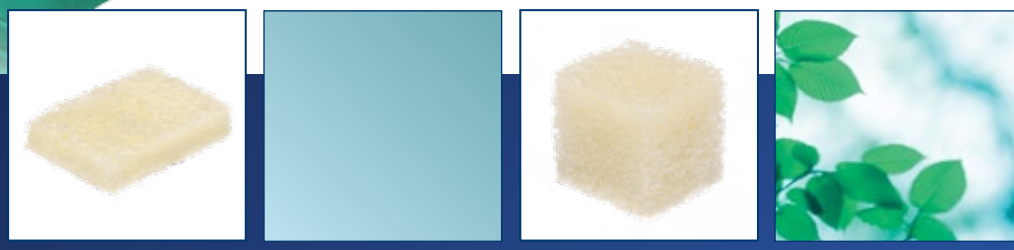
Life moves us

SURGICAL TECHNIQUE



ViaSorb™

Demineralized Cancellous Sponges

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

ViaSorb™

Demineralized Cancellous Sponges

ViaSorb™ Cubes and Strips are demineralized cancellous sponges. They provide a natural osteoconductive scaffold with unique compressive capabilities to facilitate packing into bony voids and within allograft spacers. The porous structure of ViaSorb™ Sponges allows for adsorption of osteogenic cells from autologous bone marrow aspirate.

Natural Osteoconductive Structure

Large cancellous bone surface area allows for osteoblast attachment.

Osteoinductivity

Demineralized bone contains growth factors naturally found in bone.

Shape-Memory Characteristics

Graft compresses and expands back to its original height once it is rehydrated.

Interconnected Porosity

Porous structure allows for bony ingrowth and vascularization of blood vessels.

ViaSorb™

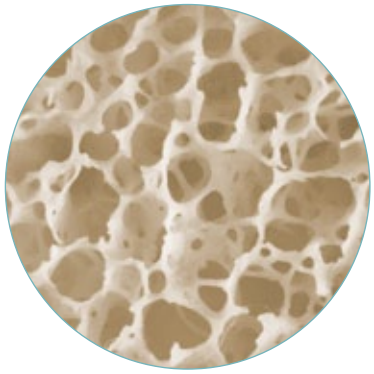
IMPLANT FEATURES

Easily conforms into osseous voids

Compressable after rehydration

Readily absorbs bone marrow aspirate

Flexible characteristics once rehydrated



Interconnected porosity
for bony ingrowth

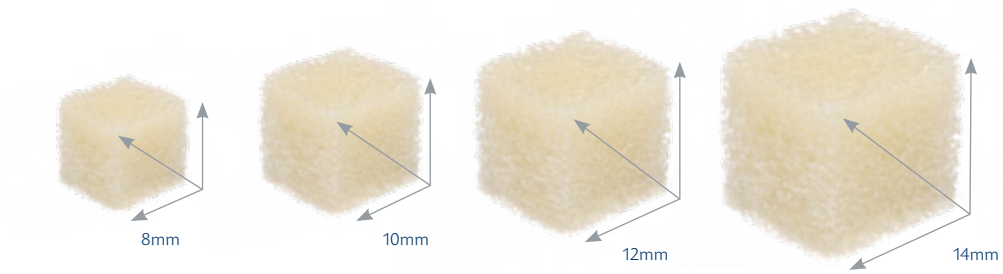
Easily cut into desired geometry

CONTENTS

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

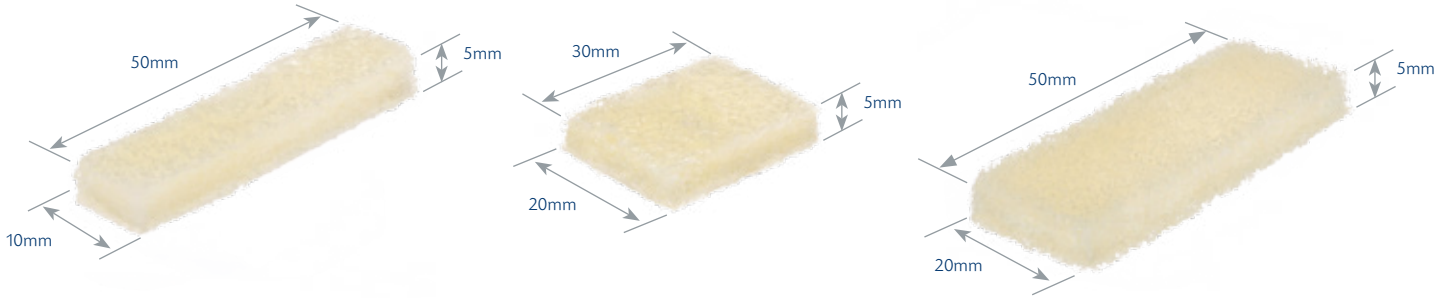
IMPLANT OVERVIEW

ViaSorb™ Cubes



0.5cc **1cc** **1.7cc** **2.7cc**

ViaSorb™ Strips



2.5cc **3cc** **5cc**

Each donor is tested and shown to be negative or nonreactive for the following: Human Immunodeficiency Varius Type 1 Antibody, Human Immunodeficiency Virus Type 2 Antibody, Hepatitis C Virus Antibody, Hepatitis B Surface Antigen, Hepatitus B Core Antibody (total), Syphilis Rapid Plasma Reagin or Treponemal Specific Assay, HIV1/HCV Nucleic Acid Test (NAT), Human T-Cell Lymphotropic Virus Type I Antibody, Human T-Cell Lymphotroic Virus Type II Antibody.

ViaSorb™ SURGICAL TECHNIQUE

Step 1 Preparation for Use

Prior to use, examine the ViaSorb™ packaging. Do not use if:

- Any part of the package or product appear to be missing, tampered with or damaged
- The product label or identifying bar code is illegible or missing
- The expiration date shown on the package label has passed

Step 2 Sizing

Determine the volume of the void to be filled. Sponges may be cut to the desired size after rehydration.

Step 3 Rehydration

Room Temperature Rehydration: Place graft in a basin with room temperature (15–35°C) water, sterile saline (0.9%), Lactated Ringer's, or any other sterile isotonic solution for up to 20 minutes. The graft should be hydrated for a minimum of one minute.

Sponges must be used within six hours after rehydration if stored at room temperature.

Sponges must be used within 24 hours after rehydration if stored refrigerated at 2–8°C (35.6 to 46.4°F).

To hydrate your ViaSorb™ Demineralized Cancellous Sponge in BMA, use the RETRIEVE® BMA Kit, 991.903

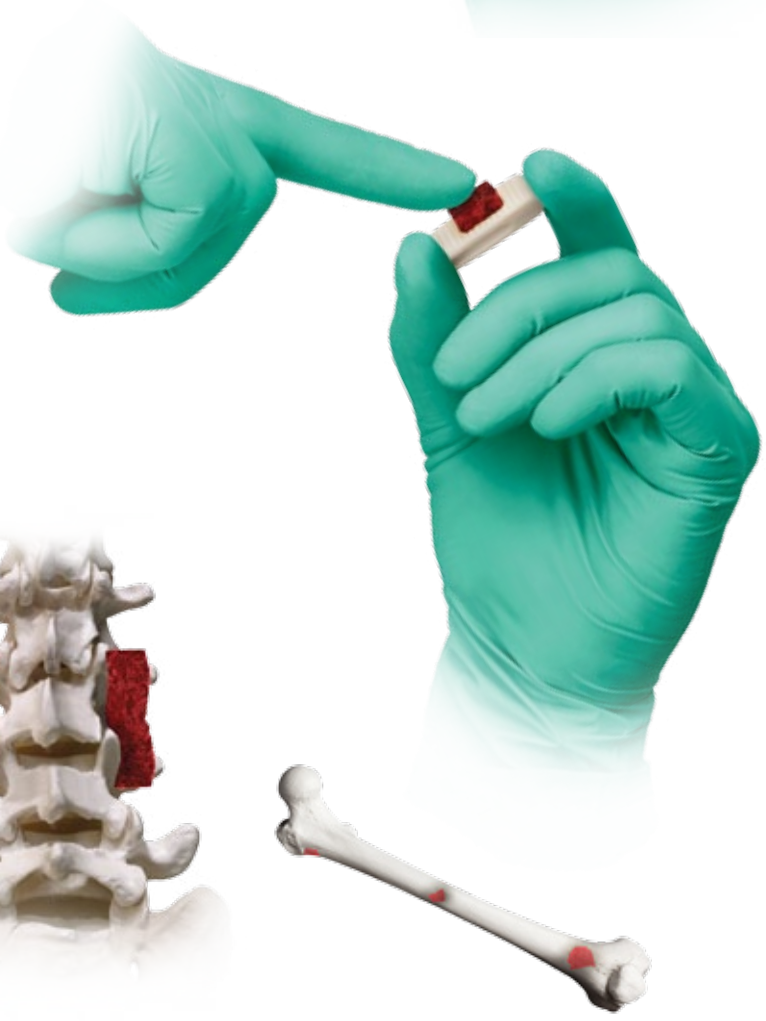
Note: If size is determined preoperatively, ViaSorb™ may be rehydrated immediately in the operating room.

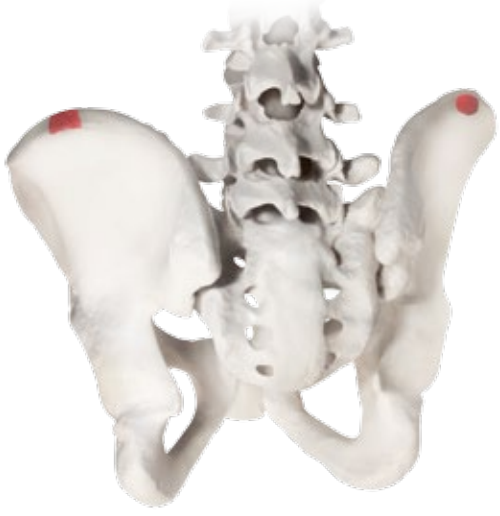
Step 4 Cutting (Optional)

ViaSorb™ demineralized Cancellous Sponges can be cut to the desired size.

Step 5 Insertion

Insert ViaSorb™ Cube or Strip into an osseous void, in the posterolateral spine or to fill an allograft spacer.





ViaSorb™ IMPLANT SET

ViaSorb™ Implant Set 9155.9003

Part No.	Description	Qty
8155.1008S	ViaSorb™ Cube, 8mm	1
8155.1010S	ViaSorb™ Cube, 10mm	2
8155.1012S	ViaSorb™ Cube, 12mm	2
8155.1014S	ViaSorb™ Cube, 14mm	2
8155.1202S	ViaSorb™ Strip, 10x50x5mm	1
8155.1205S	ViaSorb™ Strip, 20x30x5mm	2
8155.1207S	ViaSorb™ Strip, 20x50x5mm	2
9155.0003	ViaSorb™ Soft Case	

IMPORTANT INFORMATION ON ViaSorb™ DEMINERALIZED CANCELLOUS SPONGES

READ BEFORE USING

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.

DESCRIPTION

This human tissue allograft is supplied by GLOBUS MEDICAL and was processed and prepared by Texas Human Biologics (THB). All recovery, processing and distribution costs were reimbursed in part by GLOBUS MEDICAL in accordance with NOTA.

This allograft is supplied sterile.

REGULATORY CLASSIFICATION

This allograft is a human tissue product for transplantation. It is processed and distributed in accordance with FDA requirements for Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271), State regulations, and the standards of the American Association of Tissue Banks (AATB).

APPLICATIONS FOR USE

This allograft may be used for different types of surgical procedures. It may be used independently or in combination with autologous tissue or other forms of allograft tissue.

This allograft is intended for single patient use only.

DONOR RECOVERY AND SCREENING

After authorization for donation is obtained, surgical recovery of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments. Donor eligibility is carefully evaluated as required by the US FDA and in accordance with AATB standards and applicable State guidelines. Tissue donors are evaluated for high risk behaviors and relevant communicable diseases. Screening includes a review of the donor medical and social history, a physical assessment of the donor, an autopsy review (if performed), serological screening, tissue recovery microbiology, and cause of death.

Each donor is tested and shown to be **negative** or **nonreactive** for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- HIV1/HCV Nucleic Acid Test (NAT)
- Human T-Cell Lymphotropic Virus Type I Antibody (not required)
- Human T-Cell Lymphotropic Virus Type II Antibody (not required)

This testing is performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). Test kits used are approved by the FDA for testing cadaveric specimens where applicable.

Bone Bank Allografts Medical Director has determined this donor tissue to be suitable for transplantation. The testing and medical release records are maintained by **Bone Bank Allografts**.

PROCESSING

Allograft tissues are processed in a controlled environment using methods designed to prevent contamination and cross contamination. Proprietary physiological buffers, acids, alcohols and surfactants are used during processing. Allograft tissue may contain traces of these processing agents. Final products are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 standards.

Note: Allograft tissues will naturally vary in color from white, off-white, pink, pale pink, and yellow to pale yellow. Occasional dark spots or localized discoloration is a normal occurrence.

CONTRAINDICATIONS

Contraindications for the use of this allograft shall be determined by a licensed practitioner.

WARNINGS

Careful donor screening, laboratory testing, tissue processing, and gamma irradiation have been utilized to minimize the risk of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this graft cannot be guaranteed to be free of all pathogens.

Do NOT reuse or re-sterilize.

Do NOT refreeze product if thawed.

PACKAGING AND LABELING

Each allograft distributed by **GLOBUS MEDICAL** is identified by its own unique serial number. The allograft is packaged in a pouch. Each pouch features a peel back seal and is also heat sealed to provide a sterile barrier. The package label includes graft details such as dimensions and/or volumes. Contents of the package are sterile unless the package is opened or damaged.

Warning: If the innermost pouch is compromised or shows evidence of being torn or opened, **DO NOT USE!**

Allografts are supplied frozen, freeze-dried or in solution.

STORAGE OF FREEZE DRIED AND SALINE PACKAGED TISSUES

Maintain allograft at room temperature (59–86°F or 15–30°C). No refrigeration necessary.

EXPIRATION

See package label for expiration date or observe the above indications for alternate tissue storage.

It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to track expiration date accordingly.

USAGE INSTRUCTIONS

Before Usage: Examine Allograft Package – Do Not Use This Allograft If:

1. Any of the package or product elements appear to be missing, tampered with or damaged.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed.
4. Frozen allograft has not been stored according to storage temperature requirements or the allograft has been prematurely thawed.

If any of the above conditions exist or are suspected, this allograft should NOT be used.

Preparation of Allograft For Use:
Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or properly discarded. Used allograft containers should be disposed of in accordance with recognized procedures for discarding medical waste material.

1. Prepare the allograft for use using the following procedures:
   a) Open the outer container to expose and remove the 1st inner peel pouch.
   b) Open the 1st inner peel pouch and deliver the innermost sterile sealed pouch containing the graft material to a sterile field.
   c) Open the sterile sealed pouch and deliver the graft to a sterile field for rehydration.
   d) If the graft is packaged in saline, utilize sterile scissors to open the fluid filled inner pouch and deliver the graft to a sterile basin.

IMPORTANT INFORMATION ON ViaSorb™ DEMINERALIZED CANCELLOUS SPONGES

If for any reason the graft is opened and not used, it should be disposed of properly or contact GLOBUS MEDICAL Customer Service and follow appropriate return procedures. Document the reason for the non-use of the graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to BONE BANK ALLOGRAFTS.

2. Rehydrate tissue using the following method:

SALINE PACKAGED TISSUES:

No further hydration required.

Sponge Tissue ROOM TEMPERATURE REHYDRATION

1. Place the graft in a basin with sterile saline (0.9%), Lactated Ringer's, or other sterile isotonic solution for up to **20 minutes**.
2. **Allografts must be used within six hours** after rehydrating if the allograft is stored at room temperatures.
3. If refrigerated and stored between 2°C and 8°C within six hours after rehydrating, the allograft may be used within 24 hours (including rehydration time). Graft must be stored with proper precautions to prevent contamination.

RETURNS

If for any reason tissue must be returned, a return authorization is required from **GLOBUS MEDICAL** prior to shipping. **Frozen grafts are not returnable**. It is the responsibility of the health care institution returning the tissue to adequately package and label the tissue for return shipment.

PATIENT RECORD

Recipient records must be maintained for the purpose of tracking tissue post-transplant. *IMPORTANT NOTICE TO END-USER*: Please record this distinct graft identification code in your records and in the patient's medical record. It is also recommended that the following information be recorded in the patient's medical record:

1. Description of Tissue
2. Product Code
3. Expiration Date
4. Description of Procedure
5. Date and Time of Procedure
6. Surgeon Name
7. Any Other Pertinent Information

A Transplant Record has been included with each package of tissue. Please record the patient name, distinct graft identification code, date of birth, sex, name and address of the healthcare facility, name of the transplanting physician, date and type of surgery, name of the person filling out the Transplant Record and any comments. Once completed, the Transplant Record should be returned to Bone Bank Allografts. Copies of this information should be retained by the transplant facility for future reference.

POTENTIAL COMPLICATIONS

As allografts are composed of proteins such as collagen, the potential for hypersensitivity, allergic reactions or other immune responses may exist. All adverse outcomes potentially attributed to the allograft must be promptly reported to **GLOBUS MEDICAL**.

Possible complications can occur with any surgical procedure including, but not limited to pain, infection, hematoma, incomplete or lack of bony growth at treatment site, and/or immune rejection of the introduced tissue.

Disease screening methods are limited; therefore, certain diseases may not be detected.

The following complications of tissue transplantation may occur:

- Transmission of diseases of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.

DISPOSAL

Allograft disposal shall be in accordance with local, state, and federal regulations for human tissue.

INQUIRIES

For additional information, to place an order, or to report adverse reactions, contact: GLOBUS MEDICAL Customer Service at: Phone: (610) 930-1800

2560 General Armistead Avenue
Audubon, PA 19403 (610) 930-1800

ALLOGRAFT TISSUE PROCESSED BY:
Texas Human Biologics
14805 Omicron Drive, Suite 200
San Antonio, Texas 78245

TRANSPLANT RECORD RETURNED TO:
Bone Bank Allografts
P.O. Box 690988
San Antonio, Texas 78269-0988

LB-286 R00 Eff. Date: May 4, 2016; CN# 15.007

Notes

Notes

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

EC REP: RMS – UK Limited
28 Trinity Road, Nailsea, Somerset, BS48 4NU England

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