Patient Information Leaflet for Phantom Nail System

This leaflet has information about your implant. It does not contain all possible information. If you have any questions, talk to your healthcare team. All implants have potential risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.

The name and number of your nail implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Implant Description

Phantom Nails are used to stabilize bones and joints during healing after procedures for bone fixation and/or joint fusions.

Implant Material

The implant material is Titanium alloy.

Information for Safe Use

There is nothing you need 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.

You should have received a set of instructions from your doctor. These instructions may include activity restrictions, rehabilitation information, and other recommended therapies. It is very important that you follow your doctor's instructions. Your doctor will provide instructions about how to recover and restart activities. Make sure you attend all appointments. Healing takes time and your doctor will provide information on what to expect. Not following your doctor's advice may increase your risk of complications and the need for additional operations.

If you are scheduled for an MRI scan, please show your implant card to the doctor and MRI technician. The MRI scan may interact with your implant and could cause issues if your technician is unaware of your implant. This will allow them to perform your MRI scan safely.

Possible Side Effects / Risks

Your doctor will provide information about the possible side effects of your operation. All operations have potential risks. The risk of a serious issue is low. There is a risk that you may require additional operations or treatments for several reasons. Please talk to your doctor if you have concerns.

Possible risks may include:

- Loosening, Deformation or Fracture of the implant (A loose, deformed or broken implant)
- Acute post-operative infections (Including the possibility of sepsis – infection of the blood stream)

- Migration (implant shifts position), subluxation (implant partially dislocated) of the implant causing reduction in range of movement (The ability to perform certain body movements may be restricted)
- Fractures from unilateral joint loading (A break in the bone due to everyday movement)
- Thrombosis (blood clots blocking your blood vessels) and Embolism (blocked artery caused by a blood clot or an air bubble)
- Wound hematoma (bruising) and delayed wound healing
- Temporary and protracted functional neurological perturbation (Accidental nerve injury)
- Tissue reactions (Allergic reaction or foreign body reaction to dislodged particles)
- Corrosion with localized reaction (Painful reaction caused by breakdown of the implant over time)
- Pain, a feeling of malaise (Abnormal sensations due to the implant used)
- Bone loss due to stress shielding (Osteoporosis – loss of bone)
- Nonunion or malunion with rotation or angulation resulting in limb shortening or loss of anatomic positioning (Failure of the bone to heal or healing in an incorrect position.)
- Irritation of soft tissues, including impingement syndrome (Pain or inflammation possibly associated with certain movements.)

These complications may require additional operations or treatments. This list does not include all risks. Your doctor can further explain the potential risks of your operation.

MR SAFETY INFORMATION

MRI Safety Information 

A patient with the Paragon 28® Phantom® Hindfoot TTC/TC Nail may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of Device	Paragon 28® Phantom® Hindfoot TTC/TC Nail
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3T
Maximum Spacial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF trasnmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg
Limits on Scan Duration	2.0 W/kg whole body average SAR for 14 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may product an image artifact of 23 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

MRI Safety Information 

A patient with the Paragon 28® Phantom Small Bone Intramedullary Nail may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of Device	Paragon 28® Small Bone Intramedullary Nail
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3T
Maximum Spacial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF trasnmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may product an image artifact of 23 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

Expected Implant Lifetime and Follow Up

The implant materials used are safe for long-term implantable use and may remain chemically inactive in the body indefinitely.

Information specific to your implant, such as lot number/serial number and unique device identifier are included on the implant card. This information is also located in the patient records kept by your health care provider.

Reporting Adverse Effects

If you wish to report any adverse effects you believe are a result of your implant, please speak with your medical team or report the information to Paragon 28, Inc. at +1 (855) 786-2828 and the Therapeutic Goods Administration at https://www.tga.gov.au

For access to this leaflet, please visit: https://www.paragon28.com/patients/information

List of product names:

Phantom Small Bone Intramedullary Nails:

Example Model No.:	Screw:	P30-S1-3514
	Nail:	P30-L2-5538
		P30-R2-5538

Phantom Hindfoot TTC/TC Nails:

Example Model No.:	Nail:	P31-300-150L-S
		P31-300-150R-S

Phantom ActivCore Nails

Example Model No.: Nail: P31-102-1750-S
P31-115-1750-S
P31-130-1750-S

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