Instructions for Use
Tibial 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.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE 0123

Tibial Nail ADVANCED

Devices in scope

Tibial Nail ADVANCED

Length (mm)	∅ 8 mm	∅ 9 mm	∅ 10 mm
255	04.043.005S	04.043.105S	04.043.205S
270	04.043.010S	04.043.110S	04.043.210S
285	04.043.015S	04.043.115S	04.043.215S
300	04.043.020S	04.043.120S	04.043.220S
315	04.043.025S	04.043.125S	04.043.225S
330	04.043.030S	04.043.130S	04.043.230S
345	04.043.035S	04.043.135S	04.043.235S
360	04.043.040S	04.043.140S	04.043.240S
375	04.043.045S	04.043.145S	04.043.245S
390	04.043.050S	04.043.150S	04.043.250S
405	04.043.055S	04.043.155S	04.043.255S
420	04.043.060S	04.043.160S	04.043.260S
435	04.043.065S	04.043.165S	04.043.265S
450	04.043.070S	04.043.170S	04.043.270S
465	04.043.075S	04.043.175S	04.043.275S

Length (mm)	∅ 11 mm	∅ 12 mm	∅ 13 mm
255	04.043.305S	04.043.405S	04.043.505S
270	04.043.310S	04.043.410S	04.043.510S
285	04.043.315S	04.043.415S	04.043.515S
300	04.043.320S	04.043.420S	04.043.520S
315	04.043.325S	04.043.425S	04.043.525S
330	04.043.330S	04.043.430S	04.043.530S
345	04.043.335S	04.043.435S	04.043.535S
360	04.043.340S	04.043.440S	04.043.540S
375	04.043.345S	04.043.445S	04.043.545S
390	04.043.350S	04.043.450S	04.043.550S
405	04.043.355S	04.043.455S	04.043.555S
420	04.043.360S	04.043.460S	04.043.560S
435	04.043.365S	04.043.465S	04.043.565S
450	04.043.370S	04.043.470S	04.043.570S
465	04.043.375S	04.043.475S	04.043.575S

End Cap for Tibial Nail ADVANCED

Article No.	Extension (mm)
04.045.850S	0
04.045.855S	5
04.045.860S	10
04.045.865S	15

Locking Screw for Medullary Nails, ∅ 5 mm*

Article No.	Length (mm)	Article No.	Length (mm)
04.045.026	26	04.045.062	62
04.045.028	28	04.045.064	64
04.045.030	30	04.045.066	66
04.045.032	32	04.045.068	68
04.045.034	34	04.045.070	70
04.045.036	36	04.045.072	72
04.045.038	38	04.045.074	74
04.045.040	40	04.045.076	76
04.045.042	42	04.045.078	78
04.045.044	44	04.045.080	80
04.045.046	46	04.045.082	82
04.045.048	48	04.045.084	84
04.045.050	50	04.045.086	86
04.045.052	52	04.045.088	88
04.045.054	54	04.045.090	90
04.045.056	56	04.045.095	95
04.045.058	58	04.045.100	100
04.045.060	60		

Locking Screw for Medullary Nails, ∅ 4 mm*

Article No.	Length (mm)	Article No.	Length (mm)
04.045.218	18	04.045.250	50
04.045.220	20	04.045.252	52
04.045.222	22	04.045.254	54
04.045.224	24	04.045.256	56
04.045.226	26	04.045.258	58
04.045.228	28	04.045.260	60
04.045.230	30	04.045.262	62
04.045.232	32	04.045.264	64
04.045.234	34	04.045.266	66
04.045.236	36	04.045.268	68
04.045.238	38	04.045.270	70
04.045.240	40	04.045.272	72
04.045.242	42	04.045.274	74
04.045.244	44	04.045.276	76
04.045.246	46	04.045.278	78
04.045.248	48	04.045.280	80

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

Article No.	Length (mm)	Article No.	Length (mm)
04.045.326	26	04.045.362	62
04.045.328	28	04.045.364	64
04.045.330	30	04.045.366	66
04.045.332	32	04.045.368	68
04.045.334	34	04.045.370	70
04.045.336	36	04.045.372	72
04.045.338	38	04.045.374	74
04.045.340	40	04.045.376	76
04.045.342	42	04.045.378	78
04.045.344	44	04.045.380	80
04.045.346	46	04.045.382	82
04.045.348	48	04.045.384	84
04.045.350	50	04.045.386	86
04.045.352	52	04.045.388	88
04.045.354	54	04.045.390	90
04.045.356	56	04.045.395	95
04.045.358	58	04.045.400	100
04.045.360	60		

Locking Screw for Medullary Nails, Low Profile, ∅ 4 mm*

Article No.	Length (mm)	Article No.	Length (mm)
04.045.518	18	04.045.550	50
04.045.520	20	04.045.552	52
04.045.522	22	04.045.554	54
04.045.524	24	04.045.556	56
04.045.526	26	04.045.558	58
04.045.528	28	04.045.560	60
04.045.530	30	04.045.562	62
04.045.532	32	04.045.564	64
04.045.534	34	04.045.566	66
04.045.536	36	04.045.568	68
04.045.538	38	04.045.570	70
04.045.540	40	04.045.572	72
04.045.542	42	04.045.574	74
04.045.544	44	04.045.576	76
04.045.546	46	04.045.578	78
04.045.548	48	04.045.580	80

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

Locking Screw 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

Locking Screw StarDrive™ ∅ 4 mm (dark blue)*

Article No.	Length (mm)	Article No.	Length (mm)
04.005.408	18	04.005.440	50
04.005.410	20	04.005.442	52
04.005.412	22	04.005.444	54
04.005.414	24	04.005.446	56
04.005.416	26	04.005.448	58
04.005.418	28	04.005.450	60
04.005.420	30	04.005.452	62
04.005.422	32	04.005.454	64
04.005.424	34	04.005.456	66
04.005.426	36	04.005.458	68
04.005.428	38	04.005.460	70
04.005.430	40	04.005.462	72
04.005.432	42	04.005.464	74
04.005.434	44	04.005.466	76
04.005.436	46	04.005.468	78
04.005.438	48	04.005.470	80

* 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 Tibial Nail ADVANCED implants consist of cannulated tibial nails, cannulated end caps and locking screws. The Tibial Nail ADVANCED nails are manufactured from titanium alloys and polyetheretherketone (PEEK). Also, the nails are anatomically contoured and tapered to a nominal diameter of 8, 9, 10, 11, 12 or 13 mm. The nails are available in lengths from 255 mm to 465 mm. The nails with a diameter of 9 mm to 13 mm accept 5.0 mm locking screws. The nails with a diameter of 8 mm accept 4.0 mm locking screws distally and 5.0 mm locking screws proximally.

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)
Nails	Ti-6Al-4V (TAV) Titanium Alloy	ISO 5832-3
	Polyetheretherketone (PEEK)	ASTM F2026-17
End Caps	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11
Screws	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11

Intended Use
The Tibial Nail ADVANCED implants are intended to be used for temporary fixation and stabilization of tibia.

Indications
The Tibial Nail ADVANCED implants are intended for treatment of fractures in adults and adolescents (12–21) in which the growth plates have fused. Specifically, the implants are indicated for:
– Open and closed proximal and distal tibial fractures
– Open and closed tibial shaft fractures
– Tibial malunions and nonunions

Contraindications
No contraindications specific to these devices.

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device. 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 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 Tibial Nail ADVANCED implants when used according to instructions for use and recommended technique are:
– Stabilize bone fragments and facilitate healing
– Restore anatomical alignment and extremity function

Performance Characteristics of the Device
The Tibial Nail ADVANCED implants provide versatile locking options proximally and distally which enable primary compression or secondary dynamization limited by the length of the dynamic slot.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
– Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction
– Infection
– Poor Joint Mechanics
– Damage to Surrounding Structures
– Embolism
– Malunion/Nonunion
– Neuro-vascular Damage
– Pain or Discomfort
– Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis
– Soft Tissue Damage (including Compartment Syndrome)
– Injury to User
– Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage

Sterile Device

STERILE R 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 Tibial Nail ADVANCED implants can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single-Use Device

 Do not re-use

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

Re-use or clinical 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, re-use 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 Tibial 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. Physician should consider reaming to avoid under-sizing, to improve fit of nail, and to accelerate bone healing.
- 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.
- 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.

Precautions
For precautions specific to a surgical step please refer to section 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 F 2119-07
Non-clinical testing of worst-case scenario in a 3 T Magnetic Resonance Imaging (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 F 2182-11a
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 (1.5T) 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 Magnetic Resonance (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 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. 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. If the two most proximal locking screws were used, they must be removed. 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 except one.
3. Thread the extraction screw into the nail.
4. Remove the remaining locking 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".

Additional Device-Specific Information

 Caution, see instructions for use

 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** supine on a radiolucent table appropriate for the selected approach to the tibia. Position the image intensifier such that visualization of the tibia including the articular surface proximally and distally is possible in Anterior-Posterior (AP) and lateral views.
2. **Reduce fracture.**
3. **Make the incision** appropriate for the selected approach to the tibia.
4. **Determine entry point.** In the AP view the entry point is in line with the axis of the medullary canal and with the medial aspect of the lateral tubercle of the intercondylar eminence. In the lateral view the entry point is on the ventral edge of the tibial plateau.
   Precaution: Deviation from the optimal entry portal may cause irreducible malalignment, iatrogenic bone and soft tissue damage, malunion, and nonunion.
   Precaution (suprapatellar approach): Flexion of the knee must not be changed once the guide wire is inserted. A change could lead to increased pressure on the cartilage and could hinder surgical steps.
   Precaution (suprapatellar approach): Do not apply forces to the wire guide to reach the correct entry point. Adjust position of the wire guide by slight adjustments of the knee flexion (between 10° and 30°).
   Precaution (suprapatellar approach): The knee must remain in extension once the handle assembly has been inserted.

5. **Open medullary canal.** Use a protection sleeve to prevent damage to the surrounding soft tissue, monitor that the tip of the protection sleeve remains in direct contact to the proximal tibia. Drill to a depth of approximately 8–10 cm. When using nails with a diameter of 12 mm and 13 mm, the opening must be made at least 1 mm larger than the nail, using a medullary reamer system.
   Precaution: Pay special attention not to penetrate the posterior cortex.
   Precaution: The suprapatellar protection sleeve is available in two different diameters. Markings on the sleeves indicate compatible nail diameters. Suprapatellar protection sleeves are compatible with SynReam reamer heads which are up to 1.5 mm larger in diameter than the largest compatible nail.
   Precaution: Do not drill inside the protection sleeve.
   Flexible Suprapatellar protection sleeves allow nail insertion through the sleeve. Rigid Suprapatellar protection sleeves require removal of the metal rigid tube prior to nail insertion.
   Protection sleeves used for parapatellar and infrapatellar approaches do not allow nail insertion.
6. **Insert reaming rod (Optional).**
   Precaution: The Tibial Nail ADVANCED is cannulated and can be inserted over reaming rods with a diameter of up to 3.8 mm at their widest point. Compatible reaming rods will pass through the dedicated hole in the center of the aiming arm.
7. **Determine nail length and diameter.** Measure using the direct measuring device or the radiographic ruler.
8. **Reaming (Optional).**
   Precaution: Do not ream inside the protection sleeve.
   Precaution: Monitor that the tip of the protection sleeve remains in direct contact to the proximal tibia.
   Precaution (suprapatellar approach): The reamer must travel through the protection sleeve before entering the bone. This may require a longer reamer shaft.
9. **Assemble insertion instruments.** Connect the insertion handle to the nail by aligning the markings on the nail with the two slots on the barrel of the insertion handle. Push both parts together until they snap into place. Pass the connecting screw through the insertion handle to engage with the nail and securely tighten it with the screwdriver.
   Precaution: Ensure that the connection between the nail and the insertion handle is tight. Retighten if necessary, after hammering and prior to the attachment of the aiming arm.
   Precaution: Do not attach the aiming arm to the insertion handle at this point.
10. **Insert nail.** Monitor the nail passage across the fracture and control it in two planes to prevent misalignment.
    Precaution: If insertion is difficult, use the C-arm to confirm that there is no obstruction of the medullary canal. If no obstruction is found, choose a nail with a smaller diameter or enlarge the entry canal by reaming the medullary canal to a larger diameter.
    Precaution: Do not use excessive twisting motions of the insertion handle.
    Precaution: To use the hammer, attach the driving cap to the insertion handle and secure it by twisting it one quarter turn. Apply light and controlled hammer blows to seat the nail.
    Precaution: Remove reaming rod.
11. **Check proximal nail position.** Check proximal nail position under image intensifier control in the lateral view.
    Precaution: The distance between the markings on the insertion handle is 5 mm and corresponds to the extensions of the end caps. This feature can be used for over-insertion of the nail or for correcting the nail location within the medullary canal.
    Precaution: If primary compression or secondary dynamization is planned, it is recommended to over-insert the nail by at least 7 mm, which corresponds to the maximum distance between the positions in static and dynamic modes. Protrusion of the proximal end of the nail can lead to irritation of the patellar tendon.
    Trajectories of the two most proximal locking screws can be projected on a C-arm image by placing the drill bit through the dedicated holes in the aiming arm. Insert the protection sleeve and drill sleeve into the corresponding hole in the aiming arm and assess the trajectory of the screw by taking an x-ray image in which the projections of the drill bit and the drill sleeve overlay.
12. **Check distal nail position.**
    Precaution: Insertion depth is critical for distal third fractures where a minimum of two locking screws below the fracture line are required to stabilize the distal segment.
    Precaution: To achieve compression the tibial nail needs to be locked distally first. The tibial nail allows a maximum compression or dynamization of 7 mm.
    Precaution: Depending on the fracture patterns it might be advantageous to lock proximally first.
13. **Distal locking.**
    Precaution: Stop drilling immediately after penetrating both cortices.
    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: Use a ∅ 5.5 mm reamer, to make room for the threaded screw head of the 4.0 mm low profile locking screw for 8 mm nail.
    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.
14. **Proximal locking.**
    Precaution: Do not exert forces on the aiming arm, protection sleeve, drill sleeves and drill bits. These forces may prevent accurate targeting through proximal locking holes and damage drill bits.
    Precaution (medial to lateral locking options): Stop drilling immediately after penetrating both cortices.
    Precaution (oblique and AP locking options): Proximal locking requires special attention. To avoid lesion of the popliteal artery, the tibial nerve and the common peroneal nerve, as well as damage to the proximal tibiofibular joint, drilling must be stopped immediately before penetrating the far cortex. Monitor the position of the drill bit.
    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.
    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.

15. **End Cap Insertion.** Remove the connecting screw. The insertion handle can remain in place to help align the end cap to the top of the nail. Insert end cap through the barrel of the insertion handle and tighten to the nail. Select extension of end cap according to the expected secondary dynamization and flush with the bony surface.

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Instructions for Use:
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