Instructions for Use
Cable Implants

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Cable 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.
Cable Implants consist of an assembly of various devices such as cables, cerclage pins and eyes as well as reattachment devices. The Cable Implants 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).

Implant(s):	Material(s):	Standard(s):
Cable w/crimp 1.0	Stainless steel 316L	ISO 5832-1
Cable w/crimp 1.0	Ti-Al6-Nb7 (TAN)	ISO 5832-11
	TiCP	ISO 5832-2
Cable w/crimp 1.7	Stainless steel 316L	ISO 5832-1
Cable w/crimp 1.7	CoCrWNi Alloy	ISO 5832-5
	TiCP	ISO 5832-2
TRD	CoCrWNi Alloy	ISO 5832-5
	Ti-Al6-Nb7 (TAN)	ISO 5832-11
	TiCP	ISO 5832-2
CerclageFix for LCP	Stainless steel 316L	ISO 5832-1
CerclageFix for LCP	TiCP	ISO 5832-2
CerclageFix Insert	Stainless steel 316L	ISO 5832-1
CerclEye f/HexSocket	Stainless steel 316L	ISO 5832-1
CerclEye f/HexSocket	TiCP	ISO 5832-2
CerclEye f/Screw	Stainless steel 316L	ISO 5832-1
CerclEye f/Screw	TiCP	ISO 5832-2
Positioning Pin	Stainless steel 316L	ISO 5832-1
Positioning Pin	TiCP	ISO 5832-2

Intended use
Cable Implants are intended for fixation or stabilization of bones in various anatomical regions by using standard cerclage or tension band technique.

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 Cable 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 Cable 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 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
Cable System	– Orthopaedic 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	The cerclage cable ∅ 1.0 mm may not be used for fractures of the femur, or for prophylactic banding during total joint replacements.
Cerclage Passer – Cable Application	For general orthopedic trauma surgery involving the application of cerclage cables – Periprosthetic fractures of the femur – Subtrochanteric fractures – Prophylactic banding in total joint replacement – Additional fixation – Temporary reduction	No contraindication specific to these devices.
Cerclage Passer, Technique Guide (Wires)	For general orthopaedic trauma surgery involving the application of cerclage wires – Periprosthetic fractures of the femur – Subtrochanteric fractures – Prophylactic banding in total joint replacement – Additional fixation – Temporary reduction	No contraindication specific to these devices.
Epoca Shoulder Arthroplasty System – Fracture	– Irreparable fractures of the proximal humerus – Posttraumatic conditions with advanced joint destruction – Failed previous osteosynthesis A glenoid component may be indicated in cases of cartilage destruction or in case of an associated irreparable glenoid fracture where gleno-humeral stability is a concern.	– Infections, acute or chronic, local or systemic – Severe muscular, neurological or vascular deficiencies, which compromise the affected extremity – Destruction of bone or poor bone quality, which may affect stability of the implant – Any concomitant disease which may compromise the function of the implant – Any other pathology which needs treatment priority
Synthes Kirschner Wires and Cerclage Wires Technique Guide	**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.

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