Instructions for Use
Wire Implants

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

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Wire Implants
Please read these instructions for use, the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical technique.
Wire Implants consist of various dimensions and types (stiff or bendable) of implantable wires which are available sterile and/or non-sterile.

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
Titanium Alloy	ISO 5832-3
MP35N Alloy	ISO 5832-6

Intended use
Wire Implants are intended for fixation of bone fragments.

Indications
Please refer to the table at the end of this IFU.

Contraindications
Please refer to the table at the end of this IFU.

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. Do not use when packaging is damaged.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.

Single-use device

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
Re-use or clinical 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 Wire Implants 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 Wire Implants 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 Guide 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".

Clinical 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://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

Systems	Indications	Contraindications
Hybrid Ring Fixator	– The hybrid ring fixator is designed for fixation of complex proximal and distal tibial fractures, especially those involving the joint: – In soft tissue injuries which make open reduction and internal fixation impossible. – In fracture patterns which do not allow placement of Schanz screws for construction of a standard external fixator frame.	No contraindication specific to these devices.
Kirschner Wires and Cerclage Wires	**Wires Indications** Wire implants are indicated for a wide range of orthopedic trauma applications including: – Stand-alone device for fracture fixation – Fracture fixation in conjunction use with other fixation systems **Cerclage wires Indications** – Orthopedic trauma surgery (incl. periprosthetic fractures, femur fractures, olecranon fractures, patella fractures, humerus and ankle fractures) – Acromioclavicular dislocation – Hip and acetabular fractures – Prophylactic banding in total joint replacements – Temporary fixation during open reductions – Reattachment of the greater trochanter following osteotomy in total hip arthroplasty or fractures	No contraindication specific to these devices.
Mini External Fixator	The Mini External Fixator is indicated for the phalanges and metacarpals of the hand: – closed comminuted fractures – open fractures – dislocated joint fractures which can be reduced by ligamentotaxis – bone, joint and soft tissue infections – complex soft tissue injuries – bone defects caused by trauma or tumour resection in other bones or for bridging the wrist the Mini External Fixator is not recommended. Radius fractures are indications for the Small External Fixator or the Distal Radius Fixator.	No contraindication specific to these devices.
The Distraction Osteogenesis Ring System	The Distraction Osteogenesis Ring System is indicated for fracture fixation (open and closed); pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental bony or soft tissue defects.	No contraindication specific to these devices.

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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com