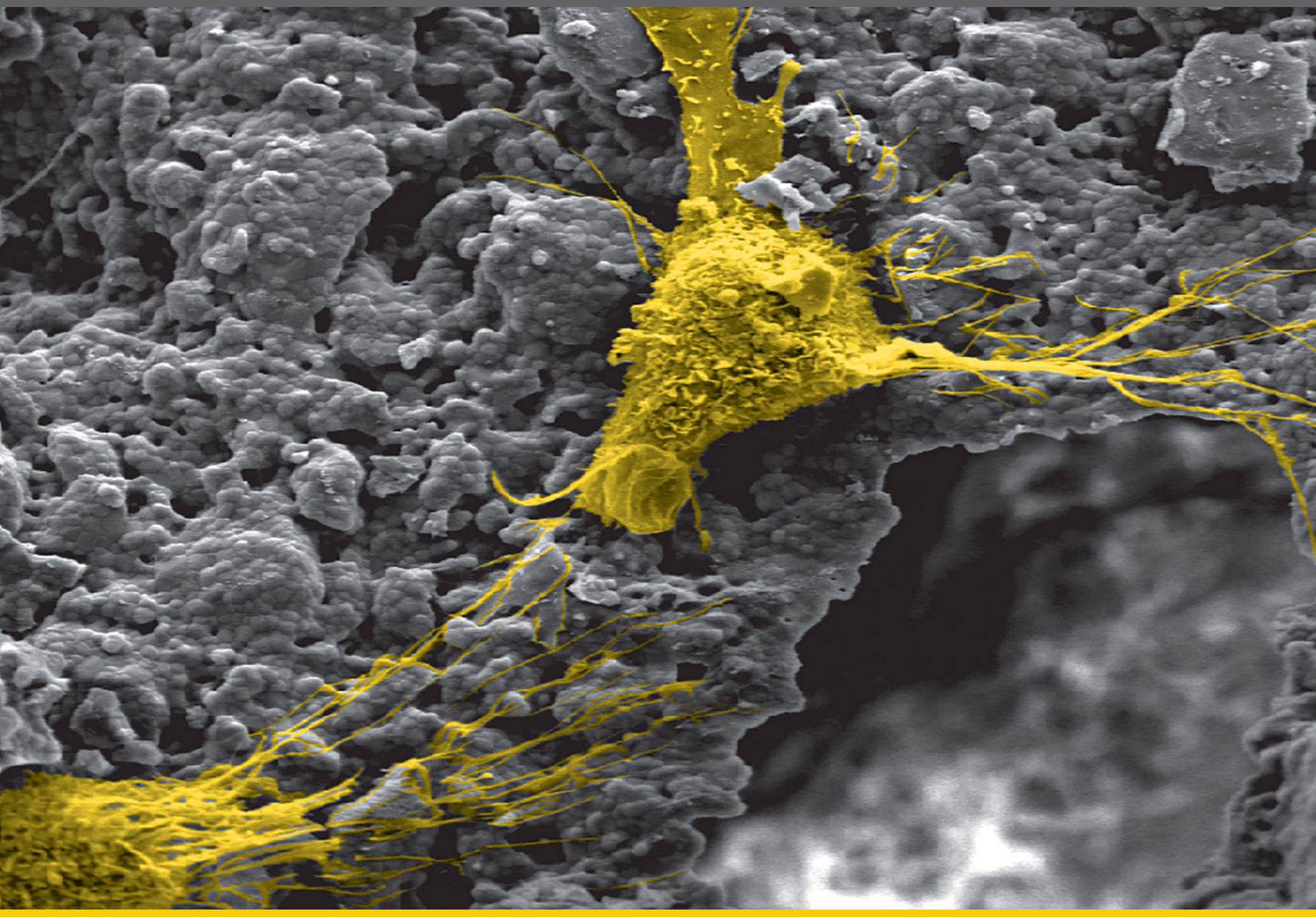
AltaPore
Bioactive Bone Graft
Enhanced Porosity with Silicate Substitution

ELEVATE CELLULAR ACTIVITY*[1]



*In vitro studies show elevated cellular responses when compared to an identical non silicate-substituted material.

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Indication[2]

ALTAPORE Bioactive Bone Graft is an implant intended to fill bony voids or gaps of the skeletal system i.e., extremities and pelvis. ALTAPORE Bioactive Bone Graft can be used in combination with autograft as a bone graft extender in the extremities and pelvis. ALTAPORE Bioactive Bone Graft can be used in combination wtih autologenous bone marrow aspirate in the extremities and pelvis. These osseous defects are surgically created or the result of traumatic injury to the bone and are not instrinsic to the stability of the bony structure. ALTAPORE Bioactive Bone Graft resorbs and is replaced with bone during the healing process.

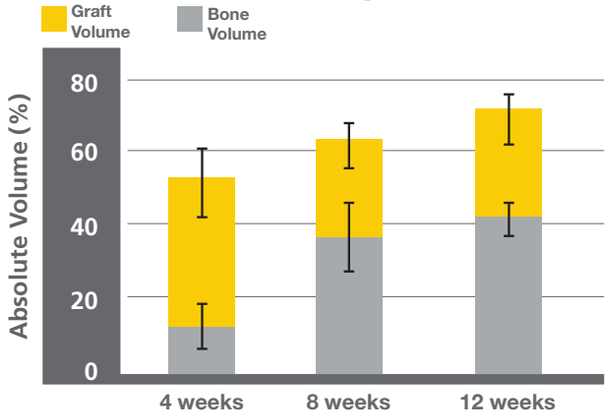
Product Description[2]

ALTAPORE Bioactive Bone Graft is a bioactive and osteoconductive silicate substituted calcium phosphate bone void filler. The interconnected and open porous structure is intended to support bone growth. Structurally, ALTAPORE Bioactive Bone Graft is similar to human cancellous bone and is composed solely of elements that exist naturally in normal bone with 80-85% total porosity, suspended in an absorbable aqueous gel carrier.

Features and Benefits

- Enhanced porosity to support bone growth[2,*4]
- Promotes early vascularization[*5]
- Bioactive and osteoconductive[2]
- Equivalent to autograft in a preclinical model[*3]
- May be used as:
  - Standalone[2]
  - Autograft extender[2]
- Replaced by bone via cell mediated remodeling[2]
- Sculptable and versatile handling characteristics
- Radiopaque[2]
- 2-year shelf life[6]
- Stored at room temperature[2]

Complete Bony Infiltration Followed by Cell Mediated Remodeling.[2,*3]



* Critical-sized defect at 4, 8 and 12 weeks in sheep.

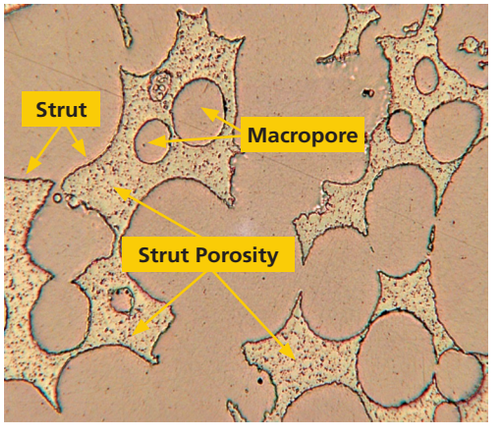
* The absolute bone volume increased (indicating osteoconduction) and absolute graft volume decreased (indicating graft resorption) over time in defects treated with ALTAPORE Bioactive Bone Graft ($p<0.05$).

* Preclinical data. Results may not correlate to performance in humans.

Porosity Similar to Human Cancellous Bone

The interconnected and open porous structure of ALTAPORE Bioactive Bone Graft is similar to human cancellous bone and is intended to support bone growth with macro- and microporosity.[2]

ALTAPORE Bioactive Bone Graft scaffold has an interconnected macroporous network. The walls of these macropores are micropores referred to as "struts." In common research terms, microporosity and strut porosity are used interchangeably. Strut pores are formed from the interconnected spaces existing between particles of calcium phosphate which have been sintered together to form the struts in the ALTAPORE Bioactive Bone Graft scaffold. The term "strut-porosity" is used to describe the pore volume fraction of each strut.*[4]



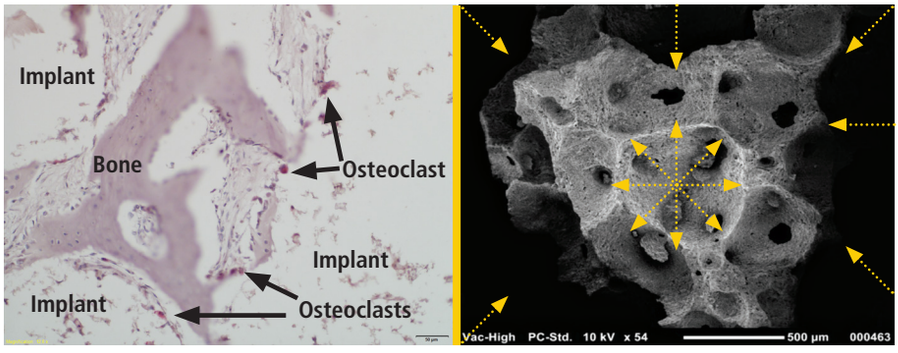
Overlaid image showing struts and macropores as viewed at x40 magnification with optical microscopy and image analysis.[6]

Promotes Early Vascularization*[5]

The level of macroporosity and strut (micro) porosity play an important role in the vascularization of the bone graft, which supports the proliferation and differentiation of osteoblasts and the ingrowth of new bone into the graft.

» ALTAPORE Bioactive Bone Graft promotes early vascularization

» ALTAPORE Bioactive Bone Graft grows bone throughout the lattice and not by creeping substitution



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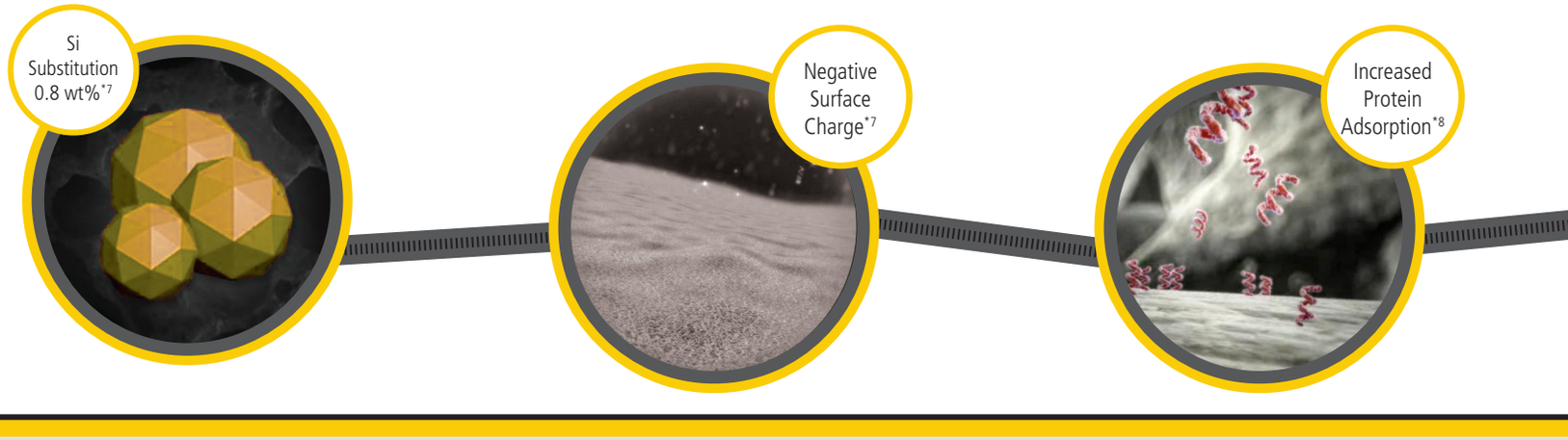


Bioactive and Osteoconductive

ALTAPORE Bioactive Bone Graft is bioactive based on in vitro studies that show it forms a surface apatite-layer when submerged in simulated body fluid (SBF) that contains the same ion concentrations as human blood plasma. This apatite layer provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect.[2]

ALTAPORE Bioactive Bone Graft is osteoconductive based on in vivo animal studies that show it achieves bone healing in a critical defect model as confirmed with radiographic, histopathological, histomorphometric and mechanical analyses. ALTAPORE Bioactive Bone Graft undergoes cell-mediated remodeling and is replaced by natural bone.[2]

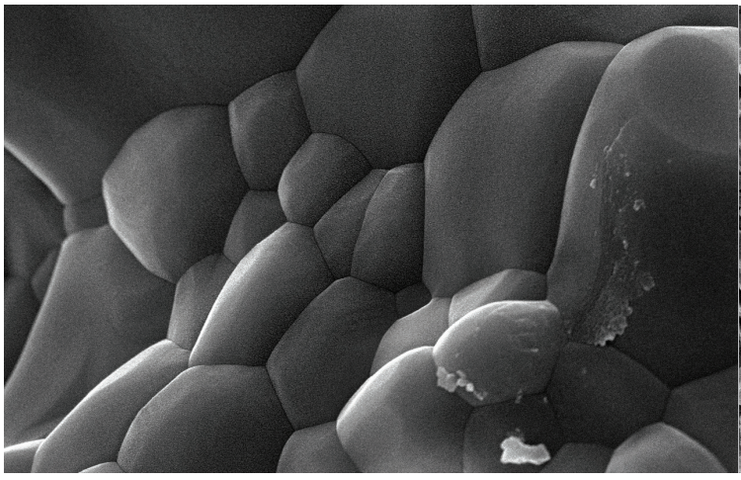
Synthetic biomaterials designed for orthopedic applications are no longer only considered safe and effective if they are inert and do not cause inflammatory reactions when implanted in the body. They must now also elicit a response from the body which favors the integration of the implant within the host bone (osteointegration).*[10]

» When ALTAPORE Bioactive Bone Graft is immersed in SBF, a thick continuous layer of hydroxy carbonate apatite (HCA) crystals with a complex microstructural architecture forms over the surface of the material.*[10]

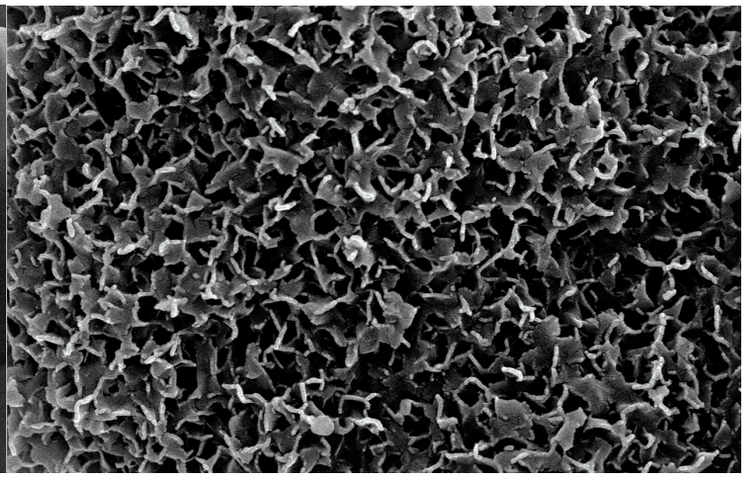
» ALTAPORE Bioactive Bone Graft has been shown to be more bioactive than ß-TCP based on the quanity of HCA on the surface of the graft material.*[10]

ALTAPORE Bioactive Bone Graft: Scaffolding Apatite Layer[6,*10]

Before Soaking in Simulated Body Fluid



After Soaking in Simulated Body Fluid for 3 Days



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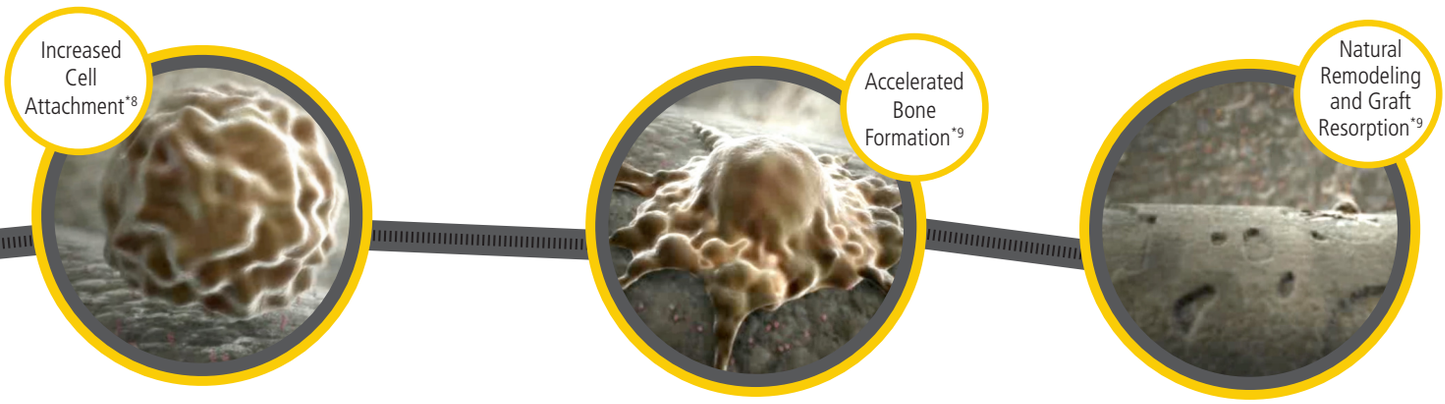
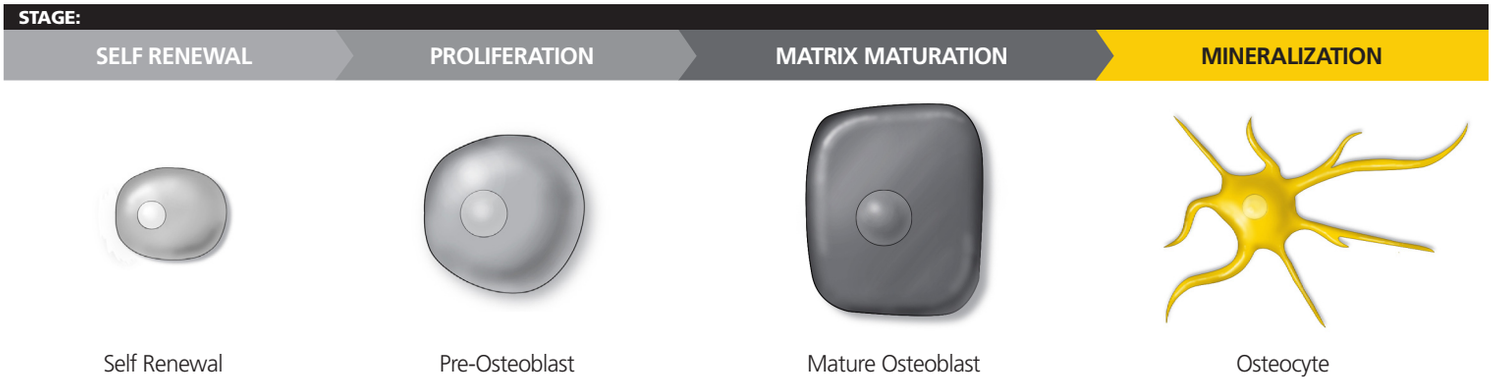


Mesenchymal Stem Cell Proliferation and Differentiation*1

In a preclinical study, silicate-substituted calcium phosphate, the key component in ALTAPORE Bioactive Bone Graft, supported attachment and proliferation of human mesenchymal stem cells (MSC). Culturing MSC on this component caused them to differentiate into bone-producing osteoblast cells in the absence of osteogenic supplements, confirming that synthetic inorganic substrates can direct stem cell differentiation in the absence of chemical factors.



Bioactive Bone Graft Extender[2]

Combined with autologous bone, or bone marrow aspirate, ALTAPORE Bioactive Bone Graft provides a bioactive scaffold enriched with osteoconductive components.

Recommended Mixing Information

Ratio up to 1:3

ALTAPORE Bioactive Bone Graft: Autologous Bone

Ratio up to 2:1

ALTAPORE Bioactive Bone Graft: Bone Marrow Aspirate

* Preclinical data. Results may not correlate to performance in humans.

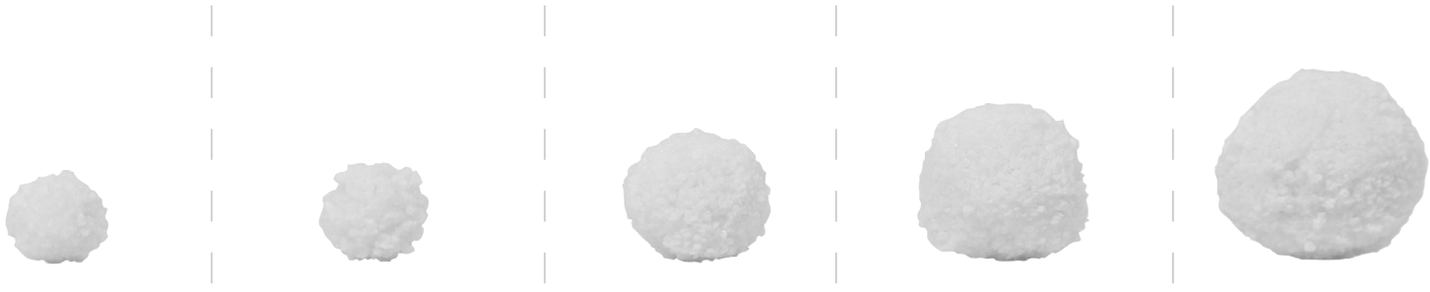
Important Risk Information

ALTAPORE is contraindicated where the device is intended as structural/load-bearing support in the skeletal system. ALTAPORE has not been cleared for use in vertebroplasty.

Attempts should not be made to modify the size of the granules or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration.

The effect of mixing ALTAPORE with substances other than bone marrow aspirate or autologous bone is unknown.

Rx Only. For safe and proper use please refer to full device Instructions for Use.



1.5 mL - 1504319 | 2.5 mL - 1504320 | 5 mL - 1504321 | 10 mL - 1504322 | 20 mL - 1504323

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For more information, contact your local sales representative or call 1-888-229-0001

References:

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