Instructions for Use
Canthal Tendon Wire

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

EC REP

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Instructions for Use

Titanium Wire with Barb and Needle
493.104.01S 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 technique DSEM/CMF/0914/0035 carefully before use. Ensure that you are familiar with the appropriate surgical technique.
493.104.01S 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)

Implant(s):	Material(s):	Standard(s):
Wire:	TiCP	ISO 5832-2 ASTM F67
Barb:	TAN	ISO 5832-11 ASTM F1295
Needle:	Custom 470 FM	ASTM F 899/A 564

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

Indications
The Synthes 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.

Device Specific Adverse Events
- 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 an approved sharps container.
The approach to the medial canthal tendon is posterior to the lacrimal duct and should not impinge on the lacrimal system.
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.

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.

Use a drill sleeve to protect the soft tissue and globes when drilling.
Ensure fixation of the wire before closure.

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.

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
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 5.4T/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 an MRI 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.

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 interpupillary 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.

Device intended to be used by a trained physician
This description alone does not provide sufficient background for direct use of Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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