
Instructions for Use External Fixator Devices

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

Instructions for Use

External Fixator Devices

Associated device systems with these instructions for use:

Elbow Hinge Fixator
External Distal Radius Fixator
Hybrid Ring Fixator
Large and Medium-Size External Fixators
Large Distractor – Tibia
Large External Fixator
MEFISTO
Mini External Fixator
Pelvic C-Clamp
Segment Transport MEFISTO
Small External Fixator
Small External Fixator, Radiolucent, Sterile
The Distraction Osteogenesis Ring System
MAXFRAME – Multi-Axial Correction System

Please read these instructions for use, the Synthes “Important Information” and the corresponding Surgical Technique Guide carefully before use. Ensure that you are familiar with the appropriate surgical technique.

External Fixator Devices include pins, wires, rods and clamps to form a frame for the reposition and fixation of bone fragments. Pins and wires are single-use implants and build the connection of the frame to the bone(s). Rods and clamps are the parts of the frame that are located outside of the body and are designed for multiple usages.

Important note for medical professionals and OR staff: These instructions for use do not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information (corresponding Surgical Technique Guide, Important Information and device-specific label).

Material(s)

Material(s):	Standard(s):
Stainless Steel	ISO 5832-1
TiCP	ISO 5832-2
HA	ASTM F 1185
Carbon	
CFK	
PEEK	ASTM F 2026
POM	ISO 16061
PVC	
Al alloy	EN 573
CoCrWNi alloy	ISO 5832-5
Ultem 1000 Series	TECAPEI (Polyetherimide (PEI))
Ultem 2300	TECAPEI (Polyetherimide (PEI))
Titanium alloy:	
Ti-6Al-4V (TAV)	ISO 5832-3
Ti-6Al-7Nb (TAN)	ISO 5832-11

Intended use

External Fixator Devices are intended for temporary fixation and intra- and post-operative treatment of open and closed fractures and elective orthopedic interventions.

Indications

For specific indications for External Fixator Devices it is mandatory to consult the corresponding Surgical Technique Guide (www.depuysynthes.com/ifu) of the product system being used.

Contraindications

For specific contraindications for External Fixation Devices it is mandatory to consult the corresponding Surgical Technique Guide (www.depuysynthes.com/ifu) of the product system being used.

Potential risks

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, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, and side effects associated with hardware prominence, malunion, non-union.

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 packaging is damaged.

 Do not resterilize

Implantable devices labeled with “Do not resterilize” symbol must not be re-sterilized because reesterilization may compromise the structural integrity of the device and/or may lead to device failure.

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 reesterilization) 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

For general precautions consult “Important Information”.

For application specific precautions related to External Fixation Devices it is mandatory to consult the corresponding Surgical Technique Guide (www.depuysynthes.com/ifu) of the product system being used.

Warnings

For general warnings consult “Important Information”.

For application specific warnings related to External Fixation Devices it is mandatory to consult the corresponding Surgical Technique Guide (www.depuysynthes.com/ifu) of the product system being used.

Combination of medical devices

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment

When a device has been evaluated for use in the MR environment, MRI information will be found in the Surgical Technique at www.depuysynthes.com/ifu

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 “Important Information”.

Processing/reprocessing of the device

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

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