Instructions for Use
External Fixator Devices

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

DePuy Synthes
TRAUMA
COMPANIES OF Johnson&Johnson

CE
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Instructions for Use

External Fixator Devices
Please read these instructions for use, the Synthes "Important Information" and the corresponding Surgical Technique Guide (www.synthes.com/lit) 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
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 postoperative 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.synthes.com/lit) 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.synthes.com/lit) of the product system being used.

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, 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 package is damaged.

Do not resterilize

Implantable devices labeled with "Do not resterilize" symbol must not be re-sterilized because resterilization my 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 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
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.synthes.com/lit) 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.synthes.com/lit) 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
For specific MRI information for External Fixator Devices it is mandatory to consult the corresponding Surgical Technique Guide (www.synthes.com/lit) of the product system being used.

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 multipart instruments" can be downloaded from http://www.synthes.com/reprocessing

Additional device-specific information

REF Reference Number

LOT Lot or batch number

Manufacturer

Manufacturing date

Expiration date

Do not use when packaging is damaged

0123 Notified body

Caution, see instructions for use

Consult instructions for use

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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
www.synthes.com