Instructions for Use
TFN-ADVANCED Proximal Femoral Nailing System

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

Not all products are currently available in all markets.

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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TFNA, ∅ 9 mm, long

Right	Left	Length (mm)	Femoral Neck Angle
04.037.916S	04.037.917S	260	125°
04.037.918S	04.037.919S	280	125°
04.037.920S	04.037.921S	300	125°
04.037.922S	04.037.923S	320	125°
04.037.924S	04.037.925S	340	125°
04.037.926S	04.037.927S	360	125°
04.037.928S	04.037.929S	380	125°
04.037.930S	04.037.931S	400	125°
04.037.932S	04.037.933S	420	125°
04.037.934S	04.037.935S	440	125°
04.037.936S	04.037.937S	460	125°
04.037.938S	04.037.939S	480	125°
04.037.946S	04.037.947S	260	130°
04.037.948S	04.037.949S	280	130°
04.037.950S	04.037.951S	300	130°
04.037.952S	04.037.953S	320	130°
04.037.954S	04.037.955S	340	130°
04.037.956S	04.037.957S	360	130°
04.037.958S	04.037.959S	380	130°
04.037.960S	04.037.961S	400	130°
04.037.962S	04.037.963S	420	130°
04.037.964S	04.037.965S	440	130°
04.037.966S	04.037.967S	460	130°
04.037.968S	04.037.969S	480	130°

TFNA, ∅ 10 mm, long

Right	Left	Length (mm)	Femoral Neck Angle
04.037.016S	04.037.017S	260	125°
04.037.018S	04.037.019S	280	125°
04.037.020S	04.037.021S	300	125°
04.037.022S	04.037.023S	320	125°
04.037.024S	04.037.025S	340	125°
04.037.026S	04.037.027S	360	125°
04.037.028S	04.037.029S	380	125°
04.037.030S	04.037.031S	400	125°
04.037.032S	04.037.033S	420	125°
04.037.034S	04.037.035S	440	125°
04.037.036S	04.037.037S	460	125°
04.037.038S	04.037.039S	480	125°
04.037.046S	04.037.047S	260	130°
04.037.048S	04.037.049S	280	130°
04.037.050S	04.037.051S	300	130°
04.037.052S	04.037.053S	320	130°
04.037.054S	04.037.055S	340	130°
04.037.056S	04.037.057S	360	130°
04.037.058S	04.037.059S	380	130°
04.037.060S	04.037.061S	400	130°
04.037.062S	04.037.063S	420	130°
04.037.064S	04.037.065S	440	130°
04.037.066S	04.037.067S	460	130°
04.037.068S	04.037.069S	480	130°

TFNA, ∅ 11 mm, long

Right	Left	Length (mm)	Femoral Neck Angle
04.037.120S	04.037.121S	300	125°
04.037.122S	04.037.123S	320	125°
04.037.124S	04.037.125S	340	125°
04.037.126S	04.037.127S	360	125°
04.037.128S	04.037.129S	380	125°
04.037.130S	04.037.131S	400	125°
04.037.132S	04.037.133S	420	125°
04.037.134S	04.037.135S	440	125°
04.037.136S	04.037.137S	460	125°
04.037.138S	04.037.139S	480	125°
04.037.150S	04.037.151S	300	130°
04.037.152S	04.037.153S	320	130°
04.037.154S	04.037.155S	340	130°
04.037.156S	04.037.157S	360	130°
04.037.158S	04.037.159S	380	130°
04.037.160S	04.037.161S	400	130°
04.037.162S	04.037.163S	420	130°
04.037.164S	04.037.165S	440	130°
04.037.166S	04.037.167S	460	130°
04.037.168S	04.037.169S	480	130°
04.037.180S	04.037.181S	300	135°
04.037.182S	04.037.183S	320	135°
04.037.184S	04.037.185S	340	135°
04.037.186S	04.037.187S	360	135°
04.037.188S	04.037.189S	380	135°
04.037.190S	04.037.191S	400	135°
04.037.192S	04.037.193S	420	135°
04.037.194S	04.037.195S	440	135°
04.037.196S	04.037.197S	460	135°
04.037.198S	04.037.199S	480	135°

TFNA, ∅ 12 mm, long

Right	Left	Length (mm)	Femoral Neck Angle
04.037.220S	04.037.221S	300	125°
04.037.222S	04.037.223S	320	125°
04.037.224S	04.037.225S	340	125°
04.037.226S	04.037.227S	360	125°
04.037.228S	04.037.229S	380	125°
04.037.230S	04.037.231S	400	125°
04.037.232S	04.037.233S	420	125°
04.037.234S	04.037.235S	440	125°
04.037.236S	04.037.237S	460	125°
04.037.238S	04.037.239S	480	125°
04.037.250S	04.037.251S	300	130°
04.037.252S	04.037.253S	320	130°
04.037.254S	04.037.255S	340	130°
04.037.256S	04.037.257S	360	130°
04.037.258S	04.037.259S	380	130°
04.037.260S	04.037.261S	400	130°
04.037.262S	04.037.263S	420	130°
04.037.264S	04.037.265S	440	130°
04.037.266S	04.037.267S	460	130°
04.037.268S	04.037.269S	480	130°

TFNA, ∅ 14 mm, long

Right	Left	Length (mm)	Femoral Neck Angle
04.037.450S	04.037.451S	300	130°
04.037.452S	04.037.453S	320	130°
04.037.454S	04.037.455S	340	130°
04.037.456S	04.037.457S	360	130°
04.037.458S	04.037.459S	380	130°
04.037.460S	04.037.461S	400	130°
04.037.462S	04.037.463S	420	130°
04.037.464S	04.037.465S	440	130°
04.037.466S	04.037.467S	460	130°
04.037.468S	04.037.469S	480	130°

TFNA, short, length 170 mm

Right	Dia. (mm)	Femoral Neck Angle
04.037.912S	9	125°
04.037.942S	9	130°
04.037.972S	9	135°
04.037.012S	10	125°
04.037.042S	10	130°
04.037.072S	10	135°
04.037.112S	11	125°
04.037.142S	11	130°
04.037.172S	11	135°
04.037.212S	12	125°
04.037.242S	12	130°
04.037.272S	12	135°

TFNA, short, length 200 mm

Right	Dia. (mm)	Femoral Neck Angle
04.037.913S	9	125°
04.037.943S	9	130°
04.037.973S	9	135°
04.037.013S	10	125°
04.037.043S	10	130°
04.037.073S	10	135°
04.037.113S	11	125°
04.037.143S	11	130°
04.037.173S	11	135°
04.037.213S	12	125°
04.037.243S	12	130°
04.037.273S	12	135°

TFNA, short, length 235 mm

Right	Left	Length (mm)	Femoral Neck Angle
04.037.914S	04.037.915S	9	125°
04.037.944S	04.037.945S	9	130°
04.037.974S	04.037.975S	9	135°
04.037.014S	04.037.015S	10	125°
04.037.044S	04.037.045S	10	130°
04.037.074S	04.037.075S	10	135°
04.037.114S	04.037.115S	11	125°
04.037.144S	04.037.145S	11	130°
04.037.174S	04.037.175S	11	135°
04.037.214S	04.037.215S	12	125°
04.037.244S	04.037.245S	12	130°
04.037.274S	04.037.275S	12	135°

TFNA Screws*

	Length (mm)		Length (mm)
04.038.070	70	04.038.105	105
04.038.075	75	04.038.110	110
04.038.080	80	04.038.115	115
04.038.085	85	04.038.120	120
04.038.090	90	04.038.125	125
04.038.095	95	04.038.130	130
04.038.100	100		

TFNA Helical Blades*

	Length (mm)		Length (mm)
04.038.270	70	04.038.305	105
04.038.275	75	04.038.310	110
04.038.280	80	04.038.315	115
04.038.285	85	04.038.320	120
04.038.290	90	04.038.325	125
04.038.295	95	04.038.330	130
04.038.300	100		

TFNA Helical Blades, perforated

	Length (mm)		Length (mm)
04.038.370S	70	04.038.405S	105
04.038.375S	75	04.038.410S	110
04.038.380S	80	04.038.415S	115
04.038.385S	85	04.038.420S	120
04.038.390S	90	04.038.425S	125
04.038.395S	95	04.038.430S	130
04.038.400S	100		

TFNA Screws, perforated

	Length (mm)		Length (mm)
04.038.170S	70	04.038.205S	105
04.038.175S	75	04.038.210S	110
04.038.180S	80	04.038.215S	115
04.038.185S	85	04.038.220S	120
04.038.190S	90	04.038.225S	125
04.038.195S	95	04.038.230S	130
04.038.200S	100		

Locking Screw for Medullary Nails, ∅ 5 mm*

	Length (mm)		Length (mm)
04.045.026	26	04.045.066	66
04.045.028	28	04.045.068	68
04.045.030	30	04.045.070	70
04.045.032	32	04.045.072	72
04.045.034	34	04.045.074	74
04.045.036	36	04.045.076	76
04.045.038	38	04.045.078	78
04.045.040	40	04.045.080	80
04.045.042	42	04.045.082	82
04.045.044	44	04.045.084	84
04.045.046	46	04.045.086	86
04.045.048	48	04.045.088	88
04.045.050	50	04.045.090	90
04.045.052	52	04.045.095	95
04.045.054	54	04.045.100	100
04.045.056	56	04.045.105	105
04.045.058	58	04.045.110	110
04.045.060	60	04.045.115	115
04.045.062	62	04.045.120	120
04.045.064	64		

Locking Screw for Medullary Nails, Low Profile, ∅ 5 mm*

	Length (mm)		Length (mm)
04.045.326	26	04.045.366	66
04.045.328	28	04.045.368	68
04.045.330	30	04.045.370	70
04.045.332	32	04.045.372	72
04.045.334	34	04.045.374	74
04.045.336	36	04.045.376	76
04.045.338	38	04.045.378	78
04.045.340	40	04.045.380	80
04.045.342	42	04.045.382	82
04.045.344	44	04.045.384	84
04.045.346	46	04.045.386	86
04.045.348	48	04.045.388	88
04.045.350	50	04.045.390	90
04.045.352	52	04.045.395	95
04.045.354	54	04.045.400	100
04.045.356	56	04.045.405	105
04.045.358	58	04.045.410	110
04.045.360	60	04.045.415	115
04.045.362	62	04.045.420	120
04.045.364	64		

End Caps

	Length (mm)
04.045.870S	0
04.045.875S	5
04.045.880S	10
04.045.885S	15

Nut and Washers

04.045.780S	Washer ∅ 14/7
04.045.781S	Nut ∅ 14
04.045.782S	Washer ∅ 17.5/11.8

Alternatively, the TFNA implants can be applied using associated instrumentation and a set of the following compatible screw implants:

Locking Screw Stardrive® ∅ 5 mm*

	Length (mm)		Length (mm)
04.005.516	26	04.005.548	58
04.005.518	28	04.005.550	60
04.005.520	30	04.005.552	62
04.005.522	32	04.005.554	64
04.005.524	34	04.005.556	66
04.005.526	36	04.005.558	68
04.005.528	38	04.005.560	70
04.005.530	40	04.005.562	72
04.005.532	42	04.005.564	74
04.005.534	44	04.005.566	76
04.005.536	46	04.005.568	78
04.005.538	48	04.005.570	80
04.005.540	50	04.005.575	85
04.005.542	52	04.005.580	90
04.005.544	54	04.005.585	95
04.005.546	56	04.005.590	100

End Caps

	Length (mm)
04.038.000S	0
04.038.005S	5
04.038.010S	10
04.038.015S	15

* Available non-sterile or sterile packed. Add "S" to the catalogue number to order sterile products."

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

The screws are also available in sterile tube packaging (corresponding article number with suffix "TS").

Screw length designations are defined to reflect the readings on the length measurement tools and do not necessarily correspond to the actual total length of the screw.

Introduction

The TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA) consists of cannulated femoral nails, helical blades or screws, end caps and locking screws. The TFNA Nail is anatomically contoured and tapers to a nominal diameter of 9, 10, 11, 12, or 14 mm. The proximal locking hole accommodates angles ranging from 125°–135°. TFNA Nails are available in short lengths (170–235 mm) and long nail lengths (260–480 mm), with the lengths 235 mm and above available in right or left versions. The TFNA accepts commercially available Synthes 4.9 mm Locking Bolts and/or 5.0 mm Locking Screws. This system is manufactured from titanium alloy and are provided in sterile and non-sterile packaging. TFNA also has the option for cement augmentation of the TFNA Blade (perforated or non-perforated) and TFNA Screw (perforated or non-perforated).

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" (SE_023827) carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials

Device(s)	Material(s)	Standard(s)
Nails	Ti-15Mo (TiMo) Titanium Alloy	ASTM F2066
Nails (Locking Mechanism), End Caps, Head Elements (helical blades and screws), Locking Screws, Nut	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11 ASTM F1295
Nails (Locking Mechanism)	40Co-20Cr-16Fe-15Ni-7Mo (Elgiloy)	ISO 5832-7 ASTM F1058
Washers	TiCP	ISO 5832-2 ASTM F67

Intended Use
Proximal Femoral Nailing Implants – including the TFNA implants – are intended to be used for temporary fixation and stabilization of the proximal femur and the femoral shaft.

Indications
TFNA SHORT (lengths 170 mm, 200 mm, 235 mm)
– 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)
– 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
– Non-unions

TFNA AUGMENTATION
– For fractures in the proximal femur with poor bone quality and/or increased risk of fixation failure at the implant/bone interface.

For indications and contraindications of the "TRAUMACEM™ V+ Injectable Bone Cement", the "TRAUMACEM V+ Syringe Kit" and the "TRAUMACEM V+ Injection Cannula", please consult the corresponding "Instructions for Use".

Contraindications
TFNA SHORT (lengths 170 mm, 200 mm, 235 mm)
– Femoral neck fractures (31-B)
– Femoral shaft fractures (32-A/B/C)

TFNA LONG (lengths 260 mm–480 mm)
– Femoral neck fractures (31-B)

TFNA AUGMENTATION
– Risk for intraarticular or vascular cement leakage
– Acute traumatic fractures with good bone quality

Patient Target Group
The TFNA implants are recommended for use in skeletally mature patients.

Intended User
This IFU alone does not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and/or the Synthes brochure "Important Information" (SE_023827) as appropriate.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of internal fixation devices such as TFNA implants when used according to instructions for use and recommended technique are:
– Stabilize bone segment and facilitate healing
– Restore anatomical alignment and extremity function

Performance Characteristics of the Device
TFNA is designed to reduce the risk of post-operative complications associated with hip fractures by providing surgical options to enhance stability in poor bone, improved anatomical fit, and increased implant strength. It is also designed to provide a range of options to support surgical preferences and patient anatomies including choice of augmentable blade or screw head elements, various locking options, and a range of nail sizes.

General Notes:
– Implants are designed for temporary fixation. Therefore, if bone consolidation is not sufficient the system may fail over time.
– There are many types of implant failures, including but not limited to implant breakage.
– There are several factors that can influence implant failure including fracture reduction, surgical technique, obesity, level of activity/weight-bearing, and non-union or delayed union. Surgeons should consider these factors in intra-operative care for bone consolidation. These failures can occur post-operatively and may require reoperation.
– The aim of post-operative care must be the promotion of bone consolidation.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
– Adverse tissue reaction, allergy/hypersensitivity reaction
– Bone damage including intra- and post-operative bone fracture, osteolysis, or bone necrosis
– Damage to vital organs or surrounding structures
– Embolism
– Infection
– Injury to user
– Malunion/Non-union
– Neuro-vascular damage
– Pain or discomfort
– Poor joint mechanics
– Soft tissue damage (including compartment syndrome)
– Symptoms resulting from implant migration, loosening, bending, cut-out, or breakage

Sterile Device

Sterilized using irradiation

Store sterile devices 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.

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.

Warnings and Precautions
The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information" (SE_023827).

It is strongly advised that TFNA implants are implanted only by operating surgeons who are familiar with the general problems of trauma surgery and who are able to master the product-specific surgical procedures. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

WARNINGS
- It is critical to ensure proper selection of the implant meets the needs of the patient anatomy and the presenting trauma.
- The TFNA Nail is not intended for full weight-bearing in patients with complex unstable fractures until sufficient bone consolidation is confirmed in the follow up X-rays.
- Conditions that place excessive stresses on bone and implant such as severe obesity or degenerative diseases should be considered. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patients.
- Use of these devices is not recommended when there is systemic infection, infection localized to the site of the proposed implantation or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Physician should consider patient bone quality to ensure it provides adequate fixation to promote healing.
- Compromised vascularity in the site of proposed implantation may prevent adequate healing and thus preclude the use of this or any orthopaedic implant.
- Physician should take into account an increase in medullary pressure occurring during medullary nailing or reaming. This releases varying amounts of bone marrow and fat into the venous blood system.
- Do not augment if X-ray contrast media leaks into the joint.
- The 6 mm minimum distance is recommended to reduce the risk of thermal injury to the adjacent cartilage tissue.
- In the event that there is danger of cement leakage into the joint, fracture gap or venous system, stop injection immediately.
- If the extravasated cement conforms to the architecture of the hip joint, it may not need to be removed. However, if it does not conform and is abrasive or damages the articular surface, then the extruded cement will need to be removed.
- To remove the cement, the treating physician has the option of either hip arthroscopy, arthroplasty, or open arthrotomy to remove the extruded pieces. The timing of the removal is at the discretion of the physician after appropriate evaluation of the patient.

PRECAUTIONS
For additional precautions specific to a surgical step, please refer to the Special Operating Instructions.

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

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F2119-07
Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

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

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

Treatment before Device is used

Non-sterile Device:
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" (SE_023827).

Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.
Store sterile devices 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.

Implant Removal
In case the physician decides to remove the implants, the following steps shall be followed:

1. Carefully dissect the soft tissues and visualize the end cap. Remove the end cap with a retaining Synthes screwdriver.
2. Carefully dissect the soft tissues and visualize the screw heads. In the case of screw head overgrowth or damaged recess, optional instruments are available for screw removal for example if required, a curette and a sharp hook to clear recess from tissue; an extractor shaft and a conical extraction screw to remove screws with damaged recess. Remove all locking screws.
3. Thread the extraction screw into the nail.
4. Disengage locking mechanism and remove helical blade or screw.
5. Remove the nail.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Processing 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" (SE_023827).

Device-related Storage and Handling Information


Caution, see instructions for use.

Additional Device-specific Information


Reference number

Lot or batch number


Legal manufacturer


Expiration date

Disposal
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.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions

1. Position the patient in the lateral decubitus or supine position on a fracture table or radiolucent operating table. Position the image intensifier to allow visualization of the proximal femur in both the AP and lateral planes.

2. Reduce fracture.
Precaution: Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
Precaution: Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.

3. Determine CCD angle.

4. Determine nail length and diameter.
Measure using the radiographic ruler.
Alternative: Nail length may also be determined by using a reaming rod.

5. Identify nail entry point.
Make a longitudinal incision proximal to the greater trochanter. In the AP view, the nail insertion point is on the tip or slightly lateral to the tip of the greater trochanter, in the curved extension of the medullary cavity. This represents a point, 5° lateral of the femoral shaft axis, measured from a point just below the lesser trochanter, as the ml angle of the nail is 5°.

6. Insert guide wire.
Confirm guide wire placement in both the AP and lateral planes. Insert to a depth of approximately 15 cm.

7. Open canal.
Guide the cannulated drill bit over the guide wire through the protection sleeve to the bone and drill to the stop.
Precaution: Guide wires are single-use items, do not re-use.
Option: Open canal with the hollow reamer.
Precaution: Monitor the drill depth under image intensifier throughout the procedure.

8. Option: Ream medullary canal.
Option: The reamer protection tube can be used to help protect the proximal metaphysis during reaming.

9. Assemble insertion instruments.
Match the geometry of the insertion handle to the nail. Pass the connecting screw through the insertion handle and into the nail. Secure the assembly with the ball hex screwdriver.
Precaution: Ensure that the connection between the nail and the insertion handle is tight (retighten if necessary).
Precaution: Do not attach the aiming arm to the insertion handle yet.
Precaution: If a 235 mm or longer nail is selected, reconfirm that the correct nail (right or left) is assembled.

10. Insert nail.
Under image intensification, verify fracture reduction and insert the nail as far as possible by hand. Use the insertion assembly to manipulate the nail across the fracture.
Option: To use a hammer, screw the driving cap onto the hybrid insertion handle. Monitor the tip of the nail using image intensification.
Precaution: Using light blows, the hammer can also be used with the hammer guide to back slap the nail if the nail has been slightly over inserted.
Precaution: Confirm that the nail is tightly connected to the insertion handle as hammering may loosen the connection.

11. Verify nail insertion depth and anteversion.
Verify nail insertion depth and position for the helical blade/screw. Adjust nail rotation.

12. Insert guide sleeve
Precaution: The distal tooth of the guide sleeve should rest on the lateral cortex. Do not overtighten on the cortex as this may affect the accuracy of the aiming assembly.
Precaution: The fatigue strength of the nail may be affected and may contribute to the potential for the nail to fracture if the nail is damaged during any step of the helical blade/screw reaming in addition to other factors such as fracture reduction, surgical technique, obesity, level of activity/weight-bearing, non-union, or delayed union.

13. Insert guide wire for helical blade/screw
Precaution: If the nail must be repositioned to improve guide wire placement, remove the guide sleeve assembly and adjust with the insertion handle. Make a new incision for insertion of the guide sleeve, if necessary. Do not pull on the guide sleeve or power tool to make this adjustment as this could affect the accuracy of the aiming.
Precaution: The fatigue strength of the nail may be affected and may contribute to the potential for the nail to fracture if the nail is damaged during any step of the helical blade/screw reaming in addition to other factors such as fracture reduction, surgical technique, obesity, level of activity/weight-bearing, non-union, or delayed union.
Precaution: Do not reuse guide wires as they may bend during initial use. If the guide is deformed during insertion, use a new guide and discard the deformed guide wire.
Precaution: Insert the guide wire for the blade or screw carefully to avoid penetration of the guide wire into the joint. Penetration of the articular surface is a contraindication for the augmentation of the blade or screw.

14. Measure helical blade/screw length.

15. Open lateral cortex for helical blade/screw insertion.
Precaution: Monitor the drill depth under image intensifier throughout the procedure.
16. Option A: Helical blade insertion.
Precaution: Image intensifier should be used during helical blade insertion to monitor positioning.
Precaution: Assure that the guide wire is in place while inserting the helical blade to prevent the cannulation from clogging, impeding an optional augmentation procedure.

17. Option B: Screw insertion.
Precaution: There is no stop on the tap, therefore monitoring insertion via the following methods is recommended:
– Monitor the depth under image intensifier
– Monitor the respective graduations of the instrument shaft in relation to the guide sleeve
Precaution: Image intensifier should be used during screw insertion to monitor positioning.
Precaution: Assure that the guide wire is in place while inserting the screw to prevent the cannulation from clogging, impeding an optional augmentation procedure.

18. Rotational locking.
Precaution: If the locking mechanism is not turned back ½ turn after initial tightening as described above, controlled collapse and compression of the fracture may not occur.

19. Interfragmentary compression (option).
Precaution: Caution should be taken when using the buttress/compression nut with the pin wrench to avoid over compression that could potentially cause the helical blade to lose purchase in the bone, especially in patients with poor bone quality.

20. Augmentation.
It is recommended to use 3 ml of cement for augmentation.
Precaution: The working time for TRAUMACEM V+ Injectable Bone Cement at room temperature (20 °C) is approximately 27 minutes. At body temperature (37 °C) the setting time is 15 minutes. After last cement injection, the patient should remain immobile for 15 minutes to facilitate proper cement curing.
Precaution: Use only radiographic contrast agents that are indicated for this application.
Precaution: Consult the manufacturer's directions on indications, contraindications, use, precautions, warnings and side effects of the radiographic contrast agent.
Precaution: Always use the full amounts of monomer liquid and polymer powder provided in the kit, respectively, when mixing TRAUMACEM V+ Injectable Bone Cement. Otherwise, the behavior of the TRAUMACEM V+ Injectable Bone Cement can no longer be guaranteed. Using only one of the components is not permitted.
Precaution: Ensure that the powder and liquid component are thoroughly mixed before starting cement transfer.
Precaution: Ensure a good fit between the syringe and the stop-cock/used access solution, but make sure to be on axis and avoid using excessive force when coupling them. They are both made of plastic and could otherwise break.
Precaution: Do not advance the cannula more than 5 mm over the selected head element length. This would result in injection of cement in front of the head element tip where no additional stability is achieved and the risk of penetration and cement leakage is increased.

21. Distal locking.
Precaution: Confirm that the nail is securely connected to the insertion handle, especially after hammering.
Read length from the calibrated drill bits or measure length using depth gauge for locking screws.
Precaution: Select adequate screw length to avoid protrusion of the screw tip and irritation of soft tissue.
5.0 mm locking screws can be connected to the screwdriver with the associated retention pin; this does not apply to the alternative locking screws Stardrive®.
Precaution: The screw must not be tightened with the power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle to bring the screw to its final position.
Ensure drill bits, screws, nuts or washers do not interfere with other medical devices (e.g. knee prosthesis, nail, other screws) and/or critical anatomy (e.g. condylar notch, joint space).
Nut should only be used with the 5.0 mm Locking Screws for Medullary Nails.

22. Insert end cap.
0 mm end cap: Remove the connecting screw using the ball hexagonal screwdriver while leaving the insertion handle connected to the nail. Insert the 0 mm end cap through the insertion handle.
5–15 mm end cap: Remove the connecting screw and insertion handle using the hexagonal screwdriver. Insert the end cap.

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