ITS.

Implants for Trauma Surgery

SURGICAL TECHNIQUE

Clavicle Hook Locking Plates System

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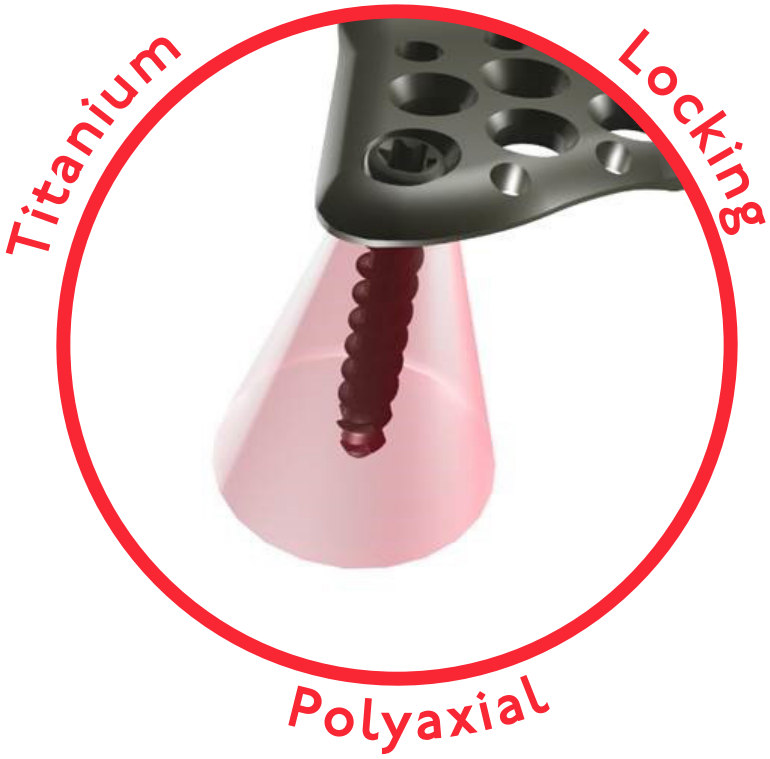
Introduction

Plate Technology

At ITS., we stand for long-term, trusting relationships with our customers, suppliers and development partners. Through our dedication to innovation and development, we continuously seek to improve and optimize products and techniques for trauma surgery.

ONE Technology for all implants

All ITS. plates are made from Titanium Grade 2, whereas the screws are made of a harder titanium-alloy. This allows the plates to have only non-threaded holes, which all (with the exception of oblong holes) accept both non-locking and locking screws.

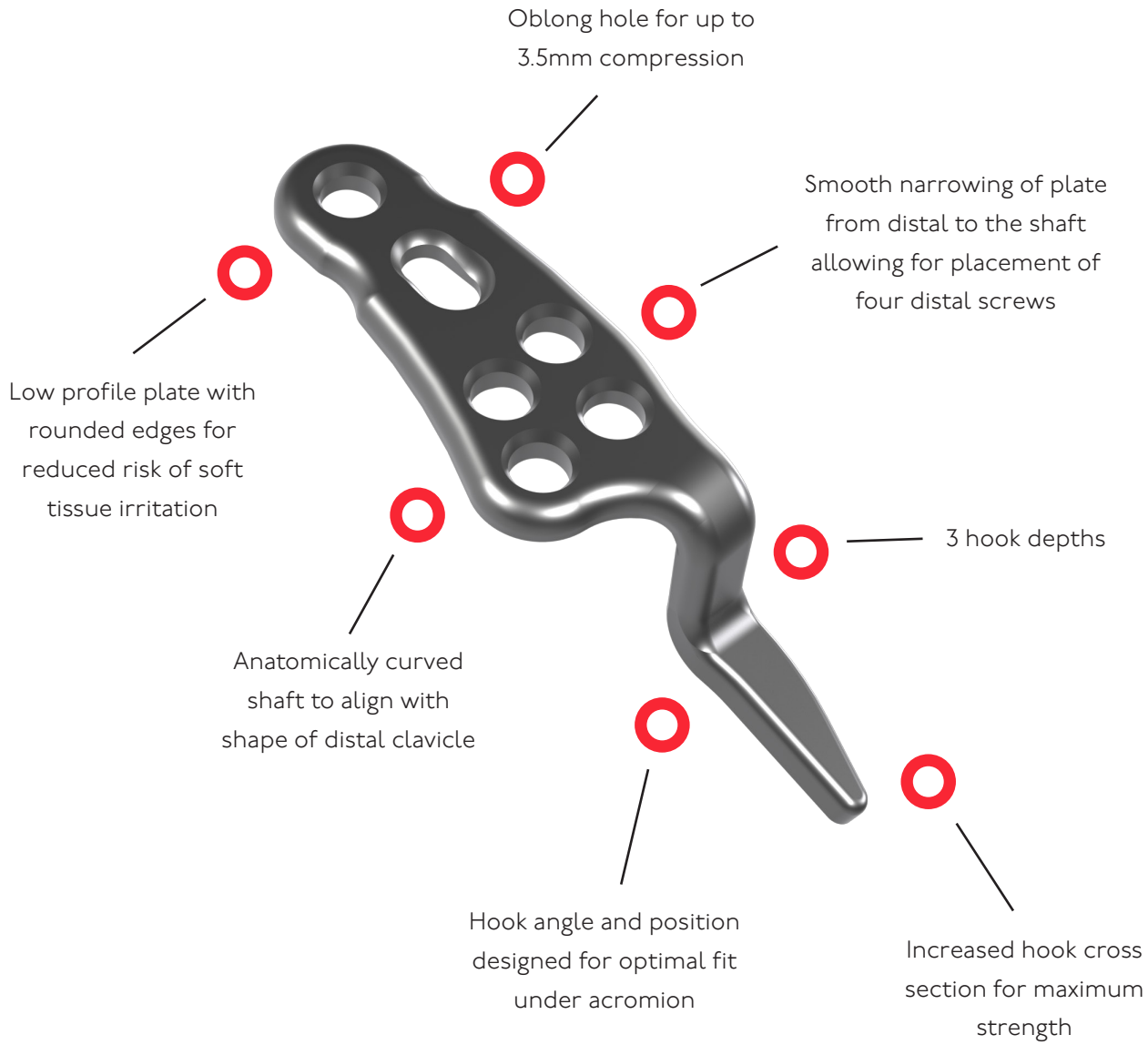


When a locking screw is inserted, it forms threads into the plate. There is no cutting and thus no debris created. Each locking screw can be locked at a free placement within a cone of angulation up to ± 15°, and can be re-positioned up to three times.

Introduction

The angular stable Clavicle Hook Locking Plate System (CHLP) provides reliable fixation for fractures of the lateral clavicle and injuries of the acromioclavicular joint. It is a part of the ITS. Clavicle Solution, building on the same screw platform and instruments as the Clavicle Locking Plates System (CLS).

Features



Indications

- Fractures of the lateral Clavicle
- Dislocation of the acromioclavicular joint
- Pseudoarthrosis
- Corrective osteotomies

Contraindications

- Existing infections near the area of the fracture
- General situations that prohibit osteosynthesis
- Lack of patient compliance

Time of Operation

- Immediately after the accident or delayed
- After swelling subsides

Surgical Technique

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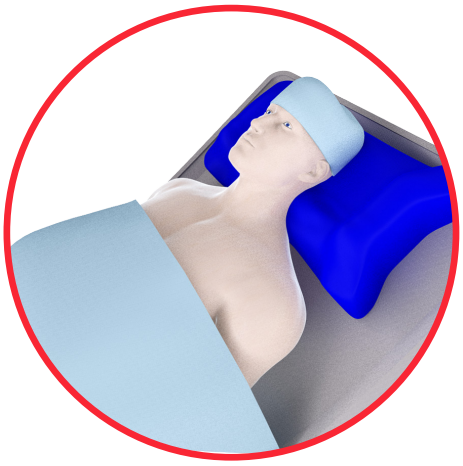
Patient Positioning

- Elevated upper body approx. 30° - 40° inclination, shoulder freely movable (optional shoulder-table).
- The arm should be freely movable to have the possibility of fracture reduction
- General anaesthesia, regional anaesthesia or a combination can be used
- Possible use of medication for blood arrest



Access

- Exposure of the clavicle and AC joint with a 3-5 cm incision centred over the fracture site.

CAUTION: Risk of injury to the supraclavicular nerves - identify and protect them

ALTERNATIVE: A vertical incision along the gap lines can be chosen, also centred over the fracture site.

Reduction

- A temporary reduction of the fracture parts is performed with the help of forceps or K-wires
- Subsequent check under fluoroscopy

Implant Selection

iMPORTANT: The correct selection of plate and hook depth is important for successful fixation of the plate to the bone, so that erosion by the hook and impingement can be avoided.

Plate shapes and sizes can be found in the charts in the section “Technical Information” see p.18.

All plates are anatomically pre-shaped. Choosing the right implant will lead to an optimal alignment of the hook at the inferior part of the acromion.

5-Hole 7-Hole 9-Hole

Plate Insertion

- The selected plate is applied in situ, with the plate flush against the clavicle and the inferior part of the acromion.
- Optionally, it is possible to fix the plate temporarily with the Temporary Plate Holder (58164-150)
- An in-situ check with an image converter is recommended to verify the correct plate position.

CAUTION: Incorrect hook selection may result in over- or under-repositioning of the medial clavicle segment, which can lead to postoperative complaints (pain, limited mobility, impingement, etc.). Therefore, a preoperative X-ray of the contralateral AC-joint is recommended.

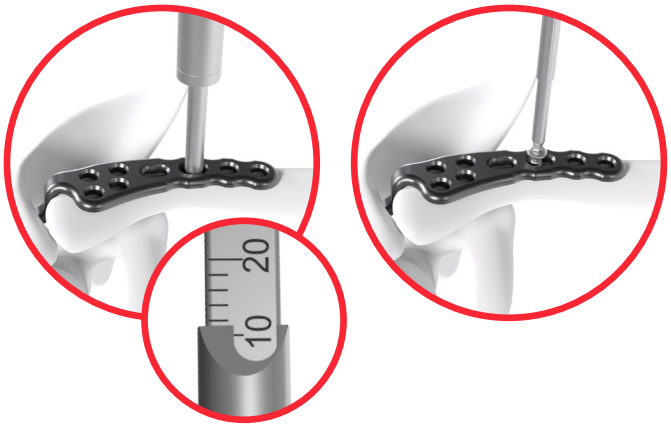
Placement of the Screws

- First, the spiral drill D=2.7mm (61273-100) is used to drill through the drill guide (62202) into (one of) the oblong compression screw hole(s).

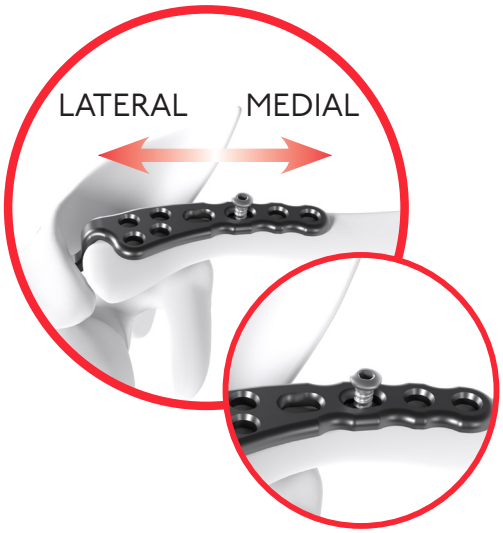
CAUTION: It is highly recommended to drill all holes using oscillating mode to avoid damage to the underlying structures.

- The length of screw is measured with the depth gauge (59022).
- The selected length of D=3,5 non-locking cortical screw (32351-xx) is inserted into the oblong compression screw hole using the WS 2.5 screwdriver (56252).

CAUTION: Only D=3.5mm non-locking cortical screws are to be used the oblong compression holes.



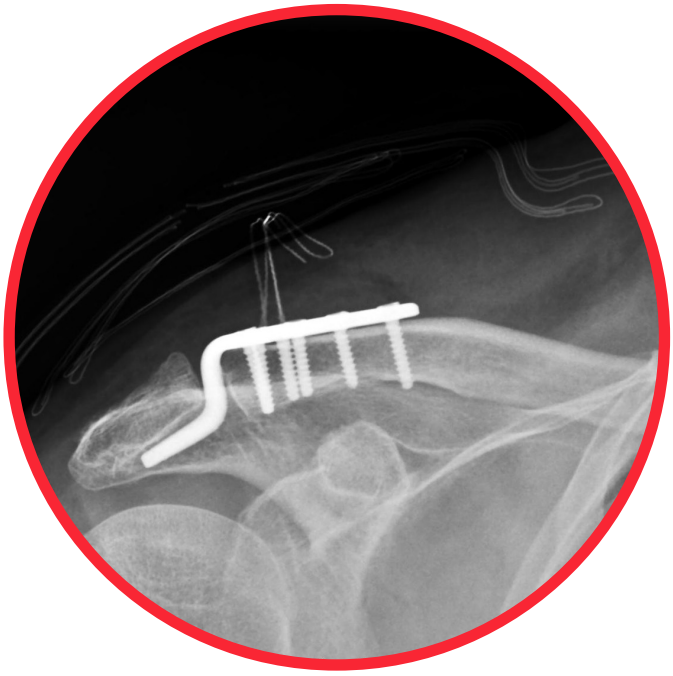
TIP: The oblong compression holes allow for adjustment of the plate position either medially or laterally.



- The remaining (round) holes can now be filled with either locking or non-locking D=3.5mm cortical screws (3735I-XX-N or 3235I-XX) using the same drilling and screw length measurements described above.

- After filling the remaining plate holes, check the position of the plates and hooks in the image converter.
- If compression is to be applied to the fracture area or if a fracture gap is to be closed, this must be done by placing a screw in the narrow area of the oblong compression hole.

CAUTION: D=3.5mm non-locking cortical screws are to be used in the compression hole without exception.



Postoperative Treatment

- Immobilization in a shoulder-arm bandage until wound healing (approx. 2 weeks).
- With exercise stability: physiotherapy possible immediately postoperatively
- Full weight bearing after fracture healing (approx. 5-7 weeks)

Explantation

Explantation of the clavicle hook plate is necessary in any case due to the fact that the hook lies flush on the inferior part of the acromion.

CAUTION: In order to prevent potential irritation of the acromion or impingement of the rotator-cuff the plate must be explanted.

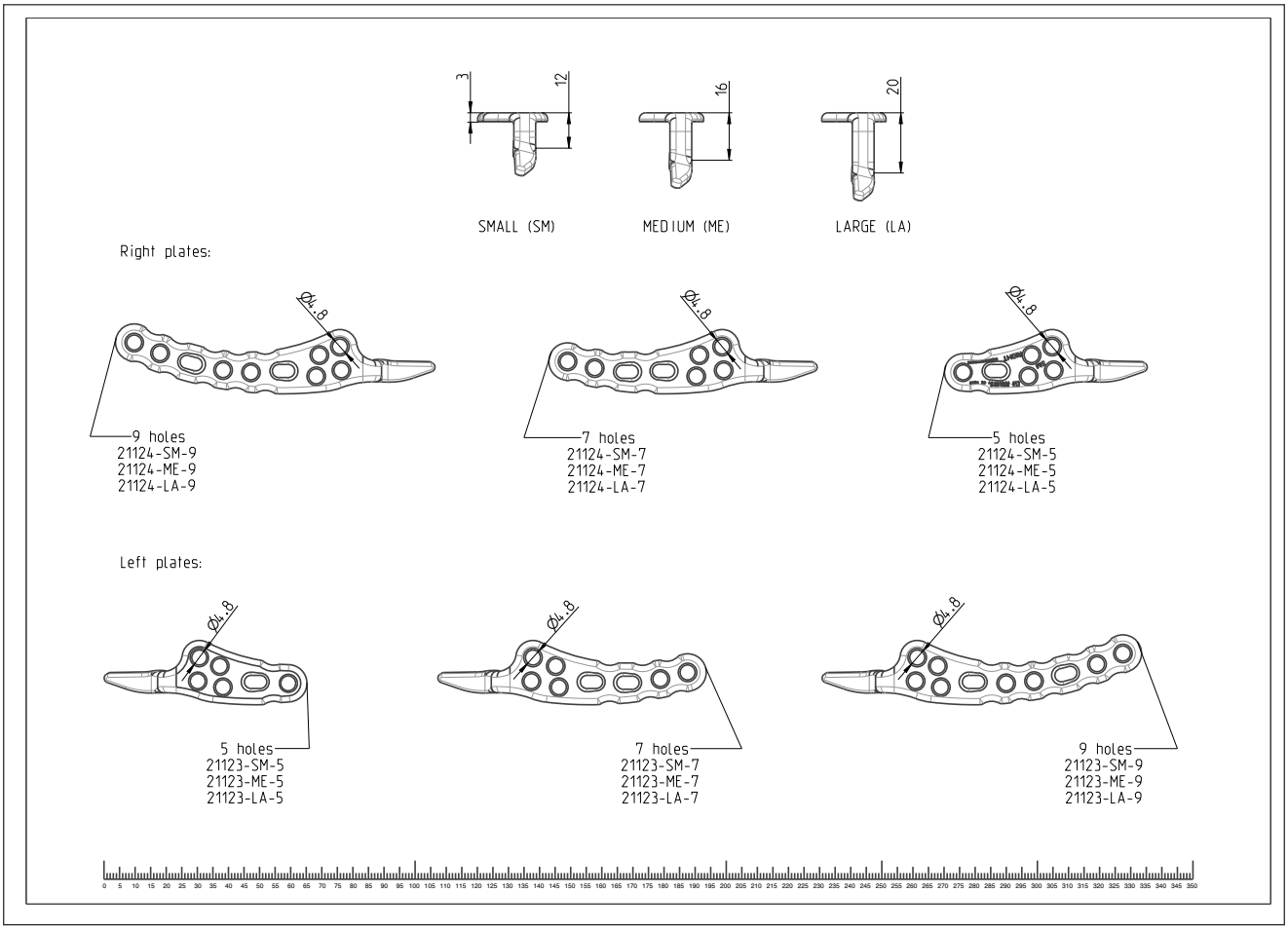
The explantation should be performed after radiologically verified bone healing (not later than approx. 12 weeks).

The risk of cold welding is reduced by a special surface treatment (for detailed information see page 19).

Information

3.

Technical Information



For detailed cleaning and sterilization instructions, please refer to package insert.

Typ II Anodization

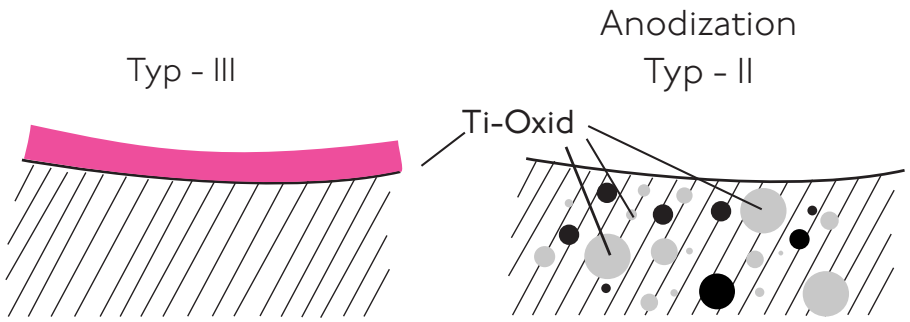
Chemical process - anodization in a strong alkaline solution*

Type III anodization

- Layer thickness 60-200nm
  - \+ Different colors
  - \- Implant surface remains sensitive to:
    - Chipping
    - Peeling
    - Discoloration

Type II anodization

- Layer thickness 2000-10 000nm
  - \+ Film becomes an interstitial part of the titanium
  - \- No visible cosmetic effect



Anodization Type II leads to the following benefits*

- Oxygen and silicon absorbing conversion layer
- Decrease in protein adsorption
- Closing of micro pores and micro cracks
- Reduced risk of inflammation and allergy
- Hardened titanium surface
- Reduced tendency of cold welding of titanium implants
- Increased fatigue resistance of implants
- Improved wear and friction characteristics

* White Paper: Ti6Al4V with Anodization Type II: Biological Behavior and Biomechanical Effects; Axel Baumann, Nils Zander

Ordering Information

Plates

Clavicle Hook Plate (Small)	Description	Hook depth*	Holes	Article Number
	Left	Small	5	2II23-SM-5
	Right	Small	5	2II24-SM-5
	Left	Small	7	2II23-SM-7
	Right	Small	7	2II24-SM-7
	Left	Small	9	2II23-SM-9
	Right	Small	9	2II24-SM-9

Clavicle Hook Plate (Medium)	Description	Hook depth*	Holes	Article Number
	Left	Medium	5	2II23-ME-5
	Right	Medium	5	2II24-ME-5
	Left	Medium	7	2II23-ME-7
	Right	Medium	7	2II24-ME-7
	Left	Medium	9	2II23-ME-9
	Right	Medium	9	2II24-ME-9

Clavicle Hook Plate (Large)	Description	Hook depth*	Holes	Article Number
	Left	Large	5	2II23-LA-5
	Right	Large	5	2II24-LA-5
	Left	Large	7	2II23-LA-7
	Right	Large	7	2II24-LA-7
	Left	Large	9	2II23-LA-9
	Right	Large	9	2II24-LA-9

*Hook depths
Small = 12mm | Medium = 16mm | Large = 20mm

(OPTIONAL)

Clavicle Hook Plate (Small)	Description	Hook depth*	Holes	Article Number
	Left	Small	6	2II23-SM-6
	Right	Small	6	2II24-SM-6
	Left	Small	8	2II23-SM-8
	Right	Small	8	2II24-SM-8

Clavicle Hook Plate (Medium)	Description	Hook depth*	Holes	Article Number
	Left	Medium	6	2II23-ME-6
	Right	Medium	6	2II24-ME-6
	Left	Medium	8	2II23-ME-8
	Right	Medium	8	2II24-ME-8

Clavicle Hook Plate (Large)	Description	Hook depth*	Holes	Article Number
	Left	Large	6	2II23-LA-6
	Right	Large	6	2II24-LA-6
	Left	Large	8	2II23-LA-8
	Right	Large	8	2II24-LA-8

*Hook depths
Small = 12mm | Medium = 16mm | Large = 20mm

Screws

Cortical Screw D=3.5mm	Length	Article Number
Locking	14	37351-14-N
	16	37351-16-N
	18	37351-18-N
	20	37351-20-N
	22	37351-22-N
	24	37351-24-N

Cortical Screw D=3.5mm	Length	Article Number
Non Locking	14	32351-14
	16	32351-16
	18	32351-19
	20	32351-20
	22	32351-22
	24	32351-24

(OPTIONAL)

Cancellous Screw D=4.2mm	Length	Article Number
Locking	14	37422-14-N
	16	37422-16-N
	18	37422-18-N
	20	37422-20-N
	22	37422-22-N
	24	37422-24-N

Instruments

Instruments		Article Number
	Screwdriver, SW 2.5, self-holding sleeve	56252
	Depth gauge, Solid Small Fragment Screw	59022
	Drill Guide, D=2.0/2.7mm	62202
	Spiral Drill, D=2.7mm, L=100mm, AO Connector	61273-100

(OPTIONAL)

Instruments		Article Number
	Spiral Drill, D=2.5mm, L=100mm, AO Connector	61253-180
	Temporary Plate Holder	58164-150
	Bending irons (Small Fragement)	KJ.207.14

Disclaimer:

The intended users are limited to medical personnel with appropriate product training by the medical product consultants or knowledge of the surgical procedure to be applied. The medical staff must ensure that the use of I.T.S. GmbH medical devices is appropriate, taking into account the medical condition and medical history of the patient. Prior to product use, medical personnel must refer to complete information on product label and in IFU, including, but not limited to, indications, contraindications, warnings and preventative measures, and cleaning and sterilization instructions. Product availability is dependent on country registrations and clearances. For more information, please visit www.its-implant.com or contact us at office@its-implant.com. Unless otherwise noted, all information herein is the intellectual property of I.T.S. GmbH.

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