
Instructions for Use Canthal Tendon Wire

This instruction for use is not intended for
distribution in the USA.

Instructions for Use

Titanium Wire with Barb and Needle

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

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques 036.000.935 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

493.104.015 Canthal Tendon Wire with Barb and Straight Needle, 28 Gauge (0.31 mm diameter), length 500 mm is offered sterile. All instruments are offered unsterile.

All articles are packed with an appropriate package material: clear envelope for unsterile articles, clear envelop with plastic tubes for screwdriver blades and carton with double sterile barriers and plastic tube for the canthal tendon wire

Material(s)

Material(s): Standard(s):

Wire:

TiCP

Standard:

ISO 5832-2

ASTM F 67

Barb:

TAN

Standard

ISO 5832-11

ASTM F1295

Needle:

Custom 470 FM

ASTM F 899 /A 564

Instrument Materials:

Stainless Steel:

Standard

DIN EN 10088-1&3

Aluminum:

Standard

ASTM B209M

ASTM B221M

DIN EN 573-3

DIN 17611

PTFE:

FDA-Compliant

Intended use

The Titanium Wire with Barb and straight Needle is intended for fixation and repair of canthal tendons and soft tissue in ophthalmic surgery.

Indications

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

Side effects

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, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage 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 hypersensitivity reactions, 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.

- Relapse
- Wire palpability
- Wire extrusion
- Wire breakage
- Disengaged wire
- Orbital hematoma
- Blepharitis
- Chemosis
- Granuloma/cyst excision
- Scar requiring revision
- Lid Support suture requiring removal

- Canthal web revision
- Lid retraction, mild
- Lid retraction requiring revision
- Lower lid malposition
- Ectropion
- Late stretching of the canthal repair
- Recurrent cicatricial ectropion due to an inadequate skin graft
- Early tarsal ectropion
- Recurrent postoperative laophthalmos
- Loss of vision in one eye (injury to the optic nerve)
- Patient might require further adjustment
- Mild conjunctival edema
- Mild asymmetry
- Revision of lateral canthus to improve symmetry
- Oronasal palatal fistula


Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Single-use device

 Do not re-use

Products intended for single-use must not be re-used.

Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and / or lead to device failure which may result in patient injury, illness or death.

Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions

Exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

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.

In an adult, the normal intercanthal distance is approximately 32–35 mm

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.

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

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

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

Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

The most inferior-posterior screw hole in the plate must be located at the planned position of canthal tendon resuspension 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.

Plate placement may depend on availability of sufficient bone.

Use the appropriate amount of screws to achieve a stable fixation.

Irrigate thoroughly to prevent overheating of the drill bit and bone.

Excessive and repetitive bending of the implant increases the risk of implant breakage. Avoid excessive bending and reverse bending of the plate.

Care should be taken to remove any sharp edges after cutting the plate to avoid soft tissue irritation or injury.

Drilling speed should never exceed 1800 rpm. Higher speeds can result in thermal necrosis of the bone and increased hole diameter, and may lead to unstable fixation.

Always irrigate during drilling.
Use a drill sleeve to protect the soft tissue and globes when drilling.
In cases of severe comminution, drilling may not be required.
The use of a transnasal awl may help facilitate wire passing.
Ensure proper fixation of the wire before closure.

Combination of medical devices

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
Drill bits is (are) combined with power tools.

Magnetic Resonance environment

CAUTION:

Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:

- Heating or migration of the device
- Artifacts on MR images

Treatment before device is used

Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Special operating instructions

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 inter-pupillary distance.

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

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

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

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.

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.

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.

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

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

To facilitate tendon placement, a titanium adaption plate should be placed on the frontal bone, extending inferiorly and posteriorly toward the medial orbital wall.

Cut and contour the plate to fit the patient's anatomy. Insert at least three bone screws to affix the plate to the bone.

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

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

Alternatively, the wire can be passed through the posterior plate hole, then come forward within the orbit to be fixated to the supraorbital/ frontal bone.

After tightening the final screw, the wire may be directed anteriorly to be fixated on the ipsilateral supraorbital or frontal bone.

Remove the needle directly under the needle crimp.


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.

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


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


Additional device-specific information


 Reference Number

 Lot or batch number

 Manufacturing date

 Expiration date

 Notified body

 Caution, see instructions for use

Disposal

Exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.


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