IXOBONE PASTE / PUTTY

INSTRUCTIONS FOR USE

EN **IMPORTANT PRODUCT INFORMATION: PLEASE READ**

Device Description

IXOBONE PASTE is a smooth paste composition of 38% nanocrystalline hydroxyapatite in water.
IXOBONE PUTTY incorporates hydroxyapatite/tri-calcium phosphate granules into IXOBONE PASTE and has a granulated putty-like texture.

These materials have been subjected to extensive and successful clinical studies for many years. IXOBONE materials are safe and fully biocompatible and are designed to act as an osteoconductive medium to support the ingrowth and fusion of adjacent viable bone when placed in an osseous environment. IXOBONE materials will fully resorb and be replaced by natural bone due to its nanocrystalline and resorbable structures which are essentially identical to the mineral phase of human bone.
IXOBONE can in many cases spare the recipient the trauma of autograft harvesting and provides a sterile fully synthetic alternative to donor bone.

Indications-for-use

IXOBONE materials are synthetic osteoconductive bone grafts that are intended to be used in veterinary applications for filling and supporting the ingrowth of adjacent viable bone in bone defects that are not intrinsic to the stability of the bone structure. These defects may be located in the extremities, spine, pelvis or cranium.
IXOBONE may be used for filling of bone defects in the case of fractures, resection of benign tumors or cysts, and for filling autograft harvest sites. IXOBONE may also be used in spinal fusion and tibial tuberosity advancement procedures (within cages).
The material may be gently pressed into the defect by hand and molded to more accurately fit the defect if and as required, and may also be mixed with bone marrow aspirate prior to implantation. IXOBONE will act as a temporary scaffold and will remain as a soft paste and is **not intended to provide structural support** during the healing process. The implant is biocompatible, radio-opaque and will resorb in a controlled way.

Contraindications

IXOBONE materials are not designed or sold for any other use except as indicated. Do not use IXOBONE in the presence of any contraindication.
IXOBONE is contraindicated where the device is intended to provide structural support in the skeletal system and MUST NOT BE USED WHERE THE IMPLANTATION SITE IS UNSTABLE AND NOT RIGIDLY FIXATED, OR BE USED TO GAIN SCREW FIXATION,

Other contraindications include:

- Existing acute or chronic infections, particularly at the implantation site
- Severe vascular or neurological disease
- Poorly vascularized implantation site
- Uncontrolled diabetes
- Severe degenerative disease
- Collagen disease
- Hypercalcemia, abnormal calcium metabolism
- Inflammatory bone disease
- Malignant tumors
- Severely impaired renal function
- Open epiphyseal plates

Precautions

IXOBONE materials are for professional use only, and are only intended for use by surgeons familiar with and skilled in the techniques of bone repair and replacement.
IXOBONE is not intended for load bearing applications. It is important to ensure that the area around the implantation site be secured mechanically with rigid fixation to provide structural support and maintain the implant in a static, load free environment. IXOBONE must not be used to gain screw fixation.
It is important to maximize the contact between existing bone and the implant to ensure proper bone regeneration.
IXOBONE should only be implanted into fresh vital bone to ensure rapid revascularization.
As with any material, care should be taken to avoid the occurrence of emboli, therefore the highly pressurized application of IXOBONE materials into a tightly confined defect with venous or arterial access should be avoided.
The effects of IXOBONE on recipients having long term infection, metabolic bone disease, radiation bone therapy, or cardiovascular disease is not known.
The effects of mixing IXOBONE with other substances are unknown. However no special precautions have been identified at the time of issue.

Possible Complications

A successful result may not be achieved in every case.
A secondary operation to remove or replace an implant may be necessary due to surgical error, specific medical conditions or device failure. Possible adverse effects may include but are not limited to:

- Displacement of the material due to a load being applied
- Bone deformity or non-viable bone at the implantation site
- Post-operative complications including infection, hematoma, edema, swelling, and fluid accumulation, tissue thinning, and other complications that are possible with surgery.
- Allergic reaction to the product

Warnings

The contents of the package are double-sealed and **STERILE**. DO NOT USE IF OPENED, PUNCTURED OR PRODUCT OR APPLICATOR APPEARS DAMAGED OR PASTE HAS DRIED. Read the expiration date before use and DO NOT USE BEYOND THE EXPIRATION DATE.
It is recommended not to open the inner pouch until a few minutes prior to implantation.
IXOBONE materials are for SINGLE USE ONLY. Do not attempt to re-sterilize or re-use due to the risk of cross-infection.
IXOBONE should only be used in procedures where the implant can be adequately contained.
IXOBONE materials are opaque to x-rays and may hide areas under or above the implant on a radiograph.

Application

Step 1: Open both the outer and inner pouches. Remove the cap from the applicator. IXOBONE PASTE and IXOBONE PUTTY are both supplied in the applicator, ready for use, but may be mixed with other bone substitutes.
Step 2: Implant the quantity of IXOBONE as required by the defect. The maximum dose of IXOBONE is 20g per defect. The defect should be completely filled and the material molded to follow the natural contours of the bone. The IXOBONE material in the defect should be in direct contact with all surfaces of the defect. Where a load may be applied to the implant it should be used in combination with rigid fixation devices.
Step 3: Secure the surgical site after implanting to prevent motion and any implant displacement. When excess fluid is present at the site, cauterization, and suction may be used to reduce bleeding.

Storage

IXOBONE products should be stored between 5°C and 30°C and **DO NOT FREEZE.** Direct contact with sunlight or heating systems should be avoided.

Shelf Life and Disposal

The expiration date is printed on the labelling. Do not use IXOBONE after the expiration date.
IXOBONE materials are environmentally friendly. No special disposal is required. The used applicator should be disposed of as clinical waste

Note: IXOBONE is for veterinary use only. Responsibility for proper selection of recipients, for adequate training, for experience in the choice of the IXOBONE, for all aspects of the surgery, and for the choice of post-operative procedures rests entirely with the physician.


Can be used until YYYY-MM-DD


Single use only


Note: Observe accompanying documents

Sterilization by irradiation


Store out of direct sunlight


Storage temperature


Do not use if opened or damaged

Part number

Lot number

FOR VETERINARY USE ONLY

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