b.Bone™

MANAGEMENT OF BONE DEFECTS

GENERAL PRINCIPLES AND SURGICAL TECHNIQUE

GreenBone®
NATURAL BONE HEALING

The surgical technique shown is for illustrative purposes only.
The technique actually employed in each case will always depend upon the medical judgement of the surgeon who should decide on the best approach to be followed depending on their clinical experience and the patient's needs.
Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.

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1. INTRODUCTION

1.1 Instructions for Use

b.Bone is intended for use as a bone graft for voids or gaps that are not intrinsic to the stability of the bony structure.

b.Bone is indicated in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

b.Bone is intended to be implanted into bony voids or gaps in the extremities and pelvis.

1.2 Contraindications

b.Bone is not designed for any use except as indicated. Do not use **b.Bone** in the presence of any contraindication.

Use of the **b.Bone** IS NOT INDICATED in the following situations:

- Acute and chronic infections in the operation area, involving the bone or the soft tissues
- Bone malignant tumor(s)
- Concomitant infectious systemic diseases
- Inflammatory systemic diseases
- Concomitant myeloproliferative disorders
- Treatment with systemic immunosuppressive agents
- Active autoimmune disease
- Known or suspected allergy or hypersensitivity to the **b.Bone** device components
- Calcium metabolism disorder (i.e. hypercalcemia)
- Known hyperthyroidism or autonomous thyroid adenoma
- Severe, poorly controlled diabetes (diabetes mellitus) with impaired wound healing tendencies
- Known severe osteoporosis.

b.Bone is intended to be used as a bone substitute in adults. Its effect in pediatric patients and in pregnant or breast-feeding women has not been established.

1.3 Clinical Evidence

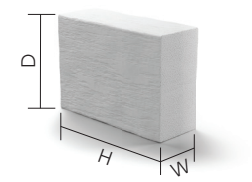
Clinical Evidence, collected through clinical studies and other post-market surveillance activities[1,2,3,4], demonstrates the product's safety and performance, and supports the benefits it provides, namely its regenerative and mechanical capabilities, previously demonstrated in vitro and in vivo.

1. Alt V. et al. Bone defect filling with a novel rattan-wood based not-sintered hydroxyapatite and beta-tricalcium phosphate material (b. Bone) after tricortical bone graft harvesting - A consecutive clinical case series of 9 patients. Trauma Case Reports 44 (2023) 100805.
2. Tosounidis T.H. et al. The use of a new grafting material (b.Bone) for the management of severely depressed tibial plateau fractures: Preliminary report of three cases. Trauma Case Reports 47 (2023) 100893.
3. Giannoudis P. et al. British Medical Bulletin, 2025, 153, 1–10.
4. Giannoudis P. et al. BMJ Case Rep 2025;18:e264131. doi:10.1136/bcr-2024-264131.

2. CONFIGURATIONS AND SIZES

b.Bone is available in four different configurations: hollow cylinder, block, granules and wedge.

The available dimensions for each configuration are reported in Figure 1.

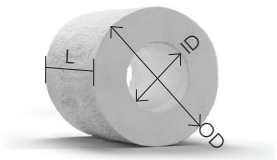


BLOCK
Available size

PRODUCT CODE	WIDTH (W)	DEPTH (D)	HEIGHT (H)
HP401020PS	10 mm	20 mm	40 mm

BLOCK
Upon request

WIDTH (W) - RANGES	DEPTH (D) - RANGES	HEIGHT (H) - RANGES
5 mm - 10 mm - 15 mm	10 mm - 20mm - 30 mm	20 mm - 30 mm - 40 mm - 50 mm

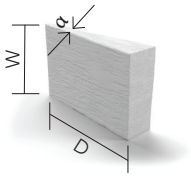


CYLINDER
Available sizes

PRODUCT CODE	OUTER DIAMETER (OD)	INNER DIAMETER (ID)	LENGTH (L)
HC100030PS	10 mm	0 mm	30 mm
HC150630PS	15 mm	6 mm	30 mm
HC201030PS	20 mm	10 mm	30 mm
HC251330PS	25 mm	13 mm	30 mm
HC301530PS	30 mm	15 mm	30 mm
HC100060PS	10 mm	0 mm	60 mm
HC150660PS	15 mm	6 mm	60 mm
HC201060PS	20 mm	10 mm	60 mm
HC251360PS	25 mm	13 mm	60 mm
HC301560PS	30 mm	15 mm	60 mm

CYLINDER
Upon request

LENGTH (L)
10 mm - 20 mm - 40 mm - 50 mm for each outer diameter



WEDGE
Available sizes

PRODUCT CODE	ANGLE (α)	DEPTH (D)	WIDTH (W)
WE093015PS	9°	30 mm	15 mm
WE113015PS	11°	30 mm	15 mm
WE133015PS	13°	30 mm	15 mm
WE094030PS	9°	40 mm	30 mm
WE114030PS	11°	40 mm	30 mm
WE134030PS	13°	40 mm	30 mm

GRANULES
Available sizes

PRODUCT CODE	RANGE	QUANTITY
GR051005PS	0.5 - 1 mm	5 g
GR102005PS	1 - 2 mm	5 g
GR204005PS	2 - 4 mm	5 g
GR407105PS	4 - 7.1 mm	5 g

Fig. 1: Confirgurations and sizes

3. SURGICAL PROCEDURE

3.1 General Prerequisites

1. Prior to the use, please read carefully the IFU code n. LI0004.

2. Adequate mechanical stability and fracture alignment should be achieved for the reconstruction of the affected extremity prior to the implantation of b.Bone.

3. b.Bone must always be in direct contact with the edges of the void. Both the bone edges and the surrounding soft tissue should be healthy and well vascularized.

4. The local bone environment MUST be clear of infection.
   Bone can be used in bone defects after control of the infection, e.g. for bone reconstruction in a2-stage Masquelet procedure with no signs of ongoing infection at stage 2.

5. The use of b.Bone is the same as the routine application of a bone substitute in bone defect reconstructive surgery.

3.1.1 b.Bone Handling and Cutting

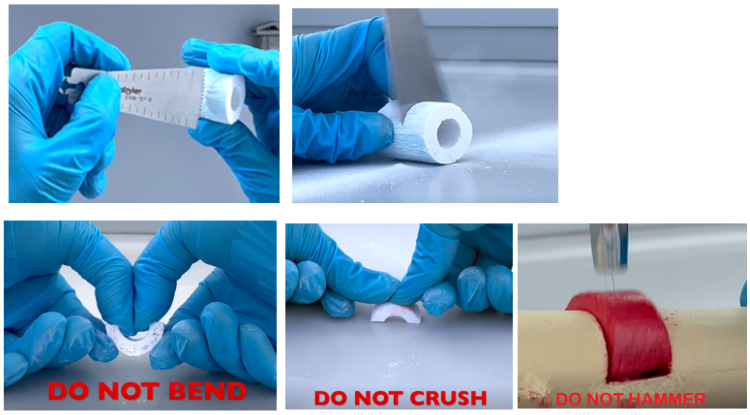
Prior to the procedure, ensure the b.Bone is handled and prepared correctly:

1. Hold the b.Bone firmly but gently on a stable, flat surface. Do not apply forces that could damage the implant.

2. Use an oscillating saw with a blade wider than the intended cut. Ensure the saw is oscillating before making contact with b. Bone.

3. Control speed and minimise vibration of the oscillating saw, allowing the blade to advance gradually without applying excessive force.

4. If necessary, adjust the implant to fit the defect and refine surfaces. Taking care to avoid bending, crushing, or hammering.



Notes:

a. *Please note that cutting b. Bone already soaked with biological fluids may generate powder agglomerates, which may reduce smoothness but do not compromise this procedure.*

b. *Cracking upon insertion is acceptable and does not compromise product performance, provided the implant fits the defect well and is securely stabilized.*

3. SURGICAL PROCEDURE

3.2 Preparation of b. Bone

1. Measure the bone defect (Fig.1) and choose the appropriate b.Bone configuration and size. If needed, b.Bone can be shaped gently with an orthopedic saw in order to better fit in the bone gap (for more details refer to 3.1.1 paragraph).

2. When selecting a cylinder, if the size corresponding to the bone diameter is not available, choose a b.Bone cylinder with a smaller diameter to facilitate callus formation around the b.Bone.

3. It is recommended to soak b.Bone with blood or bone marrow aspirate (BMA) either before implantation (Fig.2) or once implanted. (Fig.3). The surgeon should also consider soaking of b.Bone in PRP preparations.

4. b.Bone granules configuration could be used to expand the volume of autologous bone graft (i.e. pelvic, RIA graft). It is recommended to use enough material to fill the bone cavity appropriately.

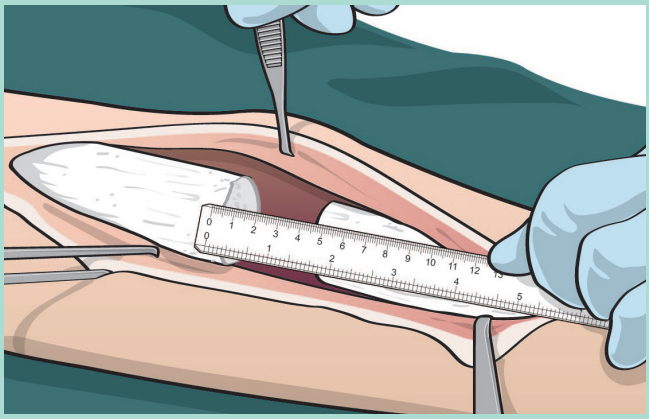


Fig.1

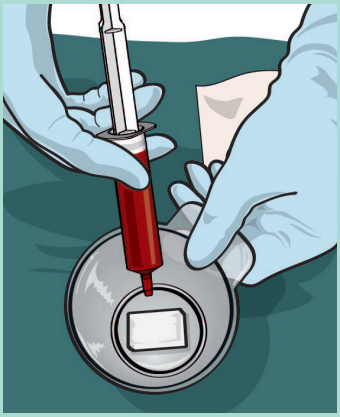


Fig. 2

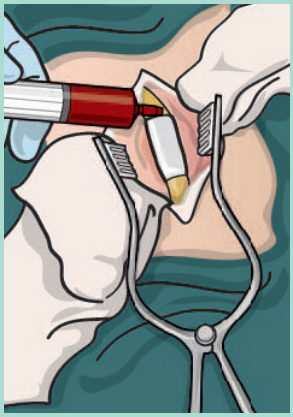


Fig. 3

3.3 Implantation of b. Bone

1. b.Bone must be implanted securely within the bone void or defect area in direct contact with the bone edges (Fig.4a), for more details refer to 3.1.1 paragraph.

    a. In case of iliac crest reconstruction: a press fit technique is recommended.
    Shape and cut b.Bone to fit the defect, and gently advance it while press fitting (Fig.4b).

    b. In case of other applications, reduce and stabilize the bone of the affected extremity with the appropriate fixation device.
    The basic principles of fixation of the selected stabilization device must be adhered.

    c. When using granules, it is recommended to use enough material to fill the bone cavity appropriately and achieve good impaction to prevent secondary fracture collapse.

2. The accurate positioning of **b.Bone** should be checked with fluoroscopy.

3. Augmentation of **b.Bone** with either BMA or PRP must be done prior to wound closure if not done previously.

4. Cracking upon insertion is acceptable and does not compromise product performance, provided the implant fits the defect well and is securely stabilized.

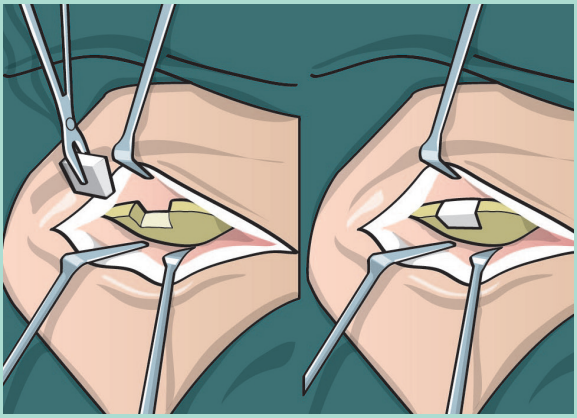


Fig. 4a

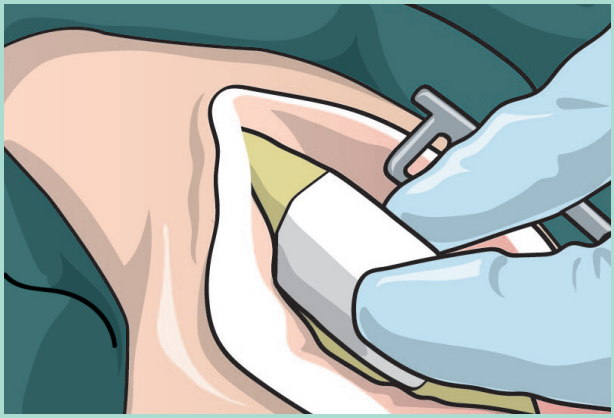


Fig. 4b

3.4 Considerations when using fixation devices

3.4.1 Intramedullary Nailing

1. When choosing a b.Bone cylinder, the internal diameter should be at least 2 mm bigger than the selected nail diameter.
   The curvature of the nail should also be considered (Fig.5).

2. Provide adequate stability and good alignment (maintaining reduction) to the proximal and the distal segment of the bone during nail insertion.
   This is essential to preserve the integrity of b.Bone.
   Note: b.Bone cannot be reamed.

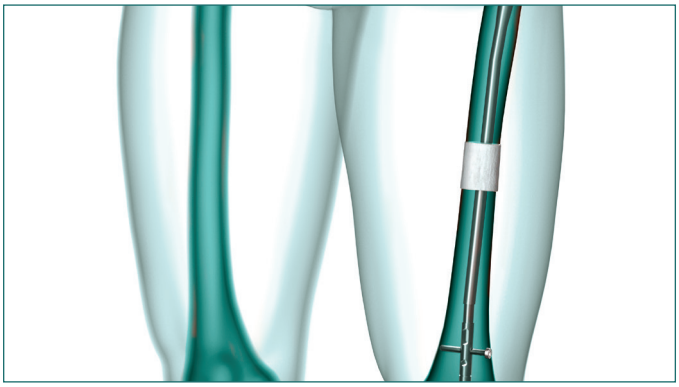


Fig. 5

3.4.2 Compression Plating

When using compression plate, it is recommended to FOLLOW the SEQUENCE below:

1. Position the plate and insert the screws with no compression mode.

2. Insert b.Bone gently in the void, making sure that it is in contact with the vital bone.

3. Check accurate positioning of the plate and screws under fluoroscopy.

4. Proceed with insertion of compression screws in the plate to facilitate good stability of the scaffold.

5. Complete the insertion of the screws according to the preoperative planning (Fig.6).

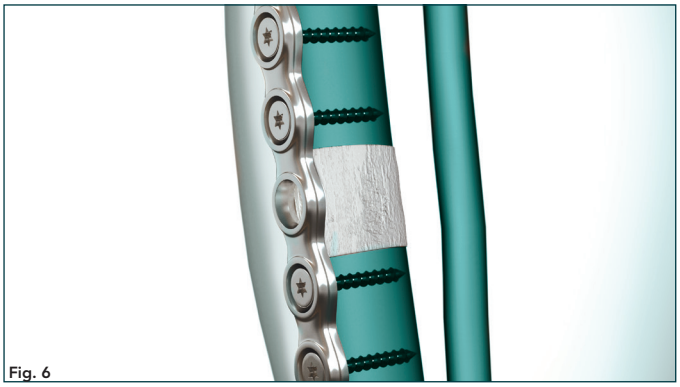


Fig. 6

Note:

b.Bone can be drilled. Surgeons should be aware that screws passing through the bone substitute should not be relied upon to provide mechanical stability.

Cracking upon insertion is acceptable and does not compromise product performance, provided the implant fits the defect well and is securely stabilized.

3.4.3 External Fixation

It is important to apply the external fixator before inserting **b.Bone** (Fig.7).

Optimum mechanical stability and alignment should be achieved for the reconstruction of the affected extremity prior to the implantation of **b.Bone**.

Good contact and compression between **b.Bone** and the bone segments is desirable to support evolution of bone healing.

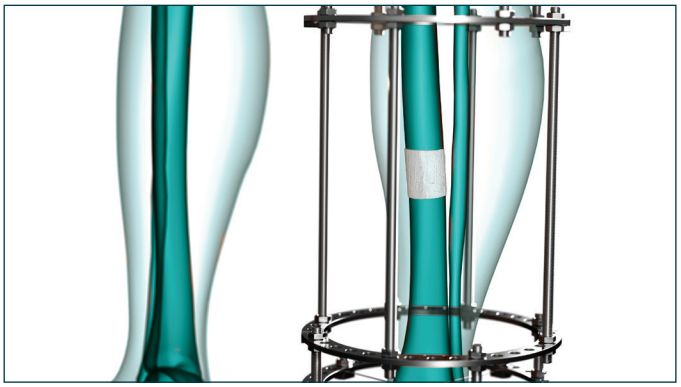


Fig. 7

3.5 Post-operative management

The surgeon should dictate the most appropriate postoperative rehabilitation protocol taking into account the fixation method, the anatomical site and the patient profile.

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GreenBone®
NATURAL BONE HEALING

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