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PONTIS™ SUTURE – CRIMP IMPLANT 400-3011
PONTIS™ 3mm ANCHORS WITH CRIMPS 400-3031W/400-3031B
PONTIS™ DILATING CATHETER, FUNNEL AND THREADER 400-3014

PONTIS Orthopaedics, LLC
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DESCRIPTION

The PONTIS™ System provides a simplified technique for tendon repair. A crimp and crimp tool are provided as an alternative to knotting. The strength of the crimps when used with PONTIS™ Multifilament SS implants, or Multifilament SS implants from the PONTIS™ 3mm anchors, are equivalent to the knot-secured suture repairs of flexor tendons.

INDICATIONS FOR USE

The PONTIS™ Multifilament SS implants with Crimps are indicated to secure soft tissue to soft tissue reattachment in the hand:

- Collateral Ligaments around the PIP, DIP and MCP Joints
- Flexor and Extensor Tendons

The PONTIS™ 3mm Anchors with Crimps are indicated to secure soft tissue to bone reattachment in the hand:

- Collateral Ligaments around the PIP, DIP and MCP Joints
- Flexor and Extensor Tendons

MATERIALS (Implantable)

- Multifilament SS implant, Crimp, and Anchor: 316 L Stainless Steel per ASTM F-138

CONTRAINDICATIONS

1. Ischemia and/or blood supply compromise.
2. Previous or current infections.
3. Patients with active sepsis.
4. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
5. Foreign-body sensitivity: Where material sensitivity is suspected, appropriate tests should be done and sensitivity ruled out prior to implantation.
6. The physical contact of the PONTIS™ implant, Crimps, and Anchor with metal implants made of anything other than the implant grade of stainless steel, such as titanium, titanium alloys, cobalt chromium, or other dissimilar metals. Such contact could result in device corrosion with localized tissue reaction.
7. Insufficient quantity or quality of bone (Anchors only).
8. Surgical procedures other than those listed in the indications sections.

PRECAUTIONS

Protective measures after tendon repair must be taken. This includes reduction in activity and possible use of immobilization devices (i.e. sling, braces, etc.) until healing is established (confirmed by clinical and radiographic examination). Factors such as the activity level and adherence to load bearing instructions affect the life of the implant. Healing may be compromised in a variety of conditions or situations such as diabetes, nutritional compromise, smoking, dysvascularity, autoimmune disease, chronic disease, etc. Physical therapy programs should be administered with appropriate restrictions based on the level of patient healing.

1. Human anatomy presents limitations on the size and strength of implants and their ability to facilitate healing. These implants are not designed to withstand the unsupported stress of normal daily activities including, among other things, gripping, pinching, lifting, and other stress and load bearing activities.
2. The devices may break, tear through, or pull out of soft tissues or bone when subjected to high loads, especially if there is delayed or incomplete healing. Loads produced by activity levels may dictate the longevity of the implant.
3. Correct handling of implants is extremely important. Notches or scratches observed or placed on the implant during the course of surgery may contribute to failure. Implant fraying or wear may contribute to failure. Multifilament SS implant should not be placed in a position where they will be subject to direct abrasion against edges of bone or other implants during normal use.
4. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
5. Postoperative care is critical. The patient's ability and willingness to follow instruction is essential for healing. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, such as slings and braces, which are intended to immobilize the surgical site and limit load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy tissue, and that the device can break or be damaged as a result of stress, activity, or load bearing. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.
6. Do not use other manufacturers' sutures as they are not validated with the PONTIS™ System.

7. Remove items from the sterile package using aseptic technique. Damaged or opened packages should not be used.

WARNINGS

NEVER REUSE IMPLANTS. While an implant may appear undamaged, previous stress and handling may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been placed in a different patient.

1. Do not use alternative tools or standard pliers to compress the multi-strand crimps in place.
2. The strength of the multifilament SS implants secured with crimps have only been tested using crimp tools provided by PONTIS™ Orthopaedics. Resistive activities should not be allowed until tendon healing has been confirmed.
3. The PONTIS™ 3mm Anchor contains a sharp tip at the distal end; handle with care.
4. Ensure the anchor is properly seated on the driver tip prior to and during implantation.
5. Avoid lateral loading and bending while inserting the PONTIS™ 3mm Anchor
6. Maintain proper alignment during insertion of the anchor and disengagement of the driver.

The PONTIS™ Anchors and Multifilament SS implants with Crimps have NOT been evaluated for safety and compatibility in the MR environment. The PONTIS™ Anchors and Multifilament SS implants with Crimps have NOT been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS

1. Infection.
2. Inadequate or delayed healing which may lead to breakage of the implant.
3. Loosening or migration of the implant.
4. Biomaterial sensitivity or allergic reaction to a foreign body.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of tissue.
8. Intra-operative or postoperative tissue damage and/or postoperative pain.

STERILITY

The PONTIS™ System components are sterilized by exposure to Ethylene Oxide. Do not re-sterilize. Do not use implants after expiration date.

STERILIZATION OF REUSABLE PONTIS™ INSTRUMENTS (Provided Separately)

Six PONTIS™ components are reusable. NOTE: Each instrument set will contain either a crimp tool with either a single-upper or a riveted-upper.

1. Part Number 000-0555-01 – Crimp Holder
2. Crimp Tool
 - a. Part Number 000-0736 – Pliers, Crimp - Fixed, Single-Upper, OR
 - b. Part Number 000-0741 – Tool, Pliers, Crimp - Fixed, Riveted-Upper
3. Part Number 000-0369 - Tap
4. Part Number 000-0320-01 - K-Wire, Smooth, SS, 1/16" x 4"
5. Part Number 000-0365-01 - Pin, Steinmann, Smooth, SS, 5/64" x 4"
6. Part Number 000-0652-01 - Pin, Steinmann, Smooth, SS, 3/32" x 4"

All products should be cleaned, decontaminated, and sterilized before use. Always clean and decontaminate immediately after use.

Clean per current AORN guidelines.

After cleaning, check for misalignment or damage. Mechanically test the working parts to verify that each device is functioning properly.

Caution:

Other acceptable cleaning methods may be available however individuals or hospitals are advised to validate any alternate method using appropriate laboratory techniques.

The reusable PONTIS™ instruments are designed to be sterilized by exposure to steam. The following Steam Sterilization Cycles have been validated by the manufacturer:

Prevacuum Sterilizer: Wrapped cases, trays and instruments, or cases, trays and instruments should be exposed to 132° C to 135° C (270° F to 275° F) for at least four minutes. Dry for 20 to 40 minutes.

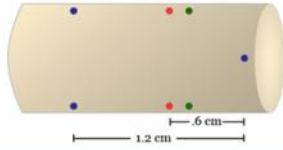
Gravity Displacement Sterilizer: Wrapped cases, trays and instruments should be exposed to 132° C to 135° C (270° F to 275° F) for at least 30 minutes, or 121° C to 123°C (250° F to 254° F) for at least 55 minutes. Dry for 20 to 50 minutes.

The use of sterilization methods or cycle parameters other than those listed above may damage the instrumentation or lead to non-sterile instruments

INSTRUCTIONS FOR USE

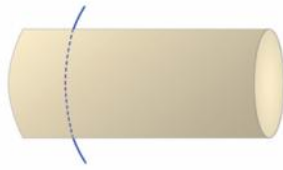
The general principles of patient selection and sound surgical judgment apply. For further information and instruction, refer to the detailed surgical technique on the next page.

Step 1



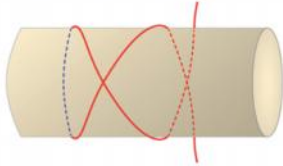
Expose 1.2 cm of tendon on each side of the laceration. This may require pulling the proximal end out of the proximal pulley. The distal tendon may be delivered by flexing the distal joints. Using a marking pen make the marks on the tendon as shown.

Step 2



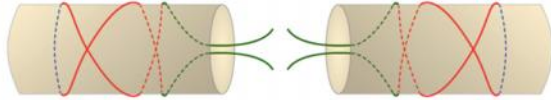
Using a PONTiS™ Multifilament SS implant, make first pass perpendicular to the long axis of the tendon, closer to the posterior surface than the palmar – pull through the tendon so the ends are of even length.

Step 3



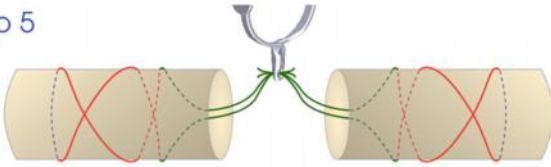
Take one end and cross the multifilament SS implant over the tendon and place the needle through the tendon at 0.6 cm perpendicular to the long axis of the tendon, and pull it through. Take the second implant end and cross the tendon so the needle enters the tendon close to the where the first needle exited, 1 mm further from the cut end. **Pull implant ends tight.**

Step 4



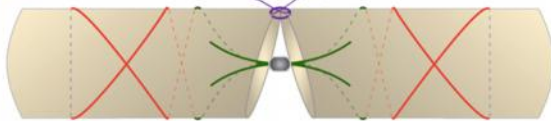
Pass each multifilament SS implant end from its exit point out the cut end of the tendon starting approximately 1mm closer to the cut end. Implant ends must exit close to the middle of the cut tendon end. Remove the needles off by cutting the shrink tube close to the needles. **Repeat on other side.***

Step 5



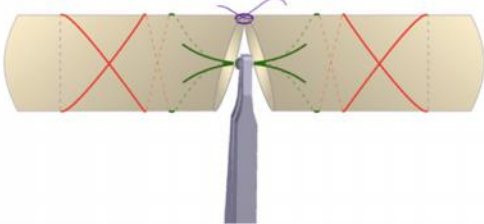
Load the crimp into the crimp holder. Position the crimp holder to pass each multifilament SS implant through the crimp. The two proximal implant strands must enter the proximal opening of the crimp and two distal implants must enter through the distal opening of the crimp. Centralize the crimp within the tendon by pulling the two implant tails exiting each side of the crimp.

Step 6



Place and tie the first epitendonous stitch at the lateral corner of the repair farthest from the surgeon. This will control rotation of the tendon.
NOTE: Leave the implant tails from the epitendonous stitch attached in order to complete the repair in Step 8.

Step 7



Tighten each multifilament SS implant individually prior to using the crimp tool. Assistant will maintain tension as the crimp tool is used to lock the implant. Insert the crimp tool transverse to the tendon. The crimp tool must be completely squeezed until cam-action (bottoming) is felt. Hold for 10 seconds.
NOTE: Ensure the crimp is entirely seated in the jaws of the crimp tool prior to crimping.

Step 8



Complete the repair by placing a few interrupted sutures on each side of the crimp and at the mid-axis of the tendon.
Take the repaired tendon through 5 or 6 excursions to ensure good motion through the pulleys.

PONTiS™ DILATING CATHETER, FUNNEL AND THREADER 400-3014 Directions for Use:

* It may be necessary to retrieve the proximal tendon using the Catheter and a Funnel.

1. Pass the Catheter from the wound into the palm. Gently advance the catheter to dilate the pulley system. Withdraw approximately 3 cm so that the catheter can be passed easily through the pulley.
2. Cut the catheter at both ends 1 cm - 2 cm distance away from the skin.
3. Thread the multifilament SS implant ends through the large diameter of the funnel. If other sutures have been used then thread the suture through the small and then the large diameter of the funnel.
4. Slide the funnel over tendon end ensuring the tendon end is fully covered.
5. **Stainless Steel Suture:** Thread multifilament SS implant ends through the lumen of the Catheter and place the tip of the Funnel in the lumen.
Other Suture: For use with other sutures, use the threader to deliver the suture through the catheter.
6. Clamp the multifilament SS implant or other suture ends at the distal end of the Catheter to hold the Funnel tip within the tube at the proximal end.
7. Pull multifilament SS implant ends and tube, as one, distally to feed the tendon through the Catheter.

PONTiS™ 3mm Anchor Directions for Use:

1. Drill to depth established by the laser line by using pre-drill (.063")
2. If Taping is necessary use the pre-drill (.093") and Tap to laser line.
3. Remove the Anchor from the tray.
4. Screw the Anchor into the bone until the laser line on the shaft is even with the bone surface.
5. Grip the wings of the Protective Sleeve. Break the connection and pull outward and away from the Driver
6. Remove the Cap and remove needles from Handle.
7. Pull Driver away from anchor.

NOTE: If the anchor is not to proper depth, apply tension to the multifilament SS implant ends, align driver to orient the multifilament SS

implant ends into the slots, align driver Hex back over the Anchor and fully seat to laser line. Turn handle to advance the anchor depth.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

FOR FURTHER INFORMATION

If further information on this product is needed please contact PONTiS Orthopaedics LLC Customer Service at the number listed below:

Authorized Representative:
PONTiS Orthopaedics, LLC
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Single Use Only
- Do Not Reuse

Not Made with
Natural Rubber

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