nanOss® 3D Plus Advanced Bone Graft Substitute
Sterile Implants

INSTRUCTIONS FOR USE

Please Read Prior to Use
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed physician.

Description

nanOss 3D Plus Advanced Bone Graft Substitute is a resorbable porous calcium phosphate bone void filler that provides a scaffold for the in-growth of new bone. The implant is an osteoconductive implant with an interconnected porosity similar to human cancellous bone. The implant is a semi-rigid three dimensional construct that consists of porous hydroxyapatite granules suspended within porous porcine gelatin-based foam matrix. It is provided in the form of strips that can be further cut as required at the time of surgery.

When hydrated at the point of use, the implant becomes a compressible and elastic sponge that allows the shape of the implant to conform to the defect maximizing direct contact with viable host bone. The implant is provided sterile by prior exposure to gamma irradiation and intended for single use only.

Indications

The implant is indicated for bony voids or gaps that are not intrinsic to the stability of bony structures. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The implant is indicated to be gently packed into bony voids or gaps of the skeletal system (extremities and pelvis) un-hydrated or in conjunction with bone marrow aspirate or autogenous blood, or in the posterolateral spine in conjunction with bone marrow aspirate and autograft bone as a bone graft extender. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Contraindications

Use of the implant is contraindicated in the presence of one or more of the following conditions:

- fractures of the epiphyseal plate
- metabolic or systemic bone disorders that affect bone or wound healing
- fractures for which stabilization of the fracture is not possible
- significant vascular impairment proximal to the graft site
- infected or contaminated wounds, or fractures for which intraoperative soft tissue coverage is not planned or possible
- acute and chronic infections in the surgical area (soft tissue infections; inflammatory, bacterial bone disorders, osteomyelitis)
- impaired calcium metabolism
- treatment with steroids and other drugs affecting calcium metabolism
- immunosuppressant therapy
- use in the area of the open epiphyseal growth plate
- patients allergic to porcine collagen products

Adverse Effects

One of the potential risks identified with any surgical procedure is death. Other potential risks which may require additional surgery include:

- inflammation
- infection
- neurological injury
- vascular or visceral injury
- implant migration
- non-union or delayed union
- dysphonia/ hoarseness
- pain
- pseudoarthrosis

Any transmission of disease that is suspected to be caused by the graft or any other adverse outcome potentially attributed to this graft must be reported promptly to Xtant Medical

Warnings

Standard internal fixation techniques such as the use of plates and/or screws must be followed to obtain rigid stabilization. The implant does not possess sufficient mechanical strength to support the reduction of a fracture site prior to soft and hard tissue in-growth or to support a load.

External stabilization alone is not sufficient to achieve the rigidity necessary for bony in-growth of the implant material.

Do not use the implant to gain screw purchase or to stabilize screw placement. Screws used with the implant and fixation devices must attain rigid fixation into the host bone.

Do not use the implant where complete soft tissue coverage cannot be achieved.

Precautions

The implant is intended for use only by surgeons familiar with bone grafting and rigid fixation techniques.

The implant is radiopaque, so the radiopacity may mask underlying pathological conditions.

The implant is intended for single use only.

Always follow recommended hydration instructions when rehydrating the implant.

Do not apply the implant dry to the posterolateral spine.

Avoid overfilling the defect site.

Ensure that after cutting or shaping, any shaped device surfaces are smooth and free from excessive loose particles.

Do not resterilize the implant.

Discard any un-used implant.

Do not expose the implant to temperature extremes such as freezing or excessive heat.

Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting.

Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

Storage

Store product in a clean, dry environment at 01 – 37°C (33 – 98.6°F). The shelf life of the implant is clearly indicated on product labels.

Sterilization

nanOss 3D Plus ABGS is provided sterile by prior exposure to gamma irradiation. The implant cannot be resterilized by any method. Excess material and opened, but unused product must be discarded. Inspect the package of any sterile product for structural integrity prior to use. If the seal of any inner or outer container is broken or otherwise damaged, the product must be assumed to be nonsterile.

MRI Safety

The implantable portion of the nanOss 3D Plus ABGS device is MR safe.

How Supplied

nanOss 3D Plus ABGS is provided sterile in strip form in a variety of sizes and volumes. Each product is packaged in a double sterile barrier system.

Instructions for Use

Radiographic assessment of the defect site preoperatively is essential to accurately evaluate the shape and volume of the defect. This assessment aids in treatment planning for appropriate product size and placement of the implant and/or internal fixation devices.

1. Estimate volume of defect to be filled and select product size of equal or greater volume. NOTE: Unit size labeled on package indicates minimum implant volume.
2. Open outer packaging and introduce the implant inner package into the sterile field.
3. Open inner packaging and transfer the implant to a clean sterile vessel or keep it in the inner pouch. Rehydrate as necessary for that application, per the below instructions using fluid volumes indicated in Table 1.
   a. Obtain a volume of BMA appropriate for the selected product size and application using conventional bone marrow aspiration techniques. For application in the pelvis or extremities, autogeneous blood may alternatively be used if desired.
   b. Transfer fluid into the sterile vessel containing the implant.
   c. Rehydrate the implant by soaking the device in the collected BMA or autogenous blood until it is saturated (approximately 5 minutes).
   d. Light manual compression may be applied to facilitate fluid uptake.
4. If necessary, cut the implant into desired shape as required by the surgical site. Ensure that after cutting or shaping, any shaped device surfaces are smooth and free from excessive loose particles.
5. For use in the posterolateral spine, place autograft into defect site. Additional autograft may be manually pressed into the rehydrated product prior to implantation.
6. Apply the implant to the defect site. If necessary, remove excess material from any unintended area(s). Avoid overfilling the defect site.

MIXING AND HANDLING GUIDE

Below are abbreviated mixing and handling instructions. See accompanying instructions for use for indications, precautions, warnings and other important information.

1. HYDRATE

   Using a sterile graduated syringe with the appropriate fluid volume (per **Table 1**), transfer fluid into a sterile vessel or the inner pouch containing nanOss 3D Plus ABGS. Hydrate by soaking in fluid until nanOss 3D Plus ABGS is saturated (approximately 5 minutes). Light manual compression may be applied to facilitate fluid uptake.

Table 1: nanOss 3D Fluid Volumes

Unit Size (as indicated on package)	Unit Volume	Fluid* Volume per Unit Pelvis/ Extremities	BMA Volume per Unit Posterolateral Spine
25 x 50 x 4mm	5cc	5.0 mL	4.0 mL
25 x 100 x 4mm	10cc	10.0 mL	8.0 mL
25 x 50 x 8mm	10cc	10.0 mL	8.0 mL
25 x 100 x 8mm	20cc	20.0 mL	16.0 mL

***Fluid refers to the use of either bone marrow aspirate or autogenous blood.*

2. CUT

   If necessary, cut into desired shape as required by the surgical site.

3. COMPRESS
   a. For Pelvis/Extremities: Apply to defect site.
   b. For Posterolateral Spine: Place autograft into defect site. Additional autograft may be lightly pressed into rehydrated product prior to implantation. Apply to defect.

Symbols Glossary

Symbol	Definition	Symbol	Definition
REF	Catalogue Number		Manufacturer
LOT	Batch Code		Use-By Date
MD	Medical device	UDI	Unique device identifier
	Caution		Do Not Re-use
Rx only	Federal Law Restricts this Device to Sale by or on the Order of a Physician	MR	MR Safe
STERILE R	Sterilized Using Irradiation	STERILIZE	Do Not Re-sterilize
	Double sterile barrier system with protective packaging		Double sterile barrier system
	Do not use if package is damaged and consult instructions for use		Keep dry
BIO	Contains biological material of animal origin	Hydroxyapatite Porcine Gelatin Carrier	Contains hydroxyapatite and porcine gelatin material
	Temperature Limit	xtantmedical.com/eifu	Consult instructions for use at this website

A complete symbols glossary is located at: https://xtantmedical.com/resources/symbols-glossary/

Returns

If for any reason tissue must be returned, a return authorization is required from Xtant Medical prior to shipping.

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Xtant Medical
664 Cruiser Lane
Belgrade, MT 59714
888-886-9354