
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)
DFN Distal Femoral Nail
Expert A2FN
Expert ALFN
Expert HAN
Expert Humeral Nailing System
Expert LFN
Expert R/AFN
Expert TN
Femoral Recon Nail System
MultiLoc Humeral Nailing System
PFN Proximal Femoral Nail
PFNA
PFNA. With Augmentation Option
PFNA-II
Set Screw for Trochanteric Fixation Nail
Suprapatellar Instrumentation for Expert Tibial Nail
TFN – Titanium Trochanteric Fixation Nail System
TFNA – Proximal Femoral Nailing System
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 brochure “Important Information” 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 tibiotibial calcaneal arthrodesis.

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

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 if 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 re-sterilized 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 processing (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.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 (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 brochure "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 multi-part instruments" can be downloaded from <http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

Systems	Indications	Contraindications
Angular Stable Locking System (ASLS)	<p>ASLS (Angular Stable Locking System) is intended for use with Synthes cannulated titanium intramedullary nails. It is used as an alternative to standard locking screws/bolts.</p> <p>ASLS is used for the operative treatment and stabilization of long bone fractures of the upper and lower extremities, according to the specific indications of the respective nail system.</p> <p>ASLS is particularly indicated in cases where increased stability is needed, for example:</p> <ul style="list-style-type: none">- In fractures closer to the metaphyseal area- In osteopenic bone	<p>Contraindications of the respective Synthes nail system are applicable.</p> <ul style="list-style-type: none">- Established patient intolerance or allergy to polylactides- Situations in which internal fixation is contraindicated for other reasons, e.g. in patients with acute, potential or chronic infections, with poor bone quality, reduced blood circulation, with bone disorders or lack of compliance (e.g. alcoholism)
Antegrade Femoral Nail (AFN)	<p>AFN Standard locking Standard Locking Indications:</p> <ul style="list-style-type: none">- The Antegrade Femoral Nail with standard locking is indicated for fractures in the femoral shaft:- 32-A/B/C (except subtrochanteric fractures 32-A [1-3].1, 32-B [1-3].1, and 32-C [1-3].1) <p>AFN Reconstruction locking Recon Locking Indications:</p> <ul style="list-style-type: none">- The Antegrade Femoral Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures: 32-A/B/C combined with 31-B (double ipsilateral fractures)- Additionally the Antegrade Femoral Nail is indicated for fractures in the subtrochanteric section: 32-A [1-3].1, 32-B [1-3].1, and 32-C [1-3].1	<ul style="list-style-type: none">- Isolated femoral neck fractures- Supracondylar fractures (localisation 32)- Intertrochanteric fractures- Petrochanteric fractures
DFN Distal Femoral Nail	<p>The Distal Femoral Nail DFN is indicated for the stabilization of fractures of the distal femur. It can also be used for diaphyseal fractures in which a retrograde approach is indicated (e.g. ipsilateral tibia and/or patella fractures, proximal or distal endoprosthesis, adipositas permagna). These include according to the AO classification:</p> <p>Indications</p> <ul style="list-style-type: none">- Fractures of type 33-A1 to A3- Fractures of type 33-C1 to C3.1- Fractures of type 32-A to C	<ul style="list-style-type: none">- Fractures of type 33-B, 33-C3.2 and 33-C3.3- Proximal femoral fractures and high subtrochanteric fractures
Expert A2FN	<p>Standard Locking Indications: The Expert A2FN with standard locking is indicated for fractures in the femoral shaft:</p> <p>32-A/B/C (except subtrochanteric fractures 32-A [1-3].1, 32-B [1-3].1, and 32-C [1-3].1)</p> <p>Recon Locking Indications: The Expert A2FN with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures: 32-A/B/C combined with 31-B (double ipsilateral fractures)</p> <p>Additionally the Expert A2FN is indicated for fractures in the subtrochanteric section:</p> <p>32-A [1-3].1, 32-B [1-3].1, and 32-C [1-3].1</p>	<ul style="list-style-type: none">- Isolated femoral neck fractures- Supracondylar fractures (localisation 32)- Intertrochanteric fractures- Petrochanteric fractures

Systems	Indications	Contraindications
Expert ALFN	<p>The Expert Adolescent Lateral Femoral Nail is indicated for use in adolescent and small-stature adult patients to stabilize:</p> <ul style="list-style-type: none"> – Fractures of the femoral shaft – Subtrochanteric fractures – Ipsilateral neck/shaft fractures – Impending pathologic fractures – Nonunions and malunions 	No contraindication specific to these devices
Expert HAN	<p>The Expert Hindfoot Arthrodesis Nail is indicated to facilitate tibiototalcaneal arthrodesis to treat:</p> <ul style="list-style-type: none"> – Severe foot/ankle deformity – Arthritis – Instability and skeletal defects, including but not limited to after tumor resection and neuro-osteoarthropathy (Charcot's foot) – Avascular necrosis of the talus – Failed joint replacement or failed ankle fusion – Distal tibial fracture/non-unions – Osteoarthritis – Rheumatoid arthritis and pseudoarthrosis 	<p>The Expert Hindfoot Arthrodesis Nail system is not recommended for:</p> <ul style="list-style-type: none"> – Dysvascular limp – Active infection – Insufficient plantar pad
Expert Humeral Nailing System	<p>Expert Humeral Nail: locking with spiral blade or screws</p> <p>The range of indications for the Expert Humeral Nail includes humeral shaft fractures down to approx. 5 cm proximal to the olecranon fossa with closed epiphyseal lines (AO/ASIF classification: A–C) for:</p> <ul style="list-style-type: none"> – Stable or unstable fractures – Refractures, some fractures with delayed healing and pseudoarthroses <p>The Expert Humeral Nail can be inserted into the humeral shaft in both antegrade and retrograde directions. It can be used universally for either the left or right humerus.</p> <p>Expert Proximal Humeral Nail: standard locking with spiral blade</p> <p>The range of indications for the Expert Proximal Humeral Nail includes humerus fractures in adults in the subcapital area (AO/ASIF classification: A2, A3), or with concurrent avulsion of the greater tuberosity (AO/ASIF classification: Extra-articular bifocal fractures B1, B2, B3) for:</p> <ul style="list-style-type: none"> – Stable or unstable fractures – Refractures, some fractures with delayed healing and pseudoarthroses <p>In certain cases, this technique can also be suitable for proximal articular fractures (AO classification: C fractures), provided that the domed head fragment is large enough and that it is not itself fractured. The Expert Proximal Humeral Nail is inserted antegrade into the proximal humeral shaft and can be used universally for either the left or right humerus.</p>	No contraindication specific to these devices
Expert LFN	<p>Standard Locking Indications:</p> <p>The Expert Lateral Femoral Nail with standard locking is indicated for fractures in the femoral shaft:</p> <p>32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1)</p> <p>Recon Locking Indications:</p> <p>The Expert Lateral Femoral Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:</p> <p>32-A/B/C combined with 31-B (double ipsilateral fractures).</p> <p>Additionally, the Expert Lateral Femoral Nail is indicated for fractures in the subtrochanteric section:</p> <p>32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1</p>	No contraindication specific to these devices

Systems	Indications	Contraindications
Expert R/AFN	<p>Indications for retrograde approach</p> <p>In retrograde approach, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the distal femur:</p> <ul style="list-style-type: none"> – 33-A1/A2/A3 – 33-C1/C2/C3.1 <p>For the 33-C fractures, the Expert Retrograde/Antegrade Femoral Nail should be used in combination with other implants (not shown in the illustration).</p> <p>Additionally, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the femoral shaft:</p> <ul style="list-style-type: none"> – 32-A/B/C (except 32-A[1-3].1 and 32-B[1-3].1 (subtrochanteric fractures)) in case of: <ul style="list-style-type: none"> – combination with fractured patella – ipsilateral femur/tibia fractures (floating knee) – combination with fractured acetabulum, pelvis, or femoral neck – combinations of the fractures mentioned above – pronounced adipositas – pregnancy – polytrauma (if numerous surgical teams are involved in treatment of patient) <p>Note: In case of osteoporotic bone, it is strongly recommended to utilise spiral blade locking in the distal femur.</p> <p>Indications for antegrade approach</p> <p>In antegrade approach, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the femoral shaft:</p> <ul style="list-style-type: none"> – 32-A/B/C (except 32-A[1-3].1 and 32-B[1-3].1 (subtrochanteric fractures)) <p>Note: ASLS, the Angular Stable Locking System, is indicated in cases where increased stability is needed, such as in fractures closer to the metaphyseal area or in poor quality bone. For more details regarding the intramedullary fixator principle, please consult the ASLS technique guide (036.000.708) and concept flyer (036.001.017).</p>	No contraindication specific to these devices
Expert TN	<p>The Expert Tibial Nail is indicated for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon tibiale:</p> <ul style="list-style-type: none"> – 41-A2/A3 – All shaft fractures – 43-A1/A2/A3 – Combinations of these fractures <p>For these indications the Expert Tibial Nail should be used in combination with other implants (not shown in the illustrations):</p> <ul style="list-style-type: none"> – 41-C1/C2 – 43-C1/C2 	No contraindication specific to these devices
Femoral Recon Nail System	<p>Standard Locking Indications</p> <p>The Femoral Recon Nail with standard locking is indicated for fractures in the femoral shaft:</p> <ul style="list-style-type: none"> – 32-A/B/C (except subtrochanteric fractures 32-A [1-3].1, 32-B [1-3].1 and 32-C [1-3].1) <p>Recon Locking Indications</p> <p>The Femoral Recon Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:</p> <ul style="list-style-type: none"> – 32-A/B/C combined with 31-B (double ipsilateral fractures) <p>Additionally the Femoral Recon Nail is indicated for fractures in the subtrochanteric section:</p> <ul style="list-style-type: none"> – 32-A [1-3].1, 32-B [1-3].1 and 32-C [1-3].1 	No contraindication specific to these devices
MultiLoc Humeral Nailing System	<p>MultiLoc Proximal Humeral Nail (short)</p> <p>The MultiLoc Proximal Humeral Nail (short) is indicated for fractures of the proximal humerus, including:</p> <ul style="list-style-type: none"> – 2-part surgical neck fractures – 3-part fractures – 4-part fractures <p>MultiLoc Humeral Nail (long)</p> <p>The MultiLoc Humeral Nail (long) is indicated for:</p> <ul style="list-style-type: none"> – Fractures of the humeral diaphysis – Fractures of the proximal humerus with diaphyseal extension – Combined fractures of the proximal humerus and the humeral diaphysis 	No contraindication specific to these devices

Systems	Indications	Contraindications
PFN Proximal Femoral Nail	<p>Standard/Short PFN Indications:</p> <ul style="list-style-type: none"> – Pertrochanteric fractures – Intertrochanteric fractures – High subtrochanteric fractures <p>Long PFN Indications:</p> <ul style="list-style-type: none"> – Low and extended subtrochanteric fractures – Ipsilateral trochanteric fractures – Combination of fractures (trochanteric area/shaft) – Pathological fractures 	<p>Standard/Short PFN Contraindications:</p> <ul style="list-style-type: none"> – Low subtrochanteric fractures – Femoral shaft fractures – Isolated or combined medial femoral neck fractures <p>Long PFN Contraindications:</p> <ul style="list-style-type: none"> – Isolated or combined medial femoral neck fractures
PFNA	<p>PFNA short (length 170 mm–240 mm) Indications:</p> <ul style="list-style-type: none"> – Pertrochanteric fractures (31-A1 and 31-A2) – Intertrochanteric fractures (31-A3) – High subtrochanteric fractures (32-A1) <p>PFNA long (length 300 mm–420 mm) Indications:</p> <ul style="list-style-type: none"> – Low and extended subtrochanteric fractures – Ipsilateral trochanteric fractures – Combination fractures (in the proximal femur) – Pathological fractures 	<p>PFNA short (length 170 mm–240 mm) Contraindications:</p> <ul style="list-style-type: none"> – Low subtrochanteric fractures – Femoral shaft fractures – Isolated or combined medial femoral neck fractures <p>PFNA long (length 300 mm–420 mm) Contraindications:</p> <ul style="list-style-type: none"> – Isolated or combined medial femoral neck fractures
PFNA with Augmentation Option	<p>PFNA short (length 170 mm–240 mm) Indications:</p> <ul style="list-style-type: none"> – Pertrochanteric fractures (31-A1 and 31-A2) – Intertrochanteric fractures (31-A3) – High subtrochanteric fractures (32-A1) <p>PFNA long (length 300 mm–420 mm) Indications:</p> <ul style="list-style-type: none"> – Low and extended subtrochanteric fractures – Ipsilateral trochanteric fractures – Combination fractures (in the proximal femur) – Pathological fractures <p>PFNA Augmentation Indications:</p> <ul style="list-style-type: none"> – PFNA augmentation is indicated for severe osteoporotic fractures in the proximal femur – The perforated PFNA blade is also indicated without cement augmentation 	<p>PFNA short (length 170 mm–240 mm) Contraindications:</p> <ul style="list-style-type: none"> – Low subtrochanteric fractures – Femoral shaft fractures – Isolated or combined medial femoral neck fractures <p>PFNA long (length 300 mm–420 mm) Contraindications:</p> <ul style="list-style-type: none"> – Isolated or combined medial femoral neck fractures <p>PFNA Augmentation Contraindications:</p> <ul style="list-style-type: none"> – In cases where there is a risk of cement leakage into articular or vascular structures (e.g. via fractures and injuries, which open into the articulation) – Acute traumatic fractures of non-osteoporotic bone
The Universal Nail System	<ul style="list-style-type: none"> – Tibia fractures with bony support (stable fracture in the middle third of the tibia, with or without locking): – transverse fractures – short oblique fractures – pseudarthroses <p>Indications for Locking Technique Tibia fractures without bony support (unstable fractures in 60% of the tibial length):</p> <ul style="list-style-type: none"> – fractures near the metaphysis – long torsional fractures – segmental fractures – comminuted fractures – fractures with bone defects 	No contraindication specific to these devices

Systems	Indications	Contraindications
Titanium/ Stainless Steel Elastic Nail System	<p>Indications in Pediatrics</p> <p>Elastic stable intramedullary nailing (ESIN) with the Titanium Elastic Nail (TEN) or Stainless Steel Nail (STEN) is indicated for the management of diaphyseal and certain metaphyseal/epiphyseal fractures of long bones in children and young adults. As follows:</p> <ul style="list-style-type: none"> – diaphyseal and certain metaphyseal fractures of long bones – certain metaphyseal/-epiphyseal fractures (Salter Harris I and II), including but not limited to radial neck fractures – complex clavicular fractures (significant dislocation including shortening, “floating shoulder”) – open fractures – threat of skin perforation at fracture ends – pathologic fractures <p>Indications in Adults</p> <p>In adult patients, TEN is used for the osteosynthesis of clavicle, forearm and humerus fractures. As follows:</p> <ul style="list-style-type: none"> – diaphyseal fractures of long bone fractures in upper extremity – clavicle shaft fractures 	No contraindication specific to these devices
UHN/PHN Humeral Nailing System	<p>UHN</p> <p>The range of indications for the UHN includes humeral shaft fractures down to approx. 5 cm proximal to the olecranon fossa with closed epiphyseal lines for:</p> <ul style="list-style-type: none"> – stable or unstable fractures – refractures, fractures with delayed healing and pseudoarthroses <p>PHN</p> <p>The range of indications for the PHN includes humerus fractures in adults in the subcapital area (AO/ASIF classification: A2, A3), or with concurrent avulsion of the greater tuberosity (AO/ASIF classification: Extra-articular bifocal fractures B1, B2) for:</p> <ul style="list-style-type: none"> – stable or unstable fractures – refractures, fractures with delayed healing and pseudoarthroses <p>In certain cases, joint fractures at the head of the humerus can also be managed by this technique (AO classification: C fractures), provided that the domed head fragment is large enough and that it is not itself fractured.</p>	No contraindication specific to these devices
UTN/CTN Solid/ Cannulated Tibial Nail	<p>The Solid Tibial Nail (UTN) and Cannulated Tibial Nail (CTN) are used for the fixation of tibial shaft fractures. Because of its anatomical cross-section, the UTN is more suited to the unreamed technique, while the CTN, with its round cross-section, is more suited to the reamed technique.</p> <p>Indications for UTN</p> <ul style="list-style-type: none"> – Fractures, types 42-A to 42-C – Closed fractures, types 0 to 3 (Tscherne classification) – Open fractures, types I to IIIA, IIB and IIIC (Gustilo classification) <p>Indications for CTN</p> <ul style="list-style-type: none"> – Fractures, types 42-A to 42-C – Closed fractures, types 0 to 2 (Tscherne classification) – Open fractures, types I to IIIA (Gustilo classification) – Pseudoarthroses – Nonunions 	<p>Contraindications for UTN</p> <ul style="list-style-type: none"> – Infections – Pseudoarthroses – Nonunions <p>Contraindications for CTN</p> <ul style="list-style-type: none"> – Infections – Closed fractures, type 3 (Tscherne classification) – Open fractures, types IIB and IIIC (Gustilo classification)
PFNA-II	<p>PFNA-II short (length 170 mm–240 mm)</p> <p>Indications:</p> <ul style="list-style-type: none"> – Pertrochanteric fractures (31-A1 and 31-A2) – Intertrochanteric fractures (31-A3) – High subtrochanteric fractures (32-A1) <p>PFNA-II long (length 260 mm–420 mm)</p> <p>Indications:</p> <ul style="list-style-type: none"> – Low and extended subtrochanteric fractures – Ipsilateral trochanteric fractures – Combination fractures (in the proximal femur) – Pathological fractures 	<p>PFNA-II short (length 170 mm–240 mm)</p> <p>Contraindications:</p> <ul style="list-style-type: none"> – Low subtrochanteric fractures – Femoral shaft fractures – Isolated or combined medial femoral neck fractures <p>PFNA-II long (length 260 mm–420 mm)</p> <p>Contraindications:</p> <ul style="list-style-type: none"> – Isolated or combined medial femoral neck fractures

Systems	Indications	Contraindications
Set Screw for Trochanteric Fixation Nail	The Synthes Titanium Trochanteric Fixation Nail (TFN) is intended to treat stable and unstable pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures of osteoporotic bone (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal nonunions, malunions, and revisions.	No contraindication specific to these devices
Suprapatellar Instrumentation for Expert Tibial Nail	The Expert Tibial Nail is indicated for fractures in the tibial shaft as well as for metaphyseal and certain intra-articular fractures of the tibial head and the pilon tibiale: – 41-A2/A3 – All shaft fractures – 43-A1/A2/A3 – Combinations of these fractures For these indications the Expert Tibial Nail should be used in combination with other implants (not shown in the illustrations): – 41-C1/C2 – 43-C1/C2	No contraindication specific to these devices
TFN – Titanium Trochanteric Fixation Nail System	The Synthes Titanium Trochanteric Fixation Nail (TFN) is intended to treat stable and unstable pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures of osteoporotic bone (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal nonunions, malunions, and revisions.	No contraindication specific to these devices
TFNA – Proximal Femoral Nailing System	TFNA short (lengths 170 mm, 200 mm, 235 mm) Indications: – Pertrochanteric fractures (31-A1 and 31-A2) – Intertrochanteric fractures (31-A3) – 235 mm nails are additionally indicated for high subtrochanteric fractures TFNA LONG (lengths 260 mm–480 mm) Indications: – Pertrochanteric fractures (31-A1 and 31-A2) – Intertrochanteric fractures (31-A3) – Fractures of the trochanteric area (31-A1/A2/A3) with diaphyseal extension – Combined fractures of the trochanteric area (31-A1/A2/A3) and the femoral shaft (32-A/B/C) – Pathological fractures, including prophylactic use – Malunions – Nonunions TFNA Augmentation Indications: – For fractures in the proximal femur with poor bone quality and/or increased risk of fixation failure at the implant/bone interface	TFNA short (lengths 170 mm, 200 mm, 235 mm) Contraindications – Femoral neck fractures (31-B) – Femoral shaft fractures (32-A/B/C) TFNA LONG (lengths 260 mm–480 mm) Contraindications: – Femoral neck fractures (31-B) TFNA Augmentation Contraindications: – Tumor related pathologies at the augmentation area – Risk for intraarticular or vascular cement leakage – Acute traumatic fractures with good bone quality
TFN Advanced – for TFNA Screw only	TFNA short (lengths 170 mm, 200 mm, 235 mm) Indications: – Pertrochanteric fractures (31-A1 and 31-A2) – Intertrochanteric fractures (31-A3) – 235 mm nails are additionally indicated for high subtrochanteric fractures	TFNA short (lengths 170 mm, 200 mm, 235 mm) Contraindications – Femoral neck fractures (31-B) – Femoral shaft fractures (32-A/B/C)
Systems	Indications	Indication-Restrictions
UFN Unreamed Femoral Nail CFN Cannulated Femoral Nail	Indications for Femoral Nailing: The range of implants available for intramedullary fixation of the femur has grown over the years. They differ in design (slotted/unslotted, unreamed/cannulated, small/large diameter, static/dynamic locking), materials (steel/titanium) and technical application (with/without reaming). Considerable overlap exists for the indications. Indications for all intramedullary implants for the femur: – Shaft fractures – Metaphyseal fractures that allow the placement of locking bolts and thus stable fixation	Indication restrictions for all intramedullary implants for the femur – Serious contamination – Presence of an acute infection – Metaphyseal fractures that do not allow adequate placement of locking bolts (location, bone too weak) – Risk of unstable or displaced fixation
	CFN Cannulated Femoral Nail – Standard Locking (TAN [Titanium-Aluminum-Niobium alloy]), cannulated, for procedures with or without reaming): – All shaft fractures (32-A1–C3) and all open and closed fractures – Cases in which the use of a guide wire is considered beneficial – Pseudoarthrosis, non-union	CFN Cannulated Femoral Nail – Standard Locking (TAN [Titanium-Aluminum-Niobium alloy]), cannulated, for procedures with or without reaming): – Reaming should be avoided in patients with lung injuries, major head injuries, haemodynamic instability, coagulopathy or hypothermia – Multiple trauma patients

Systems	Indications	Indication-Restrictions
UFN Unreamed Femoral Nail CFN Cannulated Femoral Nail	UFN Unreamed Femoral Nail (Standard Locking – TAN, unreamed, for procedures without reaming): – All shaft fractures (AO 32-A1-C3) and all open and closed fractures – Cases in which the avoidance of reaming is considered beneficial – Modification of external fixator treatment.	UFN Unreamed Femoral Nail (Standard Locking – TAN, unreamed, for procedures without reaming): – Subtrochanteric fractures – Pseudoarthrosis, non-union – Multiple trauma patients
	UFN/CFN – Proximal Spiral Blade Locking (TAN): As for UFN/CFN standard locking, but with subtrochanteric fractures with an intact lesser trochanter	UFN/CFN – Proximal Spiral Blade Locking (TAN): – Fractures with fractured lesser trochanter – Pseudoarthrosis, non-union of the femoral shaft – Multiple trauma patients
	UFN – Miss-A-Nail Technique (TAN): As for UFN standard locking, but with ipsilateral femoral neck fracture	UFN – Miss-A-Nail Technique (TAN): – Fractures with fractured lesser trochanter – Pseudoarthrosis, non-union of the femoral shaft – Multiple trauma patients
	UFN/CFN – 130° Antegrade Locking (TAN): As for UFN/CFN standard locking, but with subtrochanteric fractures with intact lesser trochanter	UFN/CFN – 130° Antegrade Locking (TAN): – Fractures with fractured lesser trochanter – Pseudoarthrosis, non-union of the femoral shaft – Multiple trauma patients
	PFN Proximal Femoral Nail, standard (TAN, unreamed, for procedures with or without reaming): – Inter- and high subtrochanteric fractures, incl. unstable fractures – Petrochanteric fractures	PFN Proximal Femoral Nail, standard (TAN, unreamed, for procedures with or without reaming): – Long subtrochanteric or shaft fractures – Pseudoarthrosis, non-union of the femoral shaft – Femoral neck fractures (isolated or combined) – Multiple trauma patients
	PFN Proximal Femoral Nail, long (TAN, cannulated, for procedures with or without reaming): – Long subtrochanteric fractures – Petrochanteric fractures – Combined inter-, subtrochanteric and ipsilateral shaft fractures – (Impending) pathological fractures	PFN Proximal Femoral Nail, long (TAN, cannulated, for procedures with or without reaming): – Femoral neck fractures (isolated or combined) – Multiple trauma patients
DFN Distal Femoral Nail (TAN, unreamed, for procedures with or without reaming): – Fractures 33-A1–3 – Fractures 33-C1–2 – Femoral shaft fractures of the distal third 32-A1–C3	DFN Distal Femoral Nail (TAN, unreamed, for procedures with or without reaming): – Fractures AO 33-C3 – Fractures AO 33-B1–3 – Proximal shaft- and subtrochanteric fractures	
Indications for UFN/CFN: The unreamed femoral nail (UFN) and the cannulated femoral nail (CFN) are used to stabilize diaphyseal and metaphyseal fractures of the femur. The UFN is preferably used with the unreamed technique while, since it is cannulated, the CFN is primarily used with the reamed technique using a guide wire.		
Indications for UFN/CFN – Locking: The nail must be inserted carefully so as to limit the distraction on the fractured side (healing promotion). The distal end should be locked first. Before locking the proximal end, ensure that the fracture is not distracted. To close any fracture gap in a simple fracture, knock back the distally locked bone fragment with the slotted hammer. Placing screws in both distal locking holes minimizes screw deformation. In general, the femoral nails must be locked both proximally and distally. Axially stable and rotationally unstable fractures can be locked dynamically in the long slot (primary dynamization). Axially and rotationally unstable fractures should be locked statically both proximally and distally. In cases where stability cannot be assessed, or can only be assessed with difficulty, the more restrictive form of locking should always be selected.		
Indications for UFN/CFN – Dynamization: In the nailing of femoral fractures, secondary dynamization (removal of the static proximal locking bolt) does not play an important role and should not be performed as a matter of routine. Dynamization is possible however if significant distraction is present. If no callus has formed in a later treatment phase (after 3 or more months), dynamization alone is not normally beneficial.		
Indications for UFN/CFN – Weight-Bearing: The fracture type, fracture site, soft tissue situation and bone quality should be taken into account when deciding on weight-bearing. Partial weight-bearing (contact with the sole of the foot or 15 kg) is the initial situation for weight-bearing on the broken leg. Full weight-bearing should be avoided. The increase in weight-bearing is determined by the fracture type, fracture site, soft tissue situation and bone quality and also by the presence or absence of pain on weight-bearing.		

Systems	Indications	Contraindications
UFN Unreamed Femoral Nail CFN Cannulated Femoral Nail	<p>Indications for UFN/CFN:</p> <p>A) Standard Locking: Two standard locking configurations are possible: static transverse and dynamic transverse locking Femoral shaft fractures</p> <p>B) Spiral Blade Locking: The spiral blade provides secure fixation of the proximal fragment and good stability for pathological or impending pathological subtrochanteric fractures. A static locking bolt may be used in conjunction with the spiral blade locking technique. Subtrochanteric fractures</p> <p>C) Miss-A-Nail Technique: The Miss-A-Nail technique permits insertion of cannulated screws into the femoral head prior to or after intramedullary fixation of the shaft fracture. In cases of occult fractures of the femoral neck, it also permits screw insertion into the femoral head after nail insertion. Ipsilateral femoral neck or shaft fractures</p> <p>D) 130° Antegrade Locking: In 130° antegrade locking, a static locking bolt may be optionally used in addition. Femoral shaft fractures or stable subtrochanteric fractures</p>	<p>Cannulated Femoral Nail (CFN)/Unreamed Femoral Nail (UFN)</p> <p>A) Standard Locking: No Specific Contraindication. B) Spiral Blade Locking: Inter- and pertrochanteric fractures C) Miss-A-Nail Technique: Fractures with a detached lesser trochanter D) 130° Antegrade Locking: Fractures with a detached lesser trochanter</p>

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