

Patient information Leaflet and Implant Card for Granules and Injectable Putty NORAKER devices

This leaflet has information about your implant and have information regarding your implant card. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have 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, reference and batch number of your implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Implant description

Granules and Injectable Putty are bioactive bone substitute devices made of 45S5 bioactive glass. They are synthetic, resorbable, biocompatible and osteoconductive materials used either separately (Granules) or in conjunction with autogenous bone for grafting (Granules and Injectable Putty). Granules consist only of 45S5 bioactive glass, composed of elements that exist naturally in bone or surrounding tissues (24.5% calcium oxide (CaO), 6% phosphate pentoxide (P₂O₅), 24.5% sodium oxide (Na₂O) and 45% silicon dioxide (SiO₂)). Injectable Putty has an additional synthetic binder composed of polyethylene glycol (PEG) and glycerol.

It is bone void filler that resorbs and is replaced with bone during the healing process.

Throughout the device resorption, the release of ions induces a surface reaction resulting in the formation of a calcium phosphate layer that is substantially equivalent in composition and structure to the hydroxyapatite found in bone mineral. This layer creates a strong link between the bone substitute and living tissue and provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect.

MR-safety

This device is MR-Safe: it is not affected by magnetic fields, for example, it doesn't interact with metal detectors at the airport or is well suited for all common radiological imaging methods (e.g. MRI) at hospitals.

Post-operative patient behavior




The success of implantation depends on the patient's behavior and good compliance with post-operative hygiene instructions provided by their surgeon.

Patients must report any incident to their surgeon that could compromise the proper integration of the implant and undergo postoperative checks.

Possible complications

No side effect directly linked to the device has been reported to date. However, an unknown allergy to one of the constituents of the product may be possible.

Possible complications are the general complications due to surgery or anesthesia or are the same as those that can occur with autologous bone grafting. Possible adverse event is not more severe than those expected of similar products if the instructions are followed correctly by a qualified surgeon familiar with bone grafting techniques. Any serious incident which may occur in connection with this device should be notified to your health care professional.











  	
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Implant card

If required by your country's medical legislation, you have been provided with one or more Implant cards after the surgery. The main purpose is to help you identify the implanted device. Furthermore, the Implant card contains information about the manufacturer, the place and time of surgery as well as access to additional information about the device.

The symbols used in the Implant card are explained in Tables below:

Information provided by the manufactured				Information to be filled out by the healthcare institution/provider	
	Medical Device Name		Reference		Patient Name or patient ID
	Manufacturer		Unique Device Identification		Date of Implantation
	Batch n°		MR-safe		Name and Address of the implanting healthcare institution/provider
		Information website for patients			

Consult latest instruction for use on our website:





<https://noraker.com/en/patients/>

Manufacturer information:

NORAKER[®]
60 Avenue Rockefeller
69008 LYON – France
www.noraker.com

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  www.noraker.com	<p>NORAKER[®] THE BIOGLASS[®] COMPANY</p> <p>IMPLANT CARD</p>
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