Instructions for Use
Plate and Screw Implants

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

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Plate and Screw Implants

Associated device systems with these instructions for use:
2.4 mm Cannulated Screw
2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius System
2.4/2.7 mm Locking Tarsal Plates
Angled Blade Plates for Adults
Angular Stable X-Plate and 2-Hole Plate
Cannulated Angled Blade Plate 3.5 and 4.5, 90°
Cannulated Pediatric Osteotomy System (CAPOS)
Cannulated Screws 3.0/3.5/4.0/4.5/6.5/7.0/7.3
DCP and LC-DCP Systems
DHS/DCS System
Distal Radius Plate 2.4/2.7 dorsal and volar
DLS Dynamic Locking Screw
Epoca Revision Set
Femoral Neck System
HCS 1.5
HCS 2.4/3.0
HCS 4.5/6.5
Humerus Block
LC-DCP System
LCP Anterolateral Distal Tibia Plate 3.5
LCP Clavicle Hook Plate
LCP Compact Foot / Compact Hand
LCP Compact Hand
LCP Compact Hand 1.5
LCP Condylar Plate 4.5/5.0
LCP DF and PLT
LCP DHHS
LCP Dia-Meta Volar Distal Radius Plates
LCP Distal Fibula Plates
LCP Distal Humerus Plates
LCP Distal Radius System 2.4
LCP Distal Tibia Plate
LCP Distal Ulna Plate
LCP Extra-articular Distal Humerus Plate
LCP Hook Plate 3.5
LCP Locking Compression Plate
LCP Low Bend Medial Distal Tibia Plates 3.5 mm
LCP Medial Distal Tibia Plate, without Tab
LCP Medial Proximal Tibial Plate 3.5
LCP Medial Proximal Tibial Plate 4.5/5.0
LCP Metaphyseal Plate for distal medial tibia
LCP Metaphyseal Plates
LCP Olecranon Plate
LCP Pediatric Condylar Plate 90°, 3.5 and 5.0
LCP Pediatric Hip Plate 2.7
LCP Pediatric Hip Plate 3.5/5.0
LCP Pediatric Hip Plates (3.5 and 5.0) 130°
LCP Pediatric Hip Plates 3.5 and 5.0
LCP Percutaneous Aiming System 3.5 for PHILOS
LCP Periarticular Proximal Humerus Plate 3.5
LCP Pilon Plate 2.7/3.5
LCP Posterior Medial Proximal Tibial Plate 3.5
LCP Proximal Femoral Hook Plate 4.5/5.0
LCP Proximal Femoral Plate 4.5/5.0
LCP Proximal Radius Plates 2.4
LCP Proximal Tibial Plate 3.5
LCP Proximal Tibial Plate 4.5/5.0
LCP Superior Anterior Clavicle Plate
LCP Superior Clavicle Plate
LCP Ulna Osteotomy System 2.7
LCP Volar Column Distal Radius Plates 2.4 mm
LCP Wrist Fusion Set
LISS DF
LISS PLT
Locking Attachment Plate
Locking Proximal Humerus Plate
Midfoot Fusion Bolt ø 6.5 mm
Orthopedic Foot Instruments
Pelvic Implants and Instruments
Periarticular Aiming Arm Instruments for LCP Condylar Plate 4.5/5.0
Periarticular Aiming Arm Instruments for LCP Proximal Tibial Plate 4.5/5.0
PHILOS and PHILOS Long
PHILOS WITH AUGMENTATION
Quadrilateral Surface Plates 3.5
Rotation Correction Plates 1.5 and 2.0
Sacral Bars
Slipped Capital Femoral Epiphysis (SCFE) Screw System
Spring Plates 3.5
Standard DHS Lag Screw with LCP DHHS Sideplate
The Calcaneal Plate
The Locking Calcaneal Plate
Wrist Fusion Instrument and Implant Set
TomoFix
TomoFix Medial Distal Femur (MDF)
TomoFix Medial Distal Femur (MDF)
TomoFix Medial High Tibial Plate (MHT)
VA-LCP® MEDIAL COLUMN FUSION PLATES 3.5
VA LOCKING CALCANEAL PLATES 2.7
VA-LCP Ankle Trauma System 2.7/3.5
VA-LCP Anterior Clavicle Plate
VA-LCP Condylar Plate 4.5/5.0
VA-LCP Distal Humerus Plates 2.7/3.5
VA-LCP Olecranon Plates 2.7/3.5
VA-LCP Proximal Tibial Plate 3.5
VA-Locking Intercarpal Fusion System
Variable Angle LCP 1st MTP Fusion Plates 2.4/2.7
Variable Angle LCP Dorsal Distal Radius Plate 2.4
Variable Angle LCP Forefoot/Midfoot System 2.4/2.7
Variable Angle LCP Mesh Plate 2.4/2.7
Variable Angle LCP Opening Wedge Plates 2.4/2.7
Variable Angle LCP Tarsal Plates 2.4/2.7
Variable Angle LCP TMT Fusion Plates 2.4/2.7
Variable Angle LCP Two-Column Volar Distal Radius Plate 2.4
Variable Angle LCP Volar Rim Distal Radius Plate 2.4
Variable Angle Locking Hand 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.
Plate and Screw Implants consist of various plates and screws to be implanted which are single packed, and 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 – 316L	ISO 5832-1
Stainless steel – 22-13-5	ASTM F 1314
TiCP	ISO 5832-2
CoCrMo alloy	ISO 5832-12
Titanium alloy:	
Ti-6Al-7Nb (TAN)	ISO 5832-11
Ti-6Al-4V (TAV)	ISO 5832-3
Ti-15Mo	F 2066

Intended use
Plate and Screw Implants are intended for temporary fixation, correction or stabilization of bones in various anatomical regions.

Indications
For specific indications for Plate and Screw Implants 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 Plate and Screws 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 package is damaged.

Do not resterilize

Implantable devices labeled with "Do not resterilize" symbol must not be re-sterilized because re-sterilization may compromise the structural integrity of the device and/or may lead to device failure and/or in multipart devices re-sterilization cannot be guaranteed due to initial sterilization in a sterile assembly site.

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 Plate and Screw 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 Plate and Screw 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
MRI Information
Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07
Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate (SAR) of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:
– It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
– Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
– Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
– Using the ventilation system may further contribute to reduce temperature increase in the body.

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

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