Patient User Manual for "United" Implant

Intended Use

· The "United" implant replace the joint. They areused for patients requiring a total joint replacement. Replacing the joint is done to reduce pain and restore function. Replacing the joint may be needed in cases of bone disease (like arthritis). They are also used for patients that may have increased instability and loosening.

Lifetime of the Device

· The replacement joint will not be as flexible, strong, reliable or durable as a normal healthy joint. Too much activity or an injury could damage or break the joint implant.

· Discuss with your doctor about which activities you can do and when it is safe to do them. Doing strenuous activities can loosen or break the implant and damage the bone. If this happens, more surgeries may be needed. Follow all the instructions given by your doctor to make sure your implant lasts as long as possible. The expected lifetime of the subject devices is based upon non clinical testing designed to meet at least 10 years of simulated use. Patient factors such as weight, bone quality, activity level and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopaedic device.

· The lifetime of any joint replacement depends on several factors like weight and activity level. Your doctor will counsel you about strategies to possibly prolong the lifetime of the device, including avoiding high-impact activities, such as running, as well as maintaining a healthy weight.

Let others know about your joint replacement, as in the following situations:

· Metal implants could set off the alarm in security screening machines like the ones in airports.

· Joint replacement implants may contain metal that may interact with an MRI scanner. It may also cause heating or damage to the tissue around the implant. The metal can distort the image taken by the MRI scanner.

· Make health care providers (doctors, dentists, etc.) aware of your implant as it may affect their choices for your care.

· Additional information can be found in the European database on medical devices (EUDAMED):

https://ec.europa.eu/tools/eudamed

Symbol glossary

Symbol	Description	Symbol	Description	Symbol	Description
👤?	Patient Name or patient ID	31	Date of implantation	👤+	Name and Address of the implanting healthcare institution/provider
REF	Catalogue number	🏭	Name and Address of the manufacturer	💻	Information website for patients
LOT	Lot Number / Batch Code	UDI	Unique Device Identifier	MD	Device Name