Instructions for Use
Retrograde Femoral Nail Advanced

These instructions for use are not intended for distribution in the USA.

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Nov 27, 2024

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Retrograde Femoral Nail Advanced

Devices in scope

Retrograde Femoral Nail Advanced, STANDARD NAIL

Length (mm)	∅ 9 mm	∅ 10 mm	∅ 11 mm	∅ 12 mm	∅ 14 mm
160	04.233.916S	04.233.016S	04.233.116S	04.233.216S	
200	04.233.920S	04.233.020S	04.233.120S	04.233.220S	
240	04.233.924S	04.233.024S	04.233.124S	04.233.224S	
280	04.233.928S	04.233.028S	04.233.128S	04.233.228S	04.233.428S
300	04.233.930S	04.233.030S	04.233.130S	04.233.230S	04.233.430S
320	04.233.932S	04.233.032S	04.233.132S	04.233.232S	04.233.432S
340	04.233.934S	04.233.034S	04.233.134S	04.233.234S	04.233.434S
360	04.233.936S	04.233.036S	04.233.136S	04.233.236S	04.233.436S
380	04.233.938S	04.233.038S	04.233.138S	04.233.238S	04.233.438S
400	04.233.940S	04.233.040S	04.233.140S	04.233.240S	04.233.440S
420	04.233.942S	04.233.042S	04.233.142S	04.233.242S	04.233.442S
440	04.233.944S	04.233.044S	04.233.144S	04.233.244S	04.233.444S
460	04.233.946S	04.233.046S	04.233.146S	04.233.246S	04.233.446S
480	04.233.948S	04.233.048S	04.233.148S	04.233.248S	04.233.448S

Retrograde Femoral Nail Advanced, PERIPROSTHETIC NAIL

Length (mm)	∅ 9 mm	∅ 10 mm	∅ 11 mm	∅ 12 mm
160	04.233.917S	04.233.017S	04.233.117S	04.233.217S
200	04.233.921S	04.233.021S	04.233.121S	04.233.221S
240	04.233.925S	04.233.025S	04.233.125S	04.233.225S
280	04.233.929S	04.233.029S	04.233.129S	04.233.229S
300	04.233.931S	04.233.031S	04.233.131S	04.233.231S
320	04.233.933S	04.233.033S	04.233.133S	04.233.233S
340	04.233.935S	04.233.035S	04.233.135S	04.233.235S
360	04.233.937S	04.233.037S	04.233.137S	04.233.237S
380	04.233.939S	04.233.039S	04.233.139S	04.233.239S
400	04.233.941S	04.233.041S	04.233.141S	04.233.241S
420	04.233.943S	04.233.043S	04.233.143S	04.233.243S
440	04.233.945S	04.233.045S	04.233.145S	04.233.245S
460	04.233.947S	04.233.047S	04.233.147S	04.233.247S
480	04.233.949S	04.233.049S	04.233.149S	04.233.249S

Endcap for Retrograde Femoral Nail Advanced

Article No.	Extension (mm)
04.233.000S	0
04.233.0005	5
04.233.010S	10

Locking Attachment Washer for Retrograde Femoral Nail Advanced, 5 Degree Bend

02.233.100S
02.233.101S

Locking Attachment Washer for Retrograde Femoral Nail Advanced, 10 Degree Bend

02.233.104S
02.233.105S

Nut and Washers

04.045.780S
04.045.781S
04.045.782S

Locking Screws for Medullary Nails, ∅ 5 mm*

Article No.	Length (mm)	Article No.	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 Screws for Medullary Nails, Low Profile, ∅ 5 mm*

Article No.	Length (mm)	Article No.	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		

Alternatively, the Retrograde Femoral Nail Advanced implants can be applied using associated instrumentation and a set of the following compatible screw implants:

VA Locking Screw STARDRIVE™ ∅ 5.0 mm, OPTILINK™ Technology

Article No.	Length (mm)	Article No.	Length (mm)
42.231.230	30	42.231.255	55
42.231.232	32	42.231.260	60
42.231.234	34	42.231.265	65
42.231.236	36	42.231.270	70
42.231.238	38	42.231.275	75
42.231.240	40	42.231.280	80
42.231.242	42	42.231.285	85
42.231.244	44	42.231.290	90
42.231.246	46	42.231.295	95
42.231.248	48	42.231.300	100
42.231.250	50		

3.5 mm VA Locking Screws*

Article No.	Length (mm)	Article No.	Length (mm)
02.127.110	10	02.127.144	44
02.127.112	12	02.127.146	46
02.127.114	14	02.127.148	48
02.127.116	16	02.127.150	50
02.127.118	18	02.127.152	52
02.127.120	20	02.127.154	54
02.127.122	22	02.127.156	56
02.127.124	24	02.127.158	58
02.127.126	26	02.127.160	60
02.127.128	28	02.127.165	65
02.127.130	30	02.127.170	70
02.127.132	32	02.127.175	75
02.127.134	34	02.127.180	80
02.127.136	36	02.127.185	85
02.127.138	38	02.127.190	90
02.127.140	40	02.127.195	95
02.127.142	42		

Locking Screws STARDRIVE™, ∅ 5 mm (light green)*

Article No.	Length (mm)	Article No.	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

* 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 Retrograde Femoral Nail Advanced implants consist of a cannulated femoral nail, a cannulated end cap, condylar nuts and washers, and a Locking Attachment Washer. The Retrograde Femoral Nail Advanced implants accept 5.0 mm Locking Screws. The Locking Attachment Washer accepts 3.5 Variable Angle Screws and connects to the nail via 5.0 Variable Angle OPTILINK Screws.

The Retrograde Femoral Nail Advanced Nail is anatomically contoured and tapers to a nominal diameter of 9, 10, 11, 12, or 14 mm. The Retrograde Femoral Nail Advanced Nails are available in lengths from 160 mm to 480 mm. The Retrograde Femoral Nail Advanced Nails are offered with two distal bends. These implants are manufactured from titanium and titanium alloys, stainless steel and polyethylene.

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" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials

Device(s)	Material(s)	Standard(s)
Retrograde Femoral Nail Advanced Nails & Inlay	Ti-6Al-4V (TAV) Titanium Alloy	ISO 5832-3
	UHWMPE	ISO 5834-2
End Caps	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11
Locking Attachment Washer	316L Stainless Steel	ISO 5832-1
Condylar Nut	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11
Screw & Nut Washer	Commercially Pure Titanium (Grade 4)	ISO 5832-2
Locking Screws for Medullary Nails	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11
VA Locking Screws	316L Stainless Steel	ISO 5832-1
OPTILINK Screws	316L Stainless Steel	ISO 5832-1

Intended Use
The Retrograde Femoral Nail Advanced implants are intended to be used for temporary fixation and stabilization of the distal femur and femoral shaft.

Indications
The Retrograde Femoral Nail Advanced implants are intended to stabilize fractures of the distal femur and the femoral shaft, including:
– Supracondylar fractures, including those with intra-articular extension
– Combination of ipsilateral condylar and diaphyseal fractures
– Ipsilateral femur/tibia fractures
– Femoral fractures in multiple trauma patients
– Periprosthetic fractures
– Fractures in the morbidly obese
– Fractures in osteoporotic bone
– Impending pathologic fractures
– Malunions and nonunions

Contraindications
No contraindications specific to these devices.

Patient Target Group
The Retrograde Femoral Nail Advanced implants are recommended for use in skeletally mature patients.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

The Retrograde Femoral Nail Advanced implants are 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 instructions for use, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure 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 Retrograde Femoral Nail Advanced implants when used according to instructions for use and recommended technique are
– Stabilize bone segment and facilitate healing
– Restore anatomical alignment and limb/extremity function

Performance Characteristics of the Device
The Retrograde Femoral Nail Advanced implants provide a range of options to allow for the treatment of a variety of fracture patterns and in the presence of previously implanted devices such as the femoral components of a total knee arthroplasty.

The Retrograde Femoral Nail Advanced implants include a multi-planar, angular stable, locking screw pattern designed to enhance mechanical stability and reduce the risk of non/mal-union associated with implant instability. For patients with an open-box prosthetic knee, the Retrograde Femoral Nail Advanced implants include a peri-prosthetic nail for insertion through the prosthesis. When supplementary stability or additional locking screws are desirable in distal femur fractures (due to poor bone quality or fracture pattern), the Retrograde Femoral Nail Advanced implants provide the option of a connected locking attachment device to augment stability. The device supports additional screw placement. The implants also include nuts and washers to augment the 5.0 mm locking screws for medullary nails in the condyle regions.

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 Dislocation
- Embolism
- Infection
- Injury to User
- Malunion/Nonunion
- Neuro-vascular Damage
- Pain or Discomfort
- Poor Joint Mechanics
- Soft Tissue Damage (including Compartment Syndrome)
- Symptoms resulting from Implant Migration, Loosening, Bending, 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.


Do not re-sterilize

Re-sterilization of the Retrograde Femoral Nail Advanced Nails can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single-Use device


Do not reuse

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Reuse or clinical reprocessing (e.g. cleaning and re-sterilization) 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".
It is strongly advised that Retrograde Femoral Nail Advanced 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.
- 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.
- 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.
- Compromised vascularity in the site of proposed implantation may prevent adequate healing and thus preclude the use of this or any orthopaedic implant.

Precautions
For precautions specific to a surgical step please refer to section Special Operating Instructions.

Combination of Medical Devices
DePuy 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 2052-06e1 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 instructions given by the Synthes brochure "Important Information".

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. Remove end cap. Carefully dissect the soft tissues and visualize all locking implants. Remove the end cap with Synthes STARDRIVE™ screwdriver. Thread the extraction screw into the nail.
2. Remove screws connecting Locking Attachment Washer to nail, if necessary.
3. Remove all screws, nuts, washers.
4. Remove the nail. Having ensured all locking screws are removed, remove 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".

Precaution: The nail is offered with a polymer inlay for added angular stability of the distal locking screws; however, there may be an increased risk of screw migration when using the inlay. Therefore, if added angular stability of the distal locking screws is not required, the polymer inlay can be removed.

Additional Device-Specific Information


Caution, see instructions for use

Reference number

Lot or batch number


Legal manufacturer


Expiration date

Disposal
Any DePuy 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

Notes:
- It is critical to ensure proper selection of the implant meets the needs of the patient anatomy and the presenting trauma.
- 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.
- 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.
- Compromised vascularity in the site of proposed implantation may prevent adequate healing and thus preclude the use of this or any orthopaedic implant.

Warning:
Physician should consider patient bone quality to ensure it provides adequate fixation to promote healing.

Opening the Distal Femur
1. Position patient
Position the patient supine on a radiolucent table. The knee of the injured leg should be flexed 30°–40°. A leg roll may be used to allow proper reduction and stabilization of the fracture.
Position the image intensifier to allow visualization of the proximal and distal femur in AP and lateral views.

2. Reduce fracture

Instrument	
394.350	Large Distractor

Perform closed reduction manually by axial traction, under image intensification. If reduction cannot be achieved in a closed approach, open reduction may be considered.
The use of the large distractor may be appropriate in certain circumstances. Consult the corresponding Instructions for Use.

3. Approach
Make a transligamental (ligamentum patellae) or a parapatellar incision, depending on the type and location of fracture.

Note: If planning the use of the locking attachment washer, a single lateral parapatellar or separate incisions can be made as described in the Locking Attachment Washer technique.

4. Determine entry point
The entry point for the Retrograde Femoral Nail is in line with the medullary canal. The entry point is at the top of the intercondylar notch, just anterior and lateral to the femoral attachment of the posterior cruciate ligament.
The entry point determines the anatomic position of the nail in the medullary canal. Special care should be taken to ensure an accurate entry point.

Note: In the presence of a femoral prosthesis, the entry point through an open box, may be positioned posteriorly. To accommodate this, a periprosthetic nail is available.

5. Insert guide wire

Instruments	
03.010.500	Silicone Handle, with Quick Coupling
03.010.502	13 mm Protection Sleeve for RAFN Retrograde, Quick Coupling
03.010.507	Multi Hole Wire Guide for Expert Retrograde Femoral Nail
03.045.018*	Guide Wire with Drill Tip, ∅ 3.2 mm, 400 mm
Alternative Instrument	
357.399	∅ 3.2 mm Guide Wire, 400 mm

* Available nonsterile or sterile-packed. Add "S" to the article number to order sterile product.

Assemble the handle, protection sleeve and multi hole wire guide. Insert the assembly through the incision to the bone. Hold the protection sleeve firmly and insert the guide wire through the wire guide.

Note: The nail has a distal bend and a radius of curvature to match an average femur. The nail design should be considered relative to the anatomy of the femur when choosing the guide wire starting point and entry angle to ensure proper placement.

Verify guide wire position under image intensification with AP and lateral views. Remove the wire guide.

Precaution: To reduce the risk of malreduction during nail insertion in patients with good bone quality:
Consider achieving and maintaining fracture reduction first.
Consider directing guide wire anteriorly based on nail design and fracture pattern.

5. Option: Insert guide wire in presence of TKA

Instruments

03.010.500	Silicone Handle, with Quick Coupling
03.010.502	13 mm Protection Sleeve for RAFN Retrograde, Quick Coupling
03.233.000	Periprosthetic Wire Guide
03.045.018	Guide Wire with Drill Tip, ∅ 3.2 mm, 400 mm

Alternative Instrument

357.399	∅ 3.2 mm Guide Wire, 400 mm

In the presence of a periprosthetic fracture, the dedicated periprosthetic wire guide can be used to assist in determination of nail fit through the open box prosthesis.
The distal end of the periprosthetic wire guide matches the dimensions of the distal end of the nail. Insert the distal end of the periprosthetic wire guide into the open box to confirm fit.
Assemble the handle, protection sleeve and periprosthetic wire guide. Insert the assembly through the incision to the bone. Hold the protection sleeve firmly and insert the guide wire through the wire guide.

Note: In the presence of a femoral prosthesis, the entry point through an open box may be positioned posteriorly. To accommodate this, a periprosthetic nail is available. Consider the start point and trajectory of the guide wire when selecting the appropriate nail.

6. Open medullary canal

Instrument

03.233.001	Drill Bit, Cannulated, ∅ 12.8 mm, Large Quick Coupling

Using the protection sleeve and cannulated drill bit, drill over the 3.2 mm guide wire until the drill stop on the drill reaches the protection sleeve.
Monitor progress of the drill with the image intensifier. Ensure that the lateral and medial cortical walls are not compromised. Adjust the guide wire if necessary.
Remove the guide wire, protection sleeve, and drill bit.

Precaution: For the larger, 14 mm nails, in addition to the 12.8 mm drill bit, the use of the medullary reaming system is needed to open the femur. In this case use the 12.8 mm drill bit for initial opening and continue using the medullary reaming system.
Consult the corresponding Instructions for Use.

Note: Dispose of the guide wire, do not reuse.

6. Option: Open medullary canal in presence of TKA

Instrument

03.233.002	Drill Bit, Cannulated, ∅ 11.2 mm, Large Quick Coupling

Using the protection sleeve and cannulated drill bit, drill over the 3.2 mm guide wire until the drill stop on the drill reaches the protection sleeve.
Monitor progress of the drill with the image intensifier. Ensure that the lateral and medial cortical walls are not compromised. Adjust the guide wire if necessary.
Remove the guide wire, protection sleeve, and drill bit.

Notes:
- Ensure care is taken not to dislodge the femoral components of any prosthesis and that any components are compatible with selected implants.
- When the femoral component has a narrow intercondylar box, the 11.2 mm drill bit can be used with nails 9–12 mm diameter.
- The medullary reaming system can be used to enlarge the opening when needed, based on the size of femoral component intercondylar box. Consult the corresponding Instructions for Use.
- Dispose of the guide wire. Do not reuse.

Option: Reduce fracture

Instruments

351.706S	2.5 mm Reaming Rod with Ball Tip, 950 mm, Sterile
351.707S	2.5 mm Reaming Rod with Ball Tip & extension, 950 mm, Sterile
351.704S	2.5 mm Reaming Rod with Ball ip & extension, 1150 mm, Sterile
03.233.010S	Reaming Rod ∅ 3.8 mm, Ball Tip, ∅ 3.0 mm, 950 mm, Sterile
03.233.011S	Reaming Rod ∅ 3.8 mm, Ball Tip, ∅ 3.0 mm, 950 mm, Sterile
03.010.495	IMN Reduction Tool, curved with Quick Coupling
03.010.496	T-Handle cannulated with Quick Coupling
03.010.093	Reaming Rod Push Rod with Ball Handle

The use of a reaming rod can facilitate reduction, serve as a guide for intramedullary reamers, and aid in keeping bone fragments aligned during nail insertion.
The RFN-ADVANCED Retrograde Femoral Nail is cannulated and can be inserted over reaming rods with a maximum diameter of 3.85 mm at the widest point, typically at the ball tip. The use of the reduction finger may be appropriate in certain circumstances to help achieve alignment of the proximal and distal fragments and guide the reaming rod to the proximal fragment.

Insert the reduction instrument to the desired depth. Pass the reaming rod through the cannulation of the instrument.
Remove the reduction instrument.

Note: Use the rod pusher to help retain the reaming rod during the extraction of the reduction instrument.

Option: Determine nail length over reaming rod

Instruments

351.717	Depth Gauge
351.719	Depth Gauge Extension Tube

Nail length can be determined over a 950 mm reaming rod. Confirm reaming rod insertion depth under image intensification and account for a possible distraction at the fracture site. Assemble the depth gauge and tube and pass the assembly over the reaming rod and down to the nail entry point. Read nail length directly from the measuring device.

Notes:
If a 1150 mm reaming rod is used, the nail length measurement should be read off the etched line on the reaming rod.
The nail diameter is determined either by reaming (optional) or radiographically.

Reaming (optional)
Ream medullary canal (optional)

Instruments

03.010.093	Reaming Rod Push Rod with Ball Handle
351.706S	2.5 mm Reaming Rod with Ball Tip, 950 mm, Sterile
351.707S	2.5 mm Reaming Rod with Ball Tip & extension, 950 mm, Sterile
351.704S	2.5 mm Reaming Rod with Ball Tip & extension, 1150 mm, Sterile
03.233.010S	Reaming Rod ∅ 3.8 mm, Ball Tip, ∅ 3.0 mm, 950 mm, Sterile
03.233.011S	Reaming Rod ∅ 3.8 mm, Ball Tip, ∅ 3.0 mm, 950 mm, Sterile
03.043.001	Universal Chuck

If necessary, enlarge the femoral canal with the medullary reamer to the desired diameter using a Synthes reamer system intended for femoral reaming procedures by following the corresponding instructions for the reamer system.
Use image intensification to confirm fracture reduction. Insert the reaming rod into the medullary canal to the desired insertion depth. The tip must be correctly positioned in the medullary canal since it determines the final position of the nail. Use image intensification in AP and lateral view to ensure that the reaming rod is placed in a central position.

Precaution: The RFN-ADVANCED Retrograde Femoral Nail is cannulated and can be inserted over reaming rods with a diameter up to 3.85 mm at the widest point. Compatible reaming rods will pass through the hole in the center of the aiming arm.

Note: Use the rod pusher to help retain the reaming rod during reamer extraction.

Insert Nail
1. Assemble insertion instruments

Instruments

03.233.005	Insertion Handle, radiolucent
03.233.003	Connecting Screw
03.233.004	Nail Assembly Instrument
03.037.031	Combination Wrench

Precaution: The nail is offered with a polymer inlay for added angular stability of the distal locking screws; however, there may be an increased risk of screw migration when using the inlay. Therefore, if added angular stability of the distal locking screws is not required, the polymer inlay can be removed.

For instructions on removal of the inlay, refer to page 14.
If the inlay is used, consider use of a 0 mm endcap to reduce the risk of screw migration.
For instruction on insertion of the end cap, refer to page 14.
Thread nail assembly instrument into connecting screw until secure. Fully insert assembly into insertion handle by turning assembly until secure.
Align the tip of the nail assembly instrument that protrudes through the insertion handle into the center of the nail and insert, matching the geometry of the insertion handle with the notches in the nail.

Note: The insertion handle will be positioned anteriorly during nail insertion.
Turn the connecting screw to secure it to the nail. Confirm the connecting screw is securely tightened to the nail with the combination wrench. Do not over-tighten.
Remove the nail assembly instrument.
Precaution: Ensure the connection between the nail and the insertion handle is tight. Retighten if necessary.

2. Insert Nail

Optional Instruments

03.010.522 Spiral Combination Hammer, 500 grams
03.010.170 Hammer Guide

With the insertion handle positioned anteriorly, insert the nail using the insertion handle over the reaming rod if used, into the medullary canal as far as possible by hand.
Monitor nail passage across the fracture. Control in two planes to avoid malalignment.
Insert the nail to the desired depth. Insertion depth is indicated by the grooves on the insertion handle. The notch indicates the end of the nail. The subsequent distances between the grooves on the insertion handle represent 5 mm and correspond to the extensions of the end caps.
Insertion depth can be verified with a lateral image. Use Blumensaats line as a reference. Check the final position of the nail in the AP and lateral views.
If necessary, insert the nail with light hammer blows. Monitor the tip of the nail using image intensification. If the nail has been slightly over-inserted, the hammer guide can be used to back slap the nail. Attach the hammer guide to the connecting screw. Use light hammer blows along the hammer guide to back slap the nail.

Precaution: Do not strike the insertion handle directly, to avoid damage to the handle.

Note: After using the hammer, ensure the connecting screw is securely tightened to the nail. Retighten, if necessary.

Remove the reaming rod, if used.

Fixation Options
Locking Screw Options
About Measuring Screw Length

Screw length is measured by using either of two methods.
1. Read length from the calibrated drill bits
2. Measure length using depth gauge for locking screws

Readings do not reflect the measured distance, they indicate the required screw length. The reading on the scale will correspond to the screw length as indicated on the screw label, taking into account the amount of screw tip protrusion required to get full screw thread engagement in the far cortex.

Notes:
– Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length.
– Beware depth gauges are implant specific. Always use the appropriate depth gauge as specified in Instructions for Use.

Precaution: Select adequate screw lengths to avoid protrusion of the screw tips and irritation of soft tissue.

RFN-ADVANCED Retrograde Femoral Nail offers two types of screws:

1. Locking Screw
Standard IM nail locking screw
2. Low Profile Locking Screw
Both types of screws have a threaded recess and can be securely attached to the screwdriver by using the retention pins. To do so, slide the retention pins through the back of the screwdriver until it stops. Further advance it by turning it clockwise, until its tip extends out of the tip of the screwdriver.
Engage the screwdriver in the recess of the locking screw and thread the retention pin into the screw's recess to lock the screw to the screwdriver.
Alternatively, the screw can be partially inserted with a power tool, by using the screwdriver shaft with its retention pin, following the same steps as described above.

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 and tighten it as appropriate.

Low Profile Screw

The Low Profile Locking Screw can be used instead of the standard locking screw, by following the same basic steps for screw insertion.
An optional sleeve is available to indicate when the screw is fully seated. Slide it over the tip of the screwdriver until it locks in place.
In its initial position, it will cover the head of the screw, protecting surrounding soft tissues from the screw head's cutting flutes. Advance the screw until the sleeve touches the cortex.

Note: Pay attention not to damage the cortex with the sleeve.

Then retract the sleeve by pushing the release button and pulling it backwards towards the screwdriver handle.
Continue to advance the screw, now sinking the screw head into the bony cortex. Once the sleeve touches the cortex a second time, the screw head will be 0.5 mm proud of the cortex.
The cutting flutes in the 5 mm low profile screw's head allows insertion of the screw without any extra steps. However, in hard bone it is recommended to enlarge the near cortex with the ∅ 5.5 mm reamer, to make room for the screw head, and avoid excessive insertion torque.

Locking
1. Connect the aiming arm

Instrument

03.233.006 Aiming Arm, Radiolucent

Attach the aiming arm to the insertion handle, by sliding the aiming arm into the hook end of the insertion handle and then rotating the aiming arm towards the insertion handle, such that the latch on the aiming arm connects to the insertion handle.

Precaution: Do not exert force on the aiming arm, protection sleeve, drill sleeves and drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bits.

2. Insert trocar combination

Instruments

03.045.019 Protection Sleeve, ∅ 11/8
03.045.020 Drill Sleeve, ∅ 4.2 mm
03.010.070 4.2 mm Trocar 210 mm

Insert the three-part trocar assembly (protection sleeve, drill sleeve and trocar) through the desired hole in the aiming arm and rotate the protection sleeve to align the arrow on the protection sleeve with the arrow on the aiming arm. Make a stab incision and insert the trocar to the bone. Twist the protection sleeve by a quarter turn to lock it into place. Remove the trocar.

Precaution: Avoid putting tension on the aiming arm and insertion handle, when locking the protection sleeves, as this can reduce the accuracy of the aiming arm. The sleeves need to contact the cortex, but tension can occur if the protection sleeves are pushed down too hard.

3. Drill and determine locking screw length

Instrument

03.045.022 Drill Bit, Calibrated, ∅ 4.2 mm, Extra-Long

Ensure that the drill sleeve is pressed firmly to the near cortex. Using the drill bit, drill to the desired depth and confirm drill bit position after drilling.
Ensure that the drill sleeve is pressed firmly to the near cortex and read the measurement from the drill bit at the back of the drill sleeve. This measurement corresponds to the appropriate length locking screw.
Remove the drill bit and the drill sleeve.

Alternative Instrument

03.019.017 Depth Gauge for Multiloc Humeral Nailing System

After drilling, remove the drill bit and the drill sleeve.
Insert the depth gauge through the protection sleeve. Confirm the position of the depth gauge hook and that the depth gauge sleeve is firmly pressed against the near cortex.
Read the measurement from the depth gauge to determine the appropriate length locking screw.

Note: For screw lengths longer than 100 mm, the 03.045.022 drill bit should be used to confirm screw length.

4. Insert locking screw

Instruments

03.045.001 Screwdriver XL25
03.045.002 Retention Pin for Screwdriver XL25

Use the screwdriver to insert the appropriate length locking screw through the protection sleeve.
Repeat Steps 2 and 3 for additional distal locking screws.
Turn the retention pin counterclockwise to disengage the retention pin from screw head. Remove screwdriver, protection sleeve and the aiming arm.

Note: In a Standard Locking construct, the use of a 0 mm end cap may reduce the risk of screw migration.

Alternative Instruments

03.045.005 Screwdriver XL25 Quick Coupling Hex 12 mm
03.045.006 Retention Pin for Screwdriver, with Quick Coupling-Hex 12 mm, XL25
03.140.027 Large Cannulated Handle with Quick Coupling, 12 mm Hex

Use the screwdriver attached to power to insert the appropriate length locking screw through the protection sleeve, until the head of the locking screw is close to contacting the near cortex.

Note: Final tightening of locking screws must be completed with manual detachable handle. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the handle to bring the screw to its final position.

The shaft of the screwdriver has two lines, one of which indicates insertion depth of the standard locking screw, and the other indicating insertion depth of the Low Profile locking screw relative to the tip of the protection sleeve.

5. Option: Insert 0 mm End Cap

Instruments	
03.045.005	Screwdriver XL25 Quick Coupling Hex 12 mm
03.045.006	Retention Pin for Screwdriver, with Quick Coupling-Hex 12 mm, XL25
03.010.496	T-handle, Cannulated, with Quick Coupling

Remove the connecting screw.
For the 0 mm end cap, the insertion handle can remain in place to help align the end cap to the nail. The end cap fits through the barrel of the insertion handle.
Insert end cap through barrel of insertion handle and tighten until secure. Thread the end cap into the nail until it engages the most distal screw. To achieve higher insertion torque, use the T-Handle to ensure the end cap is tight to the distal screw.
Image intensification may be used to visualize the end cap contacting the screw.
If desired, the end cap can be locked to the screwdriver by use of the retention pin.

Freehand Locking

1. Align image intensifier
Confirm reduction and correct alignment with AP and lateral images.
Align the image intensifier with the hole in the nail closest to the fracture until a perfect circle is visible in the center of the screen.

2. Determine incision point
Place a scalpel blade or the tip of a drill bit on the skin over the center of the hole to mark the incision point and make a stab incision.

3. Drill

Instrument	
03.010.104	4.2 mm, three-fluted Drill Bit Quick Coupling, Needle Point, 145 mm

Insert the drill bit through the incision, down to the bone.
Incline the drive so that the tip of the drill bit is centered over the locking hole. The drill bit should almost completely fill the circle of the locking hole. Hold the drill bit in this position and drill through both cortices.

Note: For greater drill bit control, discontinue drill power after perforating the near cortex. Manually guide the drill bit through the nail before resuming power to drill the far cortex.

4. Determine length of locking screw

Instruments	
03.010.104	4.2 mm, three-fluted Drill Bit Quick Coupling, Needle Point, 145 mm
03.010.429	Direct Measuring Device for Locking Screws to 100 mm for IM Nails

Stop drilling immediately after penetrating the far cortex. Disassemble the drill bit from the power equipment.
Under image intensification, ensure the correct position of the drill bit relative to the far cortex. Place the direct measuring device onto the drill bit. Read the screw length directly from the measuring device at the end of the drill bit. This corresponds to the appropriate locking screw length.

Note: Correct placement of the drill bit and measuring device are important for accurate locking screw length measurement.

Alternative Instrument	
03.019.017	Depth Gauge for Multiloc Humeral Nailing System

Measure the locking screw length using the depth gauge. Ensure the outer sleeve is in contact with the bone and the hook grasps the far cortex.
Read the locking screw length directly from the depth gauge at the back of the outer sleeve.

5. Insert locking screw

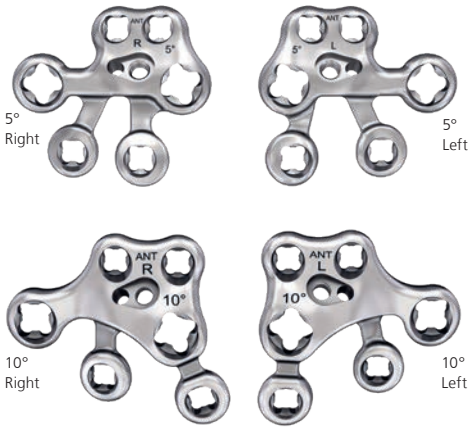
Instruments	
03.045.003	Screwdriver Short XL25
03.045.004	Retention Pin for Screwdriver, Short, XL25

Use the screwdriver to insert the appropriate length locking screw.
Verify locking screw length under image intensification. If needed, a second locking screw may be inserted using the same technique.
Repeat Steps 1 through 5 for the second proximal locking screw.

Instruments	
03.045.007	Screwdriver Short, XL25, Quick Coupling, Hex 12 mm
03.045.008	Retention Pin for Screwdriver with Quick Coupling-Hex 12 mm, Short, XL25
03.140.027	Large Cannulated Handle with Quick Coupling-12 mm Hex

Use the screwdriver attached to power to insert the appropriate length locking screw, until the head of the locking screw is close to contacting the near cortex. Remove the screwdriver from the power coupling, and attach to the handle to complete insertion manually.

LAW Technique – Locking Attachment Washer
Locking Attachment Washer for RFN-Advanced™
The Locking Attachment Washer is contoured and is offered in a 5° and a 10° version to account for screw hole position relative to the position of the nail in the bone. The Left and Right versions of each are shown below.
Note: The position of the posterior 3.5 mm VA Locking Screws is different between left and right locking attachment washers. This difference accounts for the position of the descending oblique screws when the nail is used in the left or right femur.



Locking Attachment Washer for RFN-Advanced
The Locking Attachment Washer contains etch detail to provide information on the locking attachment washer type and orientation.
ANT – indicates the anterior edge
R (or L) – indicates right or left
5° (or 10°) – indicates version

Note: There is a line etched between the 5.0 mm VA Locking holes to indicate alignment with the nail.

Locking Attachment Washer for RFN-Advanced
In certain patients, the 5° Locking Attachment Washer may be suitable for use with a periprosthetic nail, or, the 10° Locking Attachment Washer may be suitable for use with a standard bend nail. The surgeon should consider the position of the nail relative to the pre-contoured fit of the locking attachment washer.
If the position of the proximal lateral-medial screw is superior due to patient anatomy, nail insertion depth, or the presence of a TKA femoral component, the 10° Locking Attachment Washer may have improved fit due to the transition from the epicondyle.

1. Nail Insertion
Insert the nail using the retrograde technique.
Align the image intensifier to obtain an anatomic lateral view with condylar overlap. While maintaining this patient position and lateral view, reposition the nail to obtain near perfect circles.

Note: The locking washer is contoured to match the patient anatomy when the nail is positioned as described.

Note: If planning the use of the locking attachment washer in the presence of a TKA femoral component, ensure the footprint of the locking attachment washer will not interfere with or contact the femoral component.

2. Connect the aiming arm

Instrument
03.233.006 Aiming Arm, Radiolucent

Attach the aiming arm to the insertion handle.

Precaution: Do not exert force on the aiming arm, protection sleeve, drill sleeves and drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bits.

3. Secure Nail in position with a Medial Oblique Screw or Drill Bit

Instruments
03.045.019 Protection Sleeve, ∅ 11/8
03.045.020 Drill Sleeve, ∅ 4.2 mm
03.010.070 4.2 mm Trocar 210 mm
03.045.022 Drill Bit, Calibrated, ∅ 4.2 mm, Extra-Long
03.045.001 Screwdriver XL25
03.045.002 Retention Pin for Screwdriver XL25

Lock the nail to the distal fragment with the medial oblique screw or with a drill bit in the medial oblique hole to limit motion of the nail relative to the distal fragment.
Assemble the three-part trocar combination (protection sleeve, drill sleeve and trocar) and insert it through the medial oblique hole in the aiming arm. Make a stab incision and insert the trocar to the bone. Remove the trocar.
Ensure that the drill sleeve is pressed firmly to the near cortex. Using the drill bit, drill to desired depth.
If using the drill bit to stabilize the nail, decouple the drill bit from the power drill and proceed to Step 4.
If inserting a screw to stabilize the nail, ensure that the drill sleeve is pressed firmly to the near cortex and read the measurement from the drill bit at the back of the drill sleeve. This measurement corresponds to the appropriate length locking screw.
Remove the drill bit and the drill sleeve.
Use the screwdriver to insert the appropriate length locking screw through the protection sleeve, until the head of the locking screw lies against the near cortex.

4. Expose Lateral Condyle and Insert Locking Attachment Washer

Instruments
03.233.008 Holding Device Locking Pin, for Locking Attachment Washer
03.233.009 Holding Device Handle, for Locking Attachment Washer
03.045.019 Protection Sleeve, ∅ 11/8
03.045.020 Drill Sleeve, ∅ 4.2 mm

Create an incision approximately 8 cm in length laterally.

Note: The protection sleeves placed through the aiming arm can be used as an indication of locking attachment washer location.

Assemble a drill sleeve into a protection sleeve. Partially insert a sleeve assembly into each lateral to medial holes in the aiming arm, leaving space to insert the locking attachment washer.
Insert the locking pin into the holding device handle. Attach locking attachment washer to the holding device assembly by aligning the pin and tighten until secure.
Position the Locking Attachment Washer on the bone using the Holding Device such that the two 5.0 VA Locking Holes are aligned with the protection sleeves.
Note: The locking attachment washer is properly positioned when the holding device handle is pointed distally, and oriented anterior to the protection sleeves.
Hold the Locking Attachment Washer in position on the bone using the sleeves.

5. Drill 5.0 mm VA Locking Screws

Instruments
03.045.019 Protection Sleeve, ∅ 11/8
03.045.020 Drill Sleeve, ∅ 4.2 mm
03.045.022 Drill Bit, Calibrated, ∅ 4.2 mm Extra-Long

Using the drill bit, drill the proximal hole until the tip of the drill bit penetrates the far cortex.
Leave this drill bit in position by decoupling from the power drill.
Using a second drill bit, drill the distal hole until the tip of the drill bit penetrates the far cortex.
Using drill bit, determine appropriate length 5.0 mm VA locking screw for distal hole.

Note: The 03.019.017 depth gauge can also be used to determine the appropriate length locking screw.

Remove the drill bit and drill sleeve.

6. Partially Insert 5.0 mm VA Locking Screws

Instruments
03.010.109 T25 STARDRIVE™ Screwdriver Shaft
03.045.019 Protection Sleeve, ∅ 11/8

Use the screwdriver to insert the appropriate length locking screw through the protection sleeve into the distal hole, stopping approximately 1 cm before full insertion of the screw.

Note: This will allow manipulation of the Locking Attachment Washer to improve the fit on the bone.

The 5.0 mm variable angle locking screws may be inserted using power equipment and the T25 StarDrive™ screwdriver shaft.
For the proximal screw, determine the screw length using the drill bit. Remove the drill bit and drill sleeve.
Use the screwdriver to insert the appropriate length locking screw through the protection sleeve, stopping approximately 1 cm before full insertion of the screw.

Note: Proceed to the next surgical step with both 5.0 mm VA Locking Screws approximately 1 cm proud of the locking attachment washer.

7. Insert Lateral Oblique Screw in Nail (optional)

Instruments
03.045.019 Protection Sleeve, ∅ 11/8
03.045.020 Drill Sleeve, ∅ 4.2 mm
03.010.070 4.2 mm Trocar 210 mm
03.045.022 Drill Bit, Calibrated, ∅ 4.2 mm, Extra-Long
03.045.001 Screwdriver XL25
03.045.002 Retention Pin for Screwdriver XL25

Assemble the three-part trocar combination (protection sleeve, drill sleeve and trocar) and insert it through the lateral oblique hole in the aiming arm. Make a stab incision and insert the trocar to the bone. Remove the trocar.
Ensure that the drill sleeve is pressed firmly to the near cortex.
Using the drill bit, drill to the desired depth.
Confirm drill bit position.
Ensure that the drill sleeve is pressed firmly to the near cortex and read the measurement from the drill bit at the back of the drill sleeve. This measurement corresponds to the appropriate length locking screw.

Note: If a drill bit was used in the medial oblique hole to stabilize the nail, remove the drill bit and insert the appropriate length locking screw.

Use the screwdriver to insert the appropriate length locking screw through the protection sleeve, until the head of the locking screw lies against the near cortex.
Remove the protection sleeve and aiming arm.

8. Confirm Fit of LAW and Final Tighten 5.0 mm VA Locking Screws

Instruments
03.233.008 Holding Device Locking Pin, for Locking Attachment Washer
03.233.009 Holding Device Handle, for Locking Attachment Washer
03.231.015 SD25 STARDRIVE™ Screwdriver Shaft 6 mm Hex Coupling, 180 mm
03.231.018 6 Nm Torque Limiting Blue Handle with 6 mm Hex Coupling

Using the Holding Device, manipulate the position of the Locking Attachment Washer until the preferred fit on the bone is achieved.

Note: The Locking Attachment Washer is designed with two posterior 3.5 mm VA Locking Screw holes that can be contoured in situ.

When the desired fit of the Locking Attachment Washer is achieved, tighten both 5.0 mm VA Locking Screws using the 6 Nm torque limiting handle.

Notes:
Confirm screw position and length prior to final tightening.
Do not lock the screws to the locking attachment washer under power. Screw engagement and final locking must be done manually with the torque limiting handle (6.0 Nm).

Unthread the holding device locking pin from the locking washer and remove the holding device pin from the handle.

9. Option: Contour 3.5 mm VA Locking Screw Tabs

Instrument	
03.221.251	Bending Driver for 3.5 mm VA Locking Holes

The posterior screw holes have a tab feature that enables bending in situ. Use the bending driver in situ to contour the tabs to the desired position. A second bending driver can be used in an adjacent screw hole to provide leverage for contouring.
Precaution: Ensure drill bits and/or screws do not interfere with other medical devices (e.g. knee prosthesis, nail, other screws) and/or critical anatomy (e.g. condylar notch / joint space).

Note: Contouring the posterior, proximal screw hole may result in the screw crossing the nail anteriorly.

10. Drill and Insert 3.5 mm VA Locking Screw

Instruments	
03.133.003	3.5 mm VA Drill Guide
03.133.108	2.8 mm Drill Bit, Quick Coupling, 200 mm, 110 mm Calibration
03.113.019	Screwdriver Shaft STARDRIVE™ 165 mm
319.090	Depth Gauge for Small Screws
03.127.016	2.5 Nm Torque Limiting Handle with Quick Coupling

When using the cone end in the desired variable angle locking attachment washer hole, press firmly to ensure the drill guide tip keys into the cloverleaf portion of the variable angle locking screw hole securely. The notches on top of the cone are visual markers for the drill guide tip orientation. The cone will provide a secure window of 30° angulation.
When using the spherical tip end, gently press the instrument into the variable angle hole. The lip portion of the spherical tip end engages with the cloverleaf portion of the hole to provide tactile feedback of the angulations. Continue to provide light pressure while holding the drill guide at the desired angle. The spherical tip end of the drill guide provides freedom to chose angulation. To ensure a 15° angulation, use the cone end of the variable angle drill guide.
Using the 2.8 mm drill bit, drill hole.

Notes:
- When drilling the tip of the drill guide should remain fully seated in the hole.
- The drill bit angle may be verified under fluoroscopy to ensure the desired angle has been achieved.
- Radiographic imaging can be used to confirm the distal posterior screw will not be placed in the notch.
- When using the Variable Angle Drill Guides, inserting the screw at the nominal angle will ensure lowest possible profile construct.
- Drill guides are not self-retaining.

The drill bits are calibrated so that depth measurements can be read directly from the drill bit shaft when using the spherical tip end only; calibrations do not apply for the variable angle drill guide cone.
Alternatively, remove the drill bit and drill guide and use the depth gauge to measure for screw length.

Note: Calibrated drill bits should not be used to measure screw length through the cone portion of the Variable angle Drill Guides.

Insert a locking screw using the T15 StarDrive screwdriver. Final tightening of the 3.5 mm variable angle locking screws must be done manually with the 2.5 Nm torque limiting handle.
Ensure the screw trajectory is not intersecting the other screw trajectories. Advance the screw and lock it in the locking attachment washer. The torque limiting handle will provide an audible click once torque value is reached indicating that the screw is seated and locked.

Notes:
- Carefully tighten the locking screw, as excessive force is not necessary to produce effective screw locking.
- Confirm screw position and length prior to final tightening.
- Do not lock the screws to the locking attachment washer under power. Screw engagement and final locking must be done manually with the torque limiting handle (2.5 Nm).

Condylar Nut and Washer
Options for how to use Condylar Nuts
- Dual Nuts on Distal Screw
- Dual Nuts with Washers on Distal Screw
- Distal Nut with Washer for Screw Head on both Distal and Proximal Screw

Note: Nut and washers are intended for use with standard 5.0 mm screws only (04.045.026 through 04.045.120).
The number of nuts and washers to be used are according to surgeon preference, patient anatomy, or clinical condition.

Note: Nut includes a friction feature to secure nut to screw. The surgeon may experience tactile friction during nut insertion onto screw.

The use of nuts and/or washers may be limited in patients with a knee prosthesis, due to interference of the prosthesis, including the prosthesis box, pegs and borders.
The use of nuts may be limited in patients where the nail is inserted deeply into the canal or in a patient with small anatomy, which may result in insufficient insertion depth of the nut.

Note: Ensure sufficient insertion depth between nut and nail is available prior to nut insertion to avoid contact between nut and nail. If the nut contacts the nail before being fully seated, the nut may protrude off the bone.

While the actual length of the nut is 15 mm, a minimum depth gauge/drill bit measurement of 20 mm is needed to ensure sufficient insertion depth for the nut.

Note: If more than one screw with nut assembly is planned, consider the final position of adjacent screws/nuts to avoid interference.

Techniques for Nut and Washer Insertion
Two techniques are described for the insertion of the nuts and washers:
1. Nut-Over-Drill Bit Technique
2. Nut-Over-Screw Technique

Confirm position of nuts and Lock Nail in position

Instruments	
03.045.019	Protection Sleeve, ∅ 11/8
03.045.020	Drill Sleeve, ∅ 4.2 mm
03.010.070	4.2 mm Trocar 210 mm
03.045.022	Drill Bit, Calibrated, ∅ 4.2 mm, Extra-Long
03.045.001	Screwdriver XL25
03.045.002	Retention Pin for Screwdriver XL25

Lock the nail to the distal fragment to limit motion of the nail relative to the distal fragment.
Assemble the three-part trocar combination (protection sleeve, drill sleeve and trocar) and insert it through the medial oblique hole in the aiming arm. Make a stab incision and insert the trocar to the bone. Remove the trocar.
Ensure that the drill sleeve is pressed firmly to the near cortex. Using the drill bit, drill to the desired depth and confirm drill bit position after drilling. Confirm drill bit position. Ensure that the drill sleeve is pressed firmly to the near cortex and read the measurement from the drill bit at the back of the drill sleeve. This measurement corresponds to the appropriate length locking screw.
Remove the drill bit and the drill sleeve.
Use the screwdriver to insert the appropriate length locking screw through the protection sleeve, until the head of the locking screw lies against the near cortex.

Condylar Nut and Washer: Nut-Over-Drill Bit Technique
1. Drill and Determine length of locking screw

Instruments	
03.233.006	Aiming Arm Radiolucent
03.045.019	Protection Sleeve, ∅ 11/8
03.045.020	Drill Sleeve, ∅ 4.2 mm
03.010.070	4.2 mm Trocar 210 mm
03.045.022	Drill Bit, Calibrated, ∅ 4.2 mm, Extra-Long

Assemble the three-part trocar combination (protection sleeve, drill sleeve and trocar) and insert it through the desired hole in the aiming arm. Make a stab incision and insert the trocar to the bone. Remove the trocar.
Ensure that the drill sleeve is pressed firmly to the near cortex. Using the drill bit, drill through both cortices until the tip of the drill bit penetrates the far cortex.
Confirm drill bit position.
Ensure that the drill sleeve is pressed firmly to the near cortex and read the measurement from the drill bit at the back of the drill sleeve. This measurement corresponds to the appropriate length locking screw.
Keep the drill bit in position in the bone. Decouple the drill bit from the power tool.
Confirm a minimum distance of 48 mm is measured bicortically with the drill bit/depth gauge to ensure sufficient insertion depth for each nut.

Note: Consider anatomy and/or position of the nail in the bone. A minimum distance of 20 mm measured with the drill bit/depth gauge from the surface of the bone to the outer surface of the nail is needed to ensure the nut does not contact the nail at final tightening.

2. Insert Distal Nut

Instruments	
03.045.033	Driver for Nut
03.045.001	Screwdriver XL25
03.045.022	Retention Pin for Screwdriver XL25

At the contralateral position in the aiming arm, insert the nut driver partially through the aiming arm. Attach the nut to the nut driver.
Note: If using the washer for nut, position the washer over the nut prior to advancing the nut to the bone.

Advance nut to the bone, ensuring alignment with the tip of the drill bit.
While holding the drill bit in position, tighten nut with nut driver until seated.
Keep nut driver engaged in nut. Remove the drill bit.

3a. For Single, Distal Nut Configuration: Insert locking screw

Instruments
03.045.001 Screwdriver XL25
03.045.002 Retention Pin for Screwdriver XL25
03.045.019 Protection Sleeve, ∅ 11/8

To place the washer for screw, retract the protection sleeve. Insert the appropriate length locking screw through the protection sleeve, exposing the screw tip.
Position the washer for screw over the screw tip. Continue insertion until the screw head lies against the near cortex.
Keep screwdriver engaged with screw.
After insertion of the screw through the nail, use radiographic imaging to ensure the tip of the screw is aligned with the nut in the bone.
Use the nut driver to provide counter-torque to the nut while inserting the screw through the nut. Continue insertion of the screw until seated.
Note: The poly inlay inhibits sliding of the screw when using the nut to achieve compression. To reduce the potential of driving the screw and nail out of position and/or affecting bony reduction, use the screwdriver to provide counter-torque during nut insertion.
Remove nut driver, screwdriver, and protection sleeve.
Repeat Steps 1 through 4 for additional nuts, if desired.

3b. For Dual Nut Configuration: Insert locking screw

Instruments
03.045.001 Screwdriver XL25
03.045.002 Retention Pin for Screwdriver XL25
03.045.019 Protection Sleeve, ∅ 11/8

With the retention pin inserted into the screwdriver, insert the screwdriver into the screw head recess. Thread the retention pin into the screw head until secure.
Using the protection sleeve at the desired screw hole position in the aiming arm, secure the protection sleeve in a retracted position in the aiming arm to allow attachment of the nut to the screw tip.

Note: If using the washer for nut, position the washer over the nut prior to advancing the screw and nut assembly to the bone.

Note: Prior to inserting nut into bone, forceps can be used to hold nut during screw insertion until the screw head is seated in the nut.

Use the screwdriver to insert the appropriate length locking screw through the protection sleeve.
After insertion of the screw through the nail, use radiographic imaging to ensure the tip of the screw is aligned with the nut in the bone.
Use the nut driver to provide counter-torque to the nut while inserting the screw through the nut. Continue insertion of the screw and nut until seated.

Note: The poly inlay inhibits sliding of the screw when using the nut to achieve compression. To reduce the potential of driving the screw and nail out of position and/or affecting bony reduction, use the screwdriver to provide counter-torque during nut insertion.

Remove nut, screwdriver and protection sleeve.
Repeat Steps 1 through 3 for additional nuts, if desired.

Condylar Nut and Washer: Nut-Over-Screw Technique

Instruments
03.233.006 Aiming Arm Radiolucent
03.045.019 Protection Sleeve, ∅ 11/8
03.045.020 Drill Sleeve, ∅ 4.2 mm
03.010.070 4.2 mm Trocar 210 mm
03.045.022 Drill Bit, Calibrated, ∅ 4.2 mm, Extra-Long

1. Drill and Determine screw length and nut insertion depth
Assemble the three-part trocar combination (protection sleeve, drill sleeve and trocar) and insert it through the desired hole in the aiming arm. Make a stab incision and insert the trocar to the bone. Remove the trocar.
Ensure that the drill sleeve is pressed firmly to the near cortex. Using the drill bit, drill through both cortices until the tip of the drill bit penetrates the far cortex.
Confirm drill bit position.
Ensure that the drill sleeve is pressed firmly to the near cortex and read the measurement from the drill bit at the back of the drill sleeve. This measurement corresponds to the appropriate length locking screw.
Confirm a minimum distance of 48 mm is measured bicortically with the drill bit/depth gauge to ensure sufficient insertion depth for each nut.
Remove drill bit.

Note: Consider anatomy and/or position of the nail in the bone. A minimum distance of 20 mm measured with the drill bit/depth gauge from the surface of the bone to the outer surface of the nail is needed to ensure the nut does not contact the nail at final tightening.

2. Option: Countersink for Nut

Instrument
03.045.034 Countersink ∅ 7.4 mm, Quick Coupling

Countersink can be used to ease insertion of nut in hard bone.
Use countersink under power through aiming arm at the location of the desired screw hole location. Drill with countersink until the stop on the countersink contacts the cortical surface.

3a. For Single, Distal Nut Configuration: Insert locking screw

Instruments
03.045.001 Screwdriver XL25
03.045.002 Retention Pin for Screwdriver XL25
03.045.019 Protection Sleeve, ∅ 11/8

With the retention pin inserted into the screwdriver, insert the screwdriver into the screw head recess. Thread the retention pin into the screw head until secure.
To place the washer for screw, retact the protection sleeve. Insert the appropriate length locking screw through the protection sleeve, exposing the screw tip.
Position the washer for screw over the screw tip. Continue insertion of screw until the screw head lies against the near cortex.
Keep screwdriver engaged with screw.

3b. For Dual Nut Configuration: Insert locking screw
With the retention pin inserted into the screwdriver, insert the screwdriver into the screw head recess. Thread the retention pin into the screw head until secure.
Using the protection sleeve at the desired screw hole position in the aiming arm, secure the protection sleeve in a retracted position in the aiming arm to allow attachment of the nut to the screw tip.
Use the screwdriver to insert the appropriate length locking screw through the protection sleeve until the tip of the screw is visible. Thread nut onto tip of screw until secure.
Advance screw and nut assembly and protection sleeve to the bone.

Note: If using the washer for nut, position the washer over the nut prior to advancing the screw and nut assembly to the bone.

Proceed with inserting screw and nut until the nut is seated in the bone and the screw head is seated within the nut.

Note: Prior to inserting nut into bone, forceps can be used to hold nut during screw insertion until the screw head is seated in the nut. Keep screwdriver engaged with screw.

4. Insert Distal Nut and Final Tighten

Instruments
03.045.033 Driver for Nut
03.045.001 Screwdriver XL25
03.045.022 Retention Pin for Screwdriver XL25

At the contralateral position in the aiming arm, insert the nut driver partially through the aiming arm.
Attach the nut to the nut driver.
Note: If using the washer for nut, position the washer over the nut prior to advancing the nut to the bone.
Advance nut to the bone, ensuring alignment with the screw tip.
While holding the screwdriver in position, tighten nut with nut driver until seated.

Note: The poly inlay inhibits sliding of the screw when using the nut to achieve compression. To reduce the potential of driving the screw and nail out of position and/or affecting bony reduction, use the screwdriver to provide counter-torque during nut insertion.
Remove nut driver, screwdriver, and protection sleeve.
Repeat Steps 1 through 4 for additional nuts, if desired.

Insert End Cap
Option: Insert end cap

Instruments	
03.045.001	Screwdriver XL25
03.045.002	Retention Pin for Screwdriver XL25

Remove the connecting screw.
For 0 mm end cap, the insertion handle can remain in place to help align the end cap to the nail. The end cap fits through the barrel of the insertion handle. Insert end cap through barrel of insertion handle and tighten until secure.
The 5 mm and 10 mm end caps do not fit through the barrel of the insertion handle. To insert end cap, remove insertion handle. Insert end cap and tighten until secure.
If desired, the end cap can be locked to the screwdriver by use of the retention pin. To do so, slide the retention pin through the back of the screwdriver until it stops. Further advance it by turning it clockwise, until its tip extends out of the tip of the screwdriver.

Polymer Inlay removal
Option: Remove Polymer Inlay

Instrument	
03.019.017	Depth Gauge for Multiloc Humeral Nailing System
Alternative Instrument	
356.717	Guide Wire 2.8 mm Length 460 mm with Hook

To remove the inlay, remove the hook from the depth gauge by sliding the outer sleeve until disassembled.
Hold the instrument close to the hook. Insert the hook into the distal end of the nail through the cannulation. Hook the edge of the proximal inlay screw hole, ensuring that the hook is not contacting the nail. Pull the hook to remove the inlay.

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