Instructions for Use
Intramedullary Nailing Implants

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DePuy Synthes
COMPANIES OF Johnson&Johnson

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Instructions for Use

Intramedullary Nailing Implants

Associated device systems with these instructions for use:
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 Guide 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 Guide, 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 tibiotalocalcaneal 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 Guide (www.depuysynthes.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 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

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. 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 Guide (www.depuysynthes.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 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".

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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