
Instructions for Use Intramedullary Nailing Implants

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

Instructions for Use

Intramedullary Nailing Implants

Associated device systems with these instructions for use:

Angular Stable Locking System (ASLS)
Antegrade Femoral Nail (AFN)
DAD – Distal Aiming Device for UTN
DFN Distal Femoral Nail
End Cap for TEN
Expert A2FN
Expert ALFN
Expert HAN
Expert Humeral Nailing System
Expert LFN
Expert R/AFN
Expert TN
MultiLoc Humeral Nailing System
Olecranon Osteotomy Nail
PFN – Proximal Femoral Nail
PFN Proximal Femoral Nail
PFNA
PFNA. With Augmentation Option
PFNA-II
Set Screw for Trochanteric Fixation Nail
Simplified Universal Nail S.U.N.
Suprapatellar Instrumentation for Expert Tibial Nail
TFN – Titanium Trochanteric Fixation Nail System
TFNA – Proximal Femoral Nailing System
The Distal Aiming Device (DAD) for Simplified Universal Nails (S.U.N.)
The Universal Nail System
Titanium/Stainless Steel Elastic Nail System
UFN Unreamed Femoral Nail CFN Cannulated Femoral Nail
UHN/PHN Humeral Nailing System
UTN/CTN Solid/Cannulated Tibial Nail

Please read these instructions for use, the Synthes “Important Information” and the corresponding surgical technique carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Intramedullary Nailing Implants consist of metallic interlocking nails, interlocking arthrodesis nails, non-interlocking flexible nails, helical or spiral blades, femoral neck screws, hip screws, hip pins, end caps, set screws, threaded stepped screws, proximal and distal locking screws or bolts.

All implants 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, Important Information and device-specific label).

Material(s)

Material(s):	Standard(s):
Stainless steel	ISO 5832-1
UHMWPE	ISO 5834-2
40Co-20Cr-16Fe-15Ni-7Mo (Elgiloy)	ISO 5832-7

Titanium Alloy:

Ti-6Al-7Nb (TAN)	ISO 5832-11
Ti-6Al-4V (TAV)	ISO 5832-3
Ti-15Mo	ASTM F2066

Intended use

Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus.

Ankle Fusion Nails are intended for tibiotalar calcaneal arthrodesis.

TEN and STEN Nails are used as single implant or in pairs for Elastic Stable Intramedullary Fixation (ESIN).

Olecranon Osteotomy Nails are intended for fixation of simple fractures and osteotomies of the olecranon.

Indications

For specific indications of the respective Intramedullary Nailing Implant it is mandatory to consult the corresponding surgical technique (www.depuyssynthes.com/ifu) of the product system being used.

Contraindications

For specific contraindications of the respective Intramedullary Nailing Implant it is mandatory to consult the corresponding surgical technique (www.depuyssynthes.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.

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”.

Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding surgical technique, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.

For application specific precautions it is mandatory to consult the corresponding surgical technique (www.depuyssynthes.com/ifu) of the product system being used.

Warnings

For general warnings consult “Important Information”.

For application specific warnings related to Intramedullary Nailing Implants it is mandatory to consult the corresponding surgical technique (www.depuyssynthes.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.depuyssynthes.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".

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 multi-part instruments" can be downloaded from <http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance>

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