Titanium Wire with Barb and Needle.
Surgical Technique for Canthal Tendon Procedures.
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

**Processing, Reprocessing, Care and Maintenance**

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
# Table of Contents

Intended use, Indications, General Adverse Events and Warnings 2

MRI Information 3

Features, Benefits and Technique Overview 4

Preoperative Planning 5

Surgical Technique for Medial Canthal Tendon Repair 6

Product Information 12
Intended use
The Synthes Titanium Wire with Barb and Needle is intended for fixation and repair of canthal tendons and soft tissue in ophthalmic surgery.

Indications
The Titanium Wire with Barb and Needle is indicated for use in soft tissue approximation and/or ligation, for canthoplasty, canthopexy, and/or medial canthal tendon repair.

General Adverse Events
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyperreactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.

Warnings
These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed. Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.
Magnetic Resonance environment

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 5.4 T/m. The largest image artifact extended approximately 20 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal simulations of worst case scenario lead to temperature rises of 9.3°C (1.5 T) and 6.0°C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.
Features
- Manufactured from titanium and titanium alloy*
- Versatile 28 gauge (0.31 mm diameter) wire size
- Permanently affixed barb
- Straight taper-point needle
- Compatible with titanium bone fixation systems
- Available in single-use sterile packs

Benefits
- Convenient and easy handling
- Facilitates capture of the medial canthal tendon
- Minimizes palpability while providing adequate strength
- Prevents galvanic corrosion when used with titanium plates and screws

Technique Overview
- Preoperative Planning
- Medial Canthal Tendon Repair
- Postoperative Considerations
- Product Information

* Ti-6Al-7 Nb
Canthal tendon repair using the Synthes Titanium wire with Barb and Needle is indicated when the medial canthal tendon is detached from the bone as the result of trauma or a surgical approach.

**Note:** When the medial canthal tendon remains attached to a large bone fragment in the case of trauma, anatomical reduction and stabilization of the bone fragment is sufficient in most cases.

The bony skeleton must be properly restored before canthopexy by reduction and osteosynthesis of the fragments. The normal distance between the canthal tendons is approximately half the interpupillary distance.¹

**Note:** In an adult, the normal intercanthal distance is approximately 32–35 mm.²

It is recommended that the lacrimal duct be intubated prior to the start of the procedure.
1 
Surgical approaches

In the case of serious injury, a coronal approach is usually necessary to stabilize the bony fragments.

2 
Reduce fractures

Reduce and stabilize all fractures. Before canthal tendon reattachment, the bony-cartilaginous framework must be precisely repaired.

Notes:
- If the medial canthal tendon is attached to a bone fragment, repositioning and plating the fragment generally leads to the most anatomic appearance.
- After securing the wire, access to the internal orbit will be limited, therefore orbital wall reconstruction should be completed before canthal resuspension.
3

Locate tendon

Locate the traumatized medial canthal tendon. The tendon may be identified from inside the coronal flap, or through a small skin incision, or alternatively through a caruncular incision. These incisions provide direct access to the tendon.

The Lacrimal Fossa can be used as a point of reference when locating the medial canthal tendon.

Precaution: The approach to the medial canthal tendon is posterior to the lacrimal duct and should not impinge on the lacrimal system.

If using the skin incision, the tendon does not necessarily need to be visualized to complete this procedure. The tendon can be palpated by using the needle to find the area of most resistance.
Capture canthal tendon

To capture the canthal tendon with the barb on the wire, the needle is guided through a small skin incision below the medial canthus through the site of greatest resistance (approximately 2 mm medial to the canthus) toward the inside of the coronal flap. The titanium wire is guided through this flap until the barb captures the canthal tendon.

Instead of a skin incision below the lid margin, an incision can be made in the caruncula.

Alternate method: By using the caruncular incision, the barb will become engaged in the tendon after the needle and wire are passed through it.

Note: If the medial canthal tendon has been severely traumatized, wire fixation may not be possible. Another method may be required.

Precaution: In handling titanium wire, care should be taken to avoid damage from handling, such as kinking or excessive twisting.

Precaution: Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
5
Plan tendon position

Proper tendon repair includes positioning the canthal tendon posterior and superior to the lacrimal fossa.²

6
Tendon placement

To facilitate tendon placement, a 0.5 mm (blue) or 0.7 mm (pink) titanium adaption plate should be placed on the frontal bone, extending along the medial orbital wall.³ Cut and contour the plate to fit the patient’s anatomy. Insert at least three 1.3 mm or 1.5 mm bone screws to affix the plate to the bone.

Notes:
- The most inferior-posterior screw hole in the plate must be located at the planned position of canthal tendon reshing and must remain empty to allow passage of the titanium wire transnasally.
- In cases with minimal bone loss, an adaption plate may not be necessary for canthal tendon repair. Other methods used for ensuring the posterior and superior pull of the canthal tendon include the use of medial orbital bone grafts and passage of the titanium wire through the posterior portion of the perpendicular plate of the ethmoid bone.²
- Plate placement may depend on availability of sufficient bone.
7

Drill transnasally

Using a 2.0 mm to 2.4 mm diameter bit, drill transnasally from the nonaffected orbit to the affected orbit.

Precautions:
- Use a drill sleeve to protect the soft tissue and globes when drilling.
- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. Higher drill speed rates can result in: thermal necrosis of the bone, soft tissue burns, an oversized hole, which can lead to reduced pullout force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.
- Avoid damaging the plate threads with the drill.
- Always irrigate during drilling to avoid thermal damage to the bone.

Note: In cases of severe comminution, drilling may not be required. The use of a transnasal awl may help facilitate wire passing.

8

Transnasal passage of the wire

This can be accomplished either with a perforated awl or with the aid of a large cannula serving as a guide for the wire.

Alternate method: Prior to securing the plate to the bone, the wire can be passed through the inferior-posterior screw hole, then directed forward within the orbit.

After the plate is secured to the bone, the wire may be directed anteriorly to be secured on the ipsilateral supraorbital rim or frontal bone.
9
Remove needle

Remove the needle by cutting the wire directly below the needle crimp.

**Precaution:** Exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in an approved sharps container.

10
Apply tension

Apply moderate tension and visually check the position of the canthal tendon. For stable fixation, the canthal tendon must be moved into the desired position in a completely relaxed state.

11
Secure wire

Secure the titanium wire to the supraorbital rim on nonaffected side.

**Precaution:** Ensure fixation of the wire before closure.

12
Postoperative considerations

Frequent examinations of visual acuity during the first 24 hours postoperatively are recommended.
Product Information

493.104.01S Canthal Tendon Wire with Barb and Straight Needle, 28 Gauge (0.31 mm diameter), length 500 mm, sterile

References


