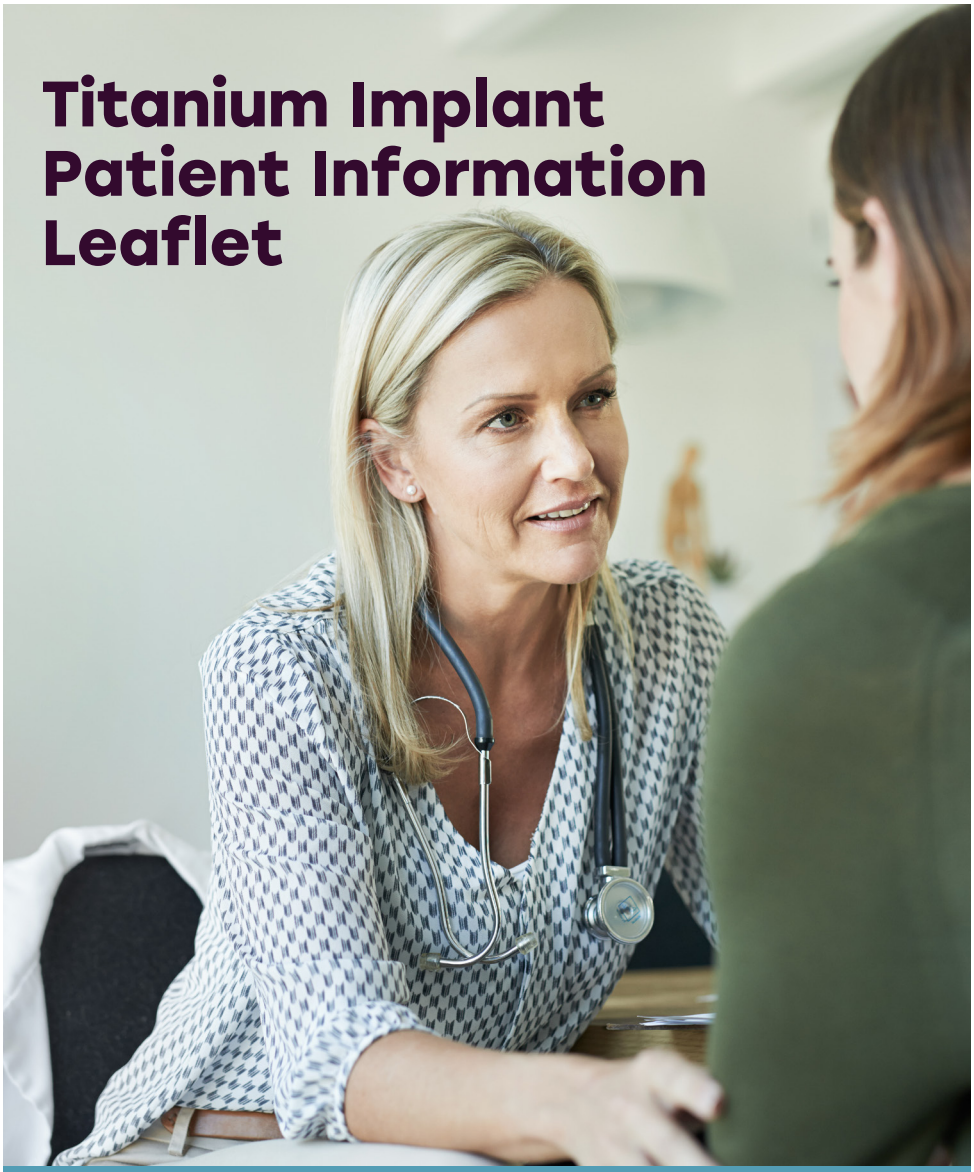
Titanium Implant Patient Information Leaflet



OSSIS

Rapid. Robust. Proven.

OSSIS Limited

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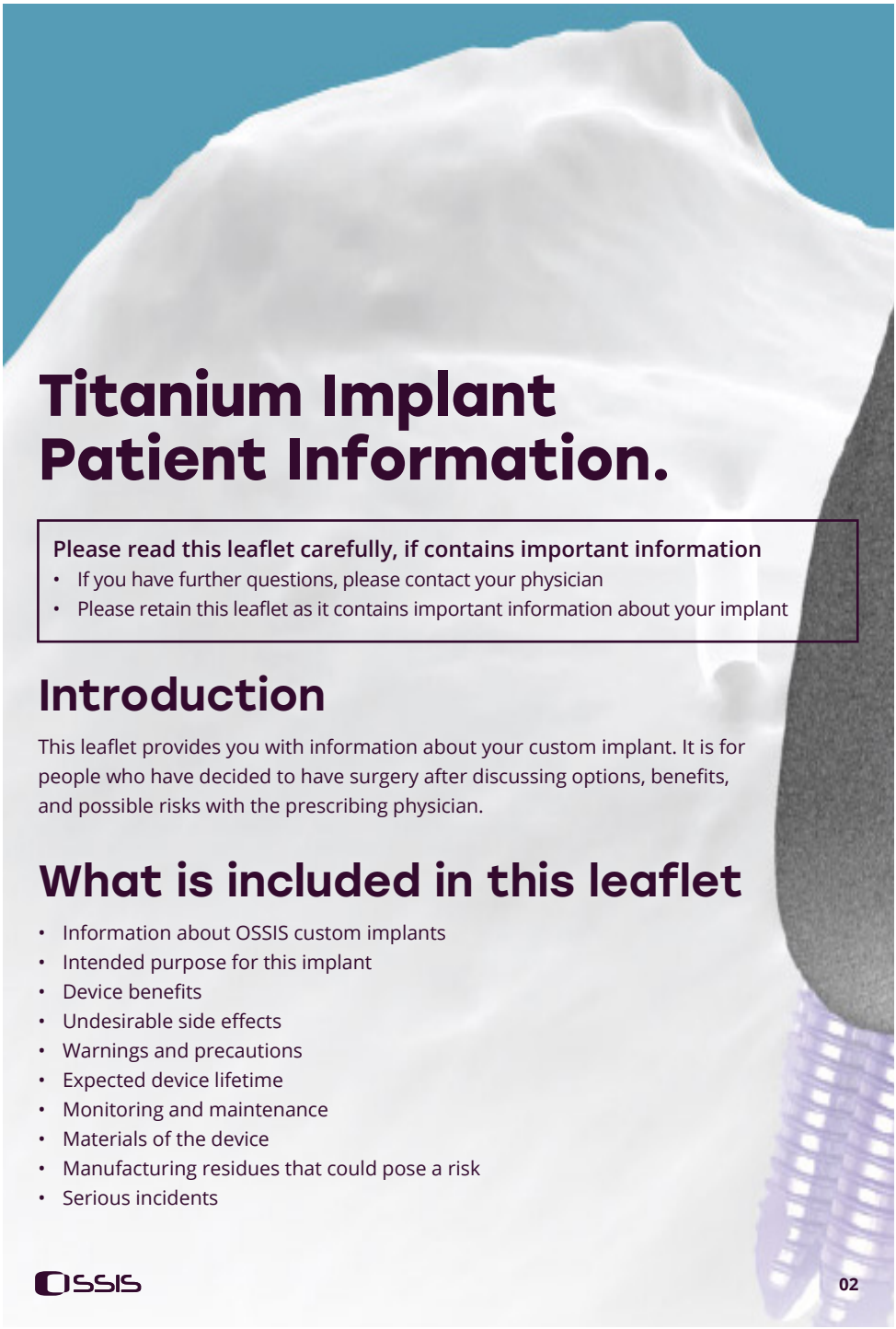

Titanium Implant Patient Information.

Please read this leaflet carefully, if contains important information

- If you have further questions, please contact your physician
- Please retain this leaflet as it contains important information about your implant

Introduction

This leaflet provides you with information about your custom implant. It is for people who have decided to have surgery after discussing options, benefits, and possible risks with the prescribing physician.

What is included in this leaflet

- Information about OSSIS custom implants
- Intended purpose for this implant
- Device benefits
- Undesirable side effects
- Warnings and precautions
- Expected device lifetime
- Monitoring and maintenance
- Materials of the device
- Manufacturing residues that could pose a risk
- Serious incidents

About the OSSIS custom implant

You are receiving a custom titanium implant from OSSIS. OSSIS manufacture custom implants to assist surgeons in the treatment of patients in unique clinical situations that typically cannot be treated with standard-line products. This custom implant has been manufactured in accordance with the written prescription of the surgeon for the sole use of you, the prescribed patient.

This leaflet includes information related to the following OSSIS custom implants:

1001 – AceOs™
1002 – AceOs™ Plus
1003 – Hemi-Pelvis
1004 – Sacrum
1008 – Custom shoulder
1009 – Spinal implant
1024 – Custom talus implant
1027 – Custom foot and ankle
1028 – Sacroiliac

Please refer to your patient implant card or ask your prescribing surgeon if you have any questions around the kind of device.

Intended purpose for this implant

OSSIS custom implants are intended for use in patients, like yourself, who require reconstruction of the bony anatomy due to disease, deformity, trauma, or revisions due to previously failed surgeries, to reduce or relieve pain and/or improve joint function in skeletally mature patients. These custom implants are for single use only and by prescription of a medical practitioner. They are typically designed where a standard commercially available implant cannot be used for treatment.

What are the benefits

OSSIS custom implants can provide many benefits including but not limited to pain reduction and increased mobility.

Undesirable side effects

While undesirable side effects are rare, if you do experience any side effects please consult your prescribing physician for appropriate actions. Some possible side effects that may occur related to your custom OSSIS implant:

- Premature loss of fixation
- Soft tissue irritation and/or nerve damage
- Premature implant wear
- Premature failure of component due to abnormal loadings or activity
- Bone loss around the implant
- Numbing or loss of sensation
- Joint dislocation
- Joint pain or stiffness
- Loss of joint mobility
- Allergic reaction to the implant's material

Warnings and precautions

Your custom implant has been designed to be exclusively used by your prescribing physician and specifically for the sole use of you, the prescribed patient.

There are inherent risks associated with the use of implants in a magnetic resonance (MR) environment. These include implant migration, heat induction, or image distortion. The implant has not been tested for safety and compatibility in an MRI environment; it is advised to present your patient implant card or notify your prescribing physician of your implant prior to MRI examination.

This implant may activate metal detectors.

There are no known residual risks that could arise due to any shortcomings of the protection measures adopted. You should follow any precautions presented to you post-operatively by your surgeon. If the performance of the device changes, please contact your surgeon.

Expected device lifetime

OSSIS has a “One implant for life” philosophy. However, as each device is custom made, the lifetime of OSSIS devices is dependent on each patient’s anatomy and pathology at the time of operation and following the operation. It is recommended to talk with your physician for further guidance.

Your prescribing physician must inform you of anything that could shorten or lengthen your custom implant’s lifetime. These include precautions to take in your daily life as your activity level and weight can affect the lifetime of the implant. Please contact your surgeon if you experience any changes to your custom implant’s performance.

Monitoring and maintenance

A recommended rehabilitation program will be implemented and catered specifically for you and your custom implant by your prescribing surgeon. The implant does not require maintenance; however regular post-operative follow-ups are recommended to monitor your custom implant and detect and early signs of wear or loosening.

Please confer with your prescribing physician for a recommended post-operative follow-up schedule. If you experience any side effects, please contact your prescribing physician to determine the appropriate action to be taken. Following a regular post-operative schedule can provide guidance at or near the end of the expected device lifetime.

Materials and substances included in the device

The OSSIS custom implant is 3D printed in a titanium alloy (Ti6Al4V).

Some OSSIS custom implants, at the prescribing surgeon’s request, are coated with HyProtect™, an antimicrobial ultra-thin plasma coating. HyProtect™ is a combination of pure silver and polysiloxane. Please refer to your patient implant card or ask your prescribing surgeon if you have any questions around the kind of device.

Manufacturing residues that could pose a risk to the patient

OSSIS custom implants are cleaned and packaged using a proven validated process to ensure the appropriate residues from the manufacturing process are removed.

What to do if a serious incident occurs involving your device

Any issues relating to the quality of this product, its identity, durability, reliability, safety, effectiveness and/or its performance, should be reported to OSSIS. If the implant has malfunctioned, or is suspected of having malfunctioned, please notify your physician immediately.

Any serious incident that occurs in relation to your implant should be reported to both OSSIS and the regulating authority where you received your implant:

COUNTRY	REGULATORY BODY / REGULATIONS	WEBSITE
Australia	Therapeutic Goods Administration (TGA)	www.tga.gov.au
European Union	Medical Device Regulation (MDR)	Report to EU competent authority of the member state where you received your custom device
United Kingdom	Medical and Healthcare products Regulatory Agency (MHRA)	www.gov.uk/guidance/contact-mhra
New Zealand	MedSafe	www.medsafe.govt.nz
United States	Food and Drug Administration (FDA)	www.fda.gov