bonalive
Smart Healing™

CE
0344

For patient

Summary of safety and clinical performance (SSCP)

Bonalive® putty, Bonalive® putty MIS and Bonalive® putty MIS 2 cc
(hereinafter called *Bonalive putty* if not otherwise stated*)*

The information presented below is intended for patients or lay persons.

The purpose of this Summary of Safety and Clinical Performance (SSCP) is to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP does not represent a source of advice on the treatment of a medical condition. Please contact your doctor or healthcare professional if you have any questions concerning your medical condition or about the use of the device in your situation. This SSCP is not intended as a replacement for the implant card or the instructions for use that provide information on the safe use of the device.

1. Identification of the *Bonalive putty* device and general information

Device trade name	*Bonalive putty, Bonalive putty MIS and Bonalive putty MIS 2 cc*
Manufacturer	Bonalive Ltd Biolinja 2, 20750 Turku, Finland
Basic UDI-DI	6438132CE102KG
Year when the device was first CE-marked	2013 Bonalive putty, 2018 Bonalive putty MIS and 2021 Bonalive putty MIS 2 cc

2. Intended use of *Bonalive putty*

- The *Bonalive putty* product 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 product dissolves slowly over a period of years and is replaced by natural bone.
- The *Bonalive putty* implantable medical device is intended for patients who need bone replacement due to bone cavities or gaps in bone following injury or other bone loss.

Indications for the use of *Bonalive putty*:

- *Bonalive putty* is used to fill bone cavities or gaps that may occur during surgery or after an injury. It can be used in any bone in the body where new bone growth and healing are needed.

The *Bonalive putty* product should NOT be used:

- The *Bonalive putty* product should not be used to fill bone cavities and gaps if there is a new or sudden infection of the bone that has not been properly treated.
- The *Bonalive putty* product should not be used without mechanical support if support is needed (for example screws, nails, wires, plates, etc.).
- The *Bonalive putty* product should not be used in patients with new or sudden injury wounds close to the defect, that are likely to become infected if the infection is not properly treated.
- The *Bonalive putty* product should not be used in patients who have just received or are about to receive chemotherapy, or radiation therapy at or near the site in the body where *Bonalive putty* would be placed.
- The *Bonalive putty* product should not be used in patients with a known allergy to bioactive glass.

Limited use of *Bonalive putty*:

- The *Bonalive putty* product is intended for use only with defects listed in the intended use of the device.
- The *Bonalive putty* product has not been clinically tested for use in pregnant women.

3. Description of the *Bonalive putty* device

- The *Bonalive putty* product is an implant that consists of S53P4 bioactive glass granules, embedded in a mixture of polyethylene glycol (PEG) and glycerol.
- Putty is a synthetic material. This means that it is not manufactured from substances of animal origin.
- The *Bonalive putty* product consists only of elements that exist naturally in the body, such as oxides of sodium, calcium, silicon, and phosphorus.
- The *Bonalive putty* product does not harm living tissue.

How the *Bonalive putty* implant works in bone:

- 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 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 the ions are important for the implant to work correctly.
- The amount of *Bonalive putty* placed in the body and the time of transformation into natural bone varies from case to case.

4. Possible complications and side-effects

Contact your doctor if you think you may be experiencing side effects related to *Bonalive putty*, if you have questions about the use of the product, or if you are concerned about the risks of possible complications and side-effects. This document is not intended to replace a consultation with your doctor.

The possible complications and side-effects of *Bonalive putty* may include:

- General complications after surgery may occur in some patients. These can include tenderness, pain, redness, bruising, swelling, and excess fluid collection in the area where the implant was placed. These may be experienced in 1-10% of patients.
- Repeated infections after long-term infection of the bone may occur in less than 1% of patients
- Local tissue irritation may occur in less than 1% of patients.
- General surgical complications related to bone grafting procedures are wound infections, delayed bone healing, unsuccessful bone positioning, loss of bone graft and graft displacement. These may occur in less than 1% of patients.
- Sometimes formation of the new bone is not sufficient. Other diseases, shape of the bone cavity or gap, and individual characteristics, such as the patient's age, can have an impact on growth of new bone and cause poor bone formation. This may occur in less than 1% of patients.

Your doctor will check the progress of the healing at routine follow-up visits. You should follow all instructions for contacting your doctor or a healthcare professional. It is important to contact your doctor if you experience symptoms of infection, such as swelling, tenderness, redness, or leaking of bodily fluids, at the site where the implant was placed.

5. Warnings and precautions

Warnings and precautions concerning patients:

- At the beginning of the healing process the *Bonalive putty* implant does not bear weight like healthy bone. The time required for the *Bonalive putty* product to become bone that is able to bear weight depends on many factors, such as the size and

nature of the defect, the patient's age and individual body biology, and how well the patient obeys the doctor's instructions after the operation.

Summary of field safety corrective action:

- Bonalive Ltd has procedures in place to conduct an effective field safety corrective action, if deemed necessary to ensure the safety of patients or to be in compliance with regulatory requirements. Field safety corrective action can include recalling the products from the hospital warehouses or informing the doctor or healthcare professional about the problem with the product. By October 2025, there have been two field safety corrective actions (one in 2019 and one in 2022). Neither of these were related to the functioning of the bioactive glass in the *Bonalive putty* product in patients.

6. Summary of clinical evaluation of *Bonalive putty*

Background and clinical evidence for *Bonalive putty:*

- In the late 1960's it was recognized that bioactive glasses bond to living bone.
- There are different types of bioactive glasses.
- The same bioactive glass that is used in the *Bonalive putty* product was first used in patients in the early 1990's. Since then, Bonalive Ltd has collected clinical data from more than 1,800 patients who have participated in clinical studies in which *Bonalive products* have been used to fill in bone cavities or gaps. These studies have either been sponsored by Bonalive Ltd or published in scientific journals. The *Bonalive putty* product is a CE-marked medical device and has been sold since 2013.
- Results of orthopedic surgery studies show that the *Bonalive putty* product is a safe and suitable material in spine surgery. Similar results were obtained in filling bone cavities after removal of benign bone cysts and removal of infected tissue. *Bonalive putty* did not cause serious side-effects in any of these studies.
- Background and clinical evidence of *Bonalive putty* equivalent device, *Bonalive granules,* can be found on the manufacturer's website (www.bonalive.com) and/or on the Eudamed https://ec.europa.eu/tools/eudamed with Basic-UDI 6438132CE101KE.

- Other studies may show different results.

Safety of *Bonalive putty*:

- The clinical investigation data for the *Bonalive putty* product shows that it is safe and well-tolerated by patients as a filler in bone cavities. The *Bonalive putty* product has not caused severe side effects or made the health of the patient worse.

The benefits of *Bonalive putty* are:

- The bone is healed.
- The limb (or spine) can function normally after the bone has healed.
- The growth of bones is not disturbed in children.
- The collection of the patient's own bone can be avoided or at least minimized.

The benefits of *Bonalive putty* are greater than the possible disadvantages and side effects.

Bonalive Ltd continuously collects information on the safety and performance of *Bonalive putty*. This information includes data from actual use (such as side-effects and other feedback reported by healthcare professionals), and data from clinical studies published in scientific papers and in public safety databases.

7. Possible treatment alternatives

There are several materials other than *Bonalive putty* which may be used to replace or treat bone defects. These include bone taken from another part of your body, proteins that stimulate bone to grow, or other synthetic materials that can be used to replace bone, such as ceramics, calcium-based biomaterials and polymers.

When considering alternative treatments, it is recommended that you contact your doctor who can take your individual situation into account.

Version: 43024p/1
Date of issue: 12.12.2025