Instructions for Use Plate and Screw Implants

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



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 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

Femoral Neck System (FNS)

HCS 1.5

HCS 2.4/3.0

HCS 4.5/6.5

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 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 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 Plate System

LCP Periarticular Proximal Humerus Plate 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 with Periarticular Aiming Arm Instruments

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 and LCP DF

LISS and LCP PLT

Locking Attachment Plate

Midfoot Fusion Bolt Ø 6.5 mm

Pelvic Implants and Instruments

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

TomoFix

TomoFix Medial Distal Femur (MDF)

TomoFix Medial High Tibial Plate (MHT)

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 Medial Column Fusion Plates 3.5

VA-LCP Olecranon Plates 2.7/3.5

VA-LCP Proximal Tibial Plate 3.5

VA-Locking Calcaneal Plates 2.7

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/Sterile Distal Radius Kit

Variable Angle LCP Two-Column Volar Distal Radius Plate 2.4/2.7, Extra-long

Variable Angle LCP Volar Rim Distal Radius Plate 2.4

Variable Angle Locking Hand System

Please read these instructions for use, the Synthes brochure"Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical

Plate and Screw Implants consist of various plates and screws to be implanted which are single packed, and available non-sterile and/or sterile (corresponding article number with suffix "S"), as well as in sterile tube packaging (corresponding article number with suffix "TS").

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

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

Contraindications

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

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



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.



Do not resterilize

Implantable devices labeled with "Do not resterilize" symbol must not be resterilized because re-sterilization may compromise the structural integrity of the device and/or may lead to device failure. Re-sterilization of implantable devices can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

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 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

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
2.4 mm Cannulated Screw	 Intra-articular fractures of the carpals, metacarpals, tarsals and metatarsals Fixation of small bone fragments Bunionectomies and osteotomies Arthrodeses of small joints 	No contraindication specific to these devices.
2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius System	The 2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius Plates are indicated for fixation of intra and extra-articular fractures and osteotomies of the distal radius.	No contraindication specific to these devices.
2.4/2.7 mm Locking Tarsal Plates	The Synthes 2.4 mm/2.7 mm locking tarsal plates are intended for the fixation of fractures, osteotomies, nonunions, replantations, and fusions of the Cuboid, Tarsal and Navicular bones, particularly in osteopenic bone.	No contraindication specific to these devices.
Angled Blade Plate for Adults	130° Angled Blade Plate Fractures and revisions of the proximal third of the femur in skeletally mature patients.	No contraindication specific to these devices.
	Condylar Plates, 95° Fractures and revisions of the proximal and distal third of the femur in skeletally mature patients.	
	Osteotomy Plates 90°/100°/110°/120°/130° Hip Plate Osteotomies on the proximal femur in skeletally mature patients.	

Systems	Indications	Contraindications
Angular Stable X-Plate and 2-Hole Plate	X-plate Arthrodesis - MTP - MTC - Talonavicular - Calcaneo-Cuboid	No contraindication specific to these devices.
	Proximal osteotomies - Crescentic - Ludloff	
	– Mau – Open wedge – Closing wedge	
	Calcaneal osteotomiesFractures - Single - Multifragmental	
	2-hole plate – Akin osteotomy	
Cannulated Pediatric Osteotomy System (CAPOS)	The CAPOS System is indicated for use in infants, toddlers, children, adolescents, and small-stature adult patients.	No contraindication specific to these devices.
(CAPOS)	Specific indications include: – Intertrochanteric derotation and varus osteotomies	
	Osteotomy Plates - Mini Infant Hip Plate, Infant Hip Plate 3.5, 90°, Child Hip Plate 3.5, 90°, Child Hip Plate 4.5, Hip Plate 80°, 90° and 100° (Adolescent) - Intertrochanteric valgus osteotomies Plates	
	- 95° Condylar Plates (Adolescent and Small Stature Adult) - Femoral neck and pertrochanteric fractures - Plates – 130° Angled Blade Plates (Adolescent and Small Stature Adult)	
Cannulated Screws 3.0/3.5/4.0/4.5/6.5/ 7.0/7.3	CSS 3.0 Fixation of fractures of the forearm, hand and foot, e.g.: - fractures and arthrodeses of the carpals and metacarpals - fractures of the distal radius and radial head - metatarsal fractures	No contraindication specific to these devices.
	CSS 3.5 Fixation of fractures with small fragments, e.g.: – wrist fractures	
	 metacarpal and metatarsal fractures and fixation inmetacarpal and metatarsal osteotomies tarsal fractures 	
	transcondylar humeral fractures in childrenCSS 4.0	
	Fixation of fractures with medium fragments, e.g.: – tarsal and metatarsal fractures and fixation in metatarsal and phalangeal osteotomies	
	 tarsometatarsal and metatarsophalangeal arthrodesis ligament fixations hallux valgus corrections 	
	CSS 4.5 Fixation of fractures with medium fragments, e.g.:	
	malleolar fracturespilon tibial fracturesfractures of the calcaneus and talus	
	tibial plateau fracturescarpal and tarsal arthrodesis	
	CSS 6.5, 7.0 and 7.3 Fixation of fractures with large fragments, e.g.: - femoral neck fractures	
	– intercondylar femoral fractures	

Systems Indications Contraindications DCP and This surgical technique applies to the below Synthes DCP and LC-DCP No contraindication specific to these devices. **LC-DCP Systems** systems and plate lines Mini Fragment System 1.5, 2.0, 2.7 - Fractures of the middle and distal phalanges and tarsals - Fractures of the metacarpals and metatarsals - Osteotomies and arthrodeses on the hand and foot - Fractures of the distal radius (double-plate technique) Compact Hand 1.0, 1.3, 1.5, 2.0, 2.4 Implant sizes 1.0/1.3: - Fixation of small fragments - Fractures of the distal and intermediate phalanges Avulsion fractures Implant sizes 1.5: - Fractures of the phalanges and metacarpals - Capturing of fragments with lag screw technique Implant sizes 2.0/2.4: - Fractures of the phalanges and metacarpals - Capturing of fragments with lag screw technique Cloverleaf Plates 3.5 - Distal tibia for comminuted fractures to buttress its medial side - Proximal humerus for comminuted fractures of the humeral head One-third tubular plate 3.5 - Fractures of smaller sized bones such as fibula, humerus and ulna. LC-DCP Plate 3.5, DCP Plate 3.5, T-Plate 3.5 - Fracture fixation and fixation after for example osteotomies, malunions, nonunions including but not limited todistal radius, proximal and disital tibia, proximal humerus, and clavicle. LC-DCP Plate 4.5, DCP Plate 4.5, T-Plate 4.5,T-Buttress Plate 4.5. L-Buttress Plate 4.5 - Fractures and osteotomies of large bones such as femur, tibia and humerus Semi-Tubular Plate 4.5 Fractures and osteotomies of smaller sized bones such as humerus, radius, ulna, clavicle, fibula, tibia and pelvis **Condylar Buttress Plate 4.5** – Buttressing of multifragmentary distal femur fractures Supracondylar fractures - Intra-articular and extra-articular condylar fractures - Malunions and nonunions of the distal femur – Periprosthetic fractures **Lateral Tibial Head Buttress Plate 4.5** Indicated for the stabilization of fractures of the proximal tibia. These include proximal shaft fractures, metaphyseal fractures, intraarticular fractures, periprosthetic fractures. Proximal Tibial Plate 4.5 Indicated for nonunions, malunions and fractures of the proximal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar and combinations of lateral wedge and depression fractures. **DHS/DCS System** The DHS system including all combinations of DHS Screw, DHS Blade, **Contraindications DHS** DHS plate with DCP holes, LCP DHS plate and LCP DHS with collar. The DHS is not to be used in cases where there is a high incidence of: - Sepsis **Indications DHS** - Malignant primary or metastatic tumors - Pertrochanteric fractures of type 31-A1 and 31-A2 - Material sensitivity - Intertrochanteric fractures of type 31-A3 Compromised vascularity - Femoral neck fractures 31-B (DHS Screw in conjunction with an antirotation screw) Contraindications DCS Subtrochanteric fractures - Pertrochanteric fractures or trochanteric fractures with subtrochanteric expansion (31-A3) Trochanter Stabilizing PlateIndications LTSP/ULTSP/TSP Unstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with separated or longitudinally split greater trochanter **Indications DCS**

- Proximal femur: Very proximally located, purely subtrochanteric-

- Distal femur: Fractures of type 33-A (extra-articular, supracondylar)

and fractures of type 33-C (fully articular fractures)

fractures of types 32-A and 32-B

Systems	Indications	Contraindications
Femoral Neck System (FNS)	Femoral neck fractures (AO type 31-B)	 Pertrochanteric fractures (AO type 31-A1 and 31-A2) Intertrochanteric fractures (AO type 31-A3) Subtrochanteric fractures
		Additionally, this system should not be used for cases where there is a high incidence of: - Sepsis - Malignant primary or metastatic tumors - Material sensitivity - Compromised vascularity
HCS 1.5	- Fixation of intra- and extra-articular fractures and non-unions of small bones and small bone fragments - Arthrodesis of small joints - Osteochondral fractures - Osteotomies - Avulsion fractures	No contraindication specific to these devices.
HCS 2.4/3.0	 Fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments Arthrodeses of small joints Bunionectomies and osteotomies Examples include, but are not limited to scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid. 	No contraindication specific to these devices.
HCS 4.5/6.5	HCS 4.5 Fracture, osteoarthritis, or deformity of small to large bones. Examples: - Calcaneus - Talus - Metatarsus - Distal and proximal tibia - Distal femur - Proximal humerus HCS 6.5 Fracture, osteoarthritis, or deformity of small to large bones. Examples:	No contraindication specific to these devices.
	CalcaneusTalusDistal and proximal tibiaDistal femur	
LCP Anterolateral Distal Tibia Plate 3.5	The LCP Anterolateral Distal Tibia Plate 3.5 is indicated for: – Extra-articular and simple intra-articular distal tibia fractures – Distal tibia fracture, percutaneous or reducible by limited arthrotomy – Distal tibia fracture extending into the diaphyseal area	No contraindication specific to these devices.
LCP Clavicle Hook Plate	– Lateral clavicle fractures: Neer type II or Jäger and Breitner type II – Acromioclavicular joint dislocation Type: Tossy III or Rockwood III to V	- Stable lateral clavicle fractures - Tossy Type I and II - Rockwood Type I and II - Acute infection
LCP Compact Foot/ Compact Hand	Indications for implants of size 2.0 and 2.4 include: - Fractures of the phalanges - Fractures of the metacarpals and metatarsals (II–V) - Fractures of the distal radius (double-plate technique) - Osteotomies and arthrodeses on the hand and foot (e.g. TMT [II–V] fusions) - Subcapital radial head fracture - As an additional implant with small fragments Indications for implants of size 2.7 include: - Fractures of metatarsal I	No contraindication specific to these devices.
	 Fractures of the tarsals MTP 1 fusions Osteotomies and arthrodeses of the tarsals (e.g. calcaneo-cuboidal fusion) 	

Systems	Indications	Contraindications
LCP Compact Hand	Compact Hand 1.0/1.3 General: - Fixation of small fragments	No contraindication specific to these devices.
	– Avulsion fractures and fractures of the distal and middle phalanges	
	Straight plate: - Shaft fractures of phalanges	
	Strut plate: - Comminuted fractures and replantations of middle or proximal phalanges T-plate and	
	Y-plate: – Condylar fractures of phalanges	
	Single cortex screws: - Capturing of fragments with lag screw technique	
	LCP Compact Hand 1.5 - Fracture fixation of the phalanges and metacarpals - Osteotomies - Arthrodeses	
	 Replantations and reconstructions of phalanges and metacarpals, particularly in osteopenic bone 	
	LCP Compact Hand 2.0 - Fractures of the phalanges, metacarpals and wrist bones - Osteotomies and arthrodeses of the interphalangeal joints - Fractures of distal radius (double-plate technique) - Subcapital radial head fractures	
	LCP Compact Hand 2.4 - Fractures of the metacarpal and wrist bones - Fractures of distal radius (double-plate technique) - Osteotomies and arthrodeses on the hand - Subcapital radial head fractures	
LCP Compact Hand 1.5	 Fracture fixation of the phalanges and metacarpals Osteotomies Arthrodeses Replantations and reconstructions of phalanges and metacarpals, particularly in osteopenic bone 	No contraindication specific to these devices.
LCP Condylar Plate 4.5/5.0	- Buttressing of multifragmentary distal femur fractures - Supracondylar fractures - Intra-articular and extra-articular condylar fractures - Malunions and nonunions of the distal femur - Periprosthetic fractures - Fractures in normal or osteopenic bone	No contraindication specific to these devices.
LCP DHHS	The LCP DHHS is indicated for the following fractures of the proximal femur: - Intertrochanteric fractures	No contraindication specific to these devices.
	Femoral neck fractures Pertrochanteric fractures Pertrochanteric fractures LCP DHHS is indicated for stable and unstable fractures in which a stable medial buttress can be reconstructed.	
LCP Dia-Meta Volar Distal Radius Plates	LCP Dia-Meta Volar Distal Radius Plates are indicated for fractures, osteotomies, and nonunions of the radius.	No contraindication specific to these devices.
LCP Distal Fibula Plates	The LCP Distal Fibula Plates are intended for fixation of fractures, osteotomies and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone.	No contraindication specific to these devices.
LCP Distal Humerus Plates	Indications for Distal Humerus Plate – Intraarticular fractures of the distal humerus – Supracondylar fractures of the distal humerus – Non-unions of the distal humerus	(for DHP and for Metaphyseal plate) – Acute infections – Children in the growth phase
LCP Distal Radius System 2.4	Displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius.	No contraindication specific to these devices.
	Dorsal approach - Dorsally displaced fractures - Extra-articular fractures with metaphyseal defect (AO classification 23-A3)	
	Open joint reconstruction (AO classification 23-C1, C2, C3) Combination of distal radius with carpal and metacarpal fractures Corrective osteotomies Palmar approach—Reversed Barton Palmarly displaced extra-articular fractures (Goyrand- Smith) Dorsally displaced extra-articular (Colles) and articular fractures Extra-articular fractures with extension into the shaft (extra-long plates)	

Systems	Indications	Contraindications
LCP Distal Tibia Plate	 Extra-articular and simple intra-articular distal tibial fractures Distal tibial fractures, percutaneous or reducible by limited arthrotomy Distal tibial fracture extending into the diaphyseal area 	No contraindication specific to these devices.
LCP Distal Ulna Plate	Fractures of the distal ulna which result in instability of the distal radioulnar joint. Fractures of the ulna head where the articular surface is either displaced, rotated or tilted. Comminuted extra-articular fractures of the ulnar neck threatening stable congruency of the distal radioulnar joint.	No contraindication specific to these devices.
LCP Extra-articular Distal Humerus Plate	 Extra-articular fractures of the distal humerus Malunions of the distal humerus Non-unions of the distal humerus 	No contraindication specific to these devices.
LCP Hook Plate 3.5	Simple fractures of the olecranon (AO Types 21–B1, 21–B3, 21–C1) Osteotomies of the olecranon for distal humerus fracture treatment Avulsion fractures of the distal tibia and fibula	No contraindication specific to these devices.
LCP Locking Compression Plate	Small Fragment plates (3.5) LCP Plates 3.5 Fixation of small bone fragments using the five standard AO plating principles (buttress plate, neutralization plate, tension band plate, bridge plate, compression plate).	No contraindication specific to these devices.
	LCP Reconstruction Plates 3.5 Fixation of small bone fragments using the five standard AO plating principles (buttress plate, neutralization plate, tension band plate, bridge plate, compression plate).	
	LCP T-Plates 3.5 Fixation of small bone fragments using the five standard AO plating principles (buttress plate, neutralization plate, tension band plate, bridge plate, compression plate). Fracture fixation and fixation after osteotomies, malunions, non-unions; e.g. including but not limited to distal radius, proximal and distal tibia, proximal humerus, clavicular.	
	LCP One-third Tubular Plates 3.5 The LCP One-third Tubular Plates 3.5 are indicated for plating of fractures of long and small bones. The plate should only be used for load-sharing purposes, e.g. buttressing, tension banding, neutralization or compression.	
	LCP Methaphyseal 3.5 The LCP Metaphyseal Plates are indicated to fix extra-articular fractures in the metaphyseal area that can extend into the shaft area. The 3.5 mm plates are indicated to fix fractures of the distal humerus and distal fibula.	
	Large Fragment plates (4.5/5.0) LCP Methaphyseal 3.5/4.5/5.0 The LCP Metaphyseal Plates are indicated for extra-articular fractures of the metaphyseal area that extend into the shaft area.	
	The 4.5/5.0 plates are indicated to fix fractures of the proximal humerus and distal tibial.	
	LCP 4.5/5.0 Narrow Plates LCP T-Plates 4.5/5.0 LCP 4.5/5.0 Broad Plates LCP 4.5/5.0 Broad Curved Plates LCP Reconstruction Plates 4.5/5.0	
	In general the LCP Generic Plates & Instruments (Large Fragment) are indicated for the osteosynthesis of fractures at the Femur, Tibia, Humerus and Pelvic at proximal, distal and shaft areas.	
LCP Low Bend Medial Distal Tibia Plates 3.5 mm	The Synthes LCP Low Bend Medial Distal Tibia Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia, as a part of the Synthes Small Fragment LCP System.	No contraindication specific to these devices.
LCP Medial Proximal Tibial Plate 3.5	The LCP Medial Proximal Tibial Plates 3.5 are indicated to buttress metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibial plateau. The plates may also be used for fixation of the proximal quarter (lateral split and the split of the split and the split of the split	No contraindication specific to these devices.
	eral and medial) of the tibia, as well as segmental fractures of the proximal tibia.	

Systems	Indications	Contraindications
LCP Medial Proximal Tibial Plate 4.5/5.0	The LCP Medial Proximal Tibial Plates 4.5/5.0 are indicated to buttress metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibial plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia, as well as segmental fractures of the proximal tibia. The LCP Medial Proximal Tibial Plates 4.5/5.0 may also be used for fixation of nonunions and malunions of the medial proximal tibia and tibia shaft, as well as opening and closing wedge tibial osteotomies.	No contraindication specific to these devices.
LCP Metaphyseal Plate for distal medial tibia	The LCP Metaphyseal Plate for distal medial tibia is a preshaped plate that allows optimal treatment of juxta-articular fractures of the distal tibia extending into the shaft area. This plate takes the following characteristics of the distal tibia into account: – Thin, soft tissue coverage – Complex anatomic shape of the bone	No contraindication specific to these devices.
LCP Metaphyseal Plates	The LCP Metaphyseal Plates are indicated to fix extra-articular fractures in the metaphyseal area that can extend into the shaft area. The 3.5 mm plates are indicated to fix fractures of the distal humerus and distal fibula. The 4.5/5.0 plates are indicated to fix fractures of the proximal humerus and distal tibial.	No contraindication specific to these devices.
LCP Olecranon Plate	 Complex extra- and intra-articular olecranon fractures Pseudoarthroses of the proximal ulna Osteotomies Simple olecranon fractures 	Acute infectionsChildren in growth phase
LCP Pediatric Plate System	The LCP Pediatric Plate System consists of different plates for different indications. The LCP Pediatric Hip Plate 2.7 is intended for use in infants up to three years, depending on body weight and bone quality. Neglected dislocation of the hip in combination with open reduction Developmental coxa valga Severe hip dysplasia	No contraindication specific to these devices.
	The LCP Pediatric Hip Plate for varus osteotomies is intended for use in pediatric patients up to adolescence and for small stature adult patients.	
	Specific indications include: - Idiopathic valgus hip - Idiopathic and acquired subluxation of the femoral head - Femoral head subluxation in neuromuscular diseases/problems - High retroversion and anteversion in combination with a high CCD-angle	
	The LCP Pediatric Hip Plate for valgus osteotomies is intended for use in pediatric patients up to adolescence and for small stature adult patients.	
	Specific indications include: - High riding of greater trochanter and low shortening of the leg - Perthes' disease - Congenital pseudarthrosis of the femoral neck - Deformity of SCFE (Slipped Capital Femoral Epiphysis) - PFFD (Proximal Femoral Focal Deficiency) - Idiopathic coxa vara - Posttraumatic pseudarthrosis of the femoral neck	
	LCP Pediatric Hip Plate (3.5 & 5.0) 120° & 130° for fracture treatment and rotation correction is indicated for trans-trochanteric fractures with sufficient medial support, and femoral neck fractures Type I to III (see AO fracture classification).	
	The LCP Pediatric Condylar Plate is intended for use in pediatric patients up to adolescence and for small stature adult patients.	
	Specific indications include: - Fixed flexion contracture of knee in neurological conditions - Deformity correction in the distal femur - Rotational malalignment of the femur (if distal correction preferred) - Supracondylar fractures of the femur	
LCP Periarticular Proximal Humerus Plate 3.5	The LCP Periarticular Proximal Humerus Plate 3.5 addresses complex fractures of the proximal humerus. The 3.5 mm LCP Periarticular Proximal Humerus Plate is indicated for fractures and fracture dislocations (Neer type 2, 3, and 4-part fractures), osteotomies, and nonunions of the proximal humerus, particularly for patients suffering from osteoporosis.	No contraindication specific to these devices.

Systems	Indications	Contraindications
LCP Posterior Medial Proximal Tibial Plate 3.5	The Synthes LCP Posterior Medial Proximal Tibial Plate 3.5 is indicated for internal fixation of posteromedial proximal tibia fractures including buttressing of fractures of the proximal, distal and metaphyseal areas of the tibia.	No contraindication specific to these devices.
LCP Proximal Femoral Hook Plate 4.5/5.0	The LCP Proximal Femoral Hook Plate 4.5/5.0 is intended for fractures of the femur including: - Fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, reversed or transverse fractures of the trochanteric region or with additional fracture of the medial cortex - Fractures of the proximal end of the femur combined with ipsilateral shaft fractures - Metastatic fracture of the proximal femur - Osteotomies of the proximal femur - Also for use in fixation of osteopenic bone and fixation of nonunions or malunions - Periprosthetic Fractures	No contraindication specific to these devices.
LCP Proximal Femoral Plate 4.5/5.0	The LCP Proximal Femoral Plate 4.5/5.0 is intended for fractures of the femur including: - Fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, reversed or transverse fractures of the trochanteric region or with additional fracture of the medial cortex - Fractures of the proximal end of the femur combined with ipsilateral shaft fractures - Metastatic fracture of the proximal femur - Osteotomies of the proximal femur - Also for use in fixation of osteopenic bone and fixation of nonunions or malunions - Periprosthetic Fractures	No contraindication specific to these devices.
LCP Proximal Radius Plates 2.4	Extra-articular and intra-articular fractures of the proximal radius and multifragmented radial neck fractures.	No contraindication specific to these devices.
LCP Proximal Tibial Plate 3.5	 Split-type fractures of the lateral tibial plateau Lateral split fractures with associated depressions Pure central depression fractures Split or depression fractures of the medial plateau 	Isolated shaft fractures.
LCP Proximal Tibial Plate 4.5/5.0 with Periarticular Aiming Arm Instruments	The Synthes LCP Proximal Tibial Plate 4.5/5.0 are indicated for treatment of nonunions, malunions and fractures of the proximal tibia including: - Simple fractures - Comminuted fractures - Lateral wedge fractures - Depression fractures - Medial wedge fractures - Bicondylar, combination of lateral wedge and depression fractures - Fractures with associated shaft fractures	No contraindication specific to these devices.
LCP Superior Anterior Clavicle Plate	- Fractures of the clavicle shaft - Fractures of the lateral clavicle - Malunions of the clavicle - Non-unions of the clavicle	No contraindication specific to these devices.
LCP Superior Clavicle Plate	 Fractures of the clavicle shaft Fractures of the lateral clavicle Malunions of the clavicle Non-unions of the clavicle 	No contraindication specific to these devices.
LCP Ulna Osteotomy System 2.7	Primary ulnar impaction syndrome - Degenerative triangular fibrocartilage complex (TFCC) tears - Lunotriquetral tears Secondary ulnar impaction syndrome - Incongruency (length discrepancy) of the distal radial-ulnar joint following distal radius fracture - Traumatic triangular fibrocartilage complex (TFCC) tears	No contraindication specific to these devices.
LCP Volar Column Distal Radius Plates 2.4 mm	The LCP Volar Column Distal Radius Plate 2.4 mm is indicated for the fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius.	No contraindication specific to these devices.
LCP Wrist Fusion Set	The LCP Wrist Fusion System is indicated for wrist arthrodesis and fractures of other small bones of the carpus. Specific indications include: - Posttraumatic arthrosis of the joints of the wrist - Rheumatoid wrist deformities requiring restoration - Complex carpal instability - Postseptic arthritis of the wrist - Severe unremitting wrist pain related to motion - Brachial plexus nerve palsies - Tumor resection - Spastic deformities	No contraindication specific to these devices.

Systems	Indications	Contraindications
LISS and LCP DF	LCP DF is indicated for the stabilization of fractures of the distal femur. These include: – Distal shaft fractures – Supracondylar fractures – Intra-articular fractures – Periprosthetic fractures	No contraindication specific to these devices.
LISS and LCP PLT	LCP PLT and LISS PLT are indicated for the stabilization of fractures of the proximal tibia. These include: – Proximal shaft fractures – Metaphyseal fractures – Intra-articular fractures – Periprosthetic fractures	No contraindication specific to these devices.
Locking Attachment Plate	 Periprosthetic femoral shaft fractures: Vancouver B Vancouver C Fractures around intramedullary implants 	No contraindication specific to these devices.
Midfoot Fusion Bolt ∅ 6.5 mm	Treatment of gross collapse of the mid/hindfoot associated with: – Charcot foot – Neuropathic disease	 Peripheral vascular disease Serious and life-threatening co-morbidities
	Charcot foot can develop in several areas of the foot. The most common is the Lisfranc area, secondarily the Chopart area, thirdly the ankle area and fourthly the calcaneus – subtalar area. It often develops in the forefoot. The idea of the Midfoot Fusion Bolt is to treat the Lisfranc and Chopart area.	
Pelvic Implants and Instruments	Symphysis fractures: Pubic Symphysis Plates Pelvic brim fractures: Reconstruction Plates Straight Plates Curved Plates (88 mm radius, 108 mm radius) J-Plates Locking Reconstruction Plates 3.5 Straight Plates J-Plates Reconstruction Plates 3.5 with wide Angle Straight Plates Ilium/Iliac wing fractures: Reconstruction Plates Straight Plates Curved Plates (88 mm radius, 108 mm radius)	In-situ Plate Contouring Instruments are contraindicated for: Plates with locking and coaxial combi-holes. In particular: - Locking Reconstruction Plates 3.5 - Pubic Symphysis Plates 3.5 - Spring Plates 3.5 - Reconstruction Plates 3.5 with coaxial combi-holes - Other plate sizes than 3.5 mm
	 Locking Reconstruction Plates 3.5 Straight Plates Low Profile Reconstruction Plates 3.5 with wide Angle Straight Plates Acetabulum fractures: Reconstruction Plates Straight Plates Curved Plates (88 mm radius, 108 mm radius) Reconstruction Plates 3.5 with wide Angle 	
	- Straight Plates	

Systems	Indications	Contraindications
PHILOS and PHILOS Long	PHILOS indications - Dislocated two-, three-, and four-fragment fractures of the proximal humerus, including fractures involving osteopenic bone - Pseudarthroses in the proximal humerus - Osteotomies in the proximal humerus	No contraindication specific to these devices.
	PHILOS long indications – As for PHILOS, but for fractures extending to the shaftor without medial support	
PHILOS with Augmentation	PHILOS indications - Dislocated two-, three-, and four-fragment fractures of the proximal humerus, including fractures involving osteopenic bone - Pseudarthroses in the proximal humerus - Osteotomies in the proximal humerus	PHILOS Augmentation contraindications – In case of potential risk of cement leakage into the fracture gap, th articulation or vascular structures (e.g. via fractures which open int the articulation)
	PHILOS long indications – As for PHILOS, but for fractures extending to the shaft or without medial support	
	PHILOS Augmentation indications - As for PHILOS and PHILOS long, but exclusively in conjunction with osteoporotic bone - The perforated screws may also be used without cement augmentation	
Quadrilateral Surface Plates 3.5	The Synthes Quadrilateral Surface Plates 3.5 are indicated for quadrilateral surface comminution associated with acetabular fractures when used in conjunction with Synthes Pelvic Reconstruction Plates.	No contraindication specific to these devices.
Rotation Correction Plates 1.5 and 2.0	1. All fractures of the phalanges and metacarpals, where the exact reposition is difficult or where a rotational error can easily occur. - subcapital fractures of the metacarpals (in particular impacted compression fractures) - transverse fractures - short oblique fractures - comminuted fractures - defect fractures (circular saw injuries) - amputation injuries to the fingers (with primary shortening) - Winterstein fracture, Rolando fracture	No contraindication specific to these devices.
	2. Corrective osteotomies for fractures of the phalanges or metacarpals that have healed with axial errors and/or rational errors. In the case of metaphyseal fractures, comminuted fractures and osteoporotic bone, the clinical results can be improved by the angular-stable screw/plate connection.	
Sacral Bars	The Synthes Sacral Bars are indicated for fixation of the posterior pelvis, in areas of the posterior superior iliac spine, posterior inferior iliac spine, for sacral fractures, and fracture dislocations of the sacroiliac joint.	No contraindication specific to these devices.
Slipped Capital Femoral Epiphysis (SCFE) Screw System	The Slipped Capital Femoral Epiphysis (SCFE) Screws are indicated for: – Slipped capital femoral epiphysis This device is not approved for screw attachment or fixation to the	No contraindication specific to these devices.
	posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.	
Spring Plates 3.5	The Synthes 3.5 mm Spring Plate is intended for pelvic and acetabular reconstructive surgery	No contraindication specific to these devices.
Standard DHS Lag Screw with LCP DHHS Sideplate	- Pertrochanteric fractures of type 31-A1 and 31-A2 - Intertrochanteric fractures of type 31-A3 - Femoral neck fractures 31-B (DHS Screw in conjunction with an antirotation screw) - Subtrochanteric fractures	The DHS is not to be used in cases where there is a high incidence of Sepsis - Malignant primary or metastatic tumors - Material sensitivity - Compromised vascularity

Systems	Indications	Contraindications
The Calcaneal Plate	The calcaneal plates address fractures of the calcaneus. The calcaneal plate is indicated for fractures and osteotomies of the calcaneus including, but not limited to, extra-articular, intra-articular, joint depression and tongue type fractures.	No contraindication specific to these devices.
The Locking Calcaneal Plate	The locking calcaneal plates address complex fractures of the calcaneus. The locking calcaneal plate is indicated for fractures and osteotomies of the calcaneus including, but not limited to, extra-articular, intra-articular, joint depression, tongue type, and severely comminuted fractures.	No contraindication specific to these devices.
TomoFix	TomoFix Medial High Tibia and Medial High Tibia Small Stature Plate: Open-wedge and closed-wedge osteotomy of the medial proximal tibia for the treatment of: - Unicompartmental medial or lateral gonarthrosis with malalignment of the proximal tibia - Idiopathic or posttraumatic varus or valgus deformity of the proximal tibia	Inflammatory arthritis
	TomoFix Lateral High Tibia Plate: Open-wedge and closed-wedge osteotomy of the lateral proximal tibia for the treatment of: - Unicompartmental medial or lateral gonarthrosis with malalignment of the proximal tibia - Idiopathic or posttraumatic varus or valgus deformity of the proximal tibia	
	TomoFix Lateral Distal Femur Plate: Open-wedge and closed-wedge osteotomy of the lateral distal femur for the treatment of: – Unicompartmental medial or lateral gonarthrosis with malalignment of the distal femur – Idiopathic or posttraumatic varus or valgus deformity of the distal femur	
TomoFix Medial Distal Femur (MDF)	Closed-wedge osteotomies of the medial distal femur for the treatment of: – Unicompartmental lateral gonarthrosis with valgus malalignment of the distal femur – Idiopathic or posttraumatic valgus deformity of the distal femur – Additional fixation for complex distal femoral fractures	Inflammatory arthritis
TomoFix Medial High Tibial Plate (MHT)	Open-wedge and closed-wedge osteotomies of the medial proximal tibia for the treatment of: – Unicompartmental medial or lateral gonarthrosis with malalignment of the proximal tibia – Idiopathic or posttraumatic varus or valgus deformity of the proximal tibia	Inflammatory arthritis
VA-LCP Ankle Trauma System 2.7/3.5	VA-LCP Medial Distal Tibial Plate 2.7/3.5 Indicated for complex intra- and extra-articular fractures of the distal tibia. VA-LCP Anteromedial Distal Tibial Plate 2.7/3.5	No contraindication specific to these devices.
	Indicated for complex intra- and extra-articular fractures of the distal tibia. VA-LCP Anterolateral Distal Tibial Plate 2.7/3.5 Indicated for complex intra- and extra-articular fractures of the distal tibia. VA-LCP Lateral Distal Fibula Plate 2.7 Indicated for fractures and non-unions of the metaphyseal and	
	diaphyseal region of the distal fibula, especially in osteopenic bone. VA-LCP Posterolateral L- and T-Plates 2.7 Indicated for buttressing of partial articular fractures and bone fragments of the distal tibia.	

Systems	Indications	Contraindications
VA-LCP Anterior Clavicle Plate	 Fractures of the clavicle shaft Fractures of the lateral clavicle Malunions of the clavicle Non-unions of the clavicle 	No contraindication specific to these devices.
VA-LCP Condylar Plate 4.5/5.0	The Synthes VA-LCP Condylar Plate 4.5/5.0 system is indicated for buttressing multifragmentary distal femur fractures including: supra-condylar, intra-articular and extra-articular condylar fractures, periprosthetic fractures, fractures in normal or osteopenic bone, nonunions and malunions.	No contraindication specific to these devices.
VA-LCP Distal Humerus Plates 2.7/3.5	 Intra-articular fractures of the distal humerus Supracondylar fractures of the distal humerus Nonunions of the distal humerus Osteotomies of the distal humerus (e.g. due to malunions, deformities) 	No contraindication specific to these devices.
VA LCP Medial Column Fusion Plates 3.5	The DePuy Synthes VA LCP Medial Column Fusion Plates 3.5 are indicated for deformities, severe arthritis, and arthrosis of the medial column consisting of the first metatarsal, medial cuneiform, navicular and talus.	No contraindication specific to these devices.
VA-LCP Olecranon Plates 2.7/3.5	VA-LCP Proximal Olecranon Plates - Fractures of the proximal olecranon - Osteotomies of the olecranon for distal humerus fracture treatment VA-LCP Olecranon Plates	No contraindication specific to these devices.
	Intra-articular fractures of the olecranon including fractures extending into the coronoid Nonunions of the olecranon Osteotomies of the olecranon (e.g. due to malunions, deformities)	
	VA-LCP Proximal Ulna Plate, extra-articular - Extra-articular fractures of the proximal ulna - Nonunions of the proximal ulna - Osteotomies of the proximal ulna (e.g. due to malunions, deformities)	
VA-LCP Proximal Tibial Plate 3.5	Fractures of the proximal tibia in adults and adolescents with closed growth plates including — Proximal split, depression or split-depression fractures — Bicondylar or pure metaphyseal fractures — Associated metaphyseal or associated shaft fractures — Periprosthetic fractures	No contraindication specific to these devices.
VA Locking Calcaneal Plates 2.7	VA Locking Calcaneal Plate 2.7 The Synthes Variable Angle Locking Calcaneal plates 2.7 are indicated for intra- and extra-articular fractures of the calcaneus, as well as deformities and malunions.	No contraindication specific to these devices.
	Variable Angle Locking Anterolateral Calcaneal Plate 2.7 The Synthes Variable Angle Locking Anterolateral Calcaneal plates 2.7 in combined use with independent screws are indicated for intra- and extra-articular fractures of the calcaneus, as well as deformities and malunions.	
VA-Locking Intercarpal Fusion System	Indicated for fusion of small bones of the hand including: hamate, capitate, lunate, and triquetrum, for the revision offailed partial wrist fusions, and is indicated for use in patients suffering pain and/or loss of function due to: Osteoarthritis Rheumatoid arthritis Post-traumatic or degenerative wrist arthritis Carpal instability	No contraindication specific to these devices.
Variable Angle LCP 1st MTP Fusion Plates 2.4/2.7	The 1st MTP Fusion Plate of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7 is indicated for deformations of the first metatarsophalangeal (MTP) joint (Hallux Rigidus) and fractures, nonunions and replantations of the first metatarsal bone, particularly in osteopenic bone.	No contraindication specific to these devices.
Variable Angle LCP Dorsal Distal Radius Plate 2.4	2.4 mm Variable Angle LCP Dorsal Distal Radius Plates are indicated for: – Dorsally displaced fractures – Extra-articular and intra-articular fractures with metaphyseal defect – Open joint reconstruction – Combination of distal radius with carpal and metacarpal fractures – Corrective osteotomies after distal radius malunion	No contraindication specific to these devices.
Variable Angle LCP Forefoot/Midfoot System 2.4/2.7	The Straight Fusion Plates, T-Fusion Plates, L-Fusion Plates, Cloverleaf Fusion Plates and X-Plates of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7 are indicated for fractures, deformations, revisions and replantations of bones (e.g. tarsals, metatarsals and phalanges) and bone fragments, particularly in osteopenic bone.	No contraindication specific to these devices.

Systems	Indications	Contraindications
Variable Angle LCP Mesh Plate 2.4/2.7	The Mesh Plate, part of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7, is indicated for fractures, deformations, severe osteoarthritis and non- and mal-unions in the forefoot and midfoot, particularly in osteopenic bone. In addition the DePuy Synthes Variable Angle LCP Mesh Plate 2.4/2.7 is indicated for fixation and stabilization of patellar fractures in normal and osteopenic bone in skeletally mature patients.	No contraindication specific to these devices.
Variable Angle LCP Opening Wedge Plates 2.4/2.7	The Opening Wedge Plate of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7 is indicated for deformations (e.g. hallux valgus), nonunions, and replantations of the first metatarsal bone, particularly in osteopenic bone.	No contraindication specific to these devices.
Variable Angle LCP Tarsal Plates 2.4/2.7	The Synthes VA locking tarsal plates are intended for the fixation of fractures, osteotomies, nonunions, replantations, and fusions of the Cuboid and Navicular bones, particularly in osteopenic bone.	No contraindication specific to these devices.
Variable Angle LCP TMT Fusion Plates 2.4/2.7	The 1st TMT Fusion Plates of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7 are indicated for deformations of the first tarsometatarsal (TMT) joint (Hallux valgus) and fractures, nonunions and replantations of the first metatarsal bone, particularly in osteopenic bone. The TMT Fusion Plate of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7 is indicated for deformations of the second and third tarsometatarsal (TMT) joint and fractures, deformations, nonunions and replantations of the second and third metatarsal bone, particularly in osteopenic bone.	No contraindication specific to these devices.
Variable Angle LCP Two-Column Volar Distal Radius Plate 2.4/ Sterile Distal Radius Kit	Variable Angle LCP Two-Column Volar Distal Radius Plates 2.4 are indicated for the fixation of intra- and extra-articular fractures and osteotomies of the distal radius.	No contraindication specific to these devices.
Variable Angle LCP Two-Column Volar Distal Radius Plate 2.4/2.7mm, Extra-long	The DePuy Synthes VA-LCP Two-Column Volar Distal Radius Plate 2.4/2.7 mm, Extra-Long is intended for intra- and extra-articular fractures, osteotomies, nonunions and malunions of the distal radius, with or without extension into the radial diaphysis.	No contraindication specific to these devices.
Variable Angle LCP Volar Rim Distal Radius Plate 2.4	Variable Angle LCP Volar Rim Distal Radius Plate 2.4 is indicated for the fixation of complex intra-articular and extra-articular fractures of the distal radius.	No contraindication specific to these devices.
Variable Angle Locking Hand System	The Variable Angle Locking Hand System is indicated for the treatment of fractures, deformities and degenerative diseases in the hand.	No contraindication specific to these devices.



