

# NovaBone Product Guide



ZIMMER BIOMET  
Your progress. Our promise.™

The Synthetic Solution to Bone Regeneration



Excellent Handling,  
Uncompromised Results



**NovaBone** product lines are available in multiple dispensing systems. Variations are priced for affordability and efficiency. Products are available through a network of distributors world-wide, with a presence in over 40 countries.



NovaBone Dental Putty is a Calcium-Phosphosilicate bone substitute that uses a next-generation delivery system engineered for enhanced handling and improved performance.

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#### **CARTRIDGE SYSTEM**

EU3620 - 0.5 cc Cartridges (Blue)	2/pack
EU3640 - 0.5 cc Cartridges (Blue)	4/pack
EU4640 - 0.25 cc Cartridges (Gray)	4/pack
EU4623 - 0.3 cc Cartridges (Gray)	2/pack
EU4663 - 0.3 cc Cartridges (Gray)	6/pack
EU4600 - Cartridge Dispenser	

#### **SYRINGE**

EU1610 - 0.5 cc Syringe	1/Pack
EU1611 - 1.0 cc Syringe	1/Pack

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Not all dispensing formats are available in all territories. Please check with your local Zimmer Biomet Dental sales representative or distributor for sizes, part # and availability.



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## Product Characteristics

NovaBone Dental Putty was introduced after extensive market research which suggested that clinicians did not expect great strides in the rate of bone formation but rather in delivery, handling and performance of bone graft substitutes without a significant cost increase.

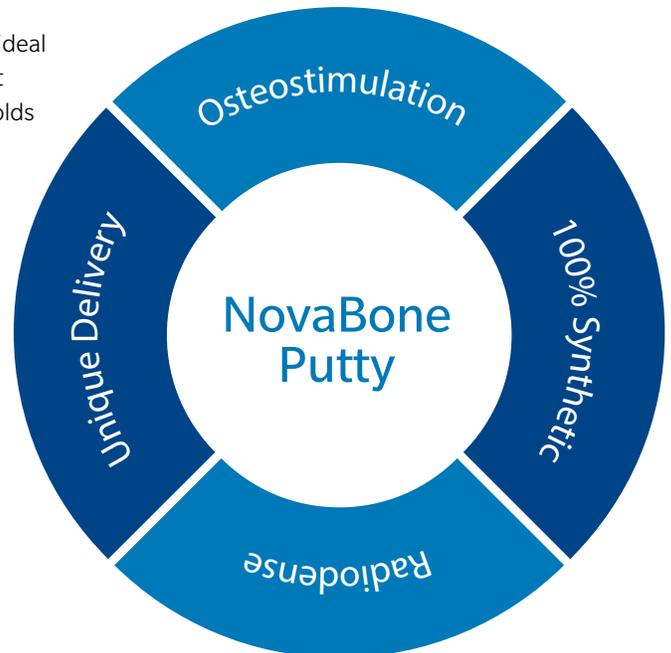
NovaBone Putty has bimodal particle distribution of Calcium Phosphosilicate (CPS) (active ingredient), with Polyethylene Glycol (PEG) as an additive and Glycerin as the Binder. The volume of the active ingredient is approximately 70%. The Putty format allows easier manipulation due to its format and eliminates the need for any preparation prior to placement. NB Putty offers clinicians various delivery systems (Cartridges & Syringes) in various sizes with benefits of consistent, reliable bone regeneration. Putty received its initial FDA clearance and CE approval for dental indications in 2006 and 2007 respectively.<sup>1</sup>

NovaBone Bone Graft Putty is available in proprietary uni-dose cartridges, ideal for minimally invasive surgeries, hard to access defects, immediate implant surgeries, osteotome sinus surgeries, etc. Each cartridge/mini cartridge holds 0.25 - 0.5 cc of putty.

Putty does not set like a cement but has a transient hemostatic effect designed to provide a comfortable environment for the clinician to work with. Putty has great retention and can adapt to the defect shape.<sup>2</sup>

Putty is radio-dense and can be visualized on radiographs. Upon implantation, it appears as a mass at the defect site which can be differentiated from surrounding bone by the lack of trabecular pattern. Over time, with bone remodeling, the grafted area appears analogous to the natural bone in the region.

Putty has a 4-year shelf life and does not need refrigeration but caution should be exercised at temperatures higher than 40°C.



## Proprietary Delivery System

NovaBone Dental Putty Bone Graft is available in multiple delivery options: pre-filled syringes and a proprietary cartridge delivery system. NovaBone is available in disposable uni-dose cartridges. The diameter of the cannula is 2.8 mm (inner) and 3.0 mm (outer), which is ideal for dispensing of the putty, especially in minimally invasive techniques such as gaps in immediate implant and crestal approach sinus lifts. Cartridges are available in various sizes and are used in conjunction with the cartridge dispenser.



1. Data on file with NovaBone Products, LLC.

2. Profeta AC, Prucher GM. Bioactive-glass in periodontal surgery and implant dentistry. Dent Mater J. 2015;34(5):559-71.

## Smart Science™ - Osteostimulation<sup>1-3</sup>

NovaBone Putty belongs to the class of bioactive regenerative materials that not only acts as an osteoconductive scaffold but also interacts with the surrounding tissues and imparts an osteostimulatory effect. NovaBone Putty is not osteoinductive but a number of in vivo studies have demonstrated an accelerated bone formation with calcium phosphosilicate particles. Also, the viability and proliferation potential of osteoblasts has been shown to be exemplified in the presence of calcium phosphosilicate particles. Studies also demonstrate increased osteocalcin and alkaline phosphatase levels in the presence of calcium phosphosilicate particles providing a favorable site for bone formation.

Osteostimulation is an active process. NovaBone Dental Putty acts as a bone matrix and encourages differentiation of new bone cells at the site. This phenomenon results in faster bone regeneration than exhibited by osteoconduction alone while simultaneously increasing the resorption rate of the graft material.

## Biologic Interpretation<sup>2,4</sup>

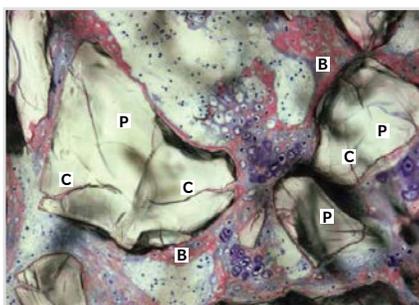
- Immediately upon implantation, silicon and calcium ion release initiates a cascade of events that signals and recruits undifferentiated cells to the site
- Several genes are regulated, resulting in proliferation and differentiation of undifferentiated cells into osteoblasts
- The osteoblasts mature into osteocytes (mature bone cells) at the terminal stage
- This process continues resulting in bone regeneration at a much faster pace than osteoconduction

## Clinical Interpretation<sup>4-5</sup>

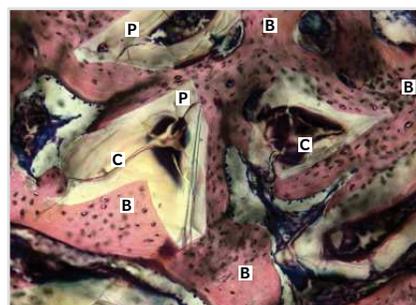
- Upon implantation, the binder gets absorbed within 24-72 hrs, creating a 3-dimensional porous scaffold that aims to active movement of blood and tissue fluids through the matrix
- Smaller CPS particles interact with blood providing the initial burst of calcium and phosphate ions
- This provides a favorable area for bone regeneration as it creates numerous calcium phosphate nodules that mature individually to form bone throughout the defect
- Subsequently, the larger particles react and continue the process of bone regeneration

## Histologic Interpretation<sup>1,5</sup>

Rabbit histology at 3 and 6 weeks helps visualize the osteostimulation phenomenon. At 3 weeks, cracks developing through individual particles can be noticed with bone growing through them. Pink areas of bone formation are also seen around the putty particles along with areas of cartilaginous cells and giant cells (purple). At 6 weeks, abundant bone around each particle can be seen (pink areas). The cracks have progressed completely into the center of each particle, and an area of bone regeneration (pink) is seen within each individual particle. This is very unique to CPS products and results in the creation of multiple foci of bone regeneration resulting in enhanced bone regeneration and consequently faster material absorption.



3 Weeks



6 Weeks

B- Bone, P- Graft Particle, C- Cracks

3. Jell G, Notingher I, Tsigkou O, Notingher P, Polak JM, Hench LL, Stevens MM. Bioactive glass-induced osteoblast differentiation: a noninvasive spectroscopic study. *J Biomed Mater Res A*. 2008 Jul;86(1):31-40.
4. Grover V, Kapoor A, Malhotra R, Uppal RS. Evaluation of the efficacy of a bioactive synthetic graft material in the treatment of intrabony periodontal defects. *J Indian Soc Periodontol*. 2013 Jan;17(1):104-10.
5. Kotsakis G, et al. Histomorphologic Evaluation of a Calcium-Phosphosilicate Putty Bone Substitute in Extraction Sockets. *Int J Periodontics Restorative Dent*. 2014 Mar-Apr; 34(2)233-9.

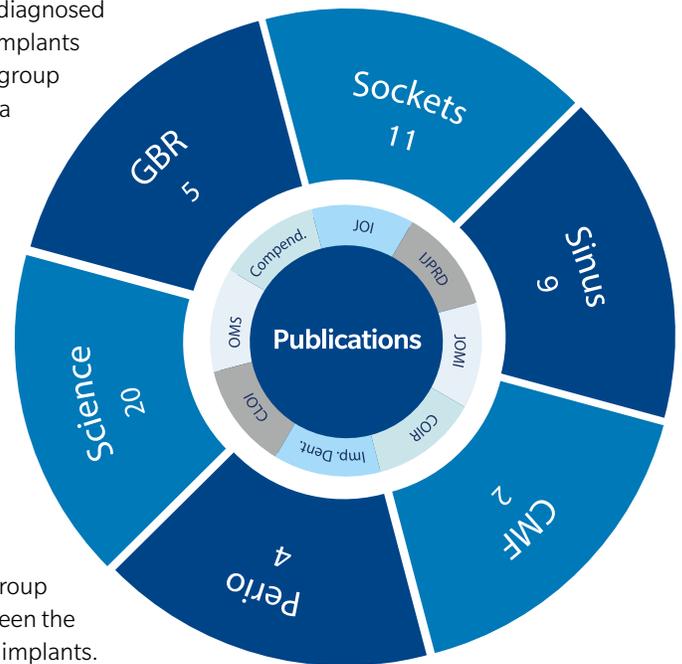
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## Clinical Evidence

With over 30 publications in peer reviewed journals, NovaBone Putty has consistently proven to regenerate bone in various osseous defects including ridge augmentations, sinuses, sockets, periodontal defects, etc. Most studies indicate that 80%-90% absorbed in 4-6 months, while regenerating bone at the same time. Putty has also redefined sinus lift techniques with minimally invasive surgical approaches and improvisations utilizing its unique dispensing system.

In a 2014 publication by Babbush et al., sixty-five patients with a mean age of 63±12 years were analyzed.<sup>6</sup> In total, 262 implants were placed. Four implant patients were diagnosed with peri-implantitis and were treated for a total of 266 grafted sites. Two implants from the extraction graft category and three implants from the all-on-four group were lost and replaced with successfully osseointegrated implants during a mean study follow-up period of 12.24±2.32 months. The implant success rate at one year was 98.1% (257/262).

AJOMI article by Kotsakis, Salama et al.<sup>7</sup>, evaluated the performance of Putty in ridge preservation as compared to the Geistlich's Bio-Oss<sup>®</sup> product. Thirty teeth were extracted from 24 patients. The sockets were debrided and received anorganic bovine bone mineral (BOV, n=12), calcium phosphosilicate putty (PUT, n=12), or no graft (CTRL, n=6). The sockets were assessed clinically and radiographically 5 months later. Eight sockets in the BOV group and nine in the PUT group received implants 5 to 6 months post-grafting. The maximum implant insertion torque (MIT) was measured as an index of primary implant stability. The data were analyzed with the Mann-Whitney test. Both test groups had statistically significantly less reduction in mean ridge width (BOV: 1.39±0.57 mm; PUT: 1.26±0.41 mm) in comparison to the control group (2.53±0.59 mm). No statistically significant difference was identified between the test groups. MIT for PUT was 35 N/cm<sup>2</sup> (MIT grade 4) for seven of the nine implants. MIT values in the BOV group ranged from grade 1 (10 to 19 N/cm<sup>2</sup>) to grade 4, which was statistically significantly lower than for the PUT group. The overall implant success rate was 94.1% (16 of 17 implants were successful). This indicated that Putty was good to preserve ridge dimensions and had favorable bone density values for implant placement as compared to Bio-Oss.



## Histomorphometry

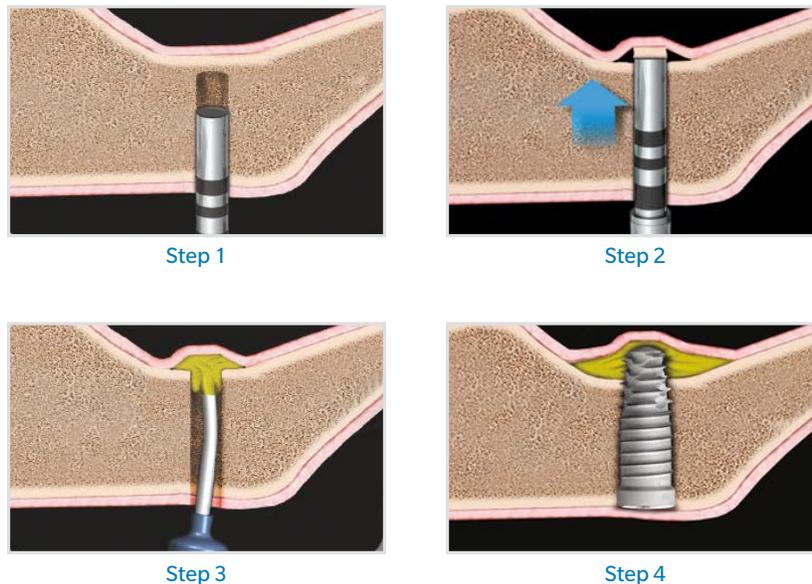
In four separate studies, histomorphometric evaluation of cores taken from extraction sockets grafted with NovaBone Dental Putty showed vital bone regeneration and significant graft resorption.<sup>7-10</sup>

	Number of Sites	Average Re-Entry Time	Mean Vital Bone Content	Mean Residual Graft
2015 Lanka et al. <sup>8</sup>	N = 10	4.9 months	47.15%	17.4%
2014 Kotsakis et al. <sup>7</sup>	N = 17	5.7 months	31.76%	11.47%
2012 Lanka et al. <sup>9</sup>	N = 20	4.9 months	49.57%	4.3%
2011 Gonshor et al. <sup>10</sup>	N = 22	5.4 months	48.2%	2.4%

6. Babbush CA, Kanawati A. Clinical evaluation of 262 osseointegrated implants placed in sites grafted with calcium phosphosilicate putty: a retrospective study. *J Oral Implantol.* 2015 Feb;41(1):63-9.  
 7. Kotsakis GA, Salama M, Chrepa V, Hinrichs JE, Gaillard P. A randomized, blinded, controlled clinical study of particulate anorganic bovine bone mineral and calcium phosphosilicate putty bone substitutes for socket preservation. *Int J Oral Maxillofac Implants.* 2014 Jan-Feb;29(1):141-51.  
 8. Lanka M, Venkataraman N, Shukla S, Prasad H, Kotsakis GA. Alveolar ridge preservation with the socket-plug technique utilizing an alloplastic putty bone substitute or a particulate xenograft: a histological pilot study. *J Oral Implantol.* 2015 Apr;41(2):178-83.  
 9. Lanka M, Salama MA, Kurtzman GM, Joachim FP. Socket grafting with calcium phosphosilicate alloplast putty: a histomorphometric evaluation. *Compend Contin Educ Dent.* 2012.  
 10. Gonshor A, et al. Histologic and Clinical Evaluation of a Bioactive Calcium Phosphosilicate Bone Graft Material in Postextraction Alveolar Sockets. *Int. J Oral Imp Clin Res.* May-August 2011;2(2):79-84.

# Minimally Invasive Transcrestal Sinus Augmentation<sup>11</sup>

There are several ways to access the sinus via crestal approach and elevate the sinus membrane prior to augmentation: A) Osteotome Technique B) Piezo Technique C) Neurosurgical Bur D) Densah® Burs, etc. Bone graft delivery into the sinus can be difficult and challenging. NovaBone Cartridge System simplifies the delivery of graft into the sinus when accessed through the crest of the ridge. The tip of the cartridge is 2.8 mm in diameter and was designed specifically to deliver the graft seamlessly into the sinus. Putty consistency can help prevent membrane tears. The delivery of the putty graft can elevate the membrane with minimal instrumentation and hydraulic pressure.



Easy access into sinus through crestal floor for sinus augmentation with Osteotome technique can be achieved in 4 simple steps.

**Step 1:** Prepare the osteotomy to less than 1 mm from the sinus floor.

**Step 2:** An osteotome is then used to gently fracture the bone in the area.

**Step 3:** The canula from the cartridge tip can be pressed against the surface of the bone and the putty is injected into the area resulting in membrane elevation with hydraulic pressure from Putty delivery.

**Step 4:** An implant can then be placed in the augmented area.

## Testimonials

*"The unique handling characteristics of the NovaBone Putty in combination with the cartridge delivery system allow for significant simplification of routinely used techniques in implant dentistry and significant reduction in intra-operative treatment time".*

–Dr. George Kotsakis, Periodontist, Assistant Prof., University of Washington, Seattle

*"The putty consistency of NovaBone is easy to manipulate, and the unique cartridge delivery allows access to unreachable areas. I am able to do sinus grafts through smaller windows with reduced intra-operative complications. The radiopacity of the material is optimum for visibility on a radiograph. Above all, the material holds its form long enough to facilitate new bone formation".*

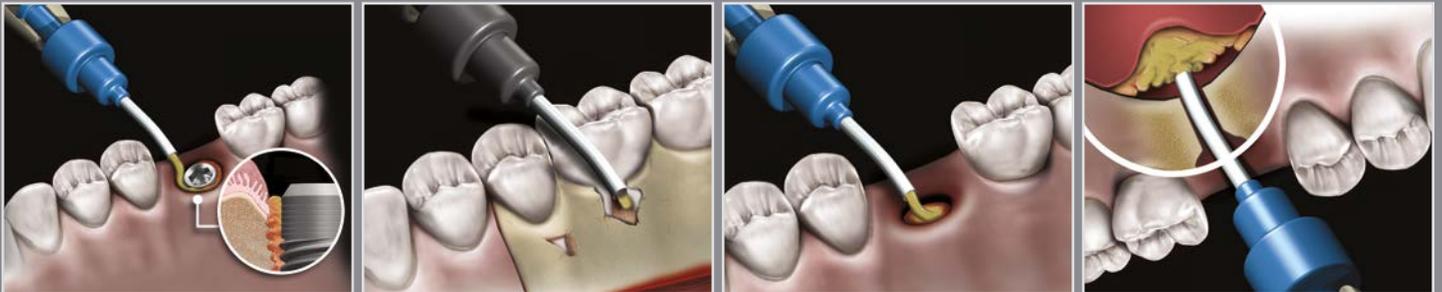
–Dr. Udatta Kher, Oral Surgeon, Private Practice, Mumbai, India

<sup>11</sup> Mazor Z, et al. Minimally Invasive Crestal Approach Technique Utilizing a Cartridge Delivery System. Implant Practice. Sept 2013; 6(4): 20-24.

\* Densah® is a registered trademark of the Versah® Company.

# Grafting Simplified

NovaBone Dental Putty redefines minimally invasive bone grafting surgeries.



Contact us at 1-800-342-5454 or visit  
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