SeaSpine

OSTEOTORRENT® & OSTEOTORRENT C

DRY DBM WITH ACCELL® BONE MATRIX

SURGICAL PREPARATION

CONTENTS

OSTEOTORRENT® & OSTEOTORRENT C

This manual is intended as a guide only. As with any surgical procedure, the surgeon should be trained and thoroughly familiar with bone grafting techniques and placement before proceeding.

STEP 1. PRODUCT PREPARATION

Open outer package using proper sterile technique and deliver contents into the sterile field (FIG. 01). OsteoTorrent® and OsteoTorrent C are provided in single barrier tray.

FIG. 01

Remove clear protective cap (FIG. 02).

FIG. 02

NOTE
5 and 10cc will have a cap with a stem (FIG. 03).

FIG. 03

STEP 2. PRODUCT HYDRATION

Draw hydration fluid with male luer syringe and connect to product syringe. OsteoTorrent® and OsteoTorrent C can be hydrated with either saline (FIG. 04) or Blood/BMA (FIG. 05).

OsteoTorrent®/OsteoTorrent C

Product Size	Hydration Volume (ml)
X-small	1
Small	2
Medium	4
Large	8

NOTE
Use sterile male luer syringe. Recommended 10cc syringe or larger.

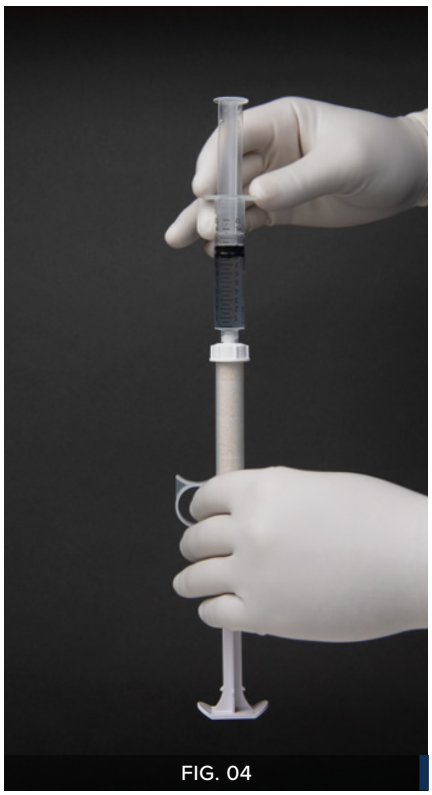
FIG. 04


FIG. 05

In vertical position, fully press and release on hydrating syringe plunger until hydration is achieved (FIG. 06–07).

NOTE
Hold the product syringe and plunger during hydration to prevent motion. Do not press on product syringe plunger.

TIP
If the syringe connection becomes blocked for 5 and 10cc syringes, the stem cap can be used to reopen a hydration channel.

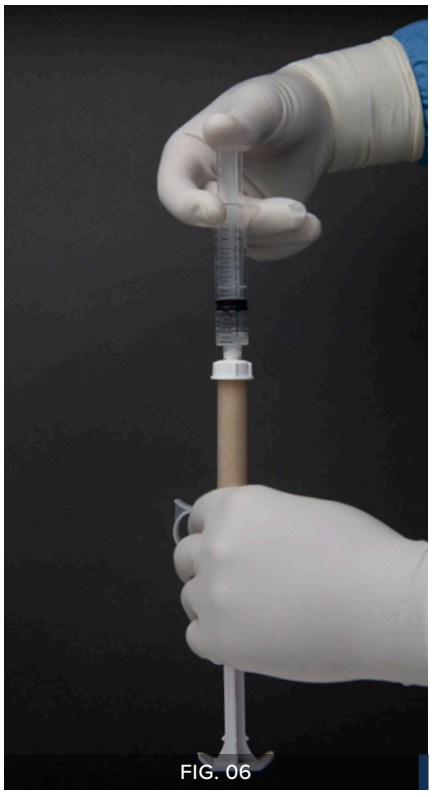
FIG. 06


FIG. 07

STEP 3. PRODUCT USE

OsteoTorrent® and OsteoTorrent C DBM should remain in the syringe until ready for use.

Unscrew white cap (FIG. 08) and extrude (FIG. 09).

TIP
Some hydration fluid will be left over in the hydration syringe and should be discarded.

FIG. 08

TIP
Before unscrewing the hydration syringe from the product syringe, **draw back the hydration syringe** to release pressure, as well as pull back any fluid that may have pooled on top of the product.

FIG. 09

Moldable mixture is ready for implantation (FIG. 10).

FIG. 10

STEP 4. PRODUCT USE WITH RAPID® OPTIONAL

If using with RAPID® bone graft delivery, the syringe will thread directly onto the RAPID bone graft delivery tube (FIG. 11).

NOTE
Recommended to use 5cc syringes with RAPID as the graft delivery tube holds approximately 5cc of bone graft.

FIG. 11

The filled bone graft delivery tube can then be connected to the RAPID graft delivery system (FIG. 12).

FIG. 12

INSTRUCTIONS FOR USE

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Indications For Use

OsteoTorrent®/OsteoTorrent C are intended to fill voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The product is indicated for use with autograft as a bone graft extender in the posterolateral spine and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone.

Description

OsteoTorrent/OsteoTorrent C are made using demineralized human bone mixed with poloxamer resorbable reverse phase medium. OsteoTorrent C includes addition of cancellous bone chips. The product is formulated into a freeze-dried putty form and is provided in a sterile, single-use package. As a human-derived material, some variations in the product should be expected, such as appearance and handling. The product is packaged in a standard syringe.

Contraindications

The product is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing contraindications include:

- Significant vascular or neurological impairment proximal to the graft site
- Severe vascular or neurological disease
- Metabolic or systemic bone disorders that affect bone or wound healing
- Uncontrolled diabetes
- Situations where graft site stabilization is not possible
- Cases where intraoperative soft tissue coverage is not planned or possible
- Infected or contaminated wounds
- Severe degenerative bone disease
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Renal impairment
- Active or latent infection in or around the surgical site
- Treatment of vertebral compression fractures
- Polymyxin B Sulfate, Bacitracin, Gentamicin, and Iodine are used in the processing of the DBM used in the product and trace amounts may remain. Since it is impossible to quantify the levels at which any individual may have an allergic response, this product is contraindicated in patients with known sensitivity to these compounds.

INSTRUCTIONS FOR USE

Warnings

- The product must be used prior to the expiration date.
- For single-use only.
- Do not re sterilize.
- Do not use if packaging has been damaged and/or the product has been compromised. In the event packaging has been compromised, discard the product. Damaged packaging should be returned to the manufacturer.
- Do not use to support reduction of a defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. Screws must gain purchase in the host bone as opposed to the product.
- Do not use to repair bone defects where soft tissue coverage cannot be achieved as complete post-operative wound closure is necessary.
- Do not overfill the graft site.

Sterilization

The product has been sterilized by electron beam irradiation. The inner package and its contents are sterile. The package should be inspected prior to use to ensure the sterility barrier has not been compromised. This product is for single-use only and must not be re-sterilized. The product must not be used beyond the stated expiration date.

Do Not Re-sterilize

Precautions

- The product is sterile for the duration of the product's shelf life, provided that the package is in its original sealed condition and that it is unopened and undamaged.
- As with all human-derived products, the tissue in the product has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissue selection and laboratory testing. To date, there have been no reports of experimental or clinical viral seroconversion attributed to the use of demineralized bone.
- As with any surgical procedure, the possibility of infection exists.
- Although the production technique is designed to eliminate antigenic properties of the product, the possibility of such a reaction is present.
- Once the container seal has been compromised, the tissue product shall be either transplanted, if appropriate, or otherwise discarded.
- Use caution when filling a closed defect. Resistance during extrusion may be an indication of overpressurization. Excessive pressurization of the device could result in fat embolization and/or embolization of the material into the bloodstream.
- When introducing the product, care must be taken to avoid excessive compaction.
- Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects.
- Overfilling the implantation site should be avoided to achieve a tension-free closure of the wound.

Single Use Only

RxOnly

CAUTION Federal law restricts this device to sale by or on the order of a physician or practitioner.

www.seaspine.com/eIFU

OSTEOTORRENT® & OSTEOTORRENT C

DRY DBM WITH ACCELL® BONE MATRIX

For more information or to place an order, please contact:
TEL 866.942.8698 | FAX 877.558.6227
customerservice@seaspine.com | **seaspine.com**

Outside USA
TEL + 1.760.727.8399 | FAX + 1.760.727.8809
INTERNATIONAL INQUIRIES intlcustomer@seaspine.com

IsoTis OrthoBiologics, Inc.
2 Goodyear, Irvine CA 92618
TEL 800.550.7155 | FAX 800.471.3248 | WEB seaspine.com
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