Patient information leaflet

CE
0344

Bonalive® putty, Bonalive® putty MIS and Bonalive® putty MIS 2 cc

(hereinafter called *Bonalive putty* if not otherwise stated)

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 empty spaces in bone (bone cavities or gaps). The material dissolves 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. *Bonalive Putty* is a synthetic material, meaning that it is not manufactured from substances of animal origin. When placed in the body, *Bonalive putty* comes into contact with body fluids which first dissolve the PEG and glycerol mixture leaving behind only the bioactive glass. Next, the body fluids activate the surface of the implant. The surface of the implant is transformed into a naturally occurring mineral called hydroxyapatite which is similar to the composition of bone. This process enables new bone to attach and grow onto the implant, and eventually to transform all *Bonalive putty* into natural bone. During this transformation into natural bone the bioactive glass slowly leaches out ions. These ions are primarily alkali ions (sodium and calcium), but also phosphate and silicon. The amount of ions is in proportion to the total amount of putty placed in the body. These ions are naturally present in the human body and all of these ions are important for the implant to work correctly. The amount of *Bonalive putty* placed in the body and the time required for transformation into natural bone varies from case to case.

If you are implanted with *Bonalive putty*

Data from clinical studies have shown that the product is safe throughout the time it takes to transform to bone. The product is not affected by external sources, such as electronic or magnetic fields. For example, the product does not interact with metal detectors at airports. All common radiological imaging methods used at hospitals, including MRI, can be used on patients implanted with *Bonalive putty*.

At the beginning of the healing process *Bonalive putty* will not bear weight like healthy bone. The time required for the implanted *Bonalive putty* to become bone that is able to bear weight depends on many factors, such as the size and nature of the defect, your age and individual body characteristics as well as your compliance with post-operative instructions. The healing of the bone is monitored as part of the routine follow-up as determined by your doctor or healthcare professional.

Possible complications and side-effects

As with all invasive procedures, including surgery, complications may arise from anesthesia and/or the surgery itself. Complications may also include irritation of the tissue at the site of the implantation, incomplete bone formation and infection. Your doctor or healthcare professional will check the progress of the healing of the bone defect (empty bone cavity or gap) during routine follow-up visits. You should follow all instructions for contacting your doctor. It is important whenever you are experiencing symptoms of infection, such as swelling, tenderness, redness, or leaking of body fluid, at the implantation site.

Special instructions concerning Australian patients:
In case of serious incident you should 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 doctor or healthcare professional first. For reporting to TGA, follow instructions on www.tga.gov.au or call the Information line at 1800 020 653.

Summary of Safety and Clinical Performance for *Bonalive putty*

A Summary of Safety and Clinical Performance (SSCP) for the *Bonalive putty* implantable medical device is available on the manufacturer's website (www.bonalive.com) and/or on the European database on medical devices (Eudamed). This database can be searched using an identifier assigned to the product (Basic UDI-DI code 6438132CE102KG).
The public Eudamed website can be accessed at: https://ec.europa.eu/tools/eudamed

Implant card

If required by your country's medical legislation, you will have been provided with one or more implant cards after the surgery. The main purpose of the implant card is to help you identify the code of the implanted device. The implant card contains information about the manufacturer, the place and time of surgery, as well as additional information about the device. You have to keep the implant card for at least 15 years, and it is advisable to scan it.

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)
0 643 8132 16110 0
0 643 8132 16120 9
0 643 8132 16130 8
0 643 8132 16140 7

Identification codes of Bonalive putty MIS (UDI-DI)
0 643 8132 18100 9
0 643 8132 18131 3
0 643 8132 18133 7

Identification codes of Bonalive putty MIS 2 cc (UDI-DI)
0 643 8132 18121 4
0 643 8132 18123 8

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: 43023/1
Date of issue: 26.06.2025

(Note: For previous revisions follow instructions on the website: www.bonalive-patient.com.)

Table 1. Explanation of symbols used on the implant card

	Manufacturer’s production code for the product.
	Manufacturer’s contact details.
	Website containing information about the product for the patient.
	Patient’s name
	Date of implantation
	Name and address of healthcare center performing the implantation
	Indicates a barcode matrix that contains unique device identifier information
	Indicates the manufacturer’s catalogue number of the implanted product
	Indicates that the implanted product is a medical device
	Indicates that the implanted product is safe for radiological imaging