3D-Shelf System
Patient Information Leaflet

Device description

Brand name	3D-Shelf System
Product code	3DSHELF01
Material	Titanium alloy
Legal manufacturer	Replasia BV Interleuvenlaan 62 bus 26 3001 Leuven Belgium www.replasia.com/patient-information

The 3D-Shelf System is a custom-made implant solution for use in patients with a full grown skeleton, for reducing the symptoms associated with Developmental Dysplasia of the Hip (DDH).

The 3D-Shelf System is designed and manufactured exclusively for a particular patient and is tailored to the patient's individual anatomical geometry. It is intended for the sole use of a specific patient with his/her individual condition and needs.

Safety

For safe use of the 3D-Shelf Implant, patients must carefully follow the instructions provided by their healthcare practitioner. In general, avoid excessive stress or heavy use of the implant while healing to avoid loosening, breakage, or wear of the implant. Please discuss with your healthcare practitioner when you can resume exercise or other physically-demanding activities.

Medical examinations

There is a possibility that the implant can reduce the image quality of computer tomography (CT) or magnetic resonance imaging (MRI) scans, which can lead to an inaccurate or incorrect diagnosis. It is recommended to wait at least six weeks after placement of the implant before undergoing an MRI to allow for proper integration with the bone and to reduce the risk of disruption of the healing process. After this period, a risk assessment should be made in consultation with the treating physician. It is therefore important that the patient informs the treating physician of the presence of the implant when CT or MR scans are needed.

Medical procedures

Please inform your healthcare practitioner that you have a hip implant when you require another medical procedure.

What are possible side effects?

As with all surgeries, there are possible side effects such as:

- **Infection**: Despite stringent sterilization protocols, there is a risk of surgical site infection following implantation of the device. Infections can lead to pain, swelling, fever, and

potentially require additional medical intervention, such as antibiotics or surgical debridement.

- **Soft Tissue Damage**: During implantation, adjacent soft tissues such as muscles, tendons, and ligaments may be injured, leading to pain, inflammation, and impaired function.
- **Nerve or Vascular Injury**: The surgical procedure to implant the device carries a risk of injury to nearby nerves or blood vessels. This can result in numbness, tingling, weakness, or circulation problems in the affected limb.
- **Thrombosis**: Prolonged immobilization after surgery can increase the risk of blood clots forming in the veins of the lower extremities (deep vein thrombosis). These clots can potentially dislodge and travel to the lungs, a condition known as pulmonary embolism.
- **Implant Failure or Dislocation**: While the implant is designed for durability and stability, there is a risk of mechanical failure or dislocation over time, particularly with high-impact activities or traumatic events. This can lead to pain, altered gait, and the need for revision surgery.
- **Allergic Reactions**: Although titanium is generally well-tolerated by the body, there is a risk of allergic reactions or hypersensitivity in some individuals. Symptoms may include rash, itching, or localized inflammation at the implant site.
- **Delayed Healing or Loosening of the Implant**: In some cases, the bone may not heal properly around the implant, leading to delayed healing or loosening of the implant. This can result in persistent pain, limited mobility, and the need for additional surgical intervention to promote bone healing.
- **Joint Stiffness or Range of Motion Limitation**: Following surgery and during the initial stages of rehabilitation, you may experience stiffness or limited range of motion in the hip joint. Physical therapy and gradual mobilization can help address these issues, but some degree of stiffness may persist.

When should you contact your healthcare practitioner?

Please consult your healthcare practitioner for guidelines in terms of medical examinations or follow-ups after the procedure.

Please consult your healthcare practitioner in case one or more of the following events occur:

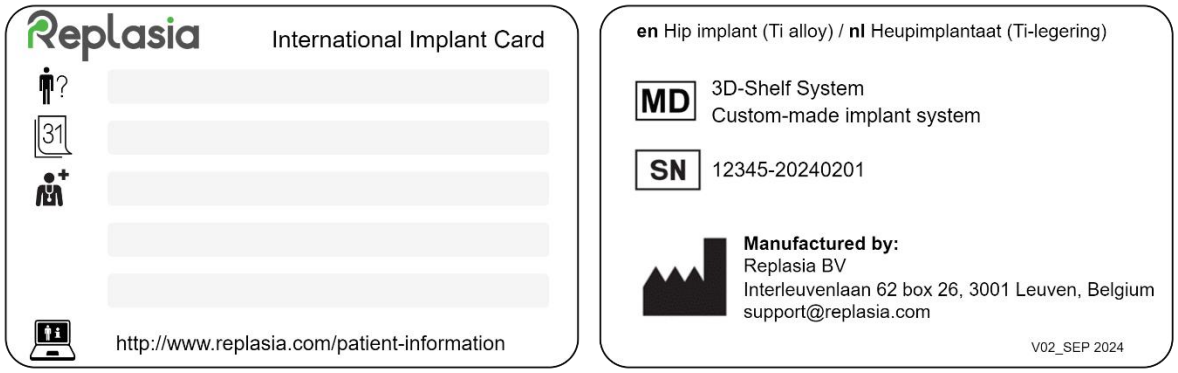
- Acute pain or swelling at the implantation site
- Skin redness, inflammation or infection at the implantation site

What is the expected lifetime of your medical device

There are currently no known effects of aging on the 3D-Shelf implant. To prolong the lifetime of your device, do not put heavy stress on the implant until it has adequately healed and properly settled in the correct location. Consult your healthcare practitioner for your specific guidelines.

Information for your implant

In order to save the identifiable details of your implant, you will receive an International Implant Card. Your surgeon will complete it with information specific to your surgery.



Label symbol legend

Symbol	Description
	Patient name
	Date of the implantation
	Name and address of the implanting healthcare institution/provider
	Information website for patients
MD	Name of the implant
SN	Serial number
	Name and address of the legal manufacturer of the implant

Signatures

	Author	Reviewer	Reviewer
Name:			
Signature:			
Date:			