

NOVABONE[®] Dental Putty

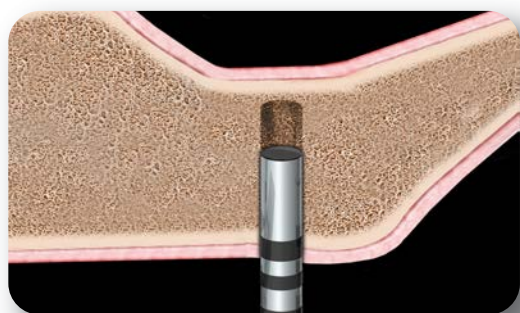
PRODUCT GUIDE



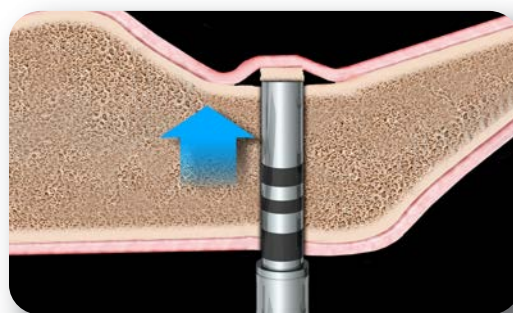
Redefining Simple in Bone Graft Surgeries

Sinus Elevation - Simplified Crestal Approach

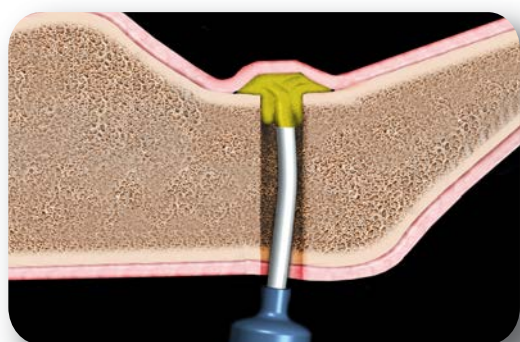
NovaBone Cartridge System simplifies the delivery of graft into the sinus when accessed through the crest of the ridge. The tip of the cartridge is 2mm in diameter and is designed specifically to deliver the graft seamlessly into the sinus. Putty consistency will help prevent membrane tears. The delivery of the putty graft can elevate the membrane with minimal instrumentation and hydraulic pressure.



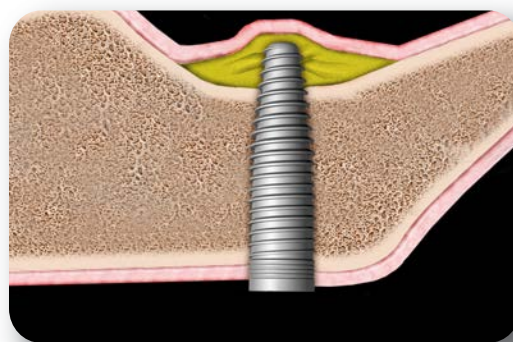
Step 1



Step 2



Step 3



Step 4

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COMPANY INFORMATION

NOVABONE Products is dedicated to delivering best-in-class synthetic bone graft substitutes to the surgical community with unprecedented focus on service and commitment to its user base.

NovaBone is headquartered in Jacksonville, FL with Manufacturing and R&D facilities in Alachua, FL. NovaBone also has a sales office in Shanghai, China. In 2012, NovaBone Products Pvt. Ltd was established in Bangalore, India as a sales and marketing office to support the growing user base in India.

All NovaBone product lines are available through a network of distributors world-wide, with a presence in over 40 countries.

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NOVABONE DENTAL PUTTY

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

PRODUCT PROFILE

NOVABONE Dental Putty (NB 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. They wanted to see improvements which would make surgical procedures easier, simpler and more predictable.

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 (Shells, Cartridges & Syringes) in various sizes with benefits of consistent, reliable bone regeneration. Built on a Calcium Phosphosilicate (CPS) platform, NB Putty demonstrates superior performance characteristics that are a result of multiple physical & chemical interactions: "Osteostimulation". Putty received its FDA & CE approval for dental indications in 2007.

NB Putty is currently sold in over 30 countries world-wide and has redefined the category of bone grafts. It was the first synthetic putty that required no handling or manipulation and the first to be available in a significantly simplified *cartridge delivery system*. NB Putty minimizes graft wastage and reduces chair-side time, thus increasing productivity while delivering reliable exceptional results.

COMPOSITION & INDICATIONS

Putty is composed of a 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 components are premixed, and the putty is delivered in a ready-to-use state. PEG & Glycerin are both water soluble and are engineered to be absorbed from the site in 3-5 days. The putty is tan in color after sterilization.



NB Putty is approved for all oral / dental / craniofacial indications that require bone grafting including:

- ❖ Immediate implant Surgeries
- ❖ Ridge Augmentations
- ❖ Extraction Sites
- ❖ Sinus Elevations
- ❖ Periodontal / Furcation Defects
- ❖ Cystic Defects - Apicoectomies
- ❖ Cranio-maxillofacial defects (CMF)
- ❖ Fenestration & Dehiscence defects

PUTTY CHARACTERISTICS

UNIQUE DISPENSING SYSTEM

NB Putty is available in unique uni-dose cartridges – an industry first; ideal for minimally invasive surgeries, hard to access defects, immediate implant surgeries, osteotome sinus surgeries, etc. Each cartridge holds 0.5-1.0cc of putty. A **mini cartridge system** with cartridges that hold 0.25cc is also available and is indicated for smaller defects: periodontal, peri-implant, etc.

OSTEOSTIMULATION & OSTEOCONDUCTION

Unique to NB Putty, *osteostimulation* increases the rate of bone formation, as demonstrated with *in vivo* studies. Several genes are up-regulated, resulting in enhanced osseous activity at the defect site. Bone regenerates throughout the defect simultaneously. It also provides a resorbable scaffold and creates an optimal environment for bone regeneration.

COHESION & GRAFT RETENTION

NB Putty is delivered as a pre-mixed, cohesive, workable mass. The material may be molded at time of placement without fracture or material loss. NB Putty will not washout from the graft site during irrigation and suction.

CLOT STABILIZATION

NB Putty has a transient hemostatic effect providing a comfortable environment for the clinician to work with. It encourages clot stabilization and promotes healing.

ADHERENCE TO GLOVES

Putty does not adhere to surgical gloves or instruments during manipulation. Two of the three dispensing formats (syringe & cartridge) do not require any handling.

GRAFT PLACEMENT

Many bone grafts fail because of issues related to the method of graft placement & retention at the defect site. NB Putty eliminates such concerns and consistently regenerates bone.

100% SYNTHETIC & FULLY RESORBABLE

NB Putty has no risk of antigenic response or disease transmission, thus easing patient concerns regarding use of allografts and xenografts. Putty resorbs completely and becomes a part of the natural bone remodeling process to yield healthy, vascularized normal bone.

RADIOGRAPHIC APPEARANCE

Putty appears radiodense on the radiograph. It can be visualized on the radiograph as having a very similar appearance to the adjacent bone. Upon implantation, it appears as a mass at the defect site which can be differentiated from surrounding bone by the lack of normal trabecular pattern. Over time, with bone remodeling, the restored area appears analogous to the natural bone in the region.

STORAGE TRANSPORTATION & SHELF LIFE

It is stable at room temperatures (25°C) and does not require any refrigeration. Caution should be exercised when putty is being stored and shipped in temperatures over 45°C. Do not leave the putty in your vehicle on a summer day. NB Putty has a 4 year extended shelf life as compared to the market standard of 2 years – a significant advantage!

SMART SCIENCE™ - OSTEOSTIMULATION

Unlike other synthetic grafts that are bioinert, NB 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. NB Putty is not osteoinductive but a number of *in vivo* studies have demonstrated an accelerated bone formation with CPS particles. Also, the viability and proliferation potential of osteoblasts has been shown to be exemplified in the presence of CPS particles. Studies also demonstrate increased osteocalcin and alkaline phosphatase levels in the presence of CPS 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

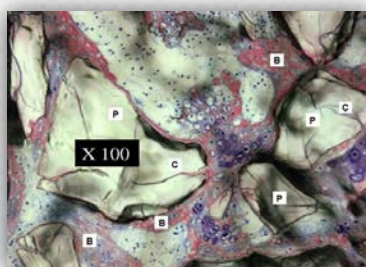
- Immediately upon implantation, silicon and calcium ion release initiates a cascade of events that signals and recruits undifferentiated cells to the site
- Several genes are regulated, resulting in proliferation and differentiation of undifferentiated cells into osteoblasts
- The osteoblasts mature 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

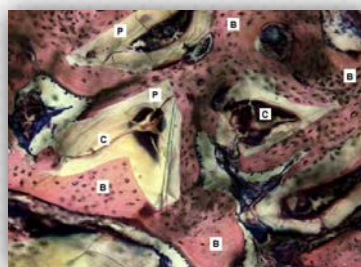
- Upon implantation, the binder gets absorbed within 24-72 hrs, creating a 3-dimensional porous scaffold that facilitates active movement of blood and tissue fluids through the matrix
- Smaller CPS particles interact with blood providing the initial burst of calcium and phosphate ions
- This provides 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

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 & giant cells (purple).



3 weeks



6 weeks

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

Figure 2 – Histology demonstrating osteostimulation phenomenon at 3 & 6 weeks

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!

CLINICAL STUDIES

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 2014 publication by **Babbush et al.**, Sixty-five patients with a mean age of 63±12 years were analyzed. In total 262 implants were placed. Four implants 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).

JOMI article by Kotsakis, Salama et al., evaluated performance of Putty in ridge preservation as compared to BioOss. 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/cm² (MIT grade 4) for seven of the nine implants. MIT values in the BOV group ranged from grade 1 (10 to 19 N/cm²) 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 BioOss.

Implant Dentistry article by **Kher, Mazor** investigated the performance of Putty in lateral window sinus augmentations. Seventeen patients who had been treated with simultaneous implant placement in sites with <5 mm of vertical bone height using a modified direct sinus lift technique were included. Implants placed in adjacent sites with at least 5 mm of bone height were included as quasi-controls. A total of 30 implants were inserted with a maximum insertion torque number >20 N/cm. Logistic regression analysis failed to show any association between residual bone height and primary implant stability. Implant survival was 96.67% (29/30) during a mean follow-up of 15.74 months postloading indicating that Putty is a great choice for grafting sinuses with less than 5 mm residual bone.

A Human Clinical Histomorphometric Study by Kotsakis et al published in IJPRD histologically evaluated socket bone regeneration capabilities of Putty. A core was obtained from 17 sockets prior to implant placement for histomorphometry at 5 to 6 months postextraction. Radiographic analysis during the same postextraction healing period showed radiopaque tissue in all sockets. Histomorphometric analysis revealed a mean vital bone content of 31.76% (± 14.20%) and residual graft content of 11.47% (± 8.99%) after a mean healing period of 5.7 months.

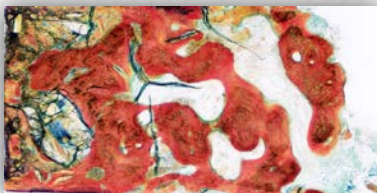


Figure 3 – Undecalcified core at 5.5 months (40x magnification)

	4-6 Months (Avg. 5.4)
% Vital Bone	31.76 ± 14.20
% Residual Graft	11.47 ± 8.99

Table 1 – Average Histomorphometric data from 60 sockets

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FREQUENTLY ASKED QUESTIONS

1. How much volume of putty do I need?

A typical extraction socket - 0.5cc; Single tooth sinus lift: 1.0cc-1.5cc; Multiple teeth sinus lift: 2.0cc-2.5cc; Perio defects: 0.25cc-0.3cc.

2. How long should I wait before re-entering the defect restored with NB Putty to place implants?

A 4-5 month wait time is recommended before re-entering a defect that was restored with NB Putty. Though over 90% of the material is absorbed at 6 months, there is sufficient bone at 4 months to support an implant. However, a radiological evaluation should be performed and the timing of the re-entry is left to the discretion of the clinician and may vary depending on the case.

3. Do I need a Membrane with NB Putty?

Membranes are used with graft materials not only to contain the graft material but also to prevent epithelial/Connective tissue growth into the defects. Membranes may not be required if close approximation of the tissues (primary closure) is achievable. In most instances, using a **collagen plug** has proven to provide barrier functionality. When necessary, Putty can be used with either non-resorbable or resorbable membranes. There is no contraindication to using one over the other and the membrane selection is left to the clinician discretion. Recently, bio-modifiers like **PRF** have been used in combination with Putty for superior results.

4. Why should I use NovaBone Dental Putty instead of DFDBA / Allografts?

Though allografts are generally considered safe, there is always a risk of disease transmission and immune response when using them. They also are mildly osteoinductive and primarily osteoconductive. Allografts also demonstrate varied resorption characteristics. NovaBone dental putty is osteostimulative and enhances bone regeneration. The active ingredient in NovaBone putty also has demonstrated bacteriostatic effects in several publications.

5. Why should I use NovaBone Dental Putty instead of xenografts like Bio-Oss?

Xenografts (Bio-Oss, NuOss, etc.) like allografts are generally considered safe. They are passive materials that act as scaffolds and demonstrate only osteoconductive characteristics. With its enhanced handling and performance characteristics, putty forms the ideal choice for grafting over xenografts.

6. Can I mix NovaBone Dental Putty with other graft materials?

Although it is not required, NovaBone Dental Putty can be mixed with other graft materials. However, to retain putty's handling characteristics a "sandwich" or "layer" technique is advised. NovaBone Dental Putty & other graft materials can be placed in layers into the defect.

7. Is NovaBone Dental Putty osteoinductive?

No. NB Putty is osteostimulative and osteoconductive.

8. Does blood profuse through the putty?

Yes. Upon placement you may not see blood profuse through the product but since all components used in putty are hydrophilic, the blood profusion continues to occur prior to and after clot formation and organization.

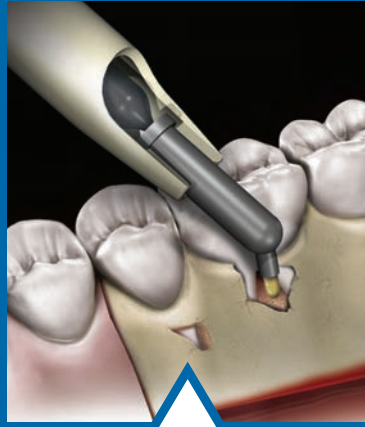
9. Are there any special post-operative instructions when using NB Putty?

No, there are no special post-op instructions for using NB Putty. The same post-op instructions apply as with other graft substitutes.

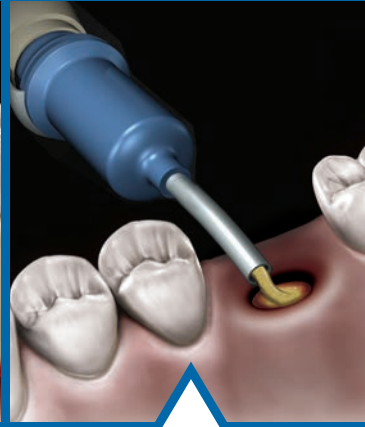
COMPLEX SURGERIES COMPREHENSIVE SOLUTIONS!



**IMPLANT
STABILIZATION**



**PERIODONTAL
DEFECTS**



**SOCKET
PRESERVATION**



**SINUS LIFT
PROCEDURES**

NOVABONE is focused exclusively on grafting solutions with a keen eye for simplifying the grafting procedures. All product lines are engineered to accelerate the body's natural healing process with a controlled release of ions and changes in surface chemistry that supercharge cellular activity with preferential development of cells that form new bone.

Release of Si from the particles is the key in signaling and recruitment of bone precursor cells to the defect site and stimulate osteoblast differentiation and proliferation. The phenomenon where both physical, chemical and biologic interactions result in bone formation is termed '**Osteostimulation**'.

NovaBone product lines are available in multiple formats. Products are priced for affordability and efficiency.

EXPERIENCE THE SHEER SIMPLICITY OF NOVABONE DENTAL PUTTY!

NOVABONE DENTAL PUTTY CARTRIDGE SYSTEM

Cartridge Dispenser.....	each
0.5cc Cartridges (blue)	2/Pack
0.5cc Cartridges (blue)	4/Pack
1.0cc Cartridges (orange).....	2/Pack

FREE Dispenser
with initial cartridge order.

NOVABONE DENTAL PUTTY SYRINGE

0.5cc Syringe	1/Pack
0.5cc Syringe	2/Pack
1.0cc Syringe	1/Pack
2.0cc Syringe	1/Pack

NOVABONE DENTAL PUTTY CLAM SHELL

0.5cc Shell	1/Pack
0.5cc Shell	2/Pack
1.0cc Shell	1/Pack
1.5cc Shell	2/Pack

NovaBone Dental Putty is available in multiple delivery mechanisms including syringes, clamshells and a unique **CARTRIDGE** system. Clinicians enjoy the simplicity of NovaBone Putty and the choice of sizes and systems available to suit various clinical indications.

INTRODUCING MINI

NOVABONE DENTAL PUTTY MINI CARTRIDGES

0.5g/0.25cc	4/Pack
Mini Dispenser	each

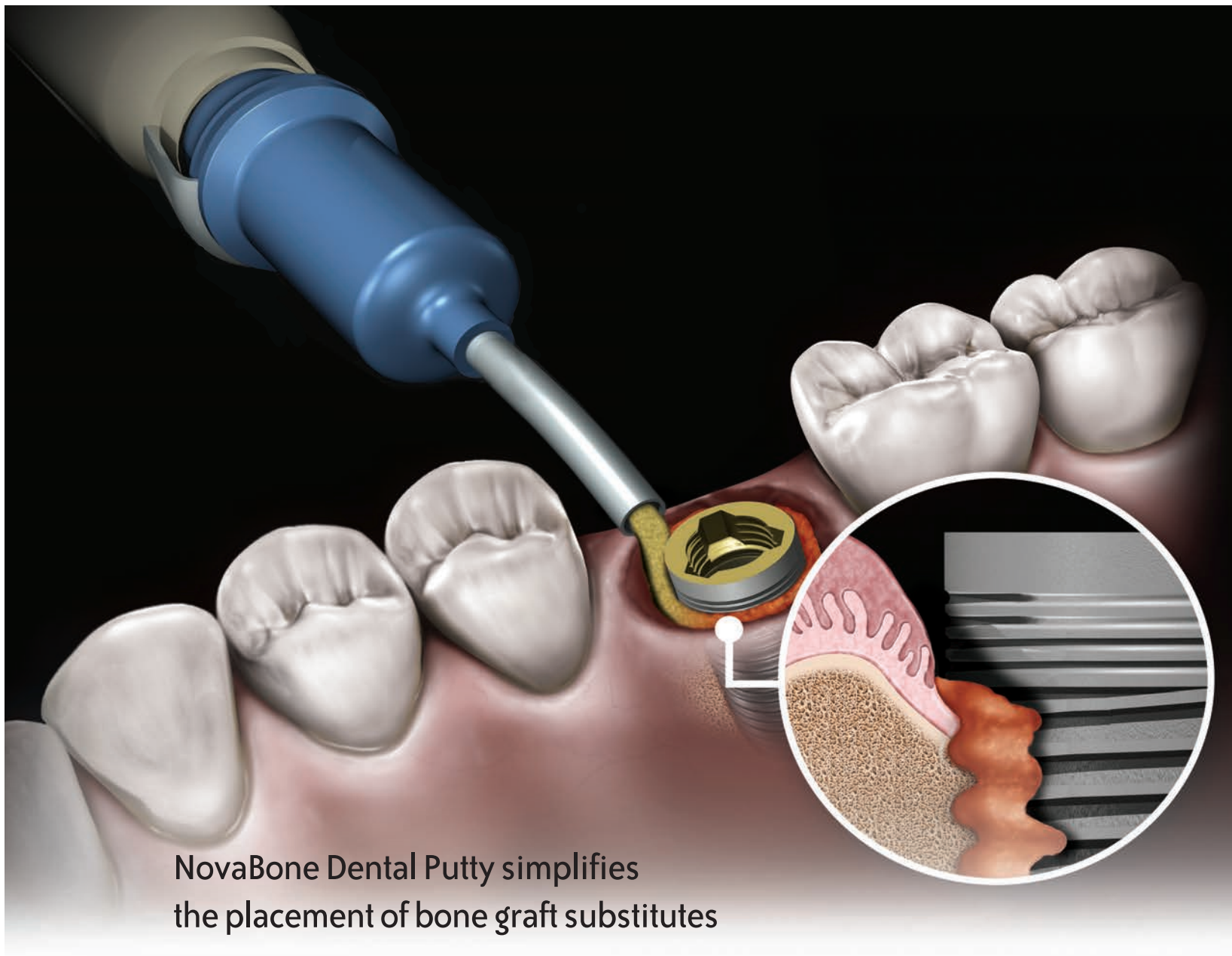
Launching in 2013, **MINI** Cartridges are ideally positioned for perio defects, peri-implant sites and smaller cysts.

NOVABONE DENTAL MORSELS

0.5gm Cups	2/Pack
1.5gm Cups	2/Pack
1.0gm Cups	2/Pack

NovaBone Dental Morsels was introduced in 2012 in select countries. The product was conceived to **SIMULATE** and **STIMULATE** natural bone. The particles are macroporous (50-100 microns) with 65% - 70% pore volume. This forms an ideal replacement to allografts. The bone integration is better due the interconnected porosity and the product completely resorbs in 12 months giving the grafted area the required long-term stability and structure.

*** Not all dispensing formats and products are available in all countries. Please contact your local dealer for Part #, sizes and availability ***



NovaBone Dental Putty simplifies the placement of bone graft substitutes

No Mixing • Easy Handling • Exceptional Results

NovaBone Dental Putty will truly revolutionize the way you use bone graft substitutes. You won't believe how easy the putty handles, yet delivering outstanding outcomes you demand.

Experience the sheer simplicity of NovaBone Dental Putty!

Think Productivity • Think Putty

NOVABONE[®]
DRIVING INNOVATION IN OSTEOBIOLOGICS

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