

Patient Information Leaflet

EXPERT™ Tibial Nail PROtect™

Expert Tibial Nail PROtect

Device Description

Expert Tibial Nail PROtect is a nail implant intended for the fixation of fractures. The nail is coated with antibiotic to prevent bacterial colonization on the implant surface.

Device Materials

Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium)
Poly (D, L-lactic acid)
Gentamicin Sulfate

The device is made of medical grade metal (Titanium Alloy) and coated with Poly (D, L-lactic acid) that contains Gentamicin Sulfate.

Information for Safe Use

There is nothing for you to do to ensure safe use of this device. You should follow your doctor's advice after surgery.

Discuss any questions, concerns or potential side effects with your physician.

This device is MR Conditional.

MRI:

If you do need a Magnetic Resonance Imaging (MRI), you should let your doctor know about any previous surgeries.

Expected Device Lifetime and Follow-up

Bone healing usually lasts no longer than 6–9 months. In terms of mechanical performance, the therapeutic lifetime of the Tibial Nailing Implants is therefore seen as up to 9 months.

The bactericidal effect of PROtect coating lasts approximately 2 weeks after implantation. It is completely resorbed after approximately 6–12 months*.

* Preclinical studies may not necessarily be indicative of clinical performance in humans.

Any updated information will be provided on the website. This includes changes to the device lifetime and information for medical professionals.



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Information specific to your implant, including the lot/serial number, unique device identifier, etc. are included on the implant card as well as within patient records as kept by your health care provider.



Patient name



Date of implantation



Name and Address of the Implanting Health Institution/
Health care Provider



Name and Address of the manufacturer



Information website for patients



Serial Number



Lot Number/Batch Code



Unique Device Identifier



Catalogue number symbol



Medical Device



MR Conditional



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