



tasarimmed[®]

TF-ERS HAND & WRIST FIXATOR

Catalogue



Table of Contents

Device Description.....	1
Indications	1
Contraindications	1
General Warnings & Precautions	1
Fixator	1
Half Pins.....	1
Symbols used in Packaging and their meanings.....	1

Warning!!!



This document is not a surgical technique.

This document shows all parts for the TF-Tubular Fixator System



TF-ERS HAND & WRIST FIXATOR

Device Description

Tasarimmed TF-ERS Hand & Wrist External fixator system consists of two different external fixators. One fixator is an assembly of clamp and rail . Clamps are connected to Rails with locking screw. Rails are connected to each other with ball joints. One fixator is assembly of two clamps on rail with threaded rod.

TF ERS Hand & Wrist fixator has got a compression-distraction module on the metacarpal side and a gliding module on the radial side. Hand & Wrist fixator is connected to upper extremity with half pins.

Indications

Tasarimmed TF-ERS Hand fixator is intended to stabilize bone fragments of hand & wrist for following indications:

- Meta/diaphyseal compound fractures of the radius and ulna
- Meta/diaphyseal bone loss in the radius and ulna
- Distal radius deformities with or without shortening
- Metaphyseal fractures of the distal radius without intra-articular involvement. (AO type A2 and A3 metaphyseal fractures)
- Fractures with very short peri-articular fragments or displaced intra-articular fractures (AO type B and type C fractures)
- Controlled joint distraction for intra-articular procedures.
- Shortening
- Delayed unreduced fractures

Tasarimmed TF-ERS hand & wrist fixator is not intended to replace healthy bone or to withstand the stresses of full weight bearing. The use of external supports are needed.

Tasarimmed TF-ERS Hand & Wrist fixator is intended for professional use only. Surgeons who supervise the use of Hand & Wrist fixator must have broad knowledge and full awareness of external fixation techniques, and hand & wrist surgery techniques and procedures.



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Device Description

Contraindications

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of external fixator surgery,
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis.
10. Suspected or documented metal allergy or intolerance.
11. Any case not needing a bone graft and fusion.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
14. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
15. Any patient unwilling to follow postoperative instructions.
16. Severe osteoporosis
17. Any case not described in the indications.



TF-ERS HAND & WRIST FIXATOR

Device Description

General Warnings & Precautions

Tasarimmed TF-ERS Hand & Wrist fixator is only to sale by or on order of exclusive operator and/or surgeon. The device shall only be used by an orthopaedic surgeon, who is trained and experiences on External Fixation Surgery techniques and Hand&Wrist surgery techniques.

- Before the surgery all risks shall be explained to the patient by the surgeon. The consent and acceptance declaration shall be signed by the patient.
- The surgeon must confirm that all necessary Tasarimmed TF-ERS Hand & Wrist Fixation System components and instruments are on hand for the planed surgical operation.
- A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, medical reasons and lead to device failure which require further surgery to remove or to replace fixation device or components.
- Preoperative and operative procedures including knowledge of surgical techniques and proper selection and placement of the external fixation devices are important for successful utilization of the Tasarimmed TF-ERS Hand & wrist fixator.
- Proper patient selection and the patient's ability to comply with surgeons instructions will greatly affect the results.
- The patient must be screened regularly by surgeon during treatment.
- If surgical candidate exhibits any contraindications or is liable to contraindications, DO NOT USE Tasarimmed Hand & Wrist Fixator.



TF-ERS Hand&Wrist Fixator and its parts are not evaluated for MRI safety.



TF-ERS HAND & WRIST FIXATOR

Part List

Fixator



Cat No	Description	Single Use / Reuseable
TF-4001	Hand & Wrist Fixator	Single Use
TF-4002	Hand & Wrist Rail Fixator	Single Use

Half Pins



Cat No	Description	Single Use / Reuseable
	L = Thread Length , TL = Total Length All Half pins have self cut, self drill tip.	
FS-4070S	ISO 5832/1 Half Pin Ø4 mm – L70mm	Single Use
FS-4075S	ISO 5832/1 Half Pin Ø4 mm – L75mm	Single Use
FS-4080S	ISO 5832/1 Half Pin Ø4 mm – L80mm	Single Use
FS-4100S	ISO 5832/1 Half Pin Ø4 mm – L100mm	Single Use
FS-4070T	ISO 5832/3 Half Pin Ø4 mm – L70mm	Single Use
FS-4075T	ISO 5832/3 Half Pin Ø4 mm – L75mm	Single Use
FS-4080T	ISO 5832/3 Half Pin Ø4 mm – L80mm	Single Use
FS-4100T	ISO 5832/3 Half Pin Ø4 mm – L100mm	Single Use

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Symbols used in Packaging and their meanings



Indicates a medical device that has not been subjected to a sterilization process.



Indicates the manufacturer's batch code so that the batch or lot can be identified NOTE: Synonyms for "batch code" are "lot number" and "batch number"



Indicates the manufacturer's catalog number so that the medical device can be identified NOTE: Synonyms for "catalogue number" are "reference number" and "reorder number"



Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.



Indicates the need for the user to consult the instructions for use.



Indicates a medical device that should not be used if the package has been damaged or opened.



Indicates the medical device manufacturer, as defined in EU Directives



Symbol for date of manufacture. This symbol is accompanied by a date.



Indicates the date after which the medical device is not to be used.



Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

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Tasarimmed Tibbi Mamuller San. Tic. A.Ş

CE1984

Topçular m. Topçular c. Setustu no:3 34055 Eyup / Istanbul

www.tasarimmed.com.tr info@tasarimmed.com.tr

Tel: 0090 212 674 22 44 / 45

Fax: 0090 212 674 22 46

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