



Knotless AP Suture Anchor

Important Product Information

Instructions for Use

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Knotless AP Suture Anchor (English)

1. Indications

The Parcus Knotless AP Suture Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

<u>Shoulder</u>	Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.
<u>Knee</u>	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.
<u>Foot/Ankle</u>	Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.
<u>Elbow</u>	Tennis Elbow Repair, Biceps Tendon Reattachment.
<u>Hand/Wrist</u>	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

2. Contraindications

- A. Any active infection.
- B. Blood supply limitations or other systemic conditions that may retard healing.
- C. Foreign body sensitivity, if suspected should be identified and precautions observed.
- D. Insufficient quality or quantity of bone. Suture anchor performance is directly related to the quality of bone into which the anchor is placed.
- E. Patient's inability or unwillingness to follow the surgeon's prescribed post-operative regimen.
- F. Any situation that would compromise the ability of the user to follow the directions for use or using the device for an indication other than those listed.

3. Adverse Effects

- A. Infection, both deep and superficial.
- B. Allergies and other reactions to device materials.
- C. Risks due to anesthesia.

4. Warnings

- A. Caution: Federal law restricts this device to sale by or on the order of a physician.
- B. The fixation provided by this device should be protected until healing is complete. Failure to follow the postoperative regimen prescribed by the surgeon could result in the failure of the device and compromised results.
- C. Anchor size selection should be made with care taking into consideration the quality of the bone in which the anchor is to be placed. (Osteopenic bone poses fixation challenges which may be addressed by larger diameter suture anchors.)
- D. Any decision to remove the device should take into consideration the potential risk of a second surgical procedure. Adequate postoperative management should be followed after implant removal.
- E. The patient should be advised of the use and limitations of this device.
- F. Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary components in achieving a good surgical result.
- G. This device must never be reused. Reuse or re-sterilization may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross-contamination leading to patient infection.
- H. This device must never be re-sterilized.
- I. Appropriate instrumentation should be used to implant this device.
- J. The device must not be used if any of the temperature sensitive warning labels appear red in color.

5. Packaging and Labeling

- A. Do not use this product if the packaging or labeling has been damaged, shows signs of exposure to moisture or extreme temperature or has been altered in any way.
- B. The Knotless AP Suture Anchors are provided within two levels of sterile packaging. While the outer pouch provides a sterile and moisture barrier, the inner pouch only preserves the sterility of the device and does not prevent moisture from getting to the anchor body. Because the Knotless AP Suture Anchors break down by means of hydrolysis, devices must be stored within both pouches. Devices found within only one layer of packaging should be discarded.
- C. Please contact Parcus Medical Customer Service to report any package damage or alterations.

6. Material Specifications

- A. Anchor Body: The Knotless AP Suture Anchors are manufactured using a composite of β TCP (beta tricalcium phosphate) and PLGA (poly lactic-co-glycolic acid). These devices are MR Safe.
- B. Shaft: Stainless steel.
- C. Handle: ABS.
- D. Suture Threader: Nitinol and Stainless Steel.

7. Sterilization

The Knotless AP Suture Anchors are supplied in sterile packaging. The contents are sterilized by EO gas. These products must never be re-sterilized.

8. Storage

Products must be stored in the original unopened package in a dry place and must not be used beyond the expiration date indicated on the package. The Knotless AP Suture Anchors must be stored below 25° C (77° F).

9. Instructions for Use

The Instructions below apply only to the 2.8mm Knotless AP Suture Anchor (Instructions for the 4.5mm and 5.5mm Knotless AP Suture Anchors are identified in J. - R. below)

- A. Identify bone of sufficient quantity and quality into which the anchor is to be placed.
- B. The Knotless AP Suture Anchor is inserted into a socket created with a Parcus Drill Bit. Reference the box label of the Knotless Anchor for recommended drill/awl sizes. It should be noted that while two drill/awl sizes are indicated, the smaller of the two is intended for use in less dense bone while the larger is for average to more dense bone. Arthroscopic cannulae are typically used in conjunction with these devices. Always try to approach the targeted site as close to perpendicular as possible. If using the Drill Guide, use the obturator supplied with the Drill Guide to aid in its passage through tissue.
- C. Place sutures (not supplied with anchor) through the targeted tissue. These sutures will be placed through the eye in the tip of the anchor and will be secured when the anchor is driven into the prepared socket. The 2.8mm Knotless AP Suture Anchor will accommodate two (2) strands of #2 suture. In arthroscopic applications, draw the sutures up through the same cannula through which the Drill Guide will be used.
- D. Insert the Drill Bit into a drill. When using the Drill Guide, place the distal tip of the guide on the targeted bone and insert the Drill Bit through its lumen. Advance the Drill Bit into the bone until the circumferential laser mark on the distal tip of the Drill Bit is flush with the surface of the bone, or the stop on the drill bit contacts the proximal end of the drill guide. Remove the Drill Bit and Drill Guide, carefully noting the location of the prepared socket or leave the Drill Guide and Drill Bit in position until ready to insert the anchor.
- E. Aseptically open the package containing the Knotless AP Suture Anchor. The anchor comes packaged with a suture passer to aid in placing sutures through the distal eyelet. Knotless AP Suture Anchors are used with a Parcus Driver which is either provided with the implant or separately. Drivers provided separately are available as non-sterile and reusable devices. Assemble the suture anchor to the driver by inserting the tip of the driver into the socket of the anchor and pushing until the driver is firmly attached to the anchor.
- F. Pass the sutures placed through the tissue described in Step C, through the eyelet in the distal tip of the suture anchor. Use the suture passer to aid in placing the suture through the distal tip of the anchor. If the Drill Bit was left in position as described in Step D, remove it before proceeding.
- G. Push the tip of the suture anchor into the prepared socket and using a suitable mallet, gently strike the driver handle, advancing the suture anchor into the prepared socket, until the circumferential laser mark on the distal end of the driver is flush with the bone.

Warning: Insertion of the anchor off axis from the hole may result in implant failure. Failure to insert the driver to the depth indicated by the laser mark may result in the anchor being left proud.

- H. Once implant is fully inserted, remove driver by pulling firmly and twisting slightly until the driver is free from the anchor.
- I. Cut the ends of the remaining tails of the suture.

The Instructions below apply only to the 4.5mm and 5.5mm Knotless AP Suture Anchors (Instructions for the 2.8mm Knotless AP Suture Anchor are identified in A. - I. above)

- J. Identify bone of sufficient quantity and quality into which the anchor is to be placed.
- K. The 4.5mm or 5.5mm Knotless AP Suture Anchor is inserted into a socket created with a Parcus Drill Bit or Awl. Reference the box label of the Knotless AP Anchor for recommended drill/awl sizes. It should be noted that while two drill/awl sizes are indicated, the smaller of the two is intended for use in less dense bone while the larger is for average to more dense bone. Arthroscopic cannulae are typically used in conjunction with these devices. Always try to approach the targeted site as close to perpendicular as possible. If using the Drill Guide, use the obturator supplied with the Drill Guide to aid in its passage through tissue.
- L. Place sutures (not supplied with anchor) through the targeted tissue. These sutures will be placed through the eye in the tip of the anchor and will be secured when the anchor is driven into the prepared socket. The 4.5mm and 5.5mm Knotless AP Suture Anchors will accommodate up to six (6) strands of #2 suture. In arthroscopic applications, draw the sutures up through the same cannula through which the Drill Guide will be used.
- M. **If using an Awl**, align the awl in the proper position and orientation to accommodate the insertion of the anchor. When used in bone of lesser density, awl may be stopped at the distal circumferential laser mark. When used in bone of greater density, awl may be stopped at the proximal circumferential laser mark. Remove the Awl, carefully noting the location of the prepared socket, or leave the awl in position until ready to insert the anchor.
- N. **If using a Drill Bit**, insert the Drill Bit into a drill chuck or pin driver. When using the Drill Guide, place the distal tip of the guide on the targeted bone and insert the Drill Bit through its lumen. Advance the Drill Bit into the bone until the stop on the drill bit contacts the proximal end of the drill guide. When using a Drill Bit without the Drill Guide, advance the Drill Bit into the bone until the circumferential laser mark on the distal tip of the Drill Bit is flush with the surface of the bone. Remove the Drill Bit (and Drill Guide if applicable), carefully noting the location of the prepared socket or leave the Drill Bit (and Drill Guide, if applicable) in position until ready to insert the anchor.
- O. Aseptically open the package containing the Knotless AP Suture Anchor. The anchor comes packaged with a suture passer to aid in placing sutures through the distal eyelet. Knotless AP Suture Anchors are used with a Parcus Driver which is either provided with the implant or separately. Drivers provided separately are available as non-sterile and reusable devices. Assemble the suture anchor to the driver by inserting the tip of the driver into the socket of the anchor and pushing until the driver is firmly attached to the anchor.
- P. Pass the sutures placed through the tissue described in Step L, through the eyelet in the distal tip of the suture anchor. Use the suture passer to aid in placing the suture through the distal tip of the anchor. If the Drill Bit or Awl was left in position as described in Step M, remove it before proceeding.
- Q. Push the tip of the suture anchor into the prepared socket and using a suitable mallet, gently strike the driver handle, advancing the suture anchor into the prepared socket, until the circumferential laser mark on the distal end of the driver is flush with the bone.

Warning: Insertion of the anchor off axis from the hole may result in implant failure. Failure to insert the driver to the depth indicated by the laser mark may result in the anchor being left proud.

- R. Once implant is fully inserted, remove driver by pulling firmly and twisting slightly until the driver is free from the anchor.
- S. Cut the ends of the remaining tails of the suture.