Product Overview

Allograft derived demineralized bone matrix (DBM) offers many of the elements essential for bone formation. DBM not only provides the natural scaffold for bone ingrowth, but it is also a source of a full range of growth factors (i.e., BMPs, TGFs) known to induce the osteoinductive signal\(^1\) for bone formation.

ProSpace™ DBM-D has demonstrated osteoinductive potential and is available with or without the addition of cortical-cancellous chips for an optimized osteoconductive scaffold. ProSpace DBM-D is offered in a variety of forms and quantities to meet the needs of your trauma, reconstructive, spine and sports medicine patients.

Cancelle™ SP DBM Sterilization Process
ProSpace DBM-D products are sterilized through the Cancelle SP Process, which is designed to preserve protein activity. The osteoinductive* (OI) potential is verified by 100% lot testing after sterilization. In their final form, the DBM products serve as bone void fillers in many applications.

How Does the Cancelle™ SP Process Work?
Cancelle SP is a proprietary process that sterilizes DBM gels, pastes and putties while simultaneously allowing them to maintain their osteoinductive potential*. Through a combination of oxidative treatments and acid or alcohol washes, debris is removed and pathogens are inactivated. Cleansing rinses remove residual chemicals while maintaining biocompatibility and terminal low-temperature, low-dose gamma irradiation achieves sterility (SAL 10\(^{-6}\)) while preserving the utility of the graft.

*Every DBM lot induced bone formation when implanted in a modified athymic nude rat assay. Findings from an animal model are not necessarily predictive of human clinical results.
Features and Benefits

**Easy to Use**
- Use in seconds with a few easy steps
- Mix with blood, sterile water or saline
- Combine with autograft or allograft
- Room temperature storage
- Use as a bone void filler in many surgical applications

**Handling and Versatility**
- A malleable DBM that is not water-soluble and will maintain its implanted integrity during irrigation.
- ProSpace™ DBM-D utilizes a highly purified gelatin carrier derived from Type 1 collagen which firms at body temperature, resists migration and does not interfere with the bone formation process.
- Its versatility allows for hydration with several different fluids, including the patient’s own blood or sterile water/saline.

**Stability of Growth Factors**
Studies have shown that increasing levels of moisture and heat can have a negative effect on the osteoconductive capabilities of DBM. In order to maintain the stability of growth factors over the shelf life, ProSpace DBM-D is packaged freeze-dried.
Animal testing of ProSpace™ bone paste has been conducted in various rat and rabbit models. The results of these studies show that ProSpace bone paste performs better than the tested alternative bone graft substitute (BGS) options, and the data obtained in these studies demonstrates that ProSpace DBM-D functions as intended in multiple animal models and anatomic locations.

**Spine**
Wang et al. compared ProSpace bone paste to two other commercially available bone pastes in a rat spinal fusion model. Autogenous bone graft served as a control. By the end of the study, a total of 14 out of 18 rats had demonstrated successful fusion, a higher rate of fusion than the other alternatives.5

**Performance**

**Rat Model**

- ProSpace bone paste in the spine (histology from rat study)
- ProSpace bone paste at 6 weeks (anterior-posterior radiograph of a rat)

**Rabbit Model**

- Representative low power histology. H&E.
- Representative X-rays taken in vivo. Transverse processes (TP) grafted with ProSpace DBM-D. Moderate bone formation has occurred bilaterally (arrows).

**Spine**
ProSpace allograft bone paste induced new bone formation and bridging fusion comparable to autograft in the rabbit spinal fusion model. The material performs well alone or in combination with autograft.6
Quality

100% Lot Testing for Osteoconductivity

- After sterilization is complete, every lot of DBM undergoes in vivo testing for osteoconductivity. The benefit of using the in vivo athymic rat model is its ability to capture the complex chemical and biological processes that are involved in new bone formation. This more sensitive form of testing not only screens potentially underperforming DBM from use, but it also captures any inflammatory response elicited from a donor’s DBM.

- The importance of testing every donor is that not every lot of DBM performs the same. A study evaluating the performance of 1,200 DBM lots found that only 80% met the acceptance criteria for osteoinductivity (new bone formation in 50% or more of implant area).3,4

Quality Control Release Criteria

The following tests are performed on every lot before release:

- Residual calcium testing
- Residual moisture testing
- Extrusion testing of finished product
- Dissolution testing of finished product
- Handling testing of finished product
- Osteoinductive testing of finished product

Histological depiction of the chronology of endochondral ossification of DBM implanted into athymic rats. Finished product induced bone formation when implanted in an athymic nude rat assay. Findings from an animal model are not necessarily predictive of human clinical results.
The safety of tissue is contingent upon three stages; donor screening, laboratory testing and tissue preparation (including terminal sterilization) validation to address potential disease transmission.

Stage 1: Donor Screening for Patient Safety
Medical and social history evaluations are performed for every donor. RTI's medical director, a licensed physician, must approve each donor record.

Stage 2: Donor Testing for Patient Safety
Donor testing meets FDA and AATB (American Association of Tissue Banks) requirements. Lab tests are performed using kits approved by the FDA, which include Nucleic Acid Testing (NAT) for HIV and HCV, currently the most sensitive tests available.

Seriological Testing Includes:
- HCV Antibody
- HBV Surface Antigen
- HIV 1 & 2 Antibody
- HBV Total Core Antibody
- HTLV-I & HTLV-II Antibody
- RPR for Syphilis
- HIV-I/Nat
- HCV/NAT

Microbiological Testing Includes:
- Pre-processing culturing: Performed before processing begins to remove potentially unsuitable tissue from process.
- Environmental controls: Monitors cleanliness of processing environment.

Stage 3: Viral Inactivation and Terminal Sterilization
The Cancelle™ SP DBM Sterilization Process is validated to inactivate relevant enveloped and non-enveloped viruses like HIV, Hepatitis C virus model (BVDV), Herpes virus model (PrV), Hepatitis B virus (HBV) and more. The process kills bacteria, removes debris and reduces viral load while preserving the tissue biocompatibility and osteoinductivity.

Finished product in its final packaging is sterilized using low-temperature, low-dose gamma irradiation to achieve a validated 10⁻⁶ sterility assurance level.
Order Information

### Demineralized Bone Matrix/ Flowable

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<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Size</th>
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<tbody>
<tr>
<td>ME701</td>
<td>ProSpace DBM-D Paste, Syringe</td>
<td>1 cc</td>
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<tr>
<td>ME705</td>
<td>ProSpace DBM-D Paste, Syringe</td>
<td>5 cc</td>
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<tr>
<td>ME710</td>
<td>ProSpace DBM-D Paste, Syringe</td>
<td>10 cc</td>
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### Demineralized Bone Matrix/ Moldable

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<tr>
<td>ME712</td>
<td>ProSpace DBM-D, CCC, Putty*</td>
<td>2 cc</td>
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<tr>
<td>ME715</td>
<td>ProSpace DBM-D, CCC, Putty*</td>
<td>5 cc</td>
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<tr>
<td>ME720</td>
<td>ProSpace DBM-D, CCC, Putty*</td>
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*Contains cortical cancellous chips

### Cancellous and Cortical Cancellous Chips and Cubes

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<tbody>
<tr>
<td>ME725</td>
<td>Cancellous Chips 1 mm- 4 mm</td>
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<tr>
<td>ME726</td>
<td>Cancellous Cubes 4 mm - 6 mm</td>
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<tr>
<td>ME727</td>
<td>Cortical Cancellous 40/60 Chip Mix 1 mm - 3 mm</td>
<td>15 cc</td>
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Manufactured by:
RTI Biologics™ is a trademark of RTI Biologics, Inc.
Cancell™ SP is a trademark of RTI Biologics, Inc.

For additional information, contact Customer Service at 1-866-229-3002 or visit our website at www.aesculapimplantsystems.com.

References:
