular bone anchor may be configured to shift radially outward from a delivery configuration to a deployed configuration.

In addition or alternatively to any example disclosed herein, axial translation of the elongate shaft relative to the annular bone anchor shifts the annular bone anchor from the delivery configuration to the deployed configuration.

In addition or alternatively to any example disclosed herein, axial translation of the distal tip relative to the annular bone anchor shifts the annular bone anchor from the delivery configuration to the deployed configuration.

In addition or alternatively to any example disclosed herein, axial translation of the distal tip relative to the annular bone anchor when the annular bone anchor is in the delivery configuration splits an annular wall of the annular bone anchor to define a first longitudinal edge and a second longitudinal edge facing and spaced apart from the first longitudinal edge.

In addition or alternatively to any example disclosed herein, rotation of the elongate shaft relative to the annular bone anchor shifts the annular bone anchor from the delivery configuration to the deployed configuration.

In addition or alternatively to any example disclosed herein, rotation and axial translation of the distal tip relative to the annular bone anchor when the annular bone anchor is in the delivery configuration splits the annular bone anchor apart helically to define a first edge and a second edge that moves circumferentially away from the first edge after the annular bone anchor has been split apart helically.

In addition or alternatively to any example disclosed herein, the annular bone anchor includes at least one projection extending radially outward therefrom.

In addition or alternatively to any example disclosed herein, axial compression of the annular bone anchor shifts the annular bone anchor from the delivery configuration to the deployed configuration.

In addition or alternatively to any example disclosed herein, the annular bone anchor is self-biased toward the deployed configuration.

In addition or alternatively to any example disclosed herein, the elongate shaft includes an inner member fixedly attached to the distal tip and an outer member slidably disposed over the inner member.

In addition or alternatively to any example disclosed herein, the annular bone anchor is disposed within the outer member in the delivery configuration and axial

translation of the outer member relative to the inner member exposes the annular bone anchor, thereby permitting the annular bone anchor to shift from the delivery configuration toward the deployed configuration.

In addition or alternatively to any example disclosed herein, the annular bone anchor is disposed axially between the outer member and the distal tip in the delivery configuration and axial translation of the outer member toward the distal tip shifts the annular bone anchor from the delivery configuration toward the deployed configuration.

In addition or alternatively to any example disclosed herein, the annular bone anchor is disposed axially between the outer member and the distal tip in the delivery configuration and rotation of the inner member relative to the outer member shifts the annular bone anchor from the delivery configuration toward the deployed configuration.

In addition or alternatively to any example disclosed herein, a system for deploying a bone anchor in bone may comprise an elongate shaft including an inner member and a distal tip fixed at a distal end thereof, the distal tip being configured for insertion into the bone, and an annular bone anchor surrounding the inner member proximal of the distal tip in a delivery configuration. The annular bone anchor may be self-biased toward a deployed configuration when unconstrained.

In addition or alternatively to any example disclosed herein, when the annular bone anchor is constrained in the delivery configuration, a perforation extends longitudinally along a length of the annular bone anchor.

In addition or alternatively to any example disclosed herein, axial translation of the distal tip relative to the annular bone anchor splits the annular bone anchor apart longitudinally along the perforation to define a first longitudinal edge and a second longitudinal edge facing and spaced away from the first longitudinal edge.

In addition or alternatively to any example disclosed herein, the inner member includes a cutting element extending radially outward therefrom and proximally from the distal tip.

In addition or alternatively to any example disclosed herein, axial translation of the cutting element relative to the annular bone anchor splits the annular bone anchor apart longitudinally to define a first longitudinal edge and a second longitudinal edge facing and spaced away from the first longitudinal edge.

In addition or alternatively to any example disclosed herein, when the annular bone anchor is constrained in the delivery configuration, the first longitudinal edge is directly connected to the second longitudinal edge.

In addition or alternatively to any example disclosed herein, the distal tip is configured for insertion directly into the bone without a pilot hole preformed in the bone.

In addition or alternatively to any example disclosed herein, the annular bone anchor includes a shape memory structure embedded therein, the shape memory structure being formed of a shape memory material and being self-biased toward the deployed configuration.

In addition or alternatively to any example disclosed herein, in the delivery configuration the annular bone anchor has a first outer radial extent and in the deployed configuration the annular bone anchor has a second outer radial extent that is greater than the first outer radial extent.

In addition or alternatively to any example disclosed herein, in the delivery configuration the annular bone anchor is disposed entirely proximal of the distal tip.

In addition or alternatively to any example disclosed herein, a system for securing a sheet-like implant to bone and/or tissue at a treatment site may comprise a delivery shaft including a piercing tip, and a bone anchor including a suture loop extending proximally therefrom to an anchor hook. The bone anchor may include a tightening element disposed within the bone anchor. The tightening element may be configured to shorten the suture loop.

In addition or alternatively to any example disclosed herein, the delivery shaft extends through the bone anchor.

In addition or alternatively to any example disclosed herein, the delivery shaft includes a lumen extending longitudinally therein.

In addition or alternatively to any example disclosed herein, the delivery shaft includes a longitudinal slot extending proximally from the piercing tip, the longitudinal slot being in communication with the lumen of the delivery shaft.

In addition or alternatively to any example disclosed herein, the anchor hook extends through the longitudinal slot during delivery of the bone anchor to the treatment site.

In addition or alternatively to any example disclosed herein, the suture loop is disposed within the lumen of the delivery shaft during delivery of the bone anchor to the treatment site.

In addition or alternatively to any example disclosed herein, the piecing tip is disposed distal of the bone anchor.

In addition or alternatively to any example disclosed herein, the anchor hook is configured to engage a loop extending laterally from the sheet-like implant.

In addition or alternatively to any example disclosed herein, the suture loop is configured to pull at least a portion of the anchor hook within the bone anchor.

In addition or alternatively to any example disclosed herein, the anchor hook is rigid.

In addition or alternatively to any example disclosed herein, the piercing tip is configured to pass through the bone anchor after deployment of the bone anchor within the bone at the treatment site.

In addition or alternatively to any example disclosed herein, a method of securing a sheet-like implant to bone and/or tissue at a treatment site may comprise: positioning the sheet-like implant at the treatment site, the sheet-like implant including a loop extending laterally therefrom; delivering a bone anchor to the treatment site using a delivery shaft, wherein the bone anchor is disposed on the delivery shaft; driving a piercing tip of the delivery shaft into the bone at the treatment site, thereby inserting the bone anchor into the bone at the treatment site, wherein the bone anchor includes a suture loop extending proximally therefrom to an anchor hook; coupling the anchor hook to the loop of the sheet-like implant; and shortening the suture loop of the bone anchor to apply tension to the loop of the sheet-like implant.

In addition or alternatively to any example disclosed herein, the method may comprise withdrawing the piercing tip through the bone anchor.

In addition or alternatively to any example disclosed herein, the bone anchor includes a tightening element disposed within the bone anchor, the tightening element being configured to shorten the suture loop of the bone anchor.

In addition or alternatively to any example disclosed herein, shortening the suture loop of the bone anchor includes pulling at least a portion of the anchor hook within the bone anchor.

In addition or alternatively to any example disclosed herein, the delivery shaft includes a longitudinal slot extending proximally from the piercing tip, the anchor hook extending through the longitudinal slot.

In addition or alternatively to any example disclosed herein, the method may comprise securing the sheet-like implant to the tissue at the treatment site.

In addition or alternatively to any example disclosed herein, a tissue repair implant may comprise a sheet-like implant configured to be attached to tissue and a bone adjacent the tissue, and at least one bone anchor rotatably attached to and non-removable from the sheet-like implant.

In addition or alternatively to any example disclosed herein, the at least one bone anchor is rotatable relative to the sheet-like implant.

In addition or alternatively to any example disclosed herein, each bone anchor of the at least one bone anchor includes a body portion, a proximal head, and a neck connecting the proximal head to the body portion.

In addition or alternatively to any example disclosed herein, the neck has a first radial extent, the proximal head has a second radial extent, and the body portion has a third radial extent. The first radial extent is less than the second radial extent and the third radial extent.

In addition or alternatively to any example disclosed herein, the neck extends through the sheet-like implant such that the proximal head is disposed proximal of the sheet-like implant and the body portion is disposed distal of the sheet-like implant.

In addition or alternatively to any example disclosed herein, the body portion includes a helical thread extending radially outward therefrom, the helical thread being configured to engage the bone.

In addition or alternatively to any example disclosed herein, the sheet-like implant includes a reinforcing element embedded therein.

In addition or alternatively to any example disclosed herein, the reinforcing element is a washer.

In addition or alternatively to any example disclosed herein, the reinforcing element includes an aperture and the at least one bone anchor extends through the aperture.

In addition or alternatively to any example disclosed herein, the at least one bone anchor is rotatable within the aperture.

In addition or alternatively to any example disclosed herein, a method of securing a sheet-like implant to bone and/or tissue at a treatment site may comprise: positioning the sheet-like implant at the treatment site, the sheet-like implant including at least one bone anchor rotatably attached to and non-removable from the sheet-like implant; driving the at least one bone anchor into the bone at the treatment site; and securing the sheet-like implant to the tissue at the treatment site.

In addition or alternatively to any example disclosed herein, driving the at least one bone anchor into the bone includes rotating the at least one bone anchor relative to the sheet-like implant.

In addition or alternatively to any example disclosed herein, the at least one bone anchor includes a helical thread extending radially outward from a body portion thereof, the helical thread being configured to engage the bone.

In addition or alternatively to any example disclosed herein, the at least one bone anchor is rotatably attached to and non-removable from the sheet-like implant prior to positioning the sheet-like implant at the treatment site.

In addition or alternatively to any example disclosed herein, each bone anchor of the at least one bone anchor includes a body portion, a proximal head, and a neck connecting the proximal head to the body portion. The neck extends through the sheet-like implant.

In addition or alternatively to any example disclosed herein, the proximal head is disposed proximal of the sheet-like implant and the body portion is disposed distal of the sheet-like implant.

In addition or alternatively to any example disclosed herein, the sheet-like implant includes a reinforcing element embedded therein.

In addition or alternatively to any example disclosed herein, the at least one bone anchor extends through the reinforcing element.

In addition or alternatively to any example disclosed herein, the at least one bone anchor is non-removable from the reinforcing element.

In addition or alternatively to any example disclosed herein, a bone screw may comprise a body including a helical thread extending radially outward therefrom, the body further including an aperture extending axially into the body from a proximal end of the body, and a cap including an enlarged head and a neck extending away from the enlarged head. The neck may be configured for insertion into the aperture to selectively attach the cap to the body.

In addition or alternatively to any example disclosed herein, the bone screw is configured to selectively secure a sheet-like implant between the cap and the body.

In addition or alternatively to any example disclosed herein, the neck is configured for insertion through the sheet-like implant.

In addition or alternatively to any example disclosed herein, the neck has a first radial extent, and the enlarged head has a second radial extent, the first radial extent being less than the second radial extent.

In addition or alternatively to any example disclosed herein, the first radial extent is at least 50% less than the second radial extent.

In addition or alternatively to any example disclosed herein, the neck is configured to snap into the aperture.

In addition or alternatively to any example disclosed herein, the neck is configured to screw into the aperture.

In addition or alternatively to any example disclosed herein, the neck extends substantially perpendicular to the enlarged head.

In addition or alternatively to any example disclosed herein, a method of securing a sheet-like implant to bone and/or tissue at a treatment site may comprise: driving a body of a bone screw into the bone at the treatment site, wherein the body includes an aperture extending axially into the body from a proximal end of the body; positioning the sheet-like implant at the treatment site over the body of the bone screw; and engaging a cap of the bone screw with the aperture such that the sheet-like implant is secured between the cap and the body.

In addition or alternatively to any example disclosed herein, the cap includes an enlarged head and a neck extending away from the enlarged head. The neck is configured for insertion into the aperture to selectively attach the cap to the body.

In addition or alternatively to any example disclosed herein, engaging the cap with the aperture includes urging the neck through the sheet-like implant.

In addition or alternatively to any example disclosed herein, the sheet-like implant includes a reinforcing element embedded therein.

In addition or alternatively to any example disclosed herein, after engaging the cap with the aperture, the neck extends through the reinforcing element.

In addition or alternatively to any example disclosed herein, the method may comprise securing the sheet-like implant to the tissue at the treatment site.

In addition or alternatively to any example disclosed herein, a bone screw may comprise a body including a helical thread extending radially outward therefrom, the body further including a post extending proximally from the body, and a cap including an enlarged head having an aperture formed therein, wherein the cap is configured to selectively attach to the post.

In addition or alternatively to any example disclosed herein, the bone screw is configured to selectively secure a sheet-like implant between the cap and the body.

In addition or alternatively to any example disclosed herein, the post is configured for insertion through the sheet-like implant.

In addition or alternatively to any example disclosed herein, the post has a first radial extent and the enlarged head has a second radial extent, the first radial extent being less than the second radial extent.

In addition or alternatively to any example disclosed herein, the first radial extent is at least 50% less than the second radial extent.

In addition or alternatively to any example disclosed herein, the post is configured to snap into the aperture.

In addition or alternatively to any example disclosed herein, the post is configured to screw into the aperture.

In addition or alternatively to any example disclosed herein, the post extends substantially perpendicular to the enlarged head after attachment of the cap to the post.

In addition or alternatively to any example disclosed herein, a method of securing a sheet-like implant to bone and/or tissue at a treatment site may comprise: driving a body of a bone screw into the bone at the treatment site, wherein the body includes a post extending proximally from the body; positioning the sheet-like implant at the treatment site over the post of the bone screw; and engaging a cap of the bone screw with the post such that the sheet-like implant is secured between the cap and the body.

In addition or alternatively to any example disclosed herein, the cap includes an enlarged head and an aperture formed therein. The post is configured for insertion into the aperture to selectively attach the cap to the body.

In addition or alternatively to any example disclosed herein, method may comprise urging the sheet-like implant onto the post such that the post extends through the sheet-like implant.

In addition or alternatively to any example disclosed herein, the sheet-like implant includes a reinforcing element embedded therein.

In addition or alternatively to any example disclosed herein, after engaging the cap with the post, the post extends through the reinforcing element.

In addition or alternatively to any example disclosed herein, method may comprise securing the sheet-like implant to the tissue at the treatment site.

In addition or alternatively to any example disclosed herein, a system for deploying a bone anchor at a treatment site may comprise a delivery shaft including a piercing tip configured to penetrate bone, and a bone anchor disposed on the delivery shaft proximal of the piercing tip. The piercing tip may include a plurality of branches extending radially outward from a central spine.

In addition or alternatively to any example disclosed herein, the delivery shaft extends through the bone anchor.

In addition or alternatively to any example disclosed herein, the bone anchor includes an annular wall.

In addition or alternatively to any example disclosed herein, the annular wall includes a plurality of grooves extending axially along a length of the bone anchor, each groove corresponding to one branch of the plurality of branches.

In addition or alternatively to any example disclosed herein, as the piercing tip penetrates bone at the treatment site, the plurality of branches is circumferentially offset from the plurality of grooves.

In addition or alternatively to any example disclosed herein, the delivery shaft is configured to rotate relative to the bone anchor to align the plurality of branches with the plurality of grooves for removal of the delivery shaft from the treatment site.

In addition or alternatively to any example disclosed herein, the piercing tip is configured to pass through the bone anchor after deployment of the bone anchor within the bone at the treatment site.

In addition or alternatively to any example disclosed herein, a method of deploying a bone anchor at a treatment site may comprise: delivering the bone anchor to the treatment site using a delivery shaft, wherein the bone anchor is disposed on the delivery shaft proximal a piercing tip; driving the piercing tip of the delivery shaft into the bone at the treatment site, thereby inserting the bone anchor into the bone at the treatment site; rotating the delivery shaft relative to the bone anchor to align a plurality of branches of the piercing tip with a plurality of grooves extending axially along a length of the bone anchor; and withdrawing the piercing tip through the bone anchor.

In addition or alternatively to any example disclosed herein, the plurality of branches extends radially outward from a central spine of the piercing tip.

In addition or alternatively to any example disclosed herein, the bone anchor includes an annular wall.

In addition or alternatively to any example disclosed herein, the plurality of grooves is formed in the annular wall.

In addition or alternatively to any example disclosed herein, each branch of the plurality of branches corresponds to one groove of the plurality of grooves.

In addition or alternatively to any example disclosed herein, a system for securing a sheet-like implant to bone and tissue at a treatment site may comprise an anchor delivery device including a handle, an elongate shaft extending distally from the handle to a piercing tip, and a striking surface proximate a proximal end of the handle, a suture anchor disposed on the elongate shaft, and at least one suture extending from the piercing tip. The piercing tip may be detachable from the elongate shaft.

In addition or alternatively to any example disclosed herein, each suture end of the at least one suture includes a needle secured thereto.

In addition or alternatively to any example disclosed herein, the needle is configured to pass through the tissue at the treatment site.

In addition or alternatively to any example disclosed herein, the suture anchor is devoid of helical threads extending radially outward therefrom.

In addition or alternatively to any example disclosed herein, the handle includes suture posts extending laterally from the handle. The at least one suture is wrapped around the suture posts during delivery of the suture anchor to the treatment site.

In addition or alternatively to any example disclosed herein, a method of securing a sheet-like implant to bone and tissue at a treatment site may comprise: positioning a suture anchor adjacent the bone at the treatment site using an anchor delivery device, the anchor delivery device comprising: a handle, an elongate shaft extending distally from the handle to a piercing tip, and a striking surface proximate a proximal end of the handle, wherein the suture anchor is releasably secured to the elongate shaft; driving the piercing tip and the suture anchor into the bone at the treatment site by applying a striking force to the striking surface; positioning the sheet-like implant at least partially overlaying the suture anchor at the treatment site; and securing the sheet-like implant to the bone at the treatment site using at least one suture extending from the suture anchor.

In addition or alternatively to any example disclosed herein, the method may comprise detaching the elongate shaft from the piercing tip; and removing the elongate shaft from the treatment site while leaving the piercing tip and the suture anchor within the bone.

In addition or alternatively to any example disclosed herein, the handle includes suture posts extending from the handle. The at least one suture is configured to wrap around the suture posts during delivery of the suture anchor to the treatment site.

In addition or alternatively to any example disclosed herein, each suture end of the at least one suture includes a needle secured thereto.

In addition or alternatively to any example disclosed herein, the needle is configured to pass through the tissue at the treatment site.

In addition or alternatively to any example disclosed herein, the method may comprise passing the at least one suture through the tissue at the treatment site after the suture anchor is driven into the bone at the treatment site.

The above summary of some embodiments, aspects, and/or examples is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The figures and the detailed description which follows more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure may be more completely understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

FIGS. 1-3 illustrate selected aspects of a system for deploying a bone anchor;

FIGS. 4A-4C illustrate selected aspects of the system of FIGS. 1-3 in use;

FIG. 5 illustrates selected aspects of the system of FIGS. 1-4C;

FIGS. 6A-6C illustrate selected aspects of the system of FIGS. 1-3 in an alternative use;

FIGS. 7A-7C illustrate selected aspects of a system for deploying a bone anchor in use;

FIGS. 8-9 illustrate selected aspects of a system for deploying a bone anchor in use;

FIGS. 10A-10C illustrate selected aspects of a system for deploying a bone anchor in use;

FIG. 11 illustrates selected aspects of a system for securing a sheet-like implant to bone and/or tissue;

FIG. 12 illustrates selected aspects of the system of FIG. 11 rotated about its central longitudinal axis;

FIGS. 13-16 illustrate selected aspects of a method of securing a sheet-like implant to bone and/or tissue using the system of FIGS. 11-12;

FIG. 16A is a partial cross-sectional view illustrating selected aspects of FIG. 16;

FIGS. 17-18 illustrate selected aspects of a tissue repair implant;

FIG. 19 illustrates selected aspects of an alternative configuration of the tissue repair implant of FIGS. 17-18;

FIGS. 20-21 illustrate selected aspects of a method of securing a sheet-like implant to bone and/or tissue using the system of FIGS. 17-19;

FIG. 21A is a partial cross-sectional view illustrating selected aspects of FIG. 21;

FIG. 22 is a partial cross-sectional view illustrating selected aspects of a bone screw;

FIGS. 23-24 illustrate selected aspects of a method of securing a sheet-like implant to bone and/or tissue using the bone screw of FIG. 22;

FIG. 25 is a partial cross-sectional view illustrating selected aspects of a bone screw;

FIGS. 26-27 illustrate selected aspects of a method of securing a sheet-like implant to bone and/or tissue using the bone screw of FIG. 25;

FIG. 28 illustrates selected aspects of a system for deploying a bone anchor at a treatment site;

FIGS. 29-30 illustrate selected aspects of a method of deploying a bone anchor using the system of FIG. 28;

FIG. 31A illustrates selected aspects of a system for securing a sheet-like implant to bone and tissue;

FIG. 32B illustrates selected aspects of the system of FIG. 31A rotated about its central longitudinal axis; and

FIGS. 32-35 illustrate selected aspects of a method for securing a sheet-like implant to bone and tissue using the system of FIGS. 31A-31B.

While aspects of the disclosure are amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the disclosure to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

The following description should be read with reference to the drawings, which are not necessarily to scale. Like reference numerals indicate like elements throughout the

views. The detailed description and drawings are intended to illustrate but not limit the disclosure. Those skilled in the art will recognize that the various elements described and/or shown may be arranged in various combinations and configurations without departing from the scope of the disclosure.

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about", in the context of numeric values, generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (e.g., having the same function or result). In many instances, the term "about" may include numbers that are rounded to the nearest significant figure. Other uses of the term "about" (e.g., in a context other than numeric values) may be assumed to have their ordinary and customary definition(s), as understood from and consistent with the context of the specification, unless otherwise specified.

The recitation of numerical ranges by endpoints includes all numbers within that range, including the endpoints (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

Although some suitable dimensions, ranges, and/or values pertaining to various components, features and/or specifications are disclosed, one of skill in the art, incited by the present disclosure, would understand desired dimensions, ranges, and/or values may deviate from those expressly disclosed.

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise. It is to be noted that in order to facilitate understanding, certain features of the disclosure may be described in the singular, even though those features may be plural or recurring within the disclosed embodiment(s). Each instance of the features may include and/or be encompassed by the singular disclosure(s), unless expressly stated to the contrary. For simplicity and clarity purposes, not all elements of the disclosure are necessarily shown in each figure or discussed in detail below. However, it will be understood that the following discussion may apply equally to any and/or all of the components for which there are more than one,

unless explicitly stated to the contrary. Additionally, not all instances of some elements or features may be shown in each figure for clarity.

Relative terms such as "proximal", "distal", "advance", "retract", variants thereof, and the like, may be generally considered with respect to the positioning, direction, and/or operation of various elements relative to a user/operator/manipulator of the device, wherein "proximal" and "retract" indicate or refer to closer to or toward the user and "distal" and "advance" indicate or refer to farther from or away from the user. In some instances, the terms "proximal" and "distal" may be arbitrarily assigned in an effort to facilitate understanding of the disclosure, and such instances will be readily apparent to the skilled artisan. Other relative terms, such as "axial", "circumferential", "longitudinal", "lateral", "radial", etc. and/or variants thereof generally refer to direction and/or orientation relative to a central longitudinal axis of the disclosed structure or device.

The term "extent" may be understood to mean the greatest measurement of a stated or identified dimension, unless the extent or dimension in question is preceded by or identified as a "minimum", which may be understood to mean the smallest measurement of the stated or identified dimension. For example, "outer extent" may be understood to mean an outer dimension, "radial extent" may be understood to mean a radial dimension, "longitudinal extent" may be understood to mean a longitudinal dimension, etc. Each instance of an "extent" may be different (e.g., axial, longitudinal, lateral, radial, circumferential, etc.) and will be apparent to the skilled person from the context of the individual usage. Generally, an "extent" may be considered a greatest possible dimension measured according to the intended usage, while a "minimum extent" may be considered a smallest dimension measured according to the intended usage. In some instances, an "extent" may generally be measured orthogonally within a plane and/or cross-section, but may be, as will be apparent from the particular context, measured differently – such as, but not limited to, angularly, radially, circumferentially (e.g., along an arc), etc.

It is noted that references in the specification to "an embodiment", "some embodiments", "other embodiments", etc., indicate that the embodiment(s) described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Moreover, such phrases are not necessarily referring to

the same embodiment. Further, when a particular feature, structure, or characteristic is described in connection with an embodiment, it would be within the knowledge of one skilled in the art to implement the particular feature, structure, or characteristic in connection with other embodiments, whether or not explicitly described, unless clearly stated to the contrary. That is, individual elements described herein, even if not explicitly shown in a particular combination, are contemplated as being combinable or arrangeable with each other to form other additional embodiments or to complement and/or enrich the described embodiment(s), as would be understood by one of ordinary skill in the art.

For the purpose of clarity, certain identifying numerical nomenclature (e.g., first, second, third, fourth, etc.) may be used throughout the description and/or claims to name and/or differentiate between various described and/or claimed features. It is to be understood that the numerical nomenclature is not intended to be limiting and is exemplary only. In some embodiments, alterations of and deviations from previously used numerical nomenclature may be made in the interest of brevity and clarity. That is, a feature identified as a "first" element may later be referred to as a "second" element, a "third" element, etc. or may be omitted entirely, and/or a different feature may be referred to as the "first" element. The meaning and/or designation in each instance will be apparent to the skilled practitioner.

The figures generally illustrate selected components and/or arrangements of medical devices, systems, and/or methods. It should be noted that in any given figure, some features may not be shown, or may be shown schematically, for simplicity. Additional details regarding some elements may be illustrated in other figures in greater detail. It is to be noted that in order to facilitate understanding, certain features of the disclosure may be described in the singular, even though those features may be plural or recurring within the disclosed embodiment(s). Each instance of the features may include and/or be encompassed by the singular disclosure(s), unless expressly stated to the contrary. For example, a reference to features or elements may be equally referred to all instances and quantities beyond one of said feature or element. As such, it will be understood that the following discussion may apply equally to any and/or all of the elements for which there are more than one within the medical devices, systems, and/or methods, unless explicitly stated to the contrary.

With its complexity, range of motion, and extensive use, a common soft tissue injury is damage to the rotator cuff or rotator cuff tendons. Damage to the rotator cuff is a potentially serious medical condition that may occur during hyperextension, from an acute traumatic tear, or from overuse of the joint. An accepted treatment for rotator cuff tears may include reattaching the torn tendon to the humeral head using sutures. Additionally, in treating rotator cuff tears, an accepted practice may also include the placement of a scaffold over the repaired tendon to mechanically reinforce the repaired tendon and/or promote tissue reformation. Therefore, there is an ongoing need to deliver, position, and secure medical implants to bone and/or soft tissue during an arthroscopic procedure in order to treat injuries to the rotator cuff, rotator cuff tendons, or other soft tissue or tendon injuries throughout a body.

FIGS. 1-3 illustrates selected aspects of a system 100 for deploying a bone anchor in bone. It shall be understood that a bone anchor (not limited to a bone anchor of the system 100), as used in the disclosure, may be configured to provide an anchoring point for a suture, a medical implant, or other element as is known in the art. As such, while such element(s) may not be expressly illustrated, a suture, a fastening element, a medical implant, etc. may be connected to and/or may extend from the bone anchor after deployment for use in a medical procedure and/or treatment.

In some embodiments, the system 100 may include an elongate shaft 110 including a distal tip 112 configured for insertion into the bone. In some embodiments, the distal tip 112 may be configured for insertion directly into the bone without a pilot hole preformed in the bone. For example, the distal tip 112 may be capable of piercing an outer surface of the bone via an applied axial force. In some embodiments, the elongate shaft 110 may include an inner member 114 fixedly attached to the distal tip 112 and an outer member 120 slidably disposed over the inner member 114. In some embodiments, the distal tip 112 may be fixed at a distal end of the inner member 114. In some embodiments, the distal tip 112 may have an outermost radial extent that is greater than an outer radial extent of the inner member 114. In some embodiments, the distal tip 112 may define a proximal shoulder 113 extending from the outermost radial extent of the distal tip 112 to the outer radial extent of the inner member 114. In some embodiments, the proximal shoulder 113

may extend generally perpendicular to a longitudinal axis of the elongate shaft 110 and/or the inner member 114.

In some embodiments, the elongate shaft 110 and/or the inner member 114 may include a striking surface (e.g., FIG. 8) proximate a proximal end thereof. In some embodiments, the system 100 may include a mallet or other tool configured to engage the striking surface to drive the distal tip 112 into bone.

The system 100 may include an annular bone anchor 130 positioned proximate a distal end of the elongate shaft 110 proximal of the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112, as seen in FIG. 1. In some embodiments, the annular bone anchor 130 may be configured to shift radially outward from a delivery configuration (e.g., FIGS. 1-4A) to a deployed configuration (e.g., FIG. 4C). In some embodiments, the annular bone anchor 130 may include an annular wall 132 (e.g., FIG. 4C) extending from a first end to a second end. In some embodiments, the annular bone anchor 130 may be disposed about, may extend around, and/or may surround the inner member 114 proximal of the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 in the delivery configuration. In some embodiments, the annular wall 132 of the annular bone anchor 130 may be disposed about, may extend around, and/or may surround the inner member 114 proximal of the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 in the delivery configuration. In some embodiments, the annular bone anchor 130 may be disposed between the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 and the outer member 120. In some embodiments, the annular bone anchor 130 may be disposed axially and/or longitudinally between the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 and the outer member 120 in the delivery configuration. In at least some embodiments, in the delivery configuration, the annular bone anchor 130 may be disposed entirely proximal of the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112.

In some embodiments, the annular bone anchor 130 may be self-biased toward the deployed configuration when unconstrained. In some embodiments, in the delivery configuration the annular bone anchor 130 has a first outer radial extent and in the deployed configuration the annular bone anchor 130 has a second outer radial extent that is greater than the first outer radial extent. In the deployed configuration, the annular bone anchor

130 may engage with the bone and/or exert a radially outward force against the bone to retain the annular bone anchor 130 therein.

In some embodiments, axial translation of the elongate shaft 110 relative to the annular bone anchor 130 when the annular bone anchor 130 is in the delivery configuration may shift the annular bone anchor 130 from the delivery configuration toward and/or to the deployed configuration. In some embodiments, axial translation of the distal tip 112 relative to the annular bone anchor 130 when the annular bone anchor 130 is in the delivery configuration may shift the annular bone anchor 130 from the delivery configuration toward and/or to the deployed configuration.

In some embodiments, the inner member 114 may include a cutting element 116 extending radially outward therefrom and proximally from the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112, as seen in FIG. 2. In some alternative embodiments, the cutting element 116 may extend proximally from the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 and may be radially spaced apart from the inner member 114. Other configurations are also contemplated.

In some embodiments, when the annular bone anchor 130 is constrained in the delivery configuration, a perforation 134 extends longitudinally along a length of the annular bone anchor 130 from the first end to the second end, as seen in FIG. 3. In some embodiments, when the annular bone anchor 130 is constrained in the delivery configuration, the perforation 134 may extend helically along the length of the annular bone anchor 130 from the first end to the second end.

In some embodiments, axial translation of the distal tip 112 relative to the annular bone anchor 130 when the annular bone anchor 130 is in the delivery configuration splits the annular wall 132 of the annular bone anchor 130 to define a first longitudinal edge 136 and a second longitudinal edge 138 facing and spaced apart from the first longitudinal edge 136, as seen in FIGS. 4A-4C. In at least some embodiments, axial translation of the distal tip 112 relative to the annular bone anchor 130 may be proximal translation of the distal tip 112 relative to the annular bone anchor 130.

In some embodiments, axial translation of the distal tip 112 relative to the annular bone anchor 130 when the annular bone anchor 130 is in the delivery configuration may tear or rupture the annular wall 132 of the annular bone anchor 130, thereby shifting the

annular bone anchor 130 toward and/or to the deployed configuration and/or permitting the annular bone anchor 130 to shift toward and/or to the deployed configuration.

In some embodiments, axial translation of the distal tip 112 relative to the annular bone anchor 130 when the annular bone anchor 130 is in the delivery configuration splits the annular wall 132 of the annular bone anchor 130 apart longitudinally along the perforation 134 to define the first longitudinal edge 136 and the second longitudinal edge 138 facing and spaced apart from the first longitudinal edge 136. In some embodiments, axial translation of the distal tip 112 and/or the cutting element 116 relative to the annular bone anchor 130 when the annular bone anchor 130 is in the delivery configuration splits the annular wall 132 of the annular bone anchor 130 apart longitudinally to define the first longitudinal edge 136 and the second longitudinal edge 138 facing and spaced apart from the first longitudinal edge 136. In some embodiments, axial translation of the outer member 120 toward the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 (and/or axial translation of the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 toward the outer member 120) may shift the annular bone anchor 130 from the delivery configuration toward and/or to the deployed configuration. In at least some embodiments, the axial translation may be proximal translation. In some embodiments, when the annular bone anchor 130 is constrained in the delivery configuration, the first longitudinal edge 136 is directly connected to the second longitudinal edge 138.

In some embodiments, the annular bone anchor 130 may include a shape memory structure 140, as seen in FIG. 5. The shape memory structure 140 may be formed of a shape memory material (e.g., nitinol, etc.). The shape memory structure 140 may be self-biased toward the deployed configuration. In some embodiments, the shape memory structure 140 may include a spine 142 oriented longitudinally and a plurality of circumferential ribs 144 extending therefrom. In some embodiments, the shape memory structure 140 may be a tubular member having a slit or a cut formed therein adjacent the first longitudinal edge 136 and/or the second longitudinal edge 138 after the annular bone anchor 130 has been split apart longitudinally. In some embodiments, the shape memory structure 140 may be at least partially embedded within the annular wall 132. For illustrative purposes only, the shape memory structure 140 is shown in FIG. 5 embedded within the annular wall 132 of the annular bone anchor 130. In some embodiments, the

shape memory structure 140 may be fixedly attached to the annular bone anchor 130. In some embodiments, the shape memory structure 140 may be fixedly attached to an inner surface of the annular wall 132. In some embodiments, the shape memory structure 140 may be fixedly attached to an outer surface of the annular wall 132. Other configurations, including combinations thereof, are also contemplated.

In some embodiments, rotation of the elongate shaft 110 and/or the inner member 114 relative to the annular bone anchor 130 may shift the annular bone anchor 130 from the delivery configuration toward and/or to the deployed configuration. In some embodiments, rotation and axial translation of the distal tip 112, the cutting element 116, and/or the inner member 114 relative to the annular bone anchor 130 when the annular bone anchor 130 is in the delivery configuration splits the annular bone anchor 130 apart helically to define a first edge 137 and a second edge 139 that moves circumferentially away from the first edge 137 after the annular bone anchor 130 has been split apart helically, as seen in FIGS. 6A-6C. In at least some embodiments, the axial translation may be proximal translation. In some embodiments, when the annular bone anchor 130 is constrained in the delivery configuration, the first edge 137 may be directly connected to the second edge 139.

In some embodiments, axial compression of the annular bone anchor 130 may shift the annular bone anchor 130 from the delivery configuration toward and/or to the deployed configuration, as shown in FIGS. 7A-7C. In some embodiments, the annular bone anchor 130 may be disposed axially and/or longitudinally between the outer member 120 and the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 and axial translation of the outer member 120 toward the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 (and/or axial translation of the distal tip 112 and/or the proximal shoulder 113 of the distal tip 112 toward the outer member 120) may shift the annular bone anchor 130 from the delivery configuration toward and/or to the deployed configuration. In some embodiments, axial compression of the annular bone anchor 130 may cause the annular wall 132 (e.g., FIG. 4C) to collapse axially in an accordion-like fashion while expanding radially outward. In some embodiments, after axially compressing the annular bone anchor 130, the annular wall 132 may develop a series of ridges 133 along its outer perimeter and/or circumference. The series of ridges 133 may be configured to engage with the bone

to retain the annular bone anchor 130 therein. After shifting the annular bone anchor 130 to the deployed configuration, the distal tip 112 may be pulled proximally through the annular bone anchor 130 for removal therefrom.

In some embodiments, the elongate shaft 110 and/or the inner member 114 may include a handle 118 proximate a proximal end thereof. In some embodiments, the handle 118 may include the striking surface 115, as seen in FIG. 8. In some embodiments, the striking surface 115 may be struck by and/or may cooperate with a mallet or other object to drive the distal tip 112 and/or the annular bone anchor 130 into bone. While not expressly illustrated in each figure, the handle 118 and/or the striking surface 115 may be assumed to be present in any embodiment and/or example discussed herein.

In some embodiments, the annular bone anchor 130 may include at least one projection 131 extending radially outward therefrom, as seen in FIGS. 8-9 for example. In some embodiments, after driving the distal tip 112 and the annular bone anchor 130 into the bone, the inner member 114 may be rotated relative to the outer member 120 to shift the annular bone anchor 130 from the delivery configuration (e.g., FIG. 8) toward and/or to the deployed configuration (e.g., FIG. 9).

In some embodiments, rotation of the inner member 114 relative to the outer member 120 may radially expand the annular bone anchor 130. In some embodiments, the handle 118 may be used to rotate the inner member 114 relative to the outer member 120. In some embodiments, the annular bone anchor 130 may have internal threads configured to engage the inner member 114 to facilitate shifting the annular bone anchor 130 from the delivery configuration toward and/or to the deployed configuration. In some embodiments, rotation of the inner member 114 may rotate the annular bone anchor 130 to drive and/or screw the at least one projection 131 into the bone. In some embodiments, the at least one projection 131 may crumple and/or partially collapse upon engaging the bone. The at least one projection 131 may be configured to engage with the bone to retain the annular bone anchor 130 therein. After shifting the annular bone anchor 130 to the deployed configuration, the distal tip 112 may be pulled proximally through the annular bone anchor 130 for removal therefrom.

In some embodiments, the annular bone anchor 130 may be disposed within and/or constrained by the outer member 120 in the delivery configuration, as seen in FIG. 10A.

In some embodiments, the annular bone anchor 130 may be self-expanding and/or self-biased toward the deployed configuration when unconstrained, as seen in FIG. 10B. In some embodiments, axial translation of the outer member 120 relative to the inner member 114 and/or away from the distal tip 112, and/or relative to the annular bone anchor 130, may expose the annular bone anchor 130, thereby permitting the annular bone anchor 130 to shift from the delivery configuration toward and/or to the deployed configuration. For example, proximal axial translation of the outer member 120 relative to the inner member 114, which may be held in a fixed position, may expose the annular bone anchor 130, which is disposed proximal of the distal tip 112. After shifting the annular bone anchor 130 to the deployed configuration, the distal tip 112 may be pulled proximally through the annular bone anchor 130 for removal therefrom, as seen in FIG. 10C.

As shown in FIGS. 10A-10C, the annular bone anchor 130 may include a plurality of prongs 135 extending proximally from a body of the annular bone anchor 130 and/or disposed at a proximal end of the annular bone anchor 130. The plurality of prongs 135 may be configured to flare and/or expand radially outward from the body of the annular bone anchor 130 when the annular bone anchor 130 is unconstrained and/or when the annular bone anchor 130 is in the deployed configuration. In some embodiments, the plurality of prongs 135 may give the annular bone anchor 130 a crown-like appearance. The plurality of prongs 135 may be configured to engage the bone at the treatment site after deployment of the annular bone anchor 130. The plurality of prongs 135 may be configured to resist force(s) pulling the annular bone anchor 130 out of the bone.

FIGS. 11-12 illustrate selected aspects of a system 200 for securing a sheet-like implant to bone and/or tissue at a treatment site. In some embodiments, the system 200 may include a delivery shaft 210 including a piercing tip 212. The system 200 may include a bone anchor 220 including a suture loop 230 extending proximally therefrom to an anchor hook 240. The suture loop 230 may be a flexible filament, suture, or similar biocompatible element. The anchor hook 240 may be substantially rigid and/or may be formed from a rigid material. In at least some embodiments, the bone anchor 220 may include a tightening element 250 disposed within the bone anchor 220. The tightening element 250 may be configured to shorten the suture loop 230 and/or to draw the anchor hook 240 closer to the bone anchor 220.

In some embodiments, the bone anchor 220 may include an axial cavity 222 extending from a proximal end of the bone anchor 220 toward and/or to a distal end of the bone anchor 220. In some embodiments, at least a portion of the delivery shaft 210 may extend into and/or through the bone anchor 220 and/or the axial cavity 222. In some embodiments, the piercing tip 212 may be disposed distal of the bone anchor 220. In some embodiments, the delivery shaft 210 may include a lumen 214 extending longitudinally therein. In some embodiments, the delivery shaft 210 may include a longitudinal slot 216 extending proximally from the piercing tip 212. The longitudinal slot 216 may extend through an annular wall of the delivery shaft 210. The longitudinal slot 216 may be in communication with the lumen 214 of the delivery shaft 210.

The anchor hook 240 may extend through the longitudinal slot 216 during delivery of the bone anchor 220 to the treatment site. As such, a first portion of the anchor hook 240 may be disposed within the lumen 214 of the delivery shaft 210 during delivery of the bone anchor 220 to the treatment site and a second portion of the anchor hook 240 may be disposed outside of and/or exterior to the delivery shaft 210 during delivery of the bone anchor 220 to the treatment site. The suture loop 230 may extend from the bone anchor 220 and/or the tightening element 250 to the first portion of the anchor hook 240. The suture loop 230 may be disposed within the lumen 214 of the delivery shaft 210 during delivery of the bone anchor 220 to the treatment site. In some embodiments, the suture loop 230 and/or the tightening element 250 may be configured to pull at least a portion of the anchor hook 240 into and/or within the axial cavity 222 of the bone anchor 220.

In some embodiments, the piercing tip 212 may be configured to pass through the bone anchor 220 and/or the axial cavity 222 of the bone anchor 220 after deployment of the bone anchor 220 within the bone at the treatment site. Accordingly, in at least some embodiments, the piercing tip 212 may be fixedly attached at and/or to a distal end of the delivery shaft 210. In some embodiments, the piercing tip 212 may be detachable from the delivery shaft 210 after deployment of the bone anchor 220 within the bone at the treatment site. For example, the piercing tip 212 may be releasably connected to the delivery shaft 210 with a frangible connection, a threaded connection, a mechanical connection, etc. In such embodiments, the piercing tip 212 may remain within the bone after deployment of the bone anchor 220 within the bone at the treatment site.

In some embodiments, the system 200 may be configured for use with a sheet-like implant 80, an example of which may be seen in FIG. 13. In some embodiments, the sheet-like implant 80 may be formed from collagen or other biocompatible and/or bioabsorbable material. In some embodiments, the sheet-like implant 80 may include one or more reinforcing elements. In some embodiments, the one or more reinforcing elements may be embedded within the sheet-like implant 80. Other configurations are also contemplated. In some embodiments, the anchor hook 240 may be configured to engage a loop 82 extending laterally from the sheet-like implant 80, as seen in FIG. 14. In some embodiments, the sheet-like implant 80 may include multiple loops extending laterally therefrom. In some embodiments, the loop 82 may be formed from the one or more reinforcing elements. In some embodiments, the loop 82 may be integrally and/or monolithically formed with the one or more reinforcing elements. In some embodiments, the loop 82 may be formed separately from the sheet-like implant 80 and later attached thereto and/or partially embedded therein. In some alternative embodiments, the anchor hook 240 may be configured to engage an aperture formed in and/or through the sheet-like implant 80. Other configurations are also contemplated.

A method of securing the sheet-like implant 80 to bone and/or tissue at a treatment site may include positioning the sheet-like implant 80 at the treatment site, as seen in FIG. 13. In some embodiments, the treatment site may include and/or may be a shoulder 10 and/or a joint region of a patient. The shoulder 10 includes a head 14 of the humerus 16 mating with a glenoid fossa of the scapula. A tendon 24 (e.g., the supraspinatus tendon) may become damaged due to overuse, traumatic injury, etc. In some embodiments, the sheet-like implant 80 may be used to repair and/or treat the tendon 24 (e.g., tissue) at the treatment site. As such, at least a portion of the sheet-like implant 80 may be positioned over the tendon 24. In some embodiments, it may be beneficial to secure the sheet-like implant 80 to bone (e.g., the head 14 of the humerus 16) at the treatment site. Accordingly, in some embodiments, a portion of the sheet-like implant 80 may be positioned adjacent to and/or over the bone (e.g., the head 14 of the humerus 16) at the treatment site.

The method may include delivering the bone anchor 220 to the treatment site using the delivery shaft 210, wherein the bone anchor 220 is disposed on the delivery shaft 210 during delivery. The method may include driving the piercing tip 212 of the delivery shaft

210 into the bone at the treatment site, thereby inserting the bone anchor 220 into the bone at the treatment site, wherein the bone anchor 220 includes the suture loop 230 extending proximally therefrom to the anchor hook 240. In some embodiments, the delivery shaft 210 may include a striking surface disposed proximate a proximal end of the delivery shaft 210.

As discussed herein, the anchor hook 240 may extend through the longitudinal slot 216 of the delivery shaft 210 during delivery to the treatment site. As such, orientation of the anchor hook 240 with respect to the sheet-like implant 80, the loop 82 of the sheet-like implant 80, and/or other aspects of the patient's anatomy or other medical devices may be easily accomplished visually. Other means of visualization and/or imaging may also be used.

The method may include coupling the anchor hook 240 to the loop 82 of the sheet-like implant 80, as seen in FIG. 14. In some embodiments, the method may include removing the delivery shaft 210 from the bone anchor 220 and/or the treatment site. The longitudinal slot 216 may permit the anchor hook 240 to remain in place and/or translate longitudinally along and/or within the longitudinal slot 216 when removing the delivery shaft 210 from the bone anchor 220 and/or the treatment site. In some embodiments, a free end 232 of the suture loop 230 may extend away from the bone anchor 220 and/or the tightening element 250. In some embodiments, the suture loop 230 may terminate at the tightening element 250. Other configurations are also contemplated.

In some embodiments, the method and/or removing the delivery shaft 210 from the bone anchor 220 may include withdrawing the piercing tip 212 through the bone anchor 220 and/or the axial cavity 222 of the bone anchor 220. In some embodiments, the method and/or removing the delivery shaft 210 from the bone anchor 220 may include detaching the piercing tip 212 from the delivery shaft 210. In some embodiments, the piercing tip 212 may be detached from the delivery shaft 210 prior to removing the delivery shaft 210. In some embodiments, the piercing tip 212 may be detached as the delivery shaft 210 is removed. Other configurations are also contemplated.

In some embodiments, the method may include applying tension to the loop 82 of the sheet-like implant 80. In some embodiments, the method may include shortening the suture loop 230 of the bone anchor 220 to apply tension to the loop 82 of the sheet-like

implant 80, as seen in FIG. 15. In some embodiments, applying tension to the loop 82 of the sheet-like implant 80 may include actuating the tightening element 250. In some embodiments, shortening the suture loop 230 may include actuating the tightening element 250. In some embodiments, shortening the suture loop 230 may include pulling on the free end 232 of the suture loop 230 to pull the suture loop 230 through the tightening element 250, which may act as a tension-holding element. In some embodiments, the tightening element 250 may include a ratcheting structure, a camming structure, or other means of holding tension on the suture loop 230 between the tightening element 250 and the anchor hook 240. In some embodiments, applying tension to the loop 82 of the sheet-like implant 80 and/or shortening the suture loop 230 may include pulling at least a portion of the anchor hook 240 into and/or within the bone anchor 220 and/or the axial cavity 222 of the bone anchor 220.

In some embodiments, after applying tension to the loop 82 of the sheet-like implant 80, after shortening the suture loop 230, and/or after actuating the tightening element 250, the method may include cutting and/or trimming the free end 232 of the suture loop 230 adjacent the bone anchor 220. In some embodiments, after applying tension to the loop 82 of the sheet-like implant 80, after shortening the suture loop 230, and/or after actuating the tightening element 250, the method may include detaching the free end 232 of the suture loop 230 from the tightening element 250.

In some embodiments, the method may include delivering a second bone anchor to the treatment site using a delivery shaft (e.g., the delivery shaft 210 or a second delivery shaft), driving a piercing tip (e.g., the piercing tip 212 or a second piercing tip) of the delivery shaft into the bone at the treatment site, thereby inserting the second bone anchor into the bone, coupling an anchor hook of the second bone anchor to a second loop of the sheet-like implant, and shortening the suture loop of the second bone anchor to apply tension to the second loop of the sheet-like implant. As may be appreciated, the method steps described herein may be repeated as necessary until a sufficient or desired number of bone anchors have been delivered and inserted into the bone and the sheet-like implant has been coupled to each bone anchor and tensioned as described herein to secure the sheet-like implant.

In some embodiments, the method may further include securing the sheet-like implant 80 to the tissue (e.g., the tendon 24) at the treatment site (e.g., the shoulder 10), as seen in FIGS. 16 and 16A. In some embodiments, one or more attachment elements 90 may be used to secure the sheet-like implant 80 to the tissue (e.g., the tendon 24) at the treatment site. In some embodiments, the sheet-like implant 80 may be secured to tissue (e.g., the tendon 24) at the treatment site using, and/or the one or more attachment elements 90 may be, sutures, staples, screws, or other known attachment elements. In some embodiments, the sheet-like implant 80 may be secured to the tissue (e.g., the tendon 24) at the treatment site prior to shortening the suture loop 230 and applying tension to the loop 82 of the sheet-like implant 80.

FIG. 17 illustrates selected aspects of a tissue repair implant 300 and a portion of an implant delivery device. In some embodiments, the tissue repair implant 300 may be and/or may include a sheet-like implant 310, such as and/or including, but not limited to, the sheet-like implant 80 (e.g., FIGS. 13-16). In some embodiments, the tissue repair implant 300 and/or the sheet-like implant 310 may be formed from collagen or other biocompatible and/or bioabsorbable material. In some embodiments, the tissue repair implant 300 and/or the sheet-like implant 310 may include one or more reinforcing filaments, one or more reinforcing fibers, one or more reinforcing matrices, etc. In some embodiments, the one or more reinforcing filaments, one or more reinforcing fibers, one or more reinforcing matrices, etc. may be embedded within the tissue repair implant 300 and/or the sheet-like implant 310. Other configurations are also contemplated. Additional details related to the tissue repair implant 300 and/or the sheet-like implant 310 are described below.

As seen in FIG. 17, the implant delivery device may include a frame 46 releasably attached to the tissue repair implant 300 and/or the sheet-like implant 310. The frame 46 may be disposed at and/or may be releasably attached to a shaft of the implant delivery device. The implant delivery device and the frame 46 may be used to deploy and/or position the tissue repair implant 300 and/or the sheet-like implant 310 at the treatment site (e.g., the shoulder 10), as shown in FIG. 20. The frame 46 and the tissue repair implant 300 and/or the sheet-like implant 310 may have a proximal end 42 which, for purposes of discussion herein, may be adjacent a connection to a shaft of the implant delivery device

and be configured to be positioned adjacent the head 14 of the humerus 16 at the treatment site (e.g., the shoulder 10). Further, the frame 46 and the tissue repair implant 300 and/or the sheet-like implant 310 may have a distal end 44 which, for purposes of discussion herein, may extend away from the shaft and may be configured to be positioned adjacent to the tendon 24 at the treatment site (e.g., the shoulder 10).

Returning to FIG. 17, the frame 46 may include a body portion 56 and a head portion 58. The body portion 56 may include a plurality of attachment arms 64 extending laterally therefrom. The body portion 56 may include one or more connector legs 60 extending laterally therefrom. The head portion 58 and/or the one or more connector legs 60 may be configured to attach the frame 46 to a portion of the implant delivery device (e.g., the shaft, etc.).

In some embodiments, the frame 46 may include one or more attachment members 49 which may be utilized to releasably couple the frame 46 to the tissue repair implant 300 and/or the sheet-like implant 310. In some embodiments, the one or more attachment members 49 may include coil attachment members. In some embodiments, the one or more attachment members 49 may include four attachment members. However, it is contemplated that more (or less) than four attachment members may be utilized to releasably couple the frame 46 to the tissue repair implant 300 and/or the sheet-like implant 310. In some embodiments, a first portion of each of the one or more attachment members 49 may be threaded through one or more attachment apertures located on and/or formed in the plurality of attachment arms 64 of the frame 46 while a second portion of each of the one or more attachment members 49 may be disposed on a bottom side of the tissue repair implant 300 and/or the sheet-like implant 310, whereby the tissue repair implant 300 and/or the sheet-like implant 310 is sandwiched between the second portion of each of the one or more attachment members 49 and the frame 46.

In some embodiments, the tissue repair implant 300 and/or the sheet-like implant 310 may be configured to be attached to tissue and bone adjacent the tissue at the treatment site. In some embodiments, the tissue repair implant 300 may include at least one bone anchor 320 rotatably attached to and non-removable from the sheet-like implant 310. In some embodiments, the at least one bone anchor 320 may include only one bone anchor. In some embodiments, the at least one bone anchor 320 may include two bone anchors (as

shown in FIG. 17, for example), three bone anchors, four bone anchors, or another quantity as desired and/or appropriate for the intended treatment, treatment site, and/or size of the sheet-like implant 310.

In at least some embodiments, the at least one bone anchor 320 may be rotatable relative to the sheet-like implant 310. In some embodiments, each bone anchor of the at least one bone anchor 320 may include a body portion 322, a proximal head 324, and a neck 326 connecting the proximal head 324 to the body portion 322, as seen in FIG. 18. The neck 326 may have a first radial extent, the proximal head 324 may have a second radial extent, and the body portion 322 may have a third radial extent, wherein the first radial extent is less than the second radial extent and the third radial extent. In some embodiments, the neck 326 extends through the sheet-like implant 310 such that the proximal head 324 is disposed proximal of and/or above the sheet-like implant 310 and the body portion 322 is disposed distal of and/or below the sheet-like implant 310. As such, the proximal head 324 and the body portion 322 may be disposed on opposite sides of the sheet-like implant 310.

In some embodiments, the sheet-like implant 310 may include a reinforcing element 330 embedded therein. In some embodiments, the sheet-like implant 310 may include one reinforcing element configured to engage with and/or associated with the at least one bone anchor 320. In some embodiments, the sheet-like implant 310 may include one reinforcing element configured to engage with and/or associated with each bone anchor of the at least one bone anchor 320 (e.g., two reinforcing elements for two bone anchors, etc.). For the purpose of discussion, the reinforcing element 330 is described in the singular, but all described features, elements, etc. may be understood to apply to each reinforcing element present in the tissue repair implant 300 and/or the sheet-like implant 310.

In some embodiments, the reinforcing element 330 may be a washer. In some embodiments, the reinforcing element 330 may include an aperture 332 formed in and/or extending through the reinforcing element 330. The at least one bone anchor 320 may extend through the aperture 332 and/or the reinforcing element 330. In some embodiments, the neck 326 of the at least one bone anchor 320 may be disposed within and/or may extend through the aperture 332. In some embodiments, the reinforcing element 330 may be a

plate having a plurality of apertures, wherein one bone anchor extends through one aperture of the plurality of apertures. In some embodiments, the at least one bone anchor 320 may be rotatable within the aperture 332 and/or relative to the reinforcing element 330. In at least some embodiments, the at least one bone anchor 320 may be non-removable from and/or inseparable from the reinforcing element 330.

In some embodiments, the body portion 322 of the at least one bone anchor 320 may include a helical thread 328 extending radially outward therefrom, as seen in FIG. 18. The helical thread 328 may be configured to engage the bone at the treatment site. In at least some embodiments, the helical thread 328 may be configured to screw the at least one bone anchor 320 into the bone via rotation of the at least one bone anchor 320 relative to the sheet-like implant 310 and/or the reinforcing element 330. In some embodiments, the helical thread 328 and/or the body portion 322 may be configured to be self-tapping. In some embodiments, the helical thread 328 and/or the body portion 322 may be configured for insertion into and/or to be driven into the bone without a pre-drilled pilot hole formed in the bone. In some embodiments, the helical thread 328 and/or the body portion 322 may be configured for engagement with a pre-drilled pilot hole formed in the bone. The helical thread 328 may be configured to resist force(s) pulling the at least one bone anchor 320 and/or the body portion 322 out of the bone.

In some embodiments, the body portion 322 of the at least one bone anchor 320 may include a plurality of stepped ridges 329 extending radially outward therefrom, as seen in FIG. 19. In some embodiments, the body portion 322 of the at least one bone anchor 320 may be devoid of any helical thread extending radially outward therefrom. The plurality of stepped ridges 329 may be configured to engage the bone at the treatment site. In at least some embodiments, the plurality of stepped ridges 329 may be generally parallel to each other and/or may be oriented generally perpendicular to a central longitudinal axis of the at least one bone anchor 320 and/or the body portion 322. In some embodiments, the plurality of stepped ridges 329 and/or the body portion 322 may be configured for insertion into and/or to be driven into the bone without a pre-drilled pilot hole formed in the bone. In some embodiments, the plurality of stepped ridges 329 and/or the body portion 322 may be configured for engagement with a pre-drilled pilot hole formed in the bone.

The plurality of stepped ridges 329 may be configured to resist force(s) pulling the at least one bone anchor 320 and/or the body portion 322 out of the bone.

In some embodiments, a method of securing the sheet-like implant 310 to bone and/or tissue at the treatment site may include positioning the sheet-like implant 310 at the treatment site, as shown in FIG. 20. In some embodiments, the at least one bone anchor 320 may be rotatably attached to and non-removable from the sheet-like implant 310 prior to positioning the sheet-like implant 310 at the treatment site. In some embodiments, the at least one bone anchor 320 may be rotatably attached to and non-removable from the sheet-like implant 310 prior to initiating the procedure and/or treatment (e.g., from the manufacturer).

The method may include driving the at least one bone anchor 320 into the bone at the treatment site. In some embodiments, driving the at least one bone anchor 320 into the bone may include rotating the at least one bone anchor 320 relative to the sheet-like implant 310 and/or the reinforcing element 330. In some embodiments, driving the at least one bone anchor 320 into the bone may include rotating the at least one bone anchor 320 within the aperture 332 formed in and/or through the reinforcing element 330.

In some embodiments, the method may include securing the sheet-like implant 310 to the tissue (e.g., the tendon 24) at the treatment site, as shown in FIGS. 21-21A. In some embodiments, one or more attachment elements 90 may be used to secure the sheet-like implant 310 to the tissue (e.g., the tendon 24) at the treatment site. In some embodiments, the sheet-like implant 310 may be secured to tissue (e.g., the tendon 24) at the treatment site using, and/or the one or more attachment elements 90 may be, sutures, staples, screws, or other known attachment elements.

FIG. 22 is a partial cross-sectional view illustrating selected aspects of a bone screw 400. In some embodiments, the bone screw 400 may include a body 410 including a helical thread 420 extending radially outward therefrom. In some alternative embodiments, the body 410 may include a plurality of stepped ridges that are substantially parallel to each other. Other configurations are also contemplated.

In some embodiments, the body 410 may further include an aperture 430 extending axially into the body 410 from a proximal end 412 and/or a proximally facing surface of the body 410. In some embodiments, the bone screw 400 may include a cap 440 including

an enlarged head 442 and a neck 444 extending away from the enlarged head 442. In some embodiments, the neck 444 may extend distally away from the enlarged head 442. In some embodiments, the neck 444 may extend substantially perpendicular to the enlarged head 442 and/or the enlarged head 442 may extend radially outward from the neck 444. In some embodiments, the enlarged head 442 may be substantially planar. In some embodiments, the enlarged head 442 may include a substantially planar proximal surface and/or a substantially planar distal surface.

The neck 444 may be configured for insertion into the aperture 430 to selectively attach the cap 440 to the body 410. In some embodiments, the cap 440 and/or the neck 444 may include one or more projections 450 extending radially outward from the neck 444. In some embodiments, the one or more projections 450 may extend radially outward and proximally from the neck 444. In some embodiments, the one or more projections 450 may be disposed at and/or may extend from a free end of the neck 444 and/or an end of the neck 444 opposite the enlarged head 442. In some embodiments, the one or more projections 450 may be disposed at and/or may extend from a distal end of the neck 444.

In some embodiments, the one or more projections 450 may be configured to deflect, fold, and/or bend radially inward toward the neck 444 as the one or more projections 450 is inserted into the body 410 and/or as the one or more projections 450 is passed through and/or into the aperture 430. In some embodiments, the body 410 may include at least one distally facing surface 432 extending transverse to a longitudinal axis of the body 410 and radially outward from the aperture 430. Engagement of the one or more projections 450 with the at least one distally facing surface 432 may prevent the cap 440 from being moved away from the body 410. In some embodiments, the neck 444 and/or the one or more projections 450 is configured to snap into the aperture 430 and/or the body 410. In some alternative embodiments, the neck 444 and/or the one or more projections 450 is configured to screw into the aperture 430 and/or the body 410. In some embodiments, after inserting the neck 444 into the aperture 430, the cap 440 may be nonremovable from the body 410.

In some embodiments, the neck 444 has a first radial extent or a first outer diameter, and the enlarged head 442 has a second radial extent or a second outer diameter. The first radial extent may be less than the second radial extent, and/or the first outer diameter may

be less than the second outer diameter. In some embodiments, the first radial extent is at least 50% less than the second radial extent, and/or the first outer diameter is at least 50% less than the second outer diameter. In some embodiments, the first radial extent is at least 60% less than the second radial extent, and/or the first outer diameter is at least 60% less than the second outer diameter. In some embodiments, the first radial extent is at least 70% less than the second radial extent, and/or the first outer diameter is at least 70% less than the second outer diameter. In some embodiments, the first radial extent is at least 75% less than the second radial extent, and/or the first outer diameter is at least 75% less than the second outer diameter. In some embodiments, the first radial extent is at least 80% less than the second radial extent, and/or the first outer diameter is at least 80% less than the second outer diameter. Other configurations are also contemplated.

FIGS. 23-24 illustrate selected aspects of a method of securing a sheet-like implant 402 to bone and/or tissue at a treatment site (e.g., the shoulder 10). In some embodiments, the sheet-like implant 402 may include and/or may be the sheet-like implant 80 (e.g., FIGS. 13-16), the sheet-like implant 310 (e.g., FIGS. 17-21), etc. In some embodiments, the sheet-like implant 402 may be formed from collagen or other biocompatible and/or bioabsorbable material. In some embodiments, the sheet-like implant 402 may include one or more reinforcing filaments, one or more reinforcing fibers, one or more reinforcing matrices, etc. In some embodiments, the one or more reinforcing filaments, one or more reinforcing fibers, one or more reinforcing matrices, etc. may be embedded within the sheet-like implant 402. Other configurations are also contemplated.

In FIGS. 23-24, the tendon 24 includes a damaged portion located near an insertion point where the tendon 24 joins the head 14 of the humerus 16. The damaged portion may include a tear 30 extending partially through the tendon 24. The tear 30 may be referred to as a partial thickness tear. The partial thickness tear is shown on the bursal side of the tendon 24, however, the tear may also be on the opposite or articular side of the tendon 24 and/or may include internal tears to the tendon 24 not visible on or from either surface or side of the tendon 24.

The method may include driving the body 410 of the bone screw 400 into the bone (e.g., the head 14 of the humerus 16) at the treatment site (e.g., the shoulder 10). The method may include positioning the sheet-like implant 402 at the treatment site over the

body 410 of the bone screw 400 and/or adjacent tissue (e.g., the tendon 24), as seen in FIG. 23. The method may include engaging the cap 440 of the bone screw 400 with the aperture 430 such that the sheet-like implant 402 is secured between the cap 440 (and/or the enlarged head 442) and the body 410. In some embodiments, the bone screw 400 may be configured to selectively secure the sheet-like implant 402 between the cap 440 (and/or the enlarged head 442) and the body 410.

In some embodiments, the neck 444 may be configured for insertion through the sheet-like implant 402. In some embodiments, engaging the cap 440 with the aperture 430 may include urging the neck 444 through the sheet-like implant 402. In some embodiments, the neck 444 may be configured to pierce the sheet-like implant 402. In some embodiments, the sheet-like implant 402 may include an opening formed therein, wherein the opening is configured to receive the neck 444 of the bone screw 400 therein and/or therethrough. In some embodiments, after engaging the cap 440 with the aperture 430, the neck 444 may extend through the sheet-like implant 402, as seen in FIG. 24.

In some embodiments, the sheet-like implant 402 may include a reinforcing element (e.g., the reinforcing element 330 of the sheet-like implant 310) embedded therein. In some embodiments, after engaging the cap 440 with the aperture 430, the neck 444 may extend through the reinforcing element. In some embodiments, after engaging the cap 440 with the aperture 430, the one or more projections 450 may be engaged with the aperture 430 and/or the at least one distally facing surface 432 such that the cap 440 is nonremovable from the body 410.

In some embodiments, the method may include securing the sheet-like implant 402 to the tissue (e.g., the tendon 24) at the treatment site, in a manner similar to that shown in FIGS. 21-21A with respect to the sheet-like implant 310. In some embodiments, one or more attachment elements may be used to secure the sheet-like implant 402 to the tissue (e.g., the tendon 24) at the treatment site. In some embodiments, the sheet-like implant 402 may be secured to tissue (e.g., the tendon 24) at the treatment site using, and/or the one or more attachment elements may be, sutures, staples, screws, or other known attachment elements.

FIG. 25 is a partial cross-sectional view illustrating selected aspects of a bone screw 500. In some embodiments, the bone screw 500 may include a body 510 including a helical

thread 520 extending radially outward therefrom. In some alternative embodiments, the body 510 may include a plurality of stepped ridges that are substantially parallel to each other. Other configurations are also contemplated.

In some embodiments, the body 510 may further include a post 530 extending axially away from the body 510. In some embodiments, the post 530 may extend proximally away from the body 510 and/or may extend proximally away from a proximally facing surface of the body 510. In some embodiments, the bone screw 500 may include a cap 540 including an enlarged head 542 and an aperture 544 formed in the enlarged head 542. The aperture 544 may be configured to receive the post 530 therein. In some embodiments, the post 530 may be oriented substantially perpendicular to the enlarged head 542 when the post 530 is received within the aperture 544 (e.g., after attachment of the cap 540 to the post 530). In some embodiments, the enlarged head 542 may be substantially planar. In some embodiments, the enlarged head 542 may include a substantially planar proximal surface and/or a substantially planar distal surface.

The post 530 may be configured for insertion into the aperture 544 to selectively attach the cap 540 to the post 530 and/or the body 510. In some embodiments, the post 530 may include one or more projections 550 extending radially outward from the post 530. In some embodiments, the one or more projections 550 may extend radially outward and distally from the post 530. In some embodiments, the one or more projections 550 may be disposed at and/or may extend from a free end of the post 530 and/or an end of the post 530 opposite the body 510. In some embodiments, the one or more projections 550 may be disposed at and/or may extend from a proximal end of the post 530.

In some embodiments, the one or more projections 550 may be configured to deflect, fold, and/or bend radially inward toward the post 530 as the one or more projections 550 is inserted into the cap 540 and/or as the one or more projections 550 is passed through and/or into the aperture 544. In some embodiments, the cap 540 may include at least one proximally facing surface extending transverse to a longitudinal axis of the body 510 and radially outward from the aperture 544. Engagement of the one or more projections 550 with the at least one proximally facing surface may prevent the cap 540 from being moved away from the body 510. In some embodiments, the post 530 and/or the one or more projections 550 is configured to snap into the aperture 544 and/or the cap 540. In some

alternative embodiments, the post 530 and/or the one or more projections 550 is configured to screw into the aperture 544 and/or the cap 540. In some embodiments, after inserting the post 530 into the aperture 544, the cap 540 may be nonremovable from the body 510.

In some embodiments, the post 530 has a first radial extent or a first outer diameter, and the enlarged head 542 has a second radial extent or a second outer diameter. The first radial extent may be less than the second radial extent, and/or the first outer diameter may be less than the second outer diameter. In some embodiments, the first radial extent is at least 50% less than the second radial extent, and/or the first outer diameter is at least 50% less than the second outer diameter. In some embodiments, the first radial extent is at least 60% less than the second radial extent, and/or the first outer diameter is at least 60% less than the second outer diameter. In some embodiments, the first radial extent is at least 70% less than the second radial extent, and/or the first outer diameter is at least 70% less than the second outer diameter. In some embodiments, the first radial extent is at least 75% less than the second radial extent, and/or the first outer diameter is at least 75% less than the second outer diameter. In some embodiments, the first radial extent is at least 80% less than the second radial extent, and/or the first outer diameter is at least 80% less than the second outer diameter. Other configurations are also contemplated.

FIGS. 26-27 illustrate selected aspects of a method of securing the sheet-like implant 402 to bone and/or tissue at a treatment site (e.g., the shoulder 10). The method may include driving the body 510 of the bone screw 500 into the bone (e.g., the head 14 of the humerus 16) at the treatment site (e.g., the shoulder 10). The method may include positioning the sheet-like implant 402 at the treatment site over the body 510 and/or the post 530 of the bone screw 500 and/or adjacent tissue (e.g., the tendon 24), as seen in FIG. 26. The method may include engaging the cap 540 of the bone screw 500 with the post 530 such that the sheet-like implant 402 is secured between the cap 540 (and/or the enlarged head 542) and the body 510. In some embodiments, the bone screw 500 may be configured to selectively secure the sheet-like implant 402 between the cap 540 (and/or the enlarged head 542) and the body 510.

In some embodiments, the method may include urging the sheet-like implant 402 onto the post 530 such that the post 530 extends through the sheet-like implant 402. In some embodiments, the post 530 may be configured for insertion through the sheet-like

implant 402. In some embodiments, the post 530 may be configured to pierce the sheet-like implant 402. In some embodiments, the sheet-like implant 402 may include an opening formed therein, wherein the opening is configured to receive the post 530 of the bone screw 400 therein and/or therethrough. In some embodiments, after engaging the cap 540 with the aperture 544, the post 530 may extend through the sheet-like implant 402, as seen in FIG. 27. In some embodiments, after engaging the cap 540 with the aperture 544, the post 530 may extend through the cap 540.

In some embodiments, the sheet-like implant 402 may include a reinforcing element (e.g., the reinforcing element 330 of the sheet-like implant 310) embedded therein. In some embodiments, after engaging the cap 540 with the post 530, the post 530 may extend through the reinforcing element. In some embodiments, after engaging the cap 540 with the post 530, the one or more projections 550 may be engaged with the aperture 544 and/or the at least one proximally facing surface such that the cap 540 is nonremovable from the body 510 and/or the post 530.

In some embodiments, the method may include securing the sheet-like implant 402 to the tissue (e.g., the tendon 24) at the treatment site, in a manner similar to that shown in FIGS. 21-21A with respect to the sheet-like implant 310. In some embodiments, one or more attachment elements may be used to secure the sheet-like implant 402 to the tissue (e.g., the tendon 24) at the treatment site. In some embodiments, the sheet-like implant 402 may be secured to tissue (e.g., the tendon 24) at the treatment site using, and/or the one or more attachment elements may be, sutures, staples, screws, or other known attachment elements.

FIG. 28 illustrates selected aspects of a system 600 for deploying a bone anchor 610 at a treatment site. The system 600 may include a delivery device 620. In some embodiments, the delivery device 620 may include a delivery shaft 622. In some embodiments, the delivery device 620 may include an outer sheath 624, wherein the delivery shaft 622 may be slidably and/or rotatably disposed within the outer sheath 624. In some embodiments, the delivery shaft 622 may include a piercing tip 630 configured to penetrate bone. In at least some embodiments, the piercing tip 630 may be fixedly attached to and/or at a distal end of the delivery shaft 622.

The system 600 may include the bone anchor 610 disposed on the delivery shaft 622 proximal of the piercing tip 630. In at least some embodiments, the delivery shaft 622 may extend through the bone anchor 610. In some embodiments, the bone anchor 610 may include an annular wall 612. In some embodiments, the annular wall 612 may include a plurality of grooves 614 formed therein. The plurality of grooves 614 may face and/or open radially inward from the annular wall 612 and/or toward a central longitudinal axis of the bone anchor 610. In some embodiments, the plurality of grooves 614 may extend axially along a length of the bone anchor 610 from a proximal end of the bone anchor 610 to a distal end of the bone anchor 610. In some alternative embodiments, the plurality of grooves 614 may extend helically along the length of the bone anchor 610 from the proximal end of the bone anchor 610 to the distal end of the bone anchor 610. Other configurations, including combinations thereof, are also contemplated. In some embodiments, the plurality of grooves 614 may include two grooves, three grooves, four grooves, five grooves, six grooves, or another suitable number of grooves.

The piercing tip 630 may include a plurality of branches 632 extending radially outward from a central spine 634. In some embodiments, the plurality of branches 632 may include two branches, three branches, four branches, five branches, six branches, or another suitable number of branches. In some embodiments, each groove of the plurality of grooves 614 may correspond to one branch of the plurality of branches 632. In at least some embodiments, the piercing tip 630 may include the same number of branches as the bone anchor 610 includes grooves. In some embodiments, the number of grooves and branches may differ.

In some embodiments, as the piercing tip 630 penetrates bone at the treatment site, the plurality of branches 632 may be circumferentially offset from the plurality of grooves 614 such that a radially outermost portion of the plurality of branches 632 radially overlaps at least a portion of the annular wall 612. In some embodiments, the plurality of branches 632 may be circumferentially offset from, and/or may be rotated about the central longitudinal axis of the bone anchor 610 relative to, the plurality of grooves 614 by about 45 degrees. In some embodiments, other circumferential offsets are also contemplated which may correspond to the number of grooves and/or branches present in the system 600. In the illustrated example, four branches and four grooves are shown. In some

embodiments, the circumferential offset may be greater than 45 degrees (e.g., 60 degrees, 75 degrees, 90 degrees, 120 degrees, 180 degrees, etc.). In some embodiments, the circumferential offset may be less than 45 degrees (e.g., 30 degrees, 15 degrees, etc.).

The delivery shaft 622 may be configured to rotate relative to the bone anchor 610 to align the plurality of branches 632 with the plurality of grooves 614 for removal of the delivery shaft 622 and/or the piercing tip 630 from the bone anchor 610 and/or the treatment site. In some embodiments, the delivery shaft 622 may be configured to rotate relative to the bone anchor 610 to align the radially outermost portion of the plurality of branches 632 with the plurality of grooves 614 for removal of the delivery shaft 622 and/or the piercing tip 630 from the bone anchor 610 and/or the treatment site. In at least some embodiments, the piercing tip 630 may be configured to pass through an interior of the bone anchor 610 after deployment of the bone anchor 610 within the bone at the treatment site.

FIGS. 29-30 illustrates selected aspects of a method of deploying the bone anchor 610 at a treatment site (e.g., the shoulder 10). The method may include delivering the bone anchor 610 to the treatment site using the delivery shaft 622. The method may include driving the piercing tip 630 of the delivery shaft 622 into the bone (e.g., the head 14 of the humerus 16) at the treatment site, thereby inserting the bone anchor 610 into the bone at the treatment site. The method may include rotating the delivery shaft 622 relative to the bone anchor 610 to align the plurality of branches 632 of the piercing tip 630 with the plurality of grooves 614 extending axially along the length of the bone anchor 610. The method may thereafter include withdrawing the piercing tip 630 through the bone anchor 610.

The system 600 and/or the bone anchor 610 may be used in conjunction with other treatments and/or medical procedures such as those described herein, as well as others. For example, the bone anchor 610 may be used to secure a sheet-like implant to bone at the treatment site.

FIG. 31A illustrates selected aspects of a system 700 for securing a sheet-like implant (e.g., the sheet-like implant 402, the sheet-like implant 310, etc.). For the purpose of explanation only, the following description references the sheet-like implant 402. However, it shall be understood that other sheet-like implants may also be used with the

system 700. FIG. 31B illustrates selected aspects of the system 700 of FIG. 31A rotated about 90 degrees around a central longitudinal axis of the system 700.

The system 700 may include an anchor delivery device 710 including a handle 720, an elongate shaft 730 extending distally from the handle 720 to a piercing tip 740, and a striking surface 750 proximate a proximal end of the handle 720. In some embodiments, the striking surface 750 may be a proximal surface of the handle 720. In some embodiments, the handle 720 may be fixedly attached to the elongate shaft 730. In some embodiments, the elongate shaft 730 may be fixedly attached to the striking surface 750 and/or may include the striking surface 750. Other configurations are also contemplated.

The system 700 may include a suture anchor 760 disposed on the elongate shaft 730. In some embodiments, the elongate shaft 730 may extend into and/or through an interior of the suture anchor 760. The piercing tip 740 may be configured to pierce bone (e.g., the head of the humerus) at the treatment site. In some embodiments, the piercing tip 740 may have a tap-in design configured to be urged, pushed, and/or tapped into the bone without a pilot hole preformed in the bone. In some embodiments, a pilot hole preformed in the bone may reduce insertion forces and/or make it easier to insert the piercing tip 740 and/or the suture anchor 760 into the bone. In some embodiments, the piercing tip 740 may be detachable from the elongate shaft 730 in vivo. In some embodiments, the piercing tip 740 may be formed from a metallic material. In some embodiments, the suture anchor 760 may be formed from a polymeric material or a composite material. In some alternative embodiments, the suture anchor 760 may be formed from a metallic material.

In some embodiments, the suture anchor 760 may include a plurality of stepped ridges 762 formed on an outer surface of the suture anchor 760. The plurality of stepped ridges 762 may be configured to engage the bone at the treatment site. The plurality of stepped ridges 762 may be configured to resist force(s) pulling the suture anchor 760 out of the bone. In some alternative configurations, the suture anchor 760 may include a helical thread extending radially outward therefrom. The helical thread may be configured to engage the bone at the treatment site. In at least some embodiments, the helical thread may be configured to screw and/or advance the suture anchor 760 into the bone via rotation of the suture anchor 760 relative to the bone. In some embodiments, the helical thread may

be configured to be self-tapping. In some embodiments, the helical thread and/or the suture anchor 760 may be configured for insertion into and/or to be driven into the bone without a pre-drilled pilot hole formed in the bone. In some embodiments, the helical thread and/or the suture anchor 760 may be configured for engagement with a pilot hole preformed in the bone. The helical thread may be configured to resist force(s) pulling the suture anchor 760 out of the bone.

The system 700 may include at least one suture 770 extending from the piercing tip 740 toward the handle 720. In some embodiments, each suture end of the at least one suture 770 may include a needle 780 secured thereto. The needle 780 may be configured to pass through the tissue (e.g., a tendon) at the treatment site. In at least some embodiments, the piercing tip 740 may include an aperture 742 extending transversely therethrough and/or oriented transversely relative to the central longitudinal axis. The aperture 742 may be configured to receive at least a portion of the at least one suture 770 therein and/or therethrough.

In some embodiments, the handle 720 may include suture posts 722 extending laterally from the handle 720. The at least one suture 770 may be wrapped around the suture posts 722 during delivery of the suture anchor 760 to the treatment site. In some embodiments, the handle 720 may include a needle retention structure configured to secure and/or store the needle 780 within and/or against the handle 720 during delivery of the suture anchor 760 to the treatment site.

In some embodiments, the system 700 may include a mallet or another striking device configured to engage the striking surface 750 and/or to apply a striking force to the striking surface 750 to drive the piercing tip 740 and/or the suture anchor 760 into the bone at the treatment site. In some embodiments, the system 700 may include a suture passer configured to pass the at least one suture 770 through the tissue at the treatment site.

FIGS. 32-35 illustrates selected aspects of a method of securing the sheet-like implant 402 to bone (e.g., the head 14 of the humerus 16) and tissue (e.g., the tendon 24) at the treatment site (e.g., the shoulder 10). The method may include positioning the suture anchor 760 adjacent the bone at the treatment site using the anchor delivery device 710. The suture anchor 760 may be releasably secured to the elongate shaft 730. The method

may include driving the piercing tip 740 and the suture anchor 760 into the bone at the treatment site by applying a striking force to the striking surface 750, as shown in FIG. 32.

In some embodiments, the method may include detaching the elongate shaft 730 from the piercing tip 740 in vivo. The method may include removing the elongate shaft 730 from the suture anchor 760 and/or the treatment site while leaving the piercing tip 740 and the suture anchor 760 within the bone, as seen in FIG. 33.

In some embodiments, at least one suture 770 and/or the needle(s) 780 may be detached and/or released from the handle 720 (not shown) of the anchor delivery device 710. In some embodiments, at least one suture 770 and/or the needle(s) 780 may be detached and/or released from the handle 720 (not shown) of the anchor delivery device 710 before removing the elongate shaft 730 from the suture anchor 760 and/or the treatment site. In some embodiments, at least one suture 770 and/or the needle(s) 780 may be detached and/or released from the handle 720 (not shown) of the anchor delivery device 710 as the elongate shaft 730 is removed from the suture anchor 760 and/or the treatment site. As seen in FIG. 33, the at least one suture 770 and/or the needle(s) 780 may extend away from the suture anchor 760.

The method may include positioning the sheet-like implant 402 at least partially overlaying the suture anchor 760 at the treatment site. The method may include positioning the sheet-like implant 402 at least partially overlaying the tissue (e.g., the tendon 24) at the treatment site, as shown in FIG. 34. The method may include securing the sheet-like implant 402 to the bone (e.g., the head 14 of the humerus 16) at the treatment site using the at least one suture 770 extending from the suture anchor 760, as seen in FIG. 35. In at least some embodiments, the method may further include passing the needle 780 and/or the at least one suture 770 through the tissue (e.g., the tendon 24) at the treatment site after the suture anchor 760 is driven into the bone at the treatment site. In some embodiments, the method may include passing the needle 780 and/or the at least one suture 770 through the tissue (e.g., the tendon 24) at the treatment site using a suture passer after the suture anchor 760 is driven into the bone at the treatment site.

In some embodiments, the at least one suture 770 may be tied off, knotted, adhered to the sheet-like implant 402 and/or the tissue, or otherwise secured in position at the

treatment site. The needle 780 may be detached (e.g., cut off, etc.) from the at least one suture 770 and removed from the treatment site.

The materials that can be used for the various components of the medical devices, systems, and various elements thereof disclosed herein may include those commonly associated with medical devices. For simplicity purposes, the following discussion refers to the system. However, this is not intended to limit the devices and methods described herein, as the discussion may be applied to other elements, members, components, or devices disclosed herein, such as, but not limited to, the bone anchor, the elongate shaft, the delivery shaft, the suture loop, the anchor hook, the reinforcing element, the bone screw, the piercing tip, the suture anchor, etc., and/or elements or components thereof.

In some embodiments, the system and/or components thereof, may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material.

Some examples of suitable polymers may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN®), polyether block ester, polyurethane, polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL®), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL®), polyamide (for example, DURETHAN® or CRISTAMID®), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), MARLEX® high-density polyethylene, MARLEX® low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID®), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-*b*-isobutylene-*b*-styrene) (for example, SIBS and/or SIBS 50A), polycarbonates, polyurethane silicone

copolymers (for example, Elast-Eon® or ChronoSil®), biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some embodiments, the system and/or components thereof can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6 percent LCP.

Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; platinum; palladium; gold; combinations thereof; or any other suitable material.

In some embodiments, portions or all of the system and/or components thereof may be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique (e.g., ultrasound, etc.) during a medical procedure. This relatively bright image aids a user in determining the location of the system. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. Additionally, other radiopaque marker bands and/or coils may also be incorporated into the design of the system to achieve the same result.

In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into the system. For example, the system and/or components or

portions thereof may be made of a material that does not substantially distort the image and create substantial artifacts (e.g., gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. The system or portions thereof may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R44003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R44035 such as MP35-N® and the like), nitinol, and the like, and others.

In some embodiments, the system and/or other elements disclosed herein may include and/or be treated with a suitable therapeutic agent. Some examples of suitable therapeutic agents may include anti-thrombogenic agents (such as heparin, heparin derivatives, urokinase, and PPack (dextrophenylalanine proline arginine chloromethyl ketone)); anti-protein and/or anti-bacterial agents (such as 2-methacryroyloxyethyl phosphorylcholine (MPC) and its polymers or copolymers); anti-proliferative agents (such as enoxaparin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid); anti-inflammatory agents (such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine); antineoplastic/antiproliferative/anti-mitotic agents (such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors); anesthetic agents (such as lidocaine, bupivacaine, and ropivacaine); anti-coagulants (such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, anti-thrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, and tick antiplatelet peptides); vascular cell growth promoters (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters); vascular cell growth inhibitors (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin); immunosuppressants (such as the "olimus" family of drugs, rapamycin analogues,

macrolide antibiotics, biolimus, everolimus, zotarolimus, temsirolimus, picrolimus, novolimus, myolimus, tacrolimus, sirolimus, pimecrolimus, etc.); cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The disclosure's scope is, of course, defined in the language in which the appended claims are expressed.

WHAT IS CLAIMED IS:

1. A bone screw, comprising:

a body including a helical thread extending radially outward therefrom, the body further including an aperture extending axially into the body from a proximal end of the body; and

a cap including an enlarged head and a neck extending away from the enlarged head;

wherein the neck is configured for insertion into the aperture to selectively attach the cap to the body.

2. The bone screw of claim 1, wherein the bone screw is configured to selectively secure a sheet-like implant between the cap and the body.

3. The bone screw of claim 2, wherein the neck is configured for insertion through the sheet-like implant.

4. The bone screw of claim 1, wherein the neck has a first radial extent, and the enlarged head has a second radial extent, the first radial extent being less than the second radial extent, preferably the first radial extent is at least 50% less than the second radial extent.

5. The bone screw of claim 1, wherein the neck is configured to snap or screw into the aperture.

6. A bone screw, comprising:

a body including a helical thread extending radially outward therefrom, the body further including a post extending proximally from the body; and

a cap including an enlarged head having an aperture formed therein, wherein the cap is configured to selectively attach to the post.

7. The bone screw of claim 6, wherein the bone screw is configured to selectively secure a sheet-like implant between the cap and the body.

8. The bone screw of claim 7, wherein the post is configured for insertion through the sheet-like implant.

9. The bone screw of claim 6, wherein the post has a first radial extent and the enlarged head has a second radial extent, the first radial extent being less than the second radial extent, preferably the first radial extent is at least 50% less than the second radial extent.

10. The bone screw of claim 6, wherein the post is configured to snap or screw into the aperture.

11. A method of securing a sheet-like implant to bone and/or tissue at a treatment site, comprising:

driving a body of a bone screw into the bone at the treatment site, wherein the body includes an aperture extending axially into the body from a proximal end of the body;

positioning the sheet-like implant at the treatment site over the body of the bone screw; and

engaging a cap of the bone screw with the aperture such that the sheet-like implant is secured between the cap and the body.

12. A method of securing a sheet-like implant to bone and/or tissue at a treatment site, comprising:

driving a body of a bone screw into the bone at the treatment site, wherein the body includes a post extending proximally from the body;

positioning the sheet-like implant at the treatment site over the post of the bone screw; and

engaging a cap of the bone screw with the post such that the sheet-like implant is secured between the cap and the body.

13. A method of securing a sheet-like implant to bone and tissue at a treatment site, comprising:

positioning a suture anchor adjacent the bone at the treatment site using an anchor delivery device, the anchor delivery device comprising:

a handle;

an elongate shaft extending distally from the handle to a piercing tip; and

a striking surface proximate a proximal end of the handle;

wherein the suture anchor is releasably secured to the elongate shaft;

driving the piercing tip and the suture anchor into the bone at the treatment site by applying a striking force to the striking surface;

positioning the sheet-like implant at least partially overlaying the suture anchor at the treatment site; and

securing the sheet-like implant to the bone at the treatment site using at least one suture extending from the suture anchor.

14. A tissue repair implant, comprising:

a sheet-like implant configured to be attached to tissue and a bone adjacent the tissue; and

at least one bone anchor rotatably attached to and non-removable from the sheet-like implant.

15. A method of securing a sheet-like implant to bone and/or tissue at a treatment site, comprising:

positioning the sheet-like implant at the treatment site, the sheet-like implant including at least one bone anchor rotatably attached to and non-removable from the sheet-like implant;

driving the at least one bone anchor into the bone at the treatment site; and

securing the sheet-like implant to the tissue at the treatment site.

16. A system for deploying a bone anchor in bone, comprising:

an elongate shaft including an inner member and a distal tip fixed at a distal end thereof, the distal tip being configured for insertion into the bone; and

an annular bone anchor surrounding the inner member proximal of the distal tip in a delivery configuration;

wherein the annular bone anchor is self-biased toward a deployed configuration when unconstrained.

17. A system for securing a sheet-like implant to bone and/or tissue at a treatment site, comprising:

a sheet-like implant;

a bone anchor including a suture extending proximally therefrom to an anchor hook, the anchor hook configured to engage the sheet-like implant;

wherein the bone anchor includes a tightening element disposed within the bone anchor, the tightening element being configured to shorten the suture loop.

18. The system of claim 17, wherein the anchor hook is configured to engage a loop extending laterally from the sheet-like implant.

19. The system of claim 17, wherein the suture loop is configured to pull at least a portion of the anchor hook within the bone anchor.

20. A method of securing a sheet-like implant to bone and/or tissue at a treatment site, comprising:

positioning the sheet-like implant at the treatment site, the sheet-like implant including a loop extending laterally therefrom;

delivering a bone anchor to the treatment site using a delivery shaft, wherein the bone anchor is disposed on the delivery shaft;

driving a piercing tip of the delivery shaft into the bone at the treatment site, thereby inserting the bone anchor into the bone at the treatment site, wherein the bone anchor includes a suture loop extending proximally therefrom to an anchor hook;

coupling the anchor hook to the loop of the sheet-like implant; and

shortening the suture loop of the bone anchor to apply tension to the loop of the sheet-like implant.

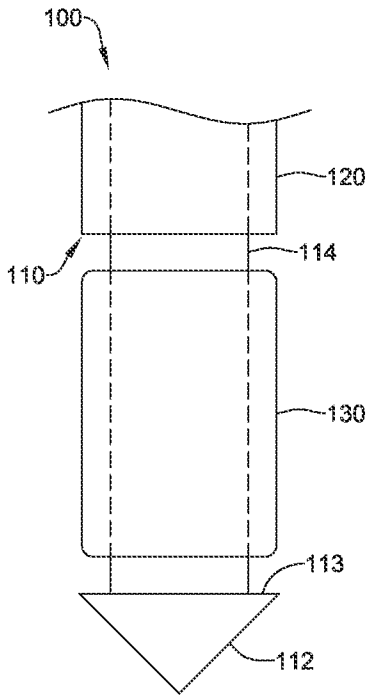

FIG. 1

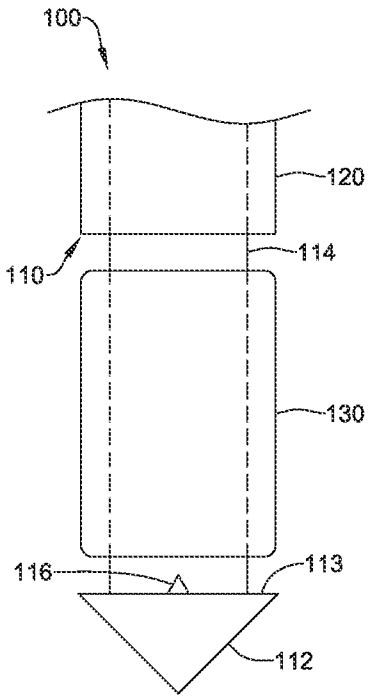

FIG. 2

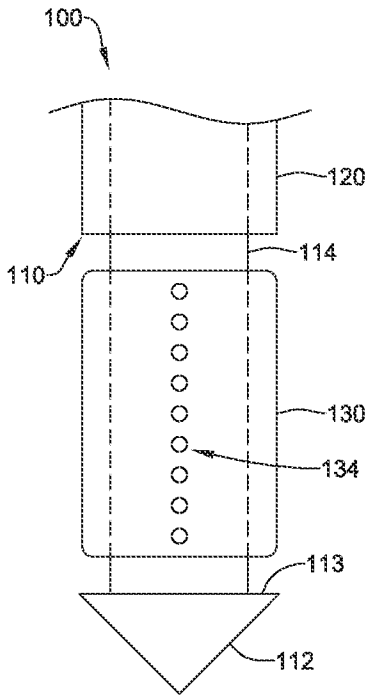

FIG. 3

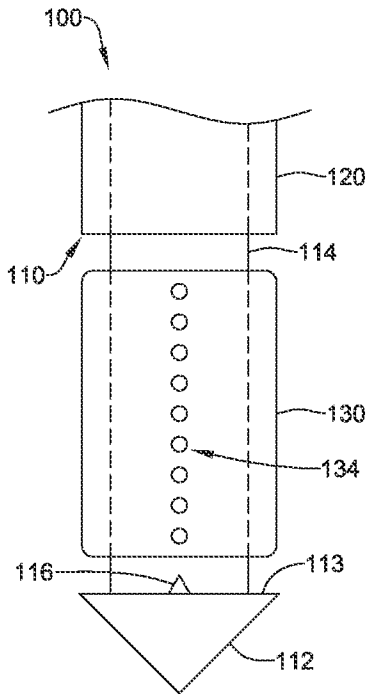

FIG. 4A

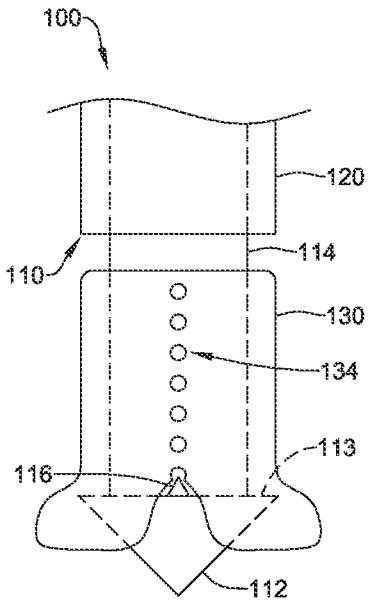

FIG. 4B

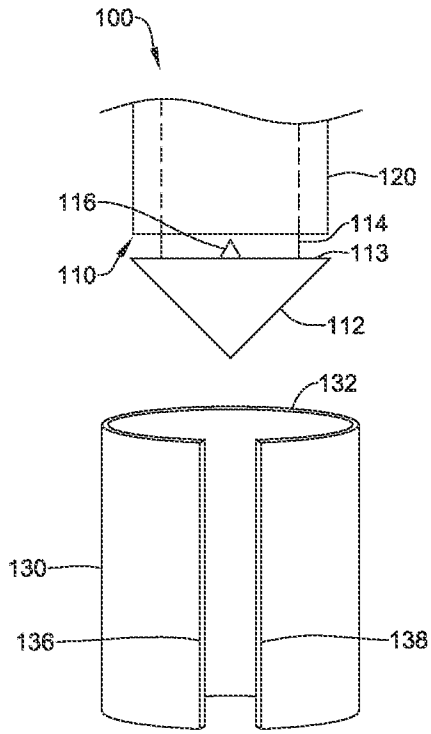

FIG. 4C

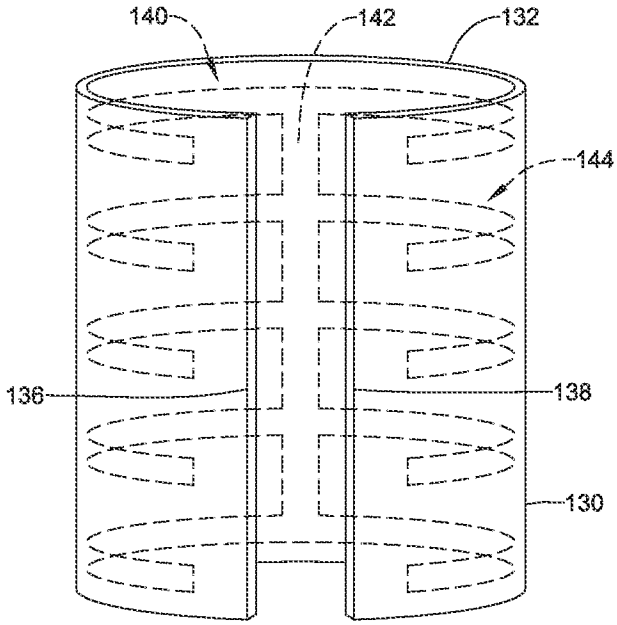

FIG. 5

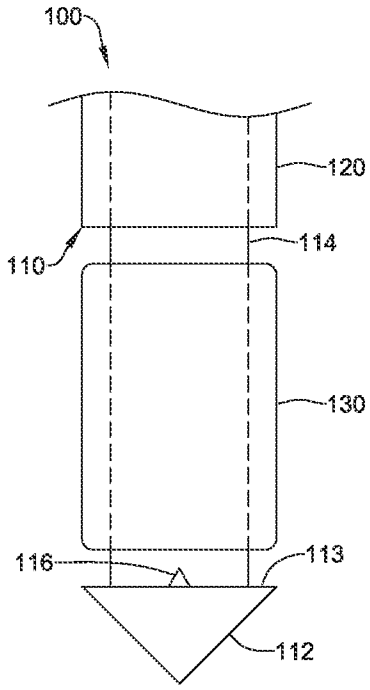

FIG. 6A

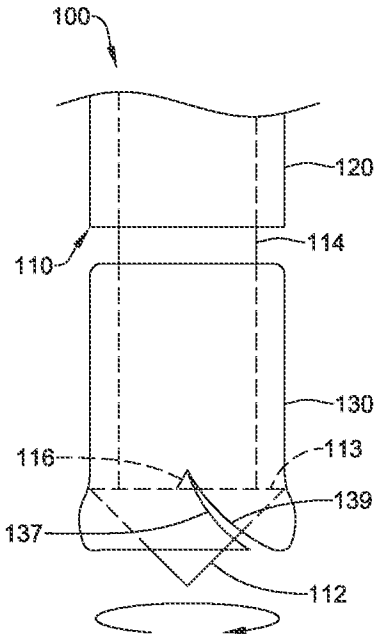

FIG. 6B

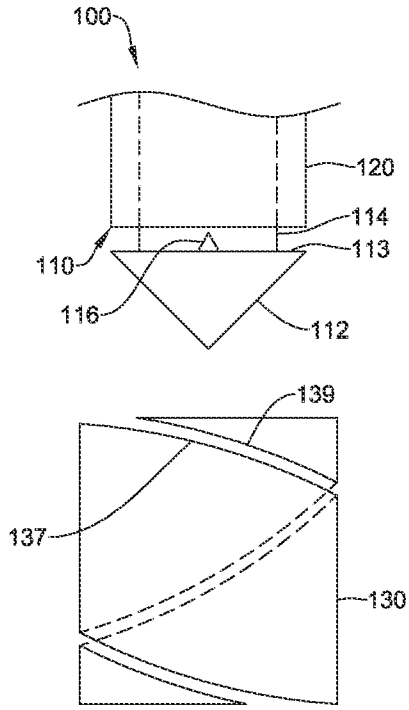

FIG. 6C

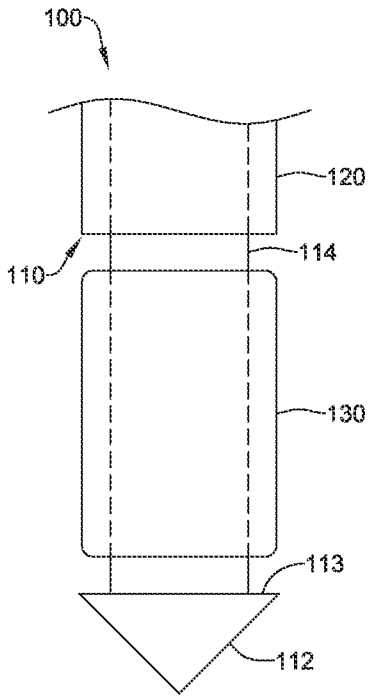

FIG. 7A

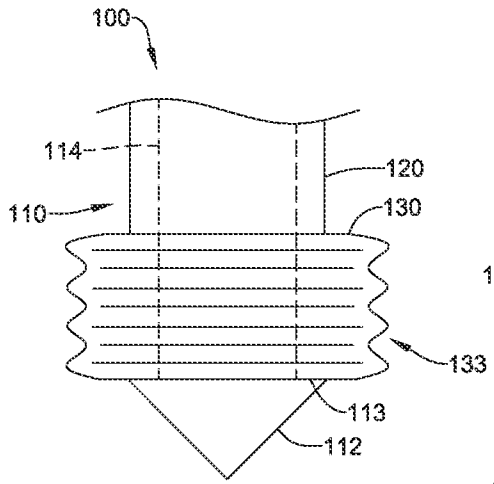

FIG. 7B

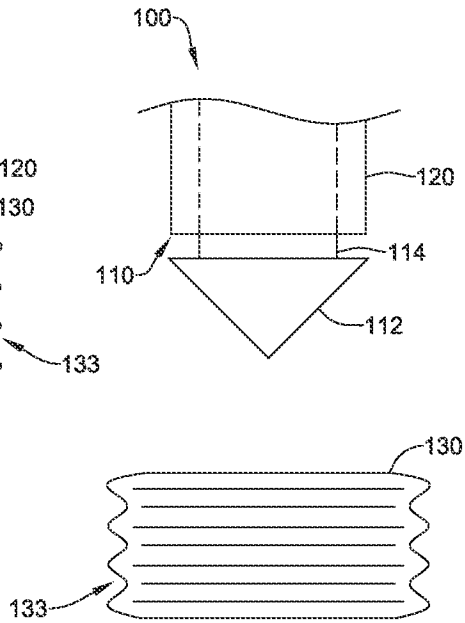

FIG. 7C

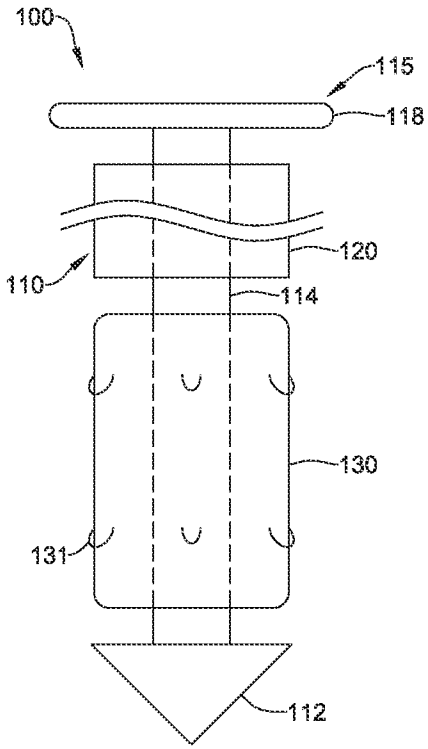
100
115
118
120
110
114
130
131
112

FIG. 8

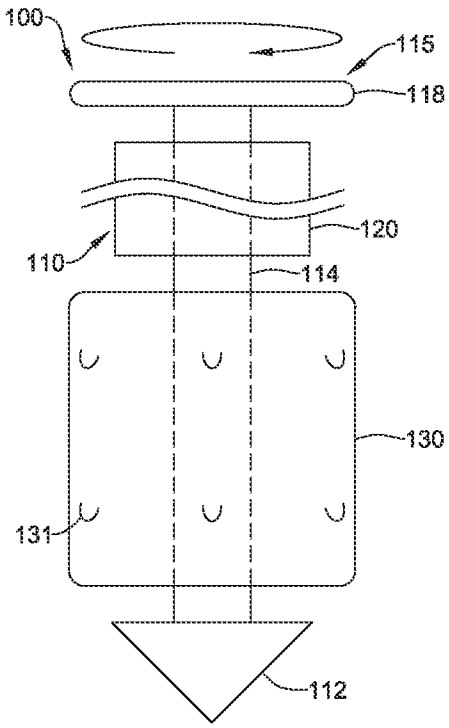
100
115
118
120
110
114
130
131
112

FIG. 9

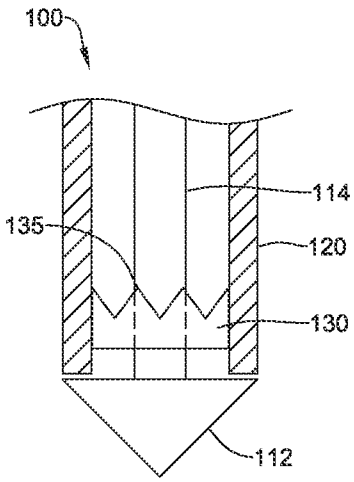

FIG. 10A

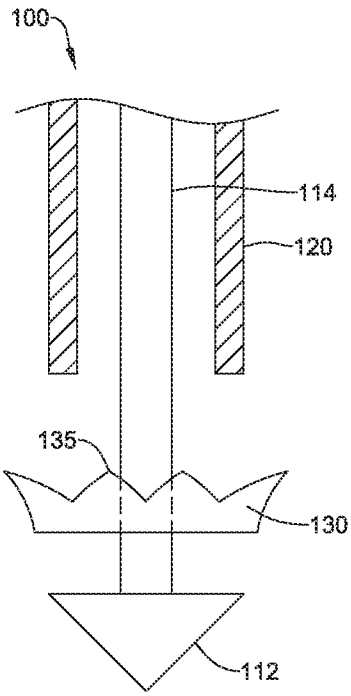

FIG. 10B

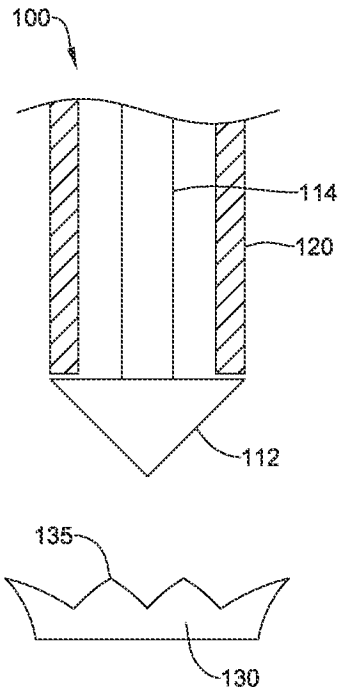

FIG. 10C

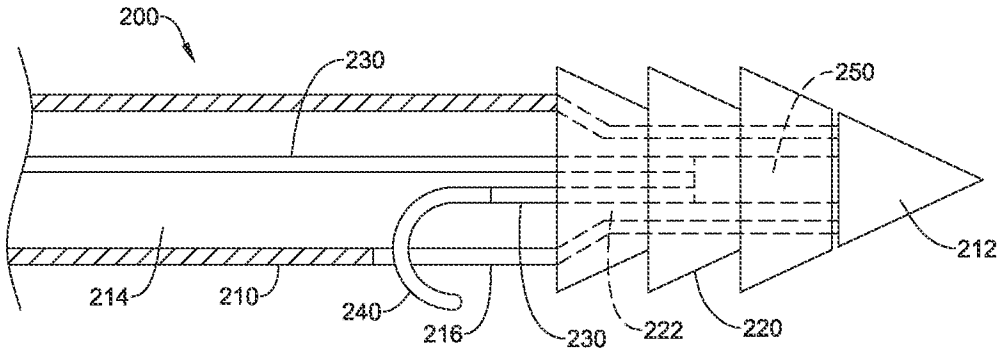
200
230
250
212
214
210
240
216
230
222
220

FIG. 11

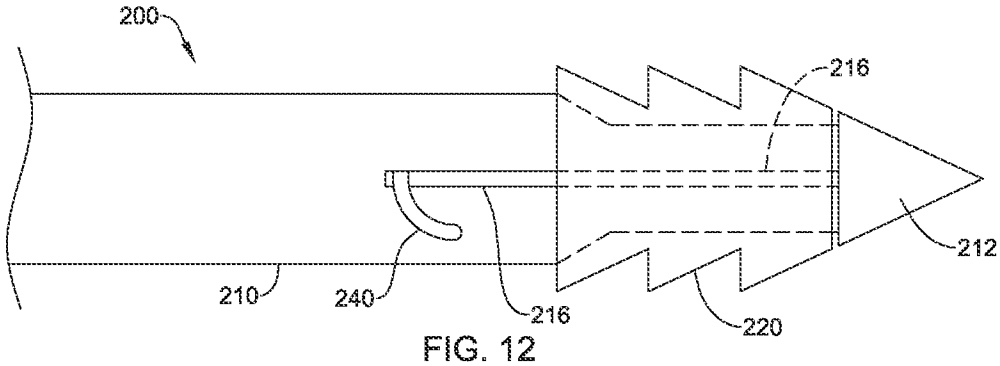
200
216
212
210
240
216
220

FIG. 12

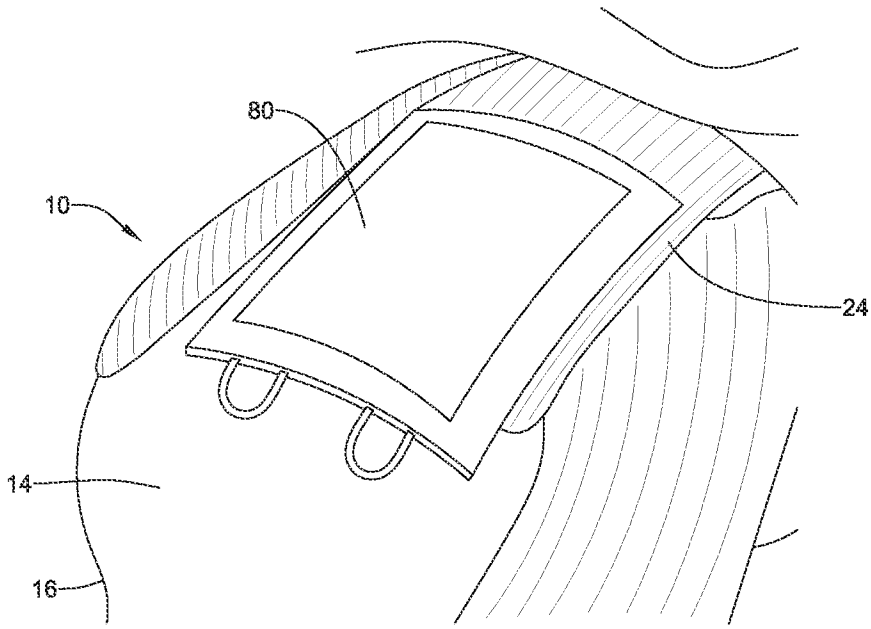

FIG. 13

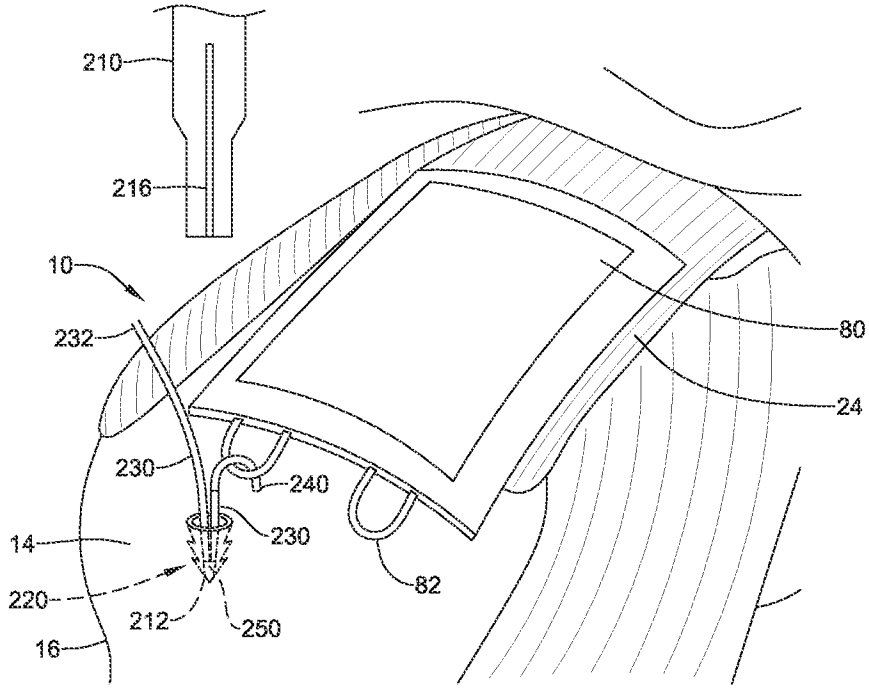

FIG. 14

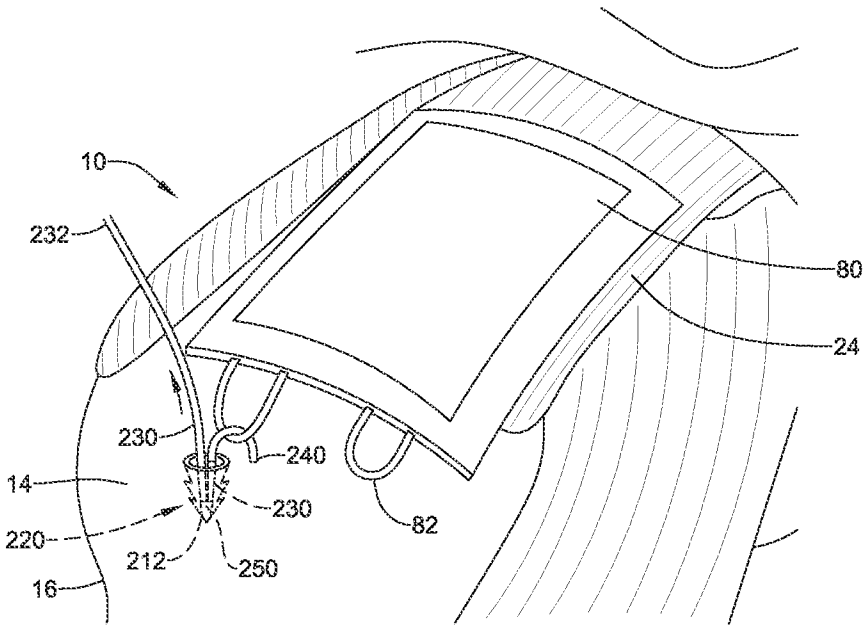

FIG. 15

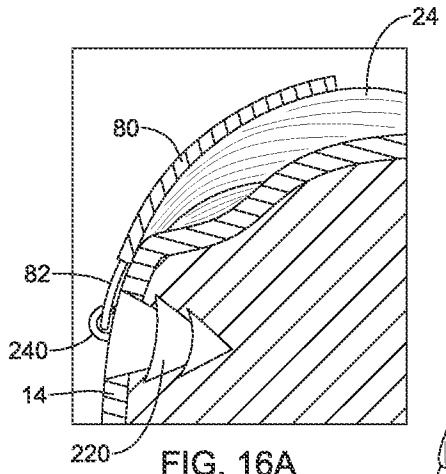

FIG. 16A

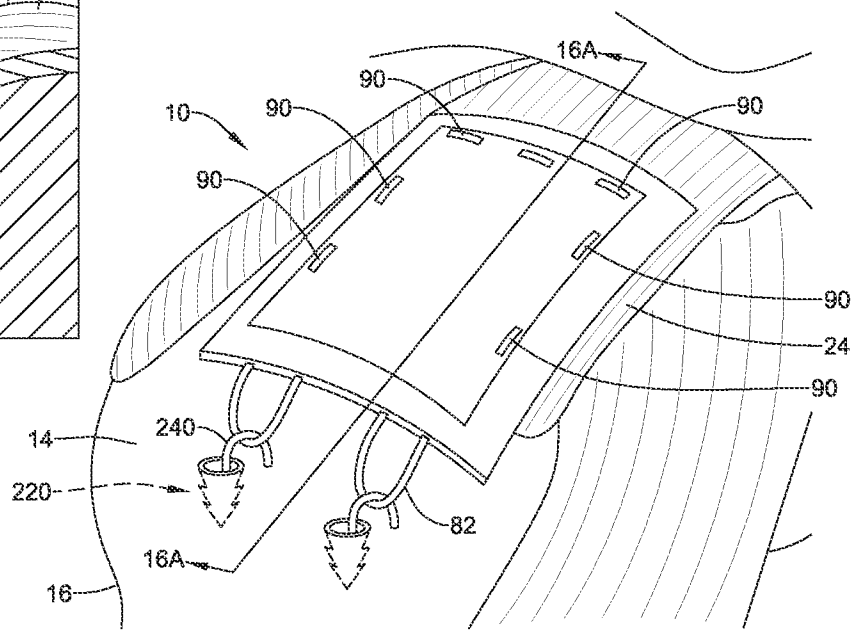

FIG. 16

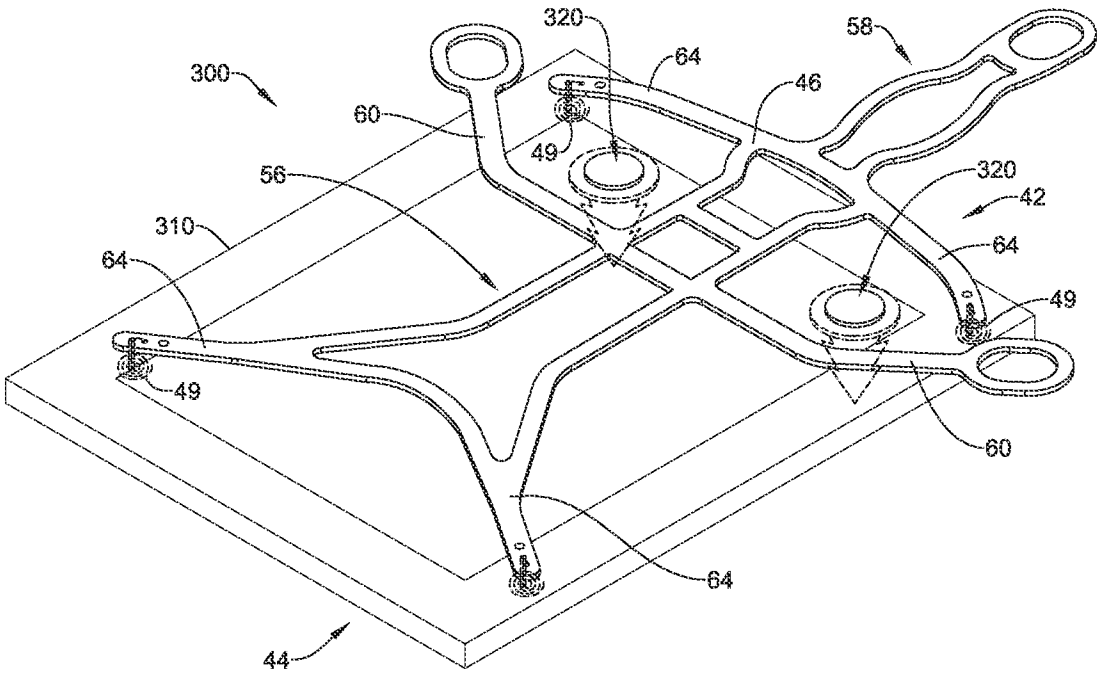

FIG. 17

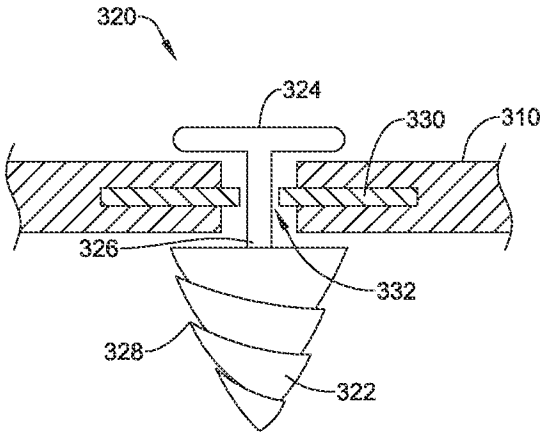

FIG. 18

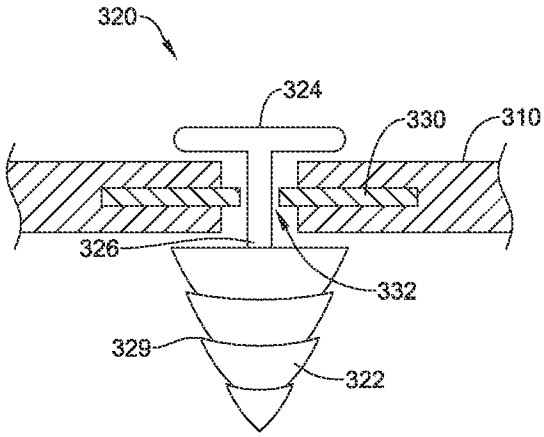

FIG. 19

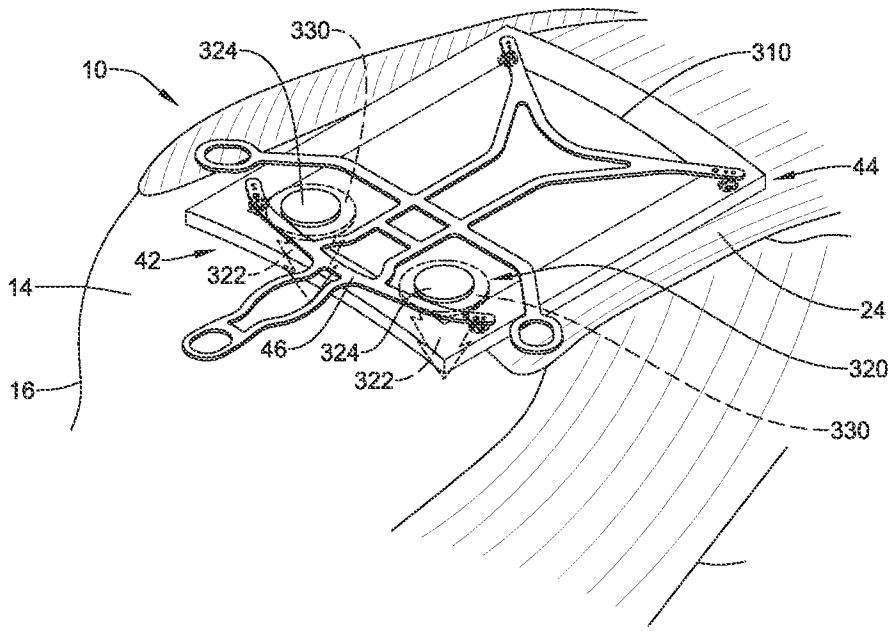

FIG. 20

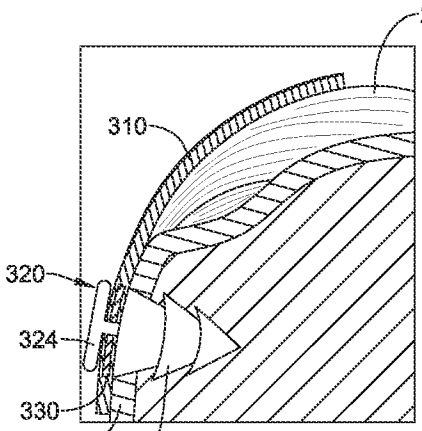

FIG. 21A

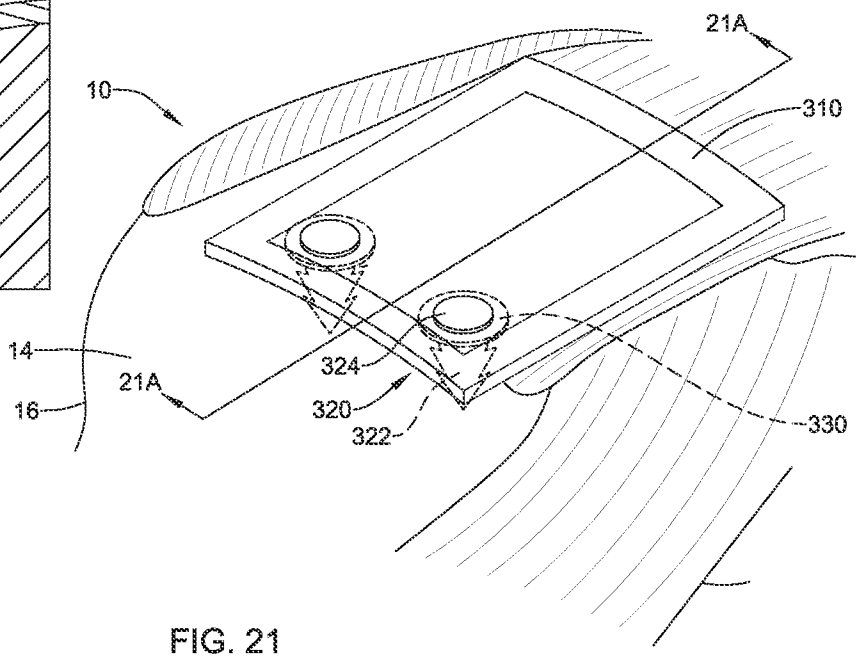

FIG. 21

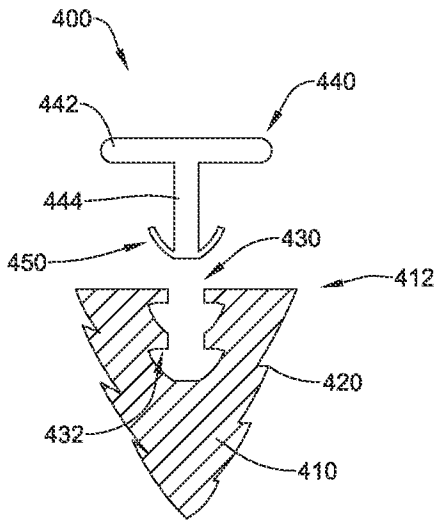

FIG. 22

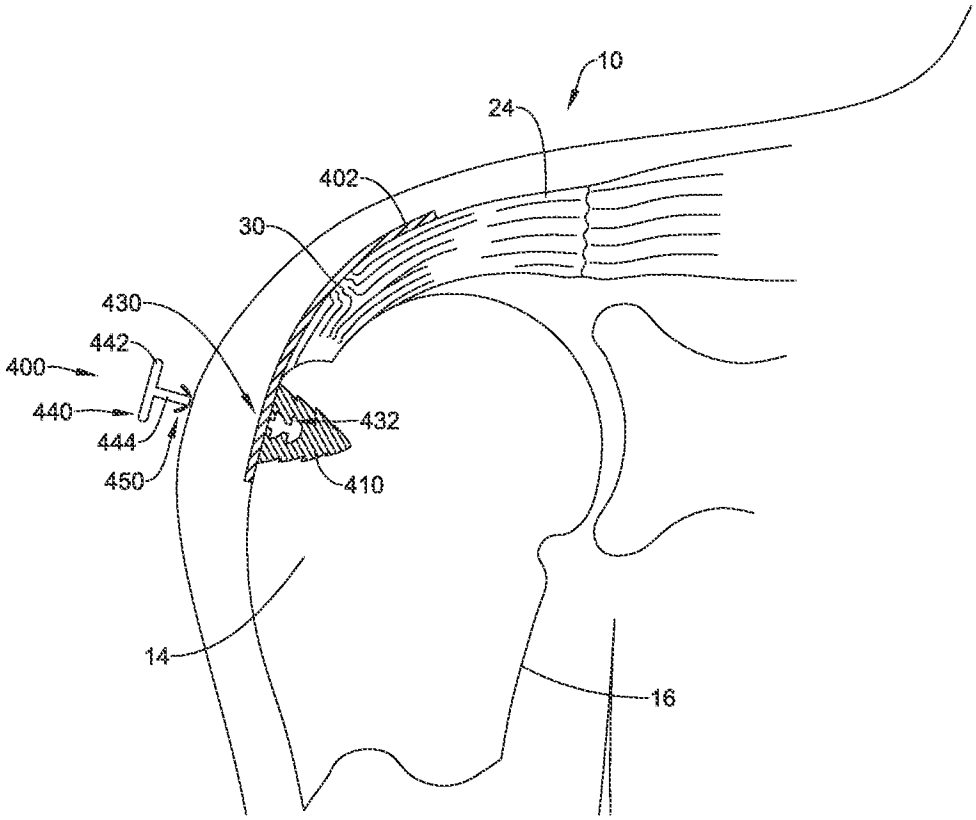

FIG. 23

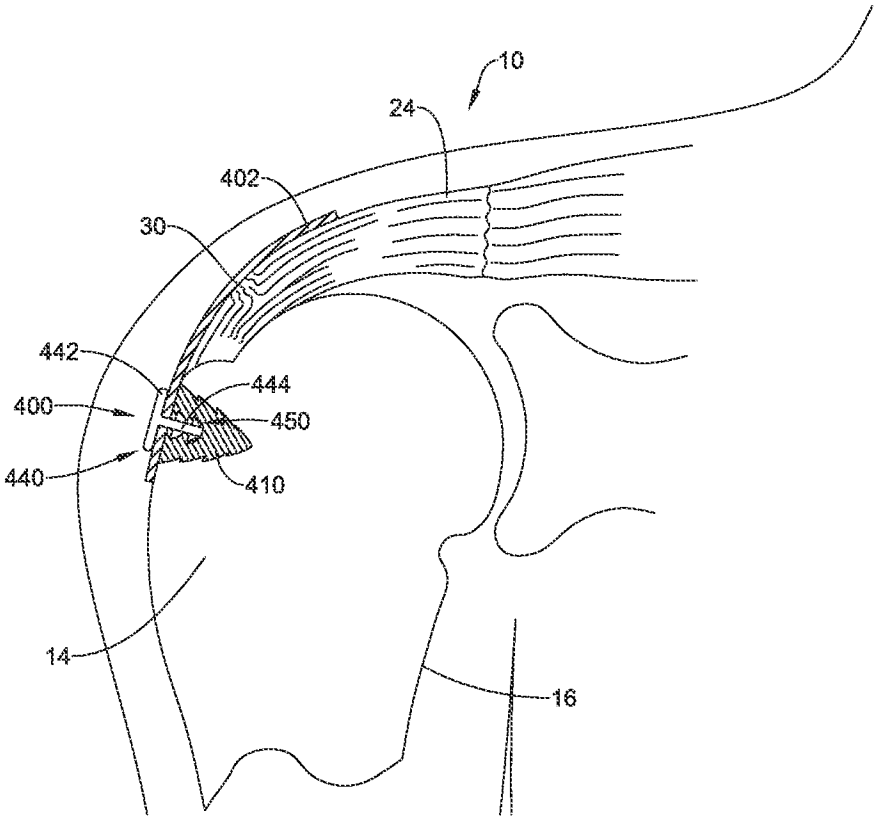

FIG. 24

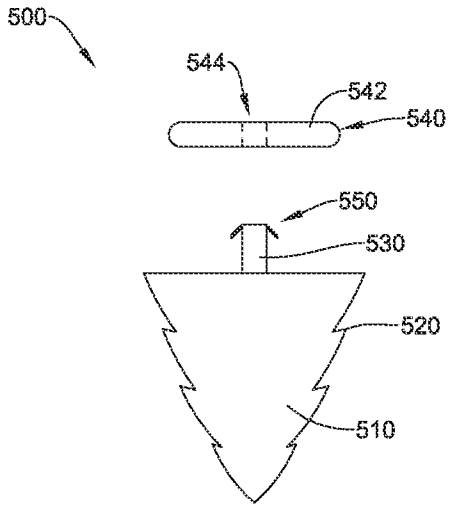

FIG. 25

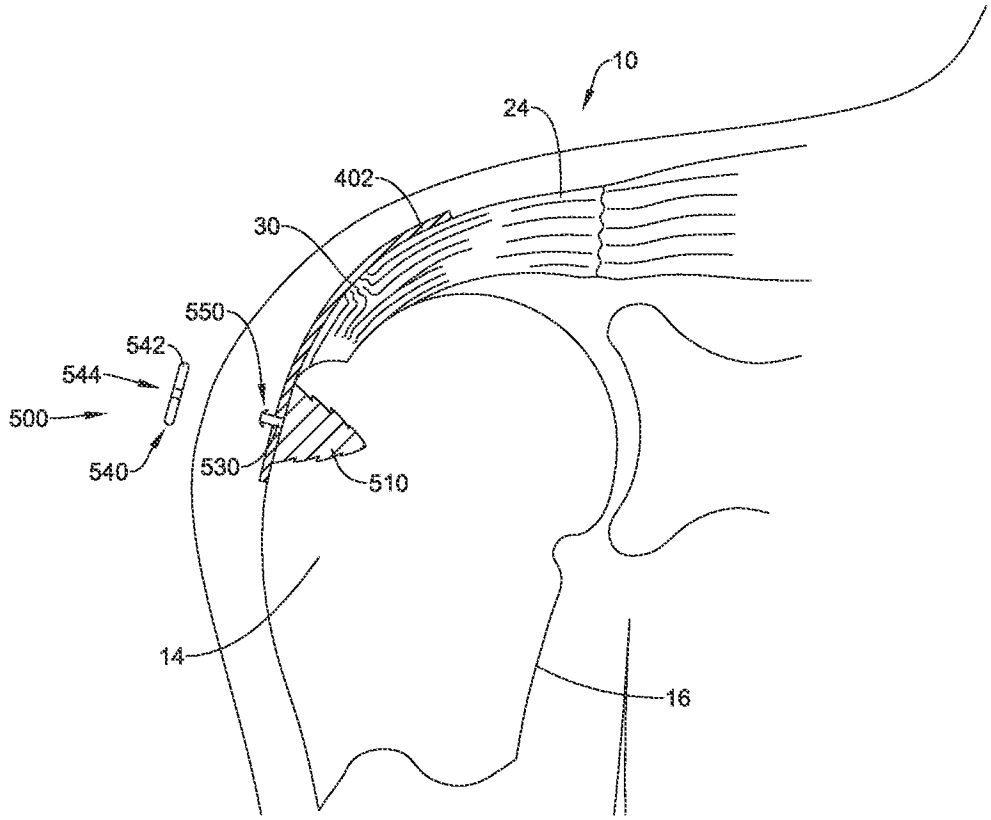

FIG. 26

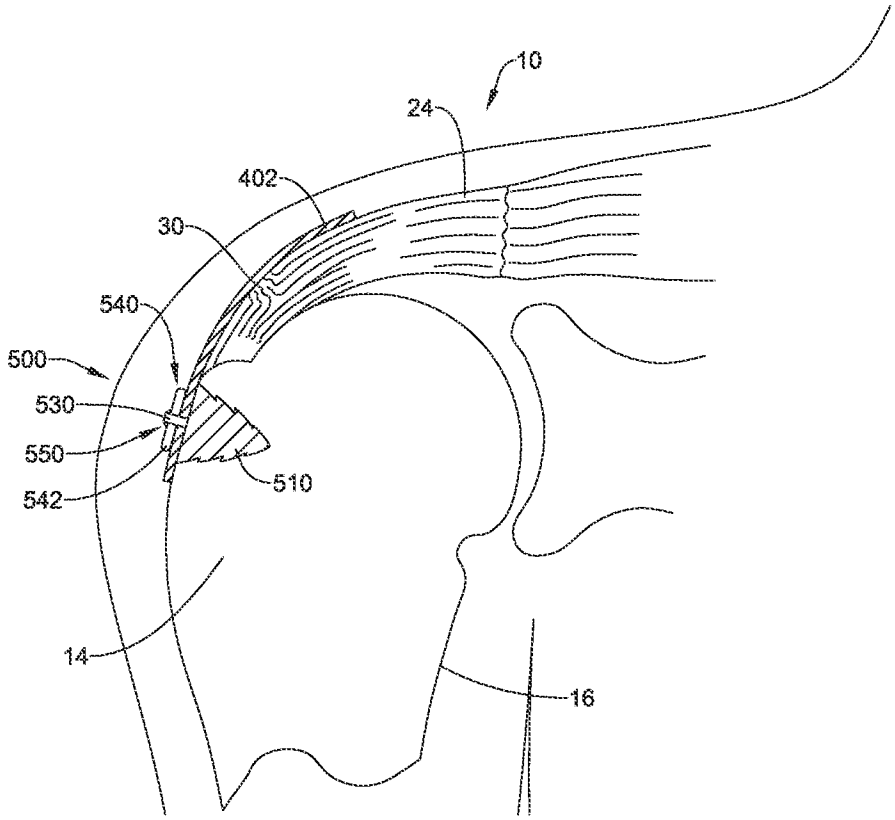

FIG. 27

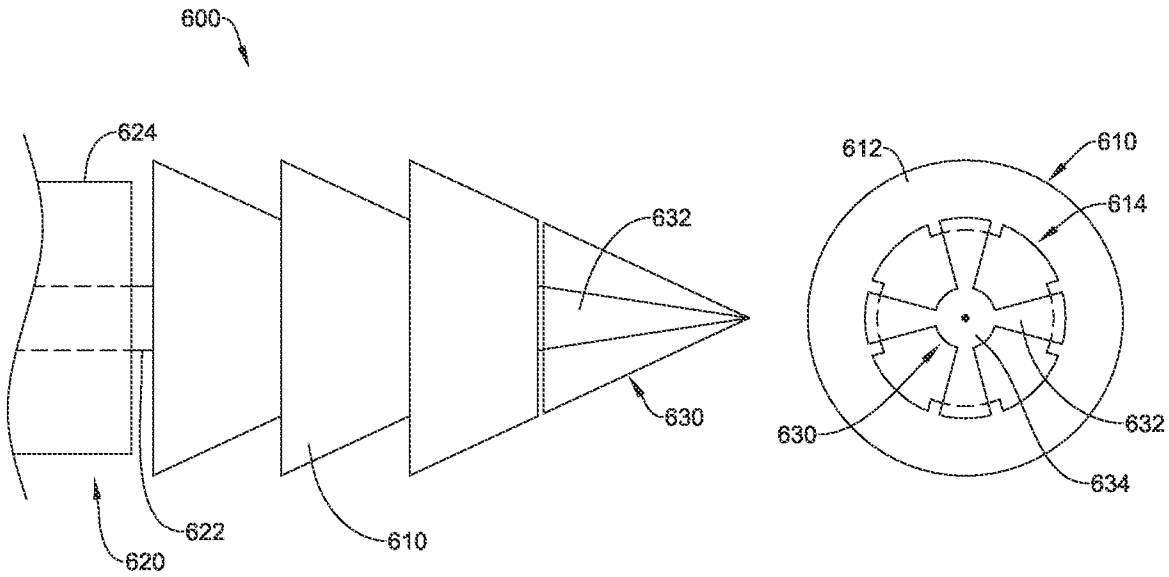

FIG. 28

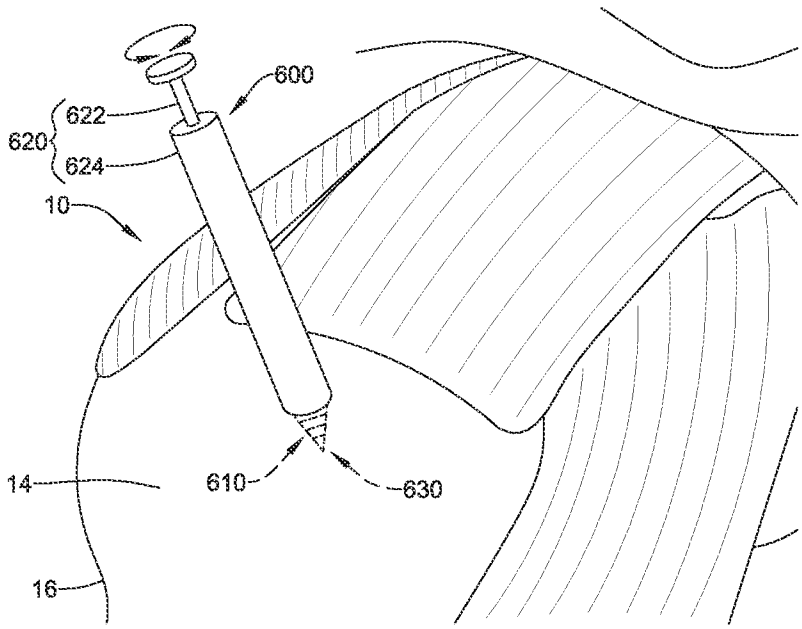

FIG. 29

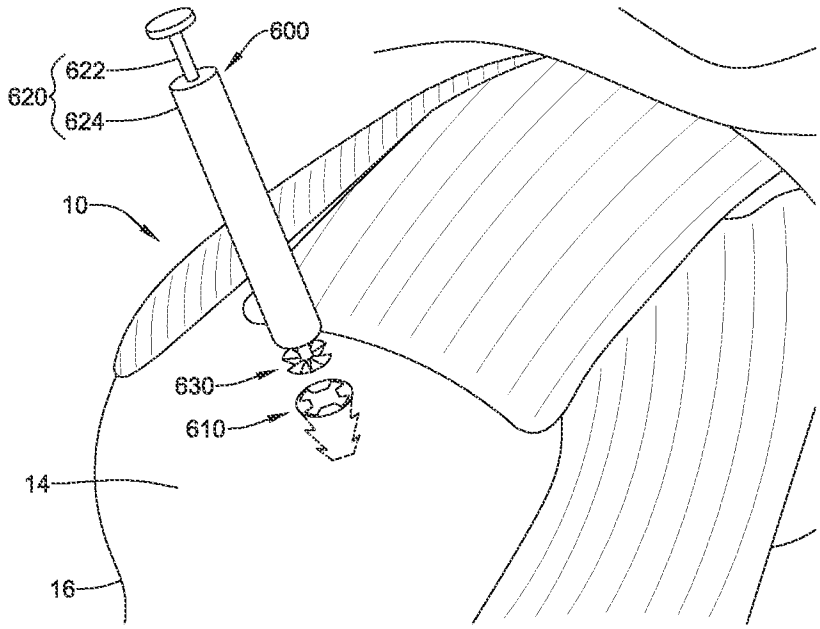

FIG. 30

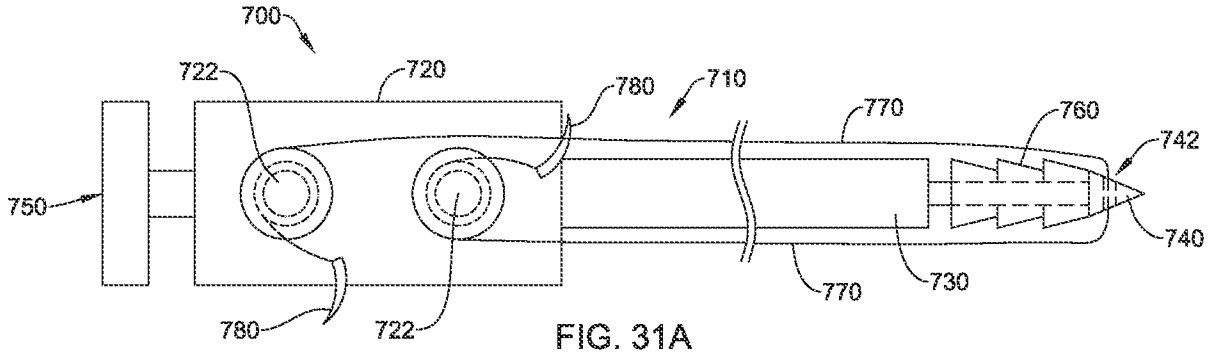

FIG. 31A

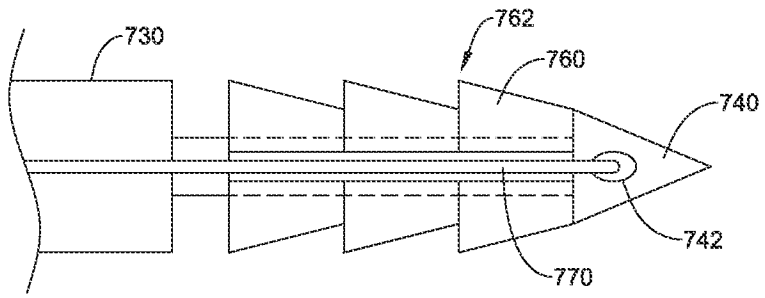

FIG. 31B

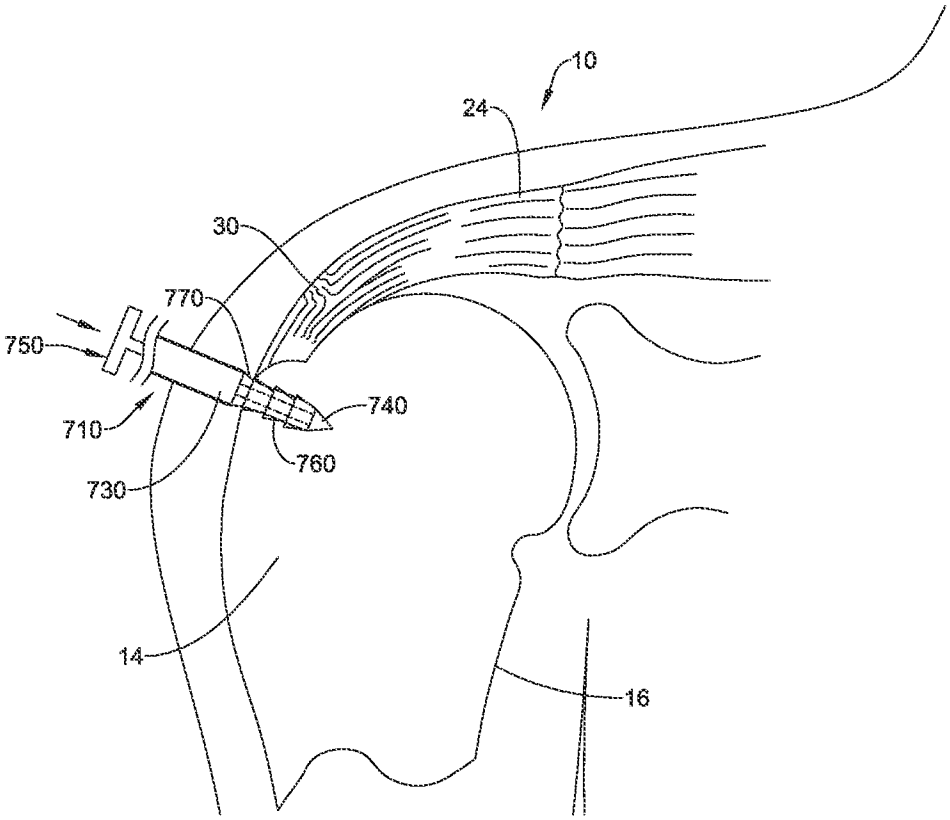

FIG. 32

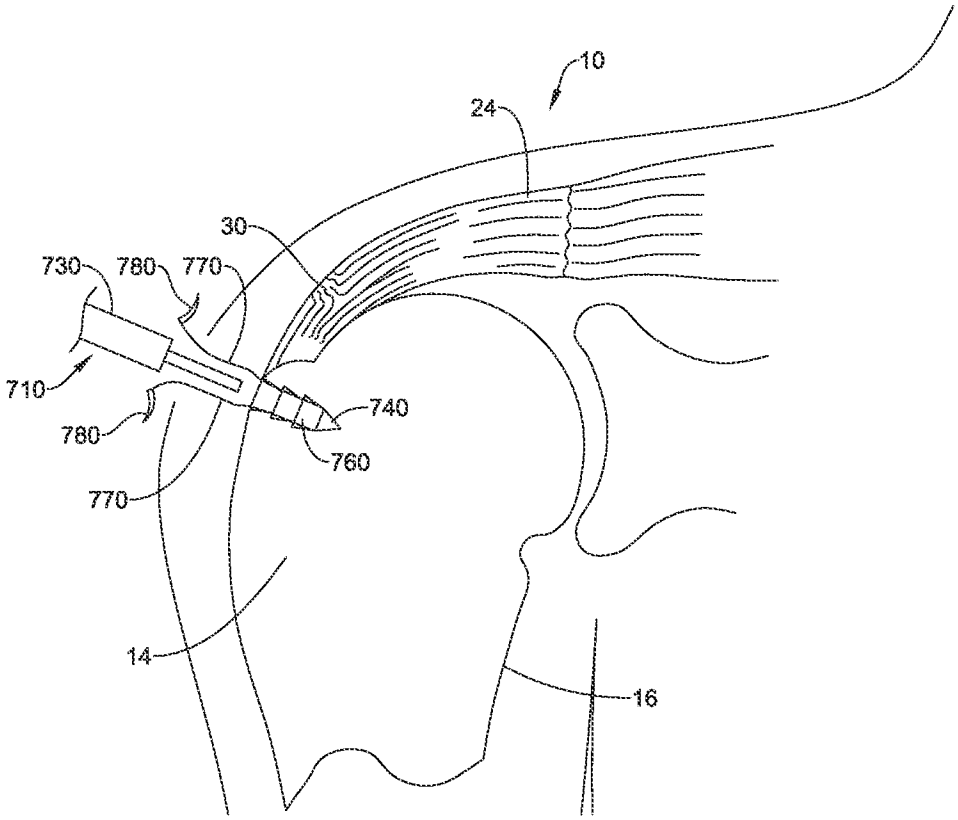

FIG. 33

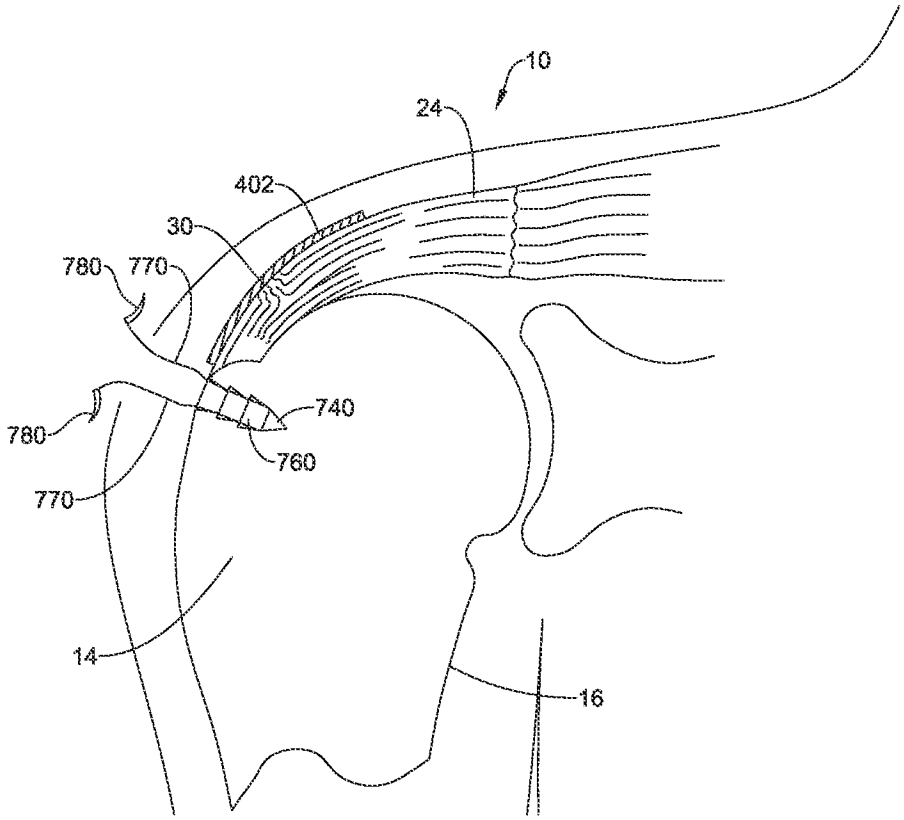

FIG. 34

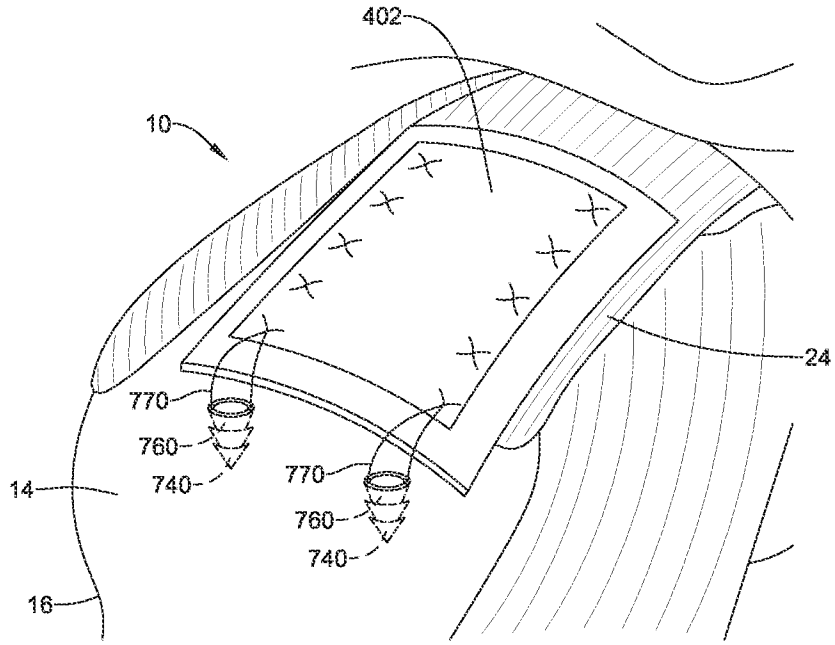

FIG. 35