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.

EC REP

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE 0123

Instructions for Use

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".

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

Positioning Patient and Approach
1. Position the patient supine on a radiolucent table. Position the image intensifier to allow visualization of the proximal and distal femur in AP and lateral views.
2. Reduce fracture.
3. Measure for length and diameter of nail.
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.
   Precaution: To reduce the risk of malreduction during nail insertion in patients with good bone quality: Consider achieving and maintaining fracture reduction first and consider directing guide wire anteriorly based on nail design and fracture pattern.
5. Open medullary canal.
   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.
   Note: Ensure care is taken not to dislodge the femoral components of any prosthesis and that any components are compatible with selected implants.
6. Ream the medullary canal (optional).

Implant Insertion
7. Insert nail.
8. Insert Distal locking option. The Retrograde Femoral Nail offers distal locking options including locking screws, screw washers, condylar nuts and washers and the Locking Attachment Washer.
   Note: 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.
   Note: Final tightening of locking screws must be completed with manual detachable handle.
   Note: 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)
   Note: Ensure care is taken not to dislodge the femoral components of any prosthesis and that any components are compatible with selected implants.
   Note: Nut should only be used with the 5.0 mm Locking Screws for Medullary Nails.
9. Insert proximal locking screws.
   Proximal locking can be performed before distal locking, when appropriate.
10. Insert End Cap.
    Note: In a Standard Locking construct, the use of a 0 mm end cap may reduce the risk of screw migration.

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