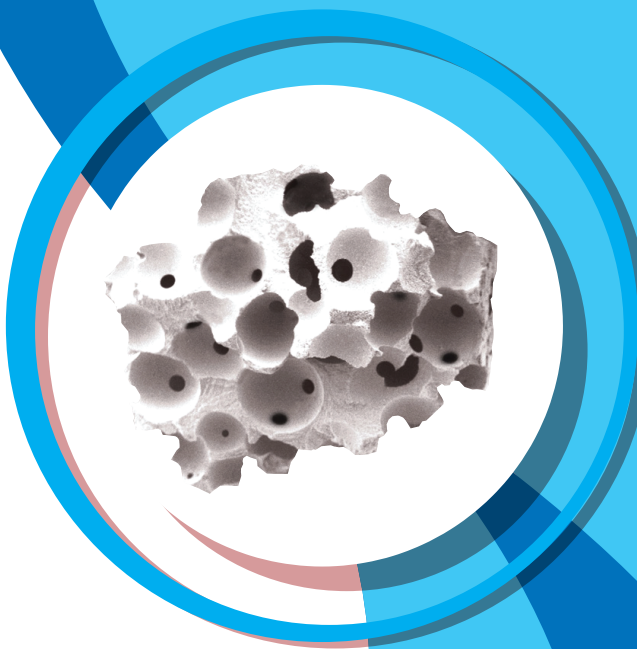
# I - BonE

Synthetic Solutions

# REGENERATIVE SOLUTIONS
## SYNTHETIC BIOMATERIALS

- Orthopaedics
- Trauma
- Spine
- Sports Medicine
- Dental



- Granule
- Stick - Block
- Flexible Strip
- Putty - Gel
- Dental Putty
- Barrier Membrane
- Chondro Matrix
- Bone Cement

Synthetic Bone Substitutes

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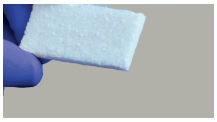
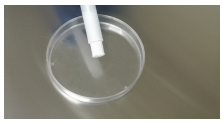
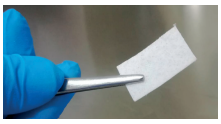
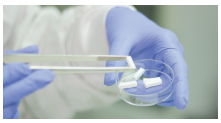
# BONE SUBSTITUTES






**I - BonE** products are indicated for use as a bone graft substitute for the support of bone tissue formation at non-load bearing osseous defects created surgically or through traumatic injury. **I - BonE** products may be combined with autogenous blood and/or bone marrow as well as with other bone grafts.

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# GENERAL FEATURES OF BONE SUBSTITUTES

• 100% Synthetic
Contains no tissue of human or animal origin therefore carries no risk of disease transmission.

• Osteoconductive
Act as a scaffold and support bone tissue regeneration. Similar to to the mineral found in bone tissue.

• Bioresorbable
With its optimized porous structure and chemical compositon, **I - BonE** is suitable for the continuous remodeling cycle of healty bone. ß-TCP resorbs over time and be replaced with bone during the healing process.

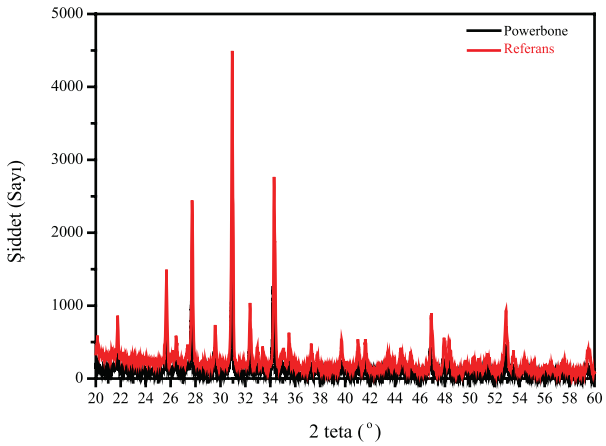
• Safe
**I - BonE** is supplied sterile and CE marked as a Class III Medical Device according to Directive 93/42/EEC.

• Biocompatible and Sterile
**I - BonE** is tested using: Pre-clinical studies, Biocompatibility tests (in vitro and in vivo), Biomechanical tests, Biodegradation tests, Bioburden and Sterility tests.

• Radiopaque
Could be detected via CT and X-ray.

• Antibacterial

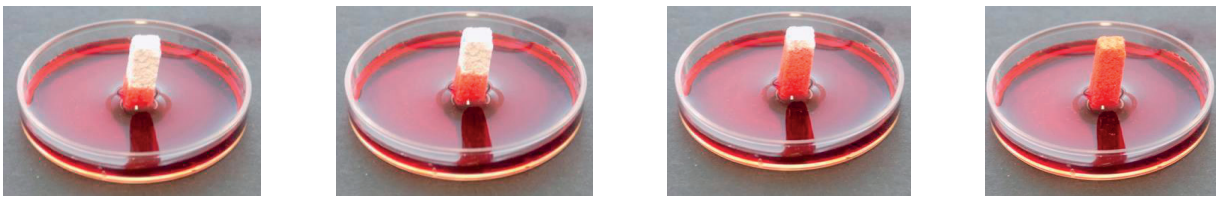
• Versatile
Available in granules, sticks, blocks, edges, putty and gel form at different sizes for different indications.



XRD Graphic of β-TCP Powder

The maximum peak 28 values of the phases are defined by matching with the JCPDS (Joint Committee on Powder Diffraction Standards) database. When examining the XRD data of the **I - BonE** branded product, the maximum peak grades were found to be compatible with whitlockit with JCPDS 090169 card number 27,77 (214), 31,03 (2010), 34,37 (220) respectively. Since ß-TCP and whitlockit have similar XRD profiles, [1,2] data are compared with a commercial product obtained from 100% crystallin ß-TCP, based on ≥ 98% beta phase according to manufacturer's description. Besides, XRD profile of Powerbone ß-TCP were compared with a well-known commercial product which has ≥98%

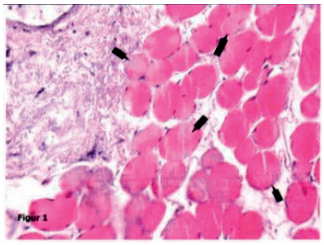
(1) Gopal R, Calvo C (1972) Structural Relationship of Whitlockite βCa3(P04)2. Nat Phys Sci 237: 30-32
(2) Frondel C. (1943) Mineralogy of the calcium phosphates insular phosphate rock. Am Mineral 28: 215-23.



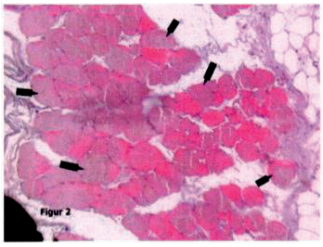
Incubating **I - BonE** Stick in red ink solution. Images captured in every 5 seconds. After 20 seconds sticks are completely covered.

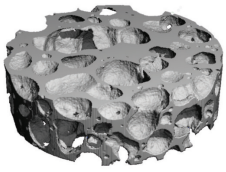
# I-BONE GRANULES, STICK & BLOCK & WEDGE

The interconnectivity of porous structure and microporosity assist capillary motion of blood and body fluids, enhanced penetration for osteogenic cells, and ossification of the synthetic matrix. For Macroporosity, I - BonE Granules and Stick & Block allows deep invasion of bone cells into the matrix. I - BonE polygonal granules have different particle size between 0,25-7 mm.
The irregularly shaped granules promote interlocking and improve mechanical stability.



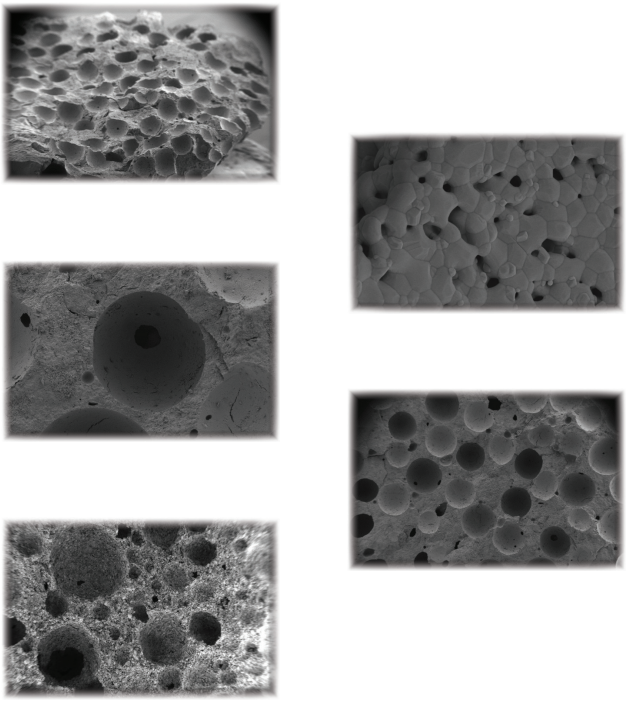
Osteoid formation (Osteoinductive characteristics) 2 months after impantation of I - BonE Granule (Crunch) in skelatal muscle





Micro CT analysis of Granules

When the images are examined, it is observed I - BonE grafts has as interconnective porous structure and this structure is spread throughout the sample. Also micro and macro pores are determined in the structure of I - BonE granules and sticks. Given cell attachment and development, the presence of interconnective pores in contact with each other promotes cell attachment and development [1-3].



SEM analysis of Granules


(1) BMP-induced osteogenesis on the surface of hydroxyapatite with geometrically feasible and nonfeasible structures: topology of osteogenesis J Biomed Mater Res, 39 (2) (1998), pp. 190-199.

(2) S.F. Hulbert, F.A. Young, R.S. Mathews, J.J. Klawitte, C.D. Talbert, F.H. Stelling potential of ceramic materials as permanently implantable skeletal prostheses J Biomed Mater Res, 4(3) 1970, pp. 433-456

(3)A.I. Itala, H.O. Ylanen, C. Ekholm, K.H. Karlsson, H.T. Aro Pore diameter of more than 100 micron isno requisite for bone ingrowth in rabbits J Biomed Mater Res, 58 (6) (2001), pp. 679-683.

# I-BONE FLEXIBLE STRIP

**I - BonE** Flexible Strip is a bioresorbable synthetic bone graft that provides great handling with high elasticity for specific cases including bone defects in the pelvis, extremities, and the posterolateral spine fusion.

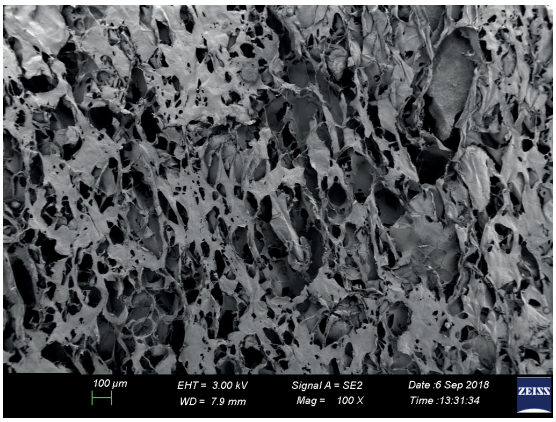
**I - BonE** Flexible Strip is composed of silicate additive β-TCP and PLA based synthetic polymer.

**I - BonE** Flexible Strip

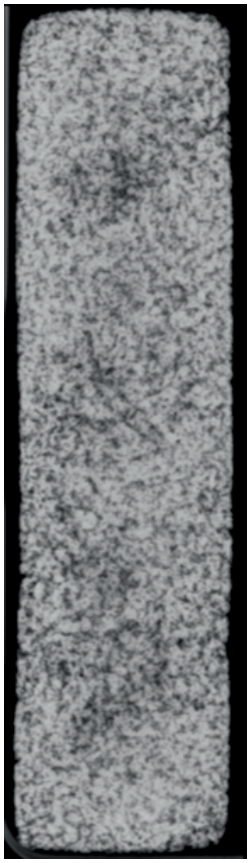
Elasticity of **I - BonE** Flexible Strip

Instructions of Implanting **I - BonE** Flexible Strip:

- **I - BonE** Flexible Strip can be applied directly or combination with bone marrow aspirate/blood to the surgical site.
- Wetting **I - BonE** Flexible Strip increases flexibility.
- Place **I - BonE** Flexible Strip into the surgical site just before the closure of the surgical area once all metallic implants are stable.
- **I - BonE** Flexible Strip can be cut to fit into a cage.




SEM Görüntüsü

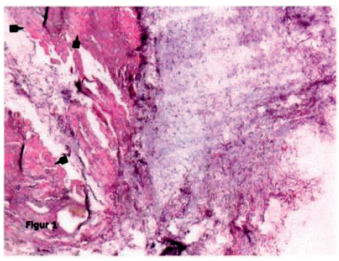


Micro-CT analysis of
**I - BonE** Flexible Strip

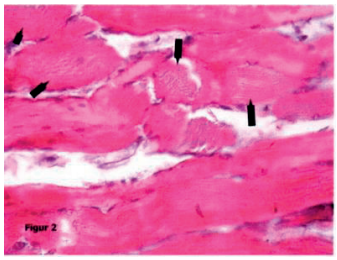
# I-BONE PUTTY, GEL, AND DENTAL PUTTY

Reasons to select I - BonE Dental Putty;

- Minimal invasive surgical protocol
- Easier and faster application
- Ready to use
- No mixing required
- Enhance bone regeneration
- No membrane usage (for dental putty only)
- Reduce chair time

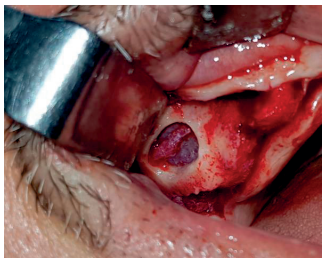


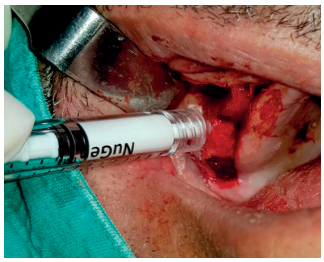
Osteoid formation (Osteoinductive characteristics) 2 months after impantation of I - BonE Putty in skelatal muscle

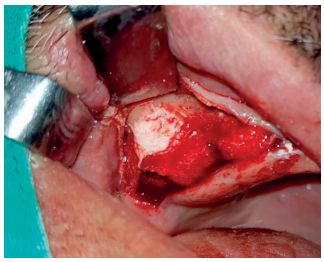


General procedure of I - BonE Dental Putty in sinüs lifting, lateral augmentation, and socket grafting;

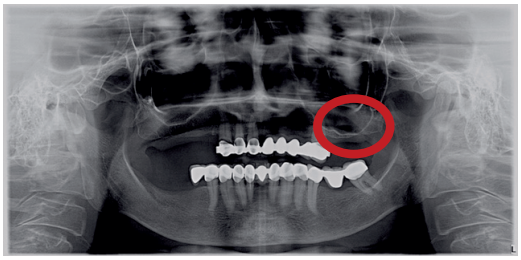
1. Lift a flap
   - The flap should be minimally reflected to open up whole graft site.
   - Prepare the defect site for grafting
2. Dental Putty application
   Inject the dental putty and press gently for 5 seconds to get the defect shape by using sterile dry gauze.



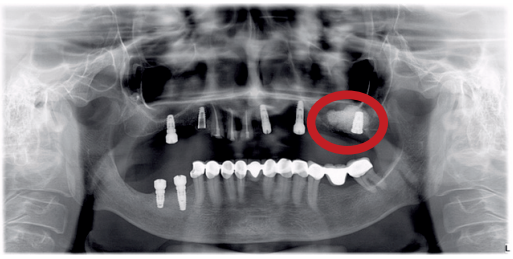




Use of I - BonE Putty in sinus lifting operation.



A- Before grafting procedure

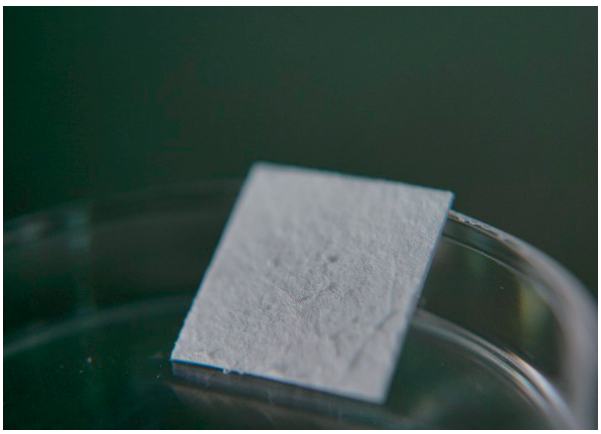


B- 5 months after grafting procedure

The sinus defect filled with I - BonE Putty heals completely after 5 months. Radiological view of before and after grafting application. As it is seen, bone tissue completely regenerated and dental implant was successfully placed.

# I-BONE CHONDRO MATRIX

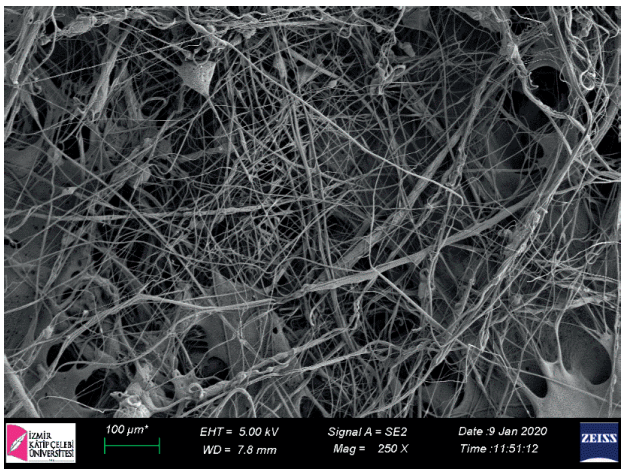
**I - BonE** Chondro Matrix is a high-tech scaffold with a flexible and hydrophilic structure, treated with Sodium hyaluronate, sterile, absorbable matrix sponge-like nonwoven Polyglycolic acid (PGA).



**I - BonE** Powerbone Chondro Matrix

Hyaluronic Acid Based **I - BonE** Cartilage Repair Matrix;

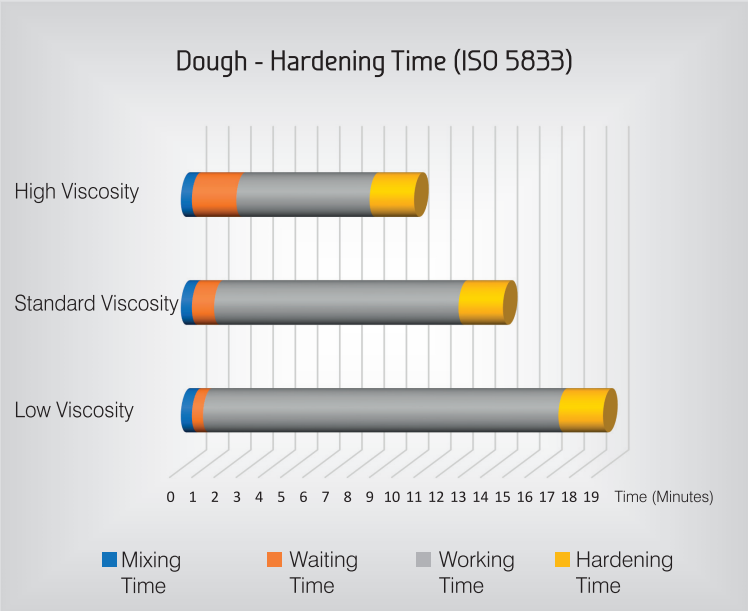
- Contains hyaluronic acid, which effectively supports cartilage formation,
- Based on PGA and hyaluronic acid and does not contain collagen and animal tissue,
- Suitable for the regeneration cycle of healthy cartilage,
- Bioresorbable and support cartilage formation during the healing process,
- No fragmentation or disintegration during cutting.
- Interconnective porous structure enables the movement of blood and body fluids to increase penetration for cells.

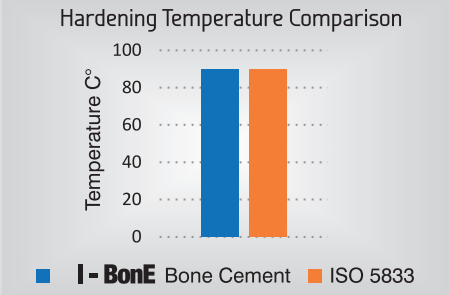


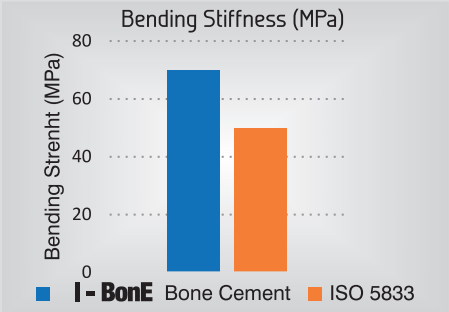

SEM Images of Hyaluronic Acid Based **I - BonE** Cartilage Repair Matrix

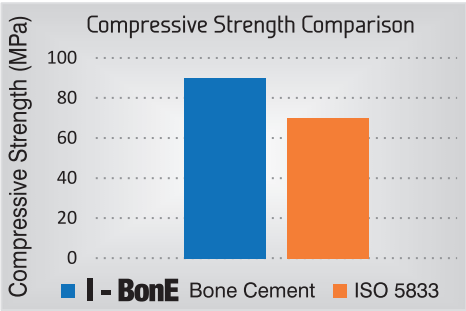
# I-BONE BONE CEMENT (FOR SPINE&ORTHO)

Bone Cement based on polymethyl methacrylate (PMMA) is a widely used biomaterial due to its ease of use in clinical practice and especially the long survival rate proven by dentures.




- Common Indications for Bone Cement: total joint replacement are bone and joint reconstructions, fracture fixation and treatment of osteoporotic vertebral fractures.
- Bone Cement consists of two phases, solid and liquid phase.
- To use the product, two phases are mixed in the mixing bowl for 30 seconds.
- Since the product is offered in three different viscosities, low, standard and high, it can be used in different surgical applications at Spine&Ortho.
- Products have paste, hardening, maximum temperature and mechanical strength values specified in ISO 5833 standard.

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PRODUCT NAME

# I-BonE Granules


| REFERENCE CODE | MEASURE | VOLUME |
|---|---|---|
| I-G02501005 | 0.25-1 mm | 0,5cc |
| I-G02501010 | 0.25-1 mm | 1 cc |
| I-G05001010 | 0.5-1 mm | 1 cc |
| I-G05001020 | 0.5-1 mm | 2 cc |
| I-G05001050 | 0.5-1 mm | 5 cc |
| I-G10002010 | 1-2 mm | 1 cc |
| I-G10002020 | 1-2 mm | 2 cc |
| I-G10002050 | 1-2 mm | 5 cc |
| I-G10002100 | 1-2 mm | 10 cc |
| I-G020405 | 2-4 mm | 5 cc |
| I-G020410 | 2-4 mm | 10 cc |
| I-G020415 | 2-4 mm | 15 cc |
| I-G020420 | 2-4 mm | 20 cc |
| I-G020430 | 2-4 mm | 30 cc |
| I-G040705 | 4-7 mm | 5 cc |
| I-G040710 | 4-7 mm | 10 cc |
| I-G040715 | 4-7 mm | 15 cc |
| I-G040720 | 4-7 mm | 20 cc |
| I-G040730 | 4-7 mm | 30 cc |

PRODUCT NAME

# I-BonE Stick Block Wedge


| REFERENCE CODE | MEASURE | VOLUME |
|---|---|---|
| I-S44204 | 4x4x20mm | 8,10 cc |
| I-S44205 | 4x4x20mm | 10,13 cc |
| I-S44206 | 4x4x20mm | 12,15 cc |
| I-S55204 | 5x5x20mm | 16,50 cc |
| I-S55205 | 5x5x20mm | 20,63 cc |
| I-S5510 | 5x5x10mm | 2,06 cc |
| I-S5520 | 5x5x20mm | 4,13 cc |
| I-S5634 | 5x6x34mm | 8,42 cc |
| I-S6717 | 6x7x17mm | 5,89 cc |
| I-S8820 | 8x8x20mm | 10,56 cc |
| I-S101020 | 10x10x20mm | 16,50 cc |
| I-S151520 | 15x15x20mm | 24,50 cc |
| I-S71214 | 7x12x14mm | 9,69 cc |

PRODUCT NAME

# I-BonE Flexible Graft


| REFERENCE CODE | MEASURE | VOLUME |
|---|---|---|
| I-F701104 | 70x110x4mm | 30,00 cc |
| I-F25805 | 25x80x5mm | 10,00 cc |
| I-F60505 | 60x50x5mm | 15,00 cc |
| I-F60606 | 60x60x6mm | 21,60 cc |
| I-F30306 | 30x30x6mm | 5,40 cc |

PRODUCT NAME

# I-BonE Putty


| REFERENCE CODE | VOLUME |
|---|---|
| I-P005 | 0,5 cc |
| I-P006 | 0,6 cc |
| I-P01 | 1 cc |
| I-P02 | 2 cc |
| I-P03 | 3 cc |
| I-P05 | 5 cc |
| I-P10 | 10 cc |

PRODUCT NAME

# I-BonE Gel


| REFERENCE CODE | VOLUME |
|---|---|
| I-J01 | 1 cc |
| I-J02 | 2 cc |
| I-J03 | 3 cc |
| I-J05 | 5 cc |
| I-J10 | 10 cc |

PRODUCT NAME

# I-BonE Dental Putty


| REFERENCE CODE | VOLUME |
|---|---|
| I-DP030 | 0,3 cc |
| I-DP050 | 0,5 cc |
| I-DP075 | 0,75 cc |
| I-DP100 | 1 cc |

PRODUCT NAME

# I-BonE Barrier Membrane


| REFERENCE CODE | DIMENSIONS |
|---|---|
| I-M1520 | 15x20mm |
| I-M1525 | 25x25mm |
| I-M2020 | 20x20mm |
| I-M2025 | 20x25mm |
| I-M2030 | 20x30mm |
| I-M3040 | 30x40mm |
| I-M2530 | 25x30mm |
| I-M3060 | 30x60mm |

PRODUCT NAME

# I-BonE Chondro Matrix


| REFERENCE CODE | DIMENSIONS |
|---|---|
| I-K202011 | 20-20-1,1mm |
| I-K203011 | 20-30-1,1mm |
| I-K251711 | 25-17-1,1mm |
| I-K252511 | 25-25-1,1mm |
| I-K253511 | 25-35-1,1mm |
| I-K353511 | 35-35-1,1mm |

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PRODUCT NAME

# I-BonE Bone Cement


| | REFERENCE CODE | WEIGHT |
|---|---|---|
| I-BONE LV Radiopaque Vertebroplasty Bone Cement, PMMA, 20g | IBONEVC-LV-20 | 20g |
| I-BONE LV Radiopaque Vertebroplasty Bone Cement, PMMA, 40g | IBONEVC-LV-40 | 40g |
| I-BONE SV Radiopaque Vertebroplasty Bone Cement, PMMA, 40g | IBONEVC-SV | 40g |
| I-BONE LV Radiopaque Kyphoplasty Bone Cement, PMMA, 20g | IBONEKC-LV-20 | 20g |
| I-BONE LV Radiopaque Kyphoplasty Bone Cement, PMMA, 40g | IBONEKC-LV-40 | 40g |
| I-BONE SV Radiopaque Kyphoplasty Bone Cement, PMMA, 40g | IBONEKC-SV | 40g |
| I-BONE SV Radiopaque Bone Cement-Normal, PMMA, 40g | IBONEOC-SV40 | 40g |
| I-BONE LV Radiopaque Bone Cement, PMMA, 20g | S-IBONEC-LV-20 | 20g |
| I-BONE LV Radiopaque Bone Cement, PMMA, 40g | S-IBONEC-LV-40 | 40g |
| I-BONE SV Radiopaque Bone Cement, PMMA | S-IBONEC-SV | 40g |
| I-BONE HV Radiopaque Bone Cement, PMMA | S-IBONEC-HV | 40g |

I-Tech Health Germany

I-Tech Health Germany UG
(haftungsbeschränkt)

Karlsruher Str 117
76327 Pfinztal