Patient information leaflet

CE
0344

Bonalive® putty

A bone graft substitute to support regeneration of bone

What is *Bonalive® putty* used for?

Bonalive® putty is an implantable medical device that supports the growth of new bone. The product is used as a material to fill bone defects (bone cavities or gaps). The material degrades slowly over a period of years and is replaced by natural bone.

How it works

Bonalive® putty is an implant that consists of S53P4 bioactive glass, embedded in a mixture of polyethylene glycol (PEG) and glycerol. It is a synthetic material that doesn't contain any substances of a biological origin. When implanted, the *Bonalive® putty* comes into contact with body fluids which activate the surface of the implant. The implant surface is transformed into a naturally occurring mineral called hydroxyapatite which resembles the composition of bone. This enables new bone to attach and grow onto the implant, and eventually to transform all *Bonalive® putty* into natural bone.

If you are implanted with *Bonalive® putty*

The product is safe throughout the time it takes to transform to bone and is not affected by external energy sources, such as electronic or magnetic fields. For example, it doesn't interact with metal detectors at the airport. *Bonalive® putty* is well suited for all common radiological imaging methods (e.g. MRI) at hospitals.

At the beginning of the healing process *Bonalive® putty* does not bear weight like healthy bone. The time required for *Bonalive® putty* to become loadbearing bone depends on many factors, such as the size and nature of the defect, the patient's age and individual physiology, and compliance with post-operative instructions. The healing of the bone is monitored as part of routine follow-up as determined by your doctor.

Possible complications

As with all invasive operations such as surgeries, complications may arise from anaesthesia and/or the surgery itself. Complications may also include incomplete bone formation. A doctor will check the progress of the healing of the bone defect at routine follow-up visits. You should follow all instructions for contacting a healthcare professional (e.g. your doctor). It is important whenever you are experiencing symptoms of infection at the implantation site (e.g. swelling, tenderness, redness, oozing of body fluid).

Special instructions concerning Australian patients:

In case of serious incidents contact the manufacturer and the Australian authority, Therapeutic Goods Administration (TGA). Serious incidents include a changed state in patient's condition necessitating an unplanned medical or surgical intervention. If you suspect that a serious incident has occurred, we encourage you to consult your healthcare professional first. For reporting to TGA: follow instructions of www.tga.gov.au or call the Information line: 1800 020 653.

Implant card

If required by your country's medical legislation, you have been provided with one or more *Implant cards* after the surgery. It's 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 Table 1.

This patient information concerns the following Bonalive products:

Identification codes of Bonalive® putty (UDI-DI)
643 8132 16110 0
643 8132 16120 9
643 8132 16130 8
643 8132 16140 7

The identification code (UDI-DI) is found in the *Implant card* provided to you by your doctor.

Manufacturer information:

Bonalive Ltd
Biolinja 2, 20750 Turku, Finland
www.bonalive-patient.com

Version: 41623a/2
Date of issue: 01 July 2021
Last revised: 16 December 2024

Table 1. Explanation of Symbols used in the *Implant card*

	Batch code
	Manufacturer
	Patient name
	Health care centre
	Date of implantation
	Patient information website
	Product is safe for radiological imaging