BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Tendon Anchor System (TAS) Instructions for Use

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com

Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

Description
The BioPro Tendon Anchor System (T.A.S.) is a toothed, titanium anchor designed for soft tissue reattachment to bone.

Material
Cobalt Chrome (ASTM F1537) or 6-4 Eli Titanium (ASTM F136)

Indications for use:
The BioPro Tendon Anchor System is indicated for use for soft tissue to bone fixation in the foot, ankle, knee, hip, hand, wrist, elbow, and shoulder. The BioPro TAS Plate and Screw(s) is supplied sterile and intended for single use only. The system is not intended for spinal use.

Contra-indications:
1) A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2) An active infection or a previous infection of the lower extremity that has not been quiescent for at least six months.
3) A local or systemic infection.
4) Significant deficiency in the vascular supply to the extremity.
5) Severe structural deficiency of the sub-chondral bone that may result in insufficient support for the device.
6) Severe compromise of the supporting muscles or ligaments.
7) It is not intended for use in the spine.
8) Foreign body sensitivity to metals specifically titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Precautions and Handling
- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured, and implants should not be used if blister or seal is damaged.
- Implants are single use devices
- Do not autoclave implants

Potential Complications and Adverse Effects
- Allergic reactions to metal
- Delayed healing
- Loosening or migration of the implant
- Pain due to bone remodeling or reaction to implant components
- Use of longer screws could result in irritation and violation of adjacent joint spaces resulting in pain and discomfort.

Contact surgeon if a change in performance or pain level is noticed.

MR Safety Information
Warning: The Tendon Anchor System has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

Sterile:
STERILE EO Rx Only

Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

Instructions for use:
Surgical Technique – For Haglund's Deformity

1. A direct midline incision is made posteriorly with the patient in the prone position. The incision is carried down to the calcaneus and calcaneal tendon insertion. The Achilles tendon is split at the line incision, full thickness, from posterior to anterior and is debrided removing all tendinopathic tissue. The Achilles tendon is released distally, and reflected medially and laterally, exposing the whole calcaneal tuberosity with a Haglund's prominence. Care is taken to maintain some medial and lateral attachments to assist with the accurate restoration of the Achilles' length. Complete tendon debridement may require complete tendon detachment in some cases.

2. The Haglund's prominence is removed using the micro-sagittal saw and osteotome. Care is taken to chamfer off the medial and lateral sides of the calcaneus so as not to leave a prominence which is palpable under the skin, creating difficulties with footwear.

3. Next, the Achilles tendon is re-approximated with a braided non-absorbable suture of choice. Care is taken to bury the suture knots. Next, the appropriately sized Tendon Anchor System Plate is placed over the tendon and temporarily secured into place with the provided K-wire. After that, the plate is permanently secured with the provided self reaming, self tapping screws. Care is taken not to over tighten the screws and risk stripping the bone. All temporary instrumentation is removed. The subcutaneous tissues and skin are closed per surgeon's preference.

Surgical Technique – For Soft-tissue Attachment

1. An incision is made using the surgeons preferred method.

2. Once the tendon in question is identified, it is re-approximated with a braided non-absorbable suture of choice. Care is taken to bury the suture knot.

3. Next, appropriately sized Tendon Anchor System Plate is placed on the tendon and temporarily secured into place with the provided K-wire. The Tendon Anchor System is permanently secured with the provided self reaming, self tapping screws. Care is taken not to over tighten the screws and risk stripping the bone. All temporary instrumentation is removed. The subcutaneous tissues and skin are closed per surgeon's preference.

4. Next, the periosteum and the joint capsule are repaired utilizing suture of choice.

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