Instructions for Use
Synthes Expert TN PROtect (with Antibiotic Coating)

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

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Instructions for Use

Introduction
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Additional information
Expert Tibial Nails with Antibiotic Coating (Expert TN PROtect) have the same design and properties as uncoated intramedullary nails. They are manufactured from titanium alloy Ti-6Al-7Nb (TAN).

The bioresorbable coating of Expert TN PROtect consists of an intrinsically amorphous polylactide carrier (PDLLA) that contains gentamicin sulfate. The surface of all PDLLA + gentamicin sulfate coated Expert TN PROtect is enhanced with 0.19 mg/cm² (±0.05 mg/cm²) of gentamicin sulfate.

The total amount of gentamicin sulfate contained in the coating varies, and is dependent upon the type of implant, its size, and its surface area. The table below provides an overview of the range of gentamicin sulfate contained in the coating appropriate for the nail's length and diameter:

Length	Diameter 8–13 mm	Length	Diameter 8–13 mm
255 mm	15–36 mg	375 mm	22–53 mg
270 mm	16–38 mg	390 mm	23–55 mg
285 mm	17–40 mg	405 mm	24–57 mg
300 mm	18–42 mg	420 mm	24–59 mg
315 mm	19–44 mg	435 mm	25–61 mg
330 mm	20–46 mg	450 mm	26–63 mg
345 mm	20–49 mg	465 mm	26–65 mg
360 mm	21–51 mg		

Material(s)

Material(s):	Standard(s):
Ti-6Al-7Nb (TAN)	ISO 5832-11
Poly(D,L-lactic acid)	ASTM F2579
Gentamicin Sulfate	Ph Eur 0331

Intended use
Expert TN PROtect is intended to be used for the surgical treatment and stabilization of fractures of the tibia.

Indications
The Expert TN PROtect is indicated for fractures in the tibial shaft as well as for metaphyseal and certain intra-articular fractures of the tibial head and the pilon tibiale:
– 41-A2/A3
– All shaft fractures
– 43-A1/A2/A3
– Combinations of these fractures

For the following indications the Expert Tibial Nail should be used in combination with other implants:
– 41-C1
– 43-C1

The Expert TN PROtect should be used in cases where there is an increased risk of local bone infections, for example, in polytraumatized or immunosuppressed patients, in patients with open fractures and in patients having complications such as non-unions requiring revision procedures. The purpose of the PROtect coating is to prevent bacterial colonization on the nail's surface after it has been implanted.

The effectiveness of the antibiotic coating should become apparent during the first few hours and days after implantation.

The effectiveness of the PDLLA + gentamicin sulfate coating is restricted to gentamicin-sensitive bacteria.[1]

Expert TN PROtect is not indicated for local antibiotic therapy of existing infections.

[1] Remark: In relation to PK/PD data, the indication is based on the results from in vitro and in vivo models that the investigated models adequately simulate the clinical situation and allow a reliable estimation of the behavior of antibiotic coated implants after implantation. The composition of the coating and the amount of coating per unit surface area on the implants used for the animal study is identical to the values specified for the Expert TN PROtect. Although clinical PK data are preferred, the present data can be considered of indirect supportive value.

Contraindications
Expert TN PROtect should not be used in the following circumstances:
– Established intolerance/allergy to gentamicin or other aminoglycosides
– Established intolerance/allergy to polylactides

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion.

Incompatibilities to the constituents of the coating of Expert TN PROtect may occur, but are not to be expected in view of the low concentrations involved.

As with all aminoglycosides, gentamicin can be nephrotoxic and/or ototoxic. Due to the extremely low systemic concentrations arising from the coating, an accumulation should not occur; however, special caution is indicated for patients with restricted renal function.

Gentamicin can produce neuromuscular blocking effects in patients with severely restricted renal function. Special cautions must also be taken in patients with neuromuscular diseases (e.g. Parkinson's disease, Myasthenia gravis), or in patients receiving concomitant muscle relaxants (e.g. during systemic administration of gentamicin). Patients receiving concomitant parenteral gentamicin must be kept under close surveillance due to the possible risk of cumulative toxicity.

Sterile device

STERILE R Sterilized using irradiation

Do not resterilize

Device-specific precautions/warnings
Expert TN PROtect are supplied sterile, using gamma irradiation.

Before opening the single units, check the integrity of the packaging. Remove products from the package in an aseptic manner. The manufacturer cannot guarantee sterility if the unit package was open or if the package is improperly opened.

The contents of an opened or damaged unit package may no longer be used and must be destroyed. Once the unit pack has been opened, the content must be used immediately. Any unused parts must be destroyed.

Do not attempt to re-sterilize the unused contents of an opened package, but dispose such remnants. Re-sterilizing of Expert TN PROtect can result in product not being sterile, and/or not meeting product properties.

Do not use after the expiry date.

Single-use device

Do not re-use

Products intended for single-use must not be re-used.

Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

For implants only
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
- Appropriate systemic antibiotic prophylaxis administered as recommended in the manual, "AO Principles of Fracture Management", is not affected by the use of an Expert TN PROtect in any way; prophylactic treatment should therefore not be reduced. Careful consideration should, however, be paid to the potential safety precautions relating to the absorption of additional antibiotics.
- Regular follow-up examinations are recommended, with heightened attention to the potential risk of the emergence of resistance and super-infections.
- In view of the low levels of gentamicin in the coating, toxic plasma levels are not expected to occur in the body following implantation of the Expert TN PROtect.
- No more than one Expert TN PROtect should be implanted per procedure.
- The possibility of cross-allergy to aminoglycosides should be taken into account.
- Expert TN PROtect is sensitive to temperature and moisture.
- Expert TN PROtect may only be used in patients with limited renal function, or in patients with autoimmune disorders, if strictly indicated.
- In patients with complete renal failure, the monitoring of serum gentamicin levels is optional and should be undertaken on a case-by-case basis.
- Gentamicin can cross the placental barrier and reach detectable concentrations in the fetal tissue and the amniotic liquor. Animal experiments have shown reproductive toxicity. Gentamicin is also excreted into breast milk. Expert TN PROtect is not recommended to be used during pregnancy or lactation. In this case the treating physician should weigh the benefits of the application of Expert TN PROtect against the potential risks for the patient and the child.
- Using the Expert TN PROtect in patients with open epiphysis may impair bone growth. The Expert TN PROtect is therefore not recommended for use in skeletally immature patients. In this case the treating physician should weigh the benefits of the application of the Expert TN PROtect against the potential risk for the patient.

Combination of the medical device with a drug
Combination of the medical device with: Gentamicin Sulfate.

Exposure

Interactions with other Substances
The concurrent or consecutive systemic or topical administration of potentially neurotoxic, hepatotoxic, ototoxic and/or nephrotoxic substances such as cisplatin, other aminoglycosides, streptomycin, cephaloridine, viomycin, polymyxin B or E, could potentiate the toxicity of gentamicin.

As some diuretics may cause ototoxic effects, the concomitant administration of strong diuretics, such as ethacrynic acid or furosemide, may potentiate the ototoxic effect of gentamicin.

During intravenous administration of diuretics, the toxic effects of aminoglycosides can increase due to a shift in serum and tissue antibiotic concentration levels. After local delivery of gentamicin, detectable levels in the bone are not reached or, at most, only for a short period (±24 h).

Gentamicin sulfate is further reported to deplete cations, e.g. Calcium, Magnesium and Potassium. Supplementation of depleted cations can reduce the possible effects arising thereof.

Iodine-containing drugs, such as some chemotherapeutics, can interact with the Gentamicin as well.

No interactions with other substances are reported.

In exceptional cases, particularly in patients with restricted renal function, interactions arising from parenteral administration may occur.

No interaction or incompatibility between this product and any other systemically or locally-delivered substance has been reported to date.

Incompatibilities
No incompatibilities with disinfectant solutions have been reported to date.

Countermeasures in the Event of Incompatibilities
In the event of proven incompatibilities to the constituents of the Expert TN PROtect's coating, the implant may need to be removed and replaced by an uncoated implant.

Restricted or Invalid Usability
The use of irrigation-suction drainage may lead to the accelerated release of gentamicin from the coating, thereby possibly reducing its effectiveness.

The implant should not be rinsed or irrigated excessively prior to or during the insertion process to avoid premature release of the Gentamicin sulfate.

Score marks in the coating, arising from the manufacturing process, may occur on the nail, but these will not adversely affect its functionality in any way.

MRI Information

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

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

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

Treatment before device is used

Device-specific treatment instructions before surgical use:

Preventive Measures for Implant Handling
- The usual surgical principles should be observed during implantation in order to ensure that the Expert TN PROtect functions properly.
- Do not open the package until use. Examine the package for damage before using the Expert TN PROtect, as damage to packaging might impair sterility. Expert TN PROtect must not be used if the sterile package is damaged.
- In removing the implant from its package, strictly observe the instructions concerning aseptic procedures.
- Do not allow the Expert TN PROtect to come into contact with moisture before implantation.
- During use, do not place the Expert TN PROtect in a wet medium. Insert the implant at the intended site using dry instruments and dry gloves.
- Care must be taken to ensure the PDLLA + gentamicin sulfate coating is not damaged before implantation.
- Implants that have been removed from their sterile packaging must not be re-sterilized and used.

Special operating instructions

Implantation Period
The implantation period of the Expert TN PROtect is similar to that of uncoated Expert TN. In this context, please refer to the relevant details in the surgical technique of the Expert TN as well as the current “AO Principles of Fracture Management”.

Device-related storage and handling information


Upper limit of temperature: 25 °C


Keep dry


Keep away from sunlight


Do not use if package is damaged

Expert TN PROtect are sensitive to moisture and temperature.

Expert TN PROtect should be stored in a dry and clean environment and protected from direct sunlight. Store below 25 °C.

Additional device-specific information

Reference Number

Lot or batch number


Manufacturer


Expiration date

Notified body

Disposal

Disposal of unused Implants
In order to prevent the development of resistance to gentamicin/aminoglycosides, any unused Expert TN PROtect should be disposed of along with the hospital’s hazardous waste.

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