nanOss® Advanced Bone Graft Substitute
nanOss® Loaded Kit Advanced Bone Graft Substitute
Sterile Implants and Sterile Instruments

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 is a resorbable porous calcium phosphate bone void filler for use as a bone graft substitute or bone void filler. It is an osteoconductive implant with a multidimensional porosity similar to human cancellous bone and acts as a scaffold for the in-growth of new bone. nanOss is composed of porous hydroxyapatite granules and a porcine gelatin based carrier. The product forms a cohesive and adhesive dough with a putty-like consistency upon rehydration, allowing the shape of the implant to conform to the defect maximizing direct contact with viable host bone.

nanOss is radiation sterilized and intended for single use only.

The product is provided pre-filled in a mixing container as nanOss or in a mixing chamber with single-use accessories as nanOss Loaded Kit. Please reference the “How Supplied” section for further details.

Indications

nanOss is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. The product is indicated to be gently packed into bony voids or gaps in the skeletal system (i.e., extremities, posterolateral spine, and pelvis). nanOss must be mixed with autogenous blood or sterile saline for use in the extremities or pelvis. nanOss must be mixed with bone marrow aspirate and autograft bone as a bone graft extender in the posterolateral spine. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Contraindications

Use of nanOss is contraindicated in the presence of one or more of the following clinical situations:

- 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

nanOss does not possess sufficient mechanical strength to support the reduction of a fracture site prior to soft and hard tissue ingrowth or to support a load. Standard internal fixation techniques such as the use of plates and/ or screws must be followed to obtain rigid stabilization. External stabilization alone is not sufficient to achieve the rigidity necessary for bony ingrowth of the nanOss.

nanOss must not be used to gain screw purchase or to stabilize screw placement. Screws used in conjunction with this product and fixation devices must attain rigid fixation into the host bone.

Complete postoperative wound closure is essential. nanOss must not be used to repair metaphyseal defects where complete soft tissue coverage cannot be achieved.

Avoid application of nanOss beyond intended treatment site, as this may damage surrounding tissues.

The following additional warnings apply when using nanOss Loaded provided in a mixing chamber:

- Never introduce nanOss into closed cavities under pressure, as this may lead to fat embolization or embolization of device into blood stream.
- Avoid over-pressurizing the device because this may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues.
- When mixing nanOss with autograft for use in posterolateral spine and using the graft applicator, morselize autograft particles to smaller than 2mm to prevent risk of clogging. Use of a bone mill to morselize autograft prior to addition to nanOss is recommended for best results.

Precautions

nanOss is intended for use by surgeons familiar with bone grafting and rigid fixation techniques. Standard postoperative practices for the treatment and rehabilitation of extremities that have received open reduction and internal fixation with bone grafting must be strictly followed.

Placement of nanOss will be determined by the site, size and configuration of the defect. nanOss does not possess sufficient mechanical strength to support the reduction of a fracture site prior to tissue in-growth or to support a load. Anatomical reduction and rigid internal fixation must be obtained independently of nanOss. Accepted internal fixation techniques must be used until ingrowth has occurred and the site is healed.

Fixation must be appropriate to reduce loading of the nanOss site in order to prevent collapse or deformity. Plates and/or screws are preferred for primary fixation.

nanOss granules are radiopaque and the radiopacity may mask underlying pathological conditions.

nanOss is intended for single use only.

Do not resterilize nanOss.

Discard any un-used nanOss.

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

Do not apply nanOss dry to the defect.

nanOss has no weight bearing function.

Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Hardware should not be removed until complete healing has taken place. The length of time required for a reduced state of loading will be determined by the complexity of the defect and the patient's physical condition. The patient should be cautioned against premature ambulation and early weight bearing.

For best results, nanOss should fill the defect and contact viable bone as much as possible. Over-filling the defect site should be avoided.

Storage

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

Sterilization

nanOss and all supplied graft delivery accessories are provided sterile by prior exposure to gamma irradiation. nanOss and all supplied graft delivery accessories 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 non-sterile and must be discarded.

MRI Safety

The implantable portion of the nanOss device is MR safe.

How Supplied

nanOss
Sizes: 1cc, 2cc, 5cc, 10cc, 20cc
Format: Granules in mixing container with spatula
Tamper evident box contains:

- Mixing container with spatula in double sterile barrier system
- Package insert

nanOss Loaded Kit
Sizes: 5cc, 10cc
Format: Granules in a mixing chamber
Tamper evident box contains:

- Mixing chamber, hydration syringe, graft applicator adapter and graft applicator in double sterile barrier system
- Package insert

Instructions for Use

Radiographic assessment of the defect site preoperatively is essential to evaluate accurately the extent of the defect. This assessment aids in treatment planning for appropriate volume and placement of nanOss and placement of internal fixation devices.

Estimate volume of defect to be filled and select product size of equal or greater volume.
NOTE: Unit size stated on package refers to approximate minimum nanOss volume when reconstituted with fluid.

Remove product from tamper evident box. Open outer packaging and aseptically introduce inner packaging into the sterile field.

Using conventional technique, obtain autograft bone (if using the product in the spine) and appropriate volume of fluid for rehydration as indicated in the Mixing and Handling Directions.

Reference the Mixing and Handling Directions for next steps.

NANOSS MIXING CONTAINER
MIXING AND HANDLING DIRECTIONS FOR USE

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

POSTEROLATERAL SPINE

1. SHAKE:
   Mix contents by shaking closed nanOss jar.

2. HYDRATE & MIX 1-TO-1 WITH AUTOGRAFT BONE
   Using a sterile graduated syringe with the appropriate volume of BMA per **Table 1**, mix with the dry granules until a cohesive paste is formed using the provided sterile spatula. After hydrating, add and mix in autograft.

Table 1: nanOss Fluid Volumes

Unit Size (as indicated on package)	Bone Marrow Aspirate (BMA) Volume
1cc	1.2cc
2cc	2.0cc
5cc	5.2cc
10cc	10.8cc
20cc	21.7cc

3. COMPRESS
   Compress firmly in the palm of your hand into desired shape using moist, gloved hands and apply.

PELVIS & EXTREMETIES

1. SHAKE:
   Mix contents by shaking closed nanOss jar.

2. HYDRATE & MIX
   Using a sterile graduated syringe, add the appropriate fluid volume per **Table 2**, then mix into a cohesive paste using the provided sterile spatula.

Table 2: nanOss Fluid Volumes

Unit Size (as indicated on package)	Autogenous Blood or Sterile Saline Volume
1cc	1.2cc
2cc	2.0cc
5cc	5.2cc
10cc	10.8cc
20cc	21.7cc

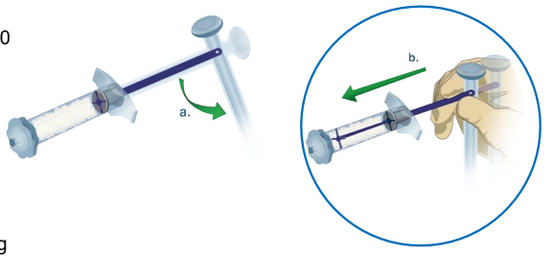
3. COMPRESS
   Compress firmly in the palm of your hand into desired shape using moist, gloved hands and apply

NANOSS LOADED MIXING CHAMBER
MIXING AND HANDLING DIRECTIONS FOR USE

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

POSTEROLATERAL SPINE

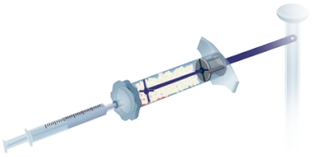
1. PREPARE FOR MIXING:
a. Withdraw the mixing rod and rotate the mixing handle 90 degrees with respect to inner mixing rod.
b. Advance the inner mixing rod through the dry graft material until it stops at the mixing chamber cap.



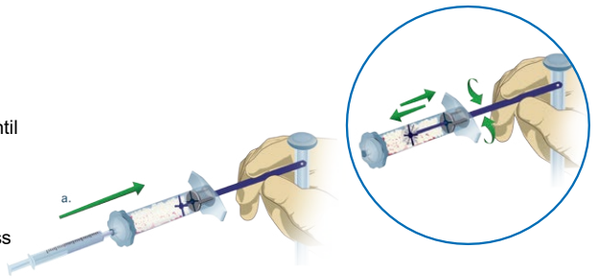
2. HYDRATE
a. Remove luer cap and attach supplied syringe containing the appropriate fluid volume per **Table 3**.
b. Inject the appropriate fluid into the mixing chamber. Leave syringe attached to mixing chamber.

Table 3: nanOss Fluid Volumes

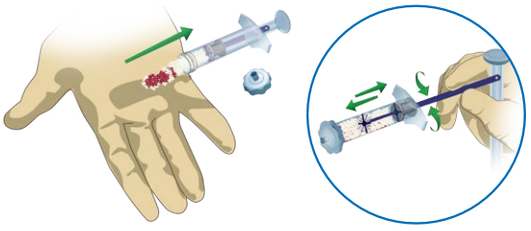
Unit Size (as indicated on package)	Bone Marrow Aspirate (BMA) Volume
5cc	5.2cc
10cc	10.8cc



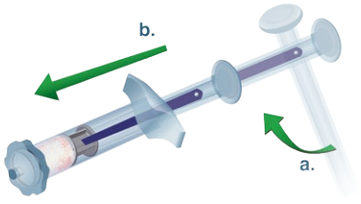
3. MIX
a. Pull the mixing rod back through the mixing chamber until it stops at the piston.
b. Mix contents by agitating the mixing rod in a clockwise-counterclockwise manner while moving it through the mixing chamber back and forth. Continue until the mixture is homogenous in color and consistency (no less than 5 rotations and full passes)



ADD AUTOGRAFT AND COMBINE
c. Unscrew the mixing chamber cap and add morselized autograft (1:1 ratio). Replace mixing chamber cap and syringe when finished. When mixing nanOss with autograft for use in posterolateral spine and using the graft applicator, morselize autograft particles to smaller than 2mm to prevent risk of clogging. Use of a bone mill to morselize autograft prior to addition to nanOss is recommended for best results.
d. Mix contents for a second time by agitating the mixing rod in a clockwise-counterclockwise manner while moving it through the mixing chamber back and forth. Continue until the mixture is homogenous in color and consistency (no less than 5 rotations and full passes).

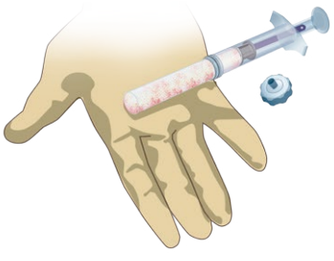


4. COMPRESS
When Mixing is completed,
a. Fully retract the mixing rod, flip mixing handle back over the mixing rod until it snaps in place, and press piston to compress the graft.
b. Advance the handle/rod into the mixing chamber as necessary to compress the graft material until no large voids are visible.

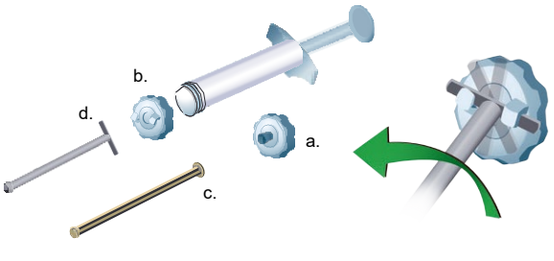


5. GRAFT PLACEMENT
Graft placement may be accomplished with or without the Graft Applicator.

Option 1: Manual Graft Placement
a. After completing compression (Step 4), unscrew the mixing chamber cap and eject prepared graft material by fully advancing handle into chamber.
b. Apply to graft site as required.
c. If necessary, wipe excess material from any unintended area(s).



Option 2: Graft Placement using Graft Applicator
a. Remove the mixing chamber cap (a) and attach applicator adapter (b) onto mixing chamber.
b. Remove the applicator piston (c) from graft applicator body (d).
c. Connect graft applicator body and adapter by rotating the graft applicator body counterclockwise until engaged by the tabs on the graft adapter.
d. Extrude product (up to 7.0 cc) into graft applicator body. Avoid overfilling and/or manual compression.
e. Remove graft applicator body from adapter/mixing chamber by rotating clockwise.
f. Replace the applicator piston in graft applicator body.
g. Apply to graft site as required.
h. If necessary, wipe excess material from any unintended area(s).

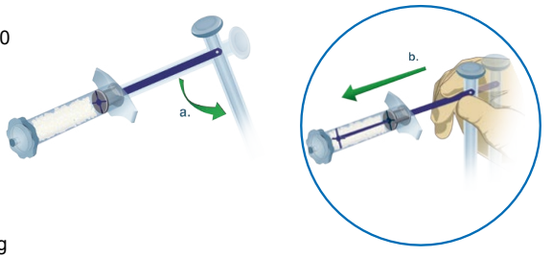


NANOSS LOADED MIXING CHAMBER
MIXING AND HANDLING DIRECTIONS FOR USE

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

PELVIS & EXTREMETIES

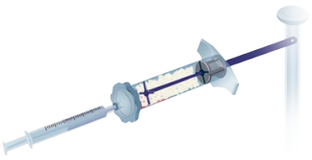
1. PREPARE FOR MIXING:
a. Withdraw the mixing rod and rotate the mixing handle 90 degrees with respect to inner mixing rod.
b. Advance the inner mixing rod through the dry graft material until it stops at the mixing chamber cap.



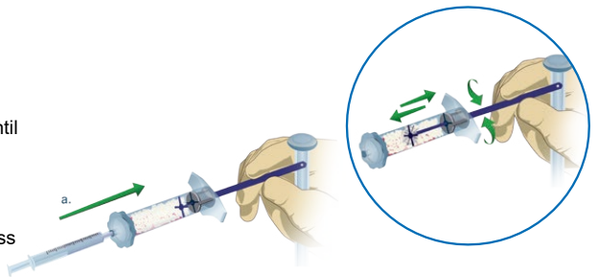
2. HYDRATE
a. Remove luer cap and attach supplied syringe containing the appropriate fluid volume per **Table 4**.
b. Inject the appropriate fluid into the mixing chamber. Leave syringe attached to mixing chamber.

Table 4: nanOss Fluid Volumes

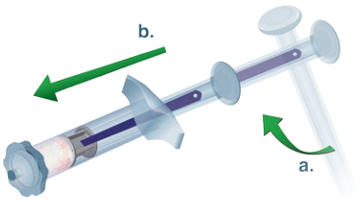
Unit Size (as indicated on package)	Autogenous Blood or Sterile Saline Volume
5cc	3.2cc
10cc	6.6cc



3. MIX
a. Pull the mixing rod back through the mixing chamber until it stops at the piston.
b. Mix contents by agitating the mixing rod in a clockwise-counterclockwise manner while moving it through the mixing chamber back and forth. Continue until the mixiture is homogenous in color and consistency (no less than 5 rotations and full passes)

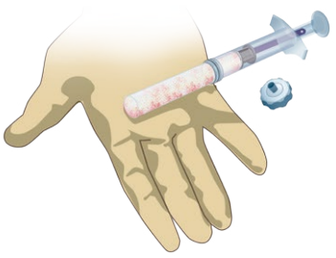


4. COMPRESS
When Mixing is completed,
a. Fully retract the mixing rod, flip mixing handle back over the mixing rod until it snaps in place, and press piston to compress the graft.
b. Advance the handle/rod into the mixing chamber as necessary to compress the graft material until no large voids are visible.

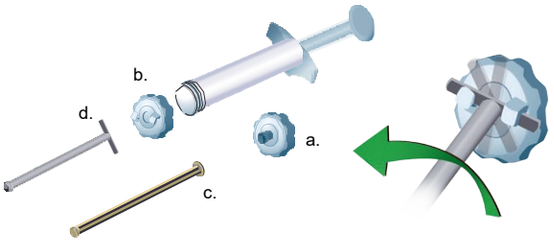


5. GRAFT PLACEMENT
Graft placement may be accomplished with or without the Graft Applicator.

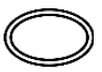
<u>Option 1: Manual Graft Placement</u>
a. After completing compression (Step 4), unscrew the mixing chamber cap and eject prepared graft material by fully advancing handle into chamber.
b. Apply to graft site as required.
c. If necessary, wipe excess material from any unintended area(s).



<u>Option 2: Graft Placement using Graft Applicator</u>
a. Remove the mixing chamber cap (a) and attach applicator adapter (b) onto mixing chamber.
b. Remove the applicator piston (c) from graft applicator body (d).
c. Connect graft applicator body and adapter by rotating the graft applicator body counterclockwise until engaged by the tabs on the graft adapter.
d. Extrude product (up to 7.0 cc) into graft applicator body. Avoid overfilling and/or manual compression.
e. Remove graft applicator body from adapter/mixing chamber by rotating clockwise.
f. Replace the applicator piston in graft applicator body.
g. Apply to graft site as required.
h. If necessary, wipe excess material from any unintended area(s).



Symbols Glossary

Symbol	Definition	Symbol	Definition
	Catalogue Number		Manufacturer
	Batch Code		Use-By Date
	Medical device		Unique device identifier
	Caution		Do Not Re-use
	Federal Law Restricts this Device to Sale by or on the Order of a Physician		MR Safe
	Sterilized Using Irradiation		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
	Contains biological material of animal origin		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.

Manufactured and Provided for distribution by Xtant Medical.
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