

TREL-X PRESS™

DEMINERALIZED BONE MATRIX

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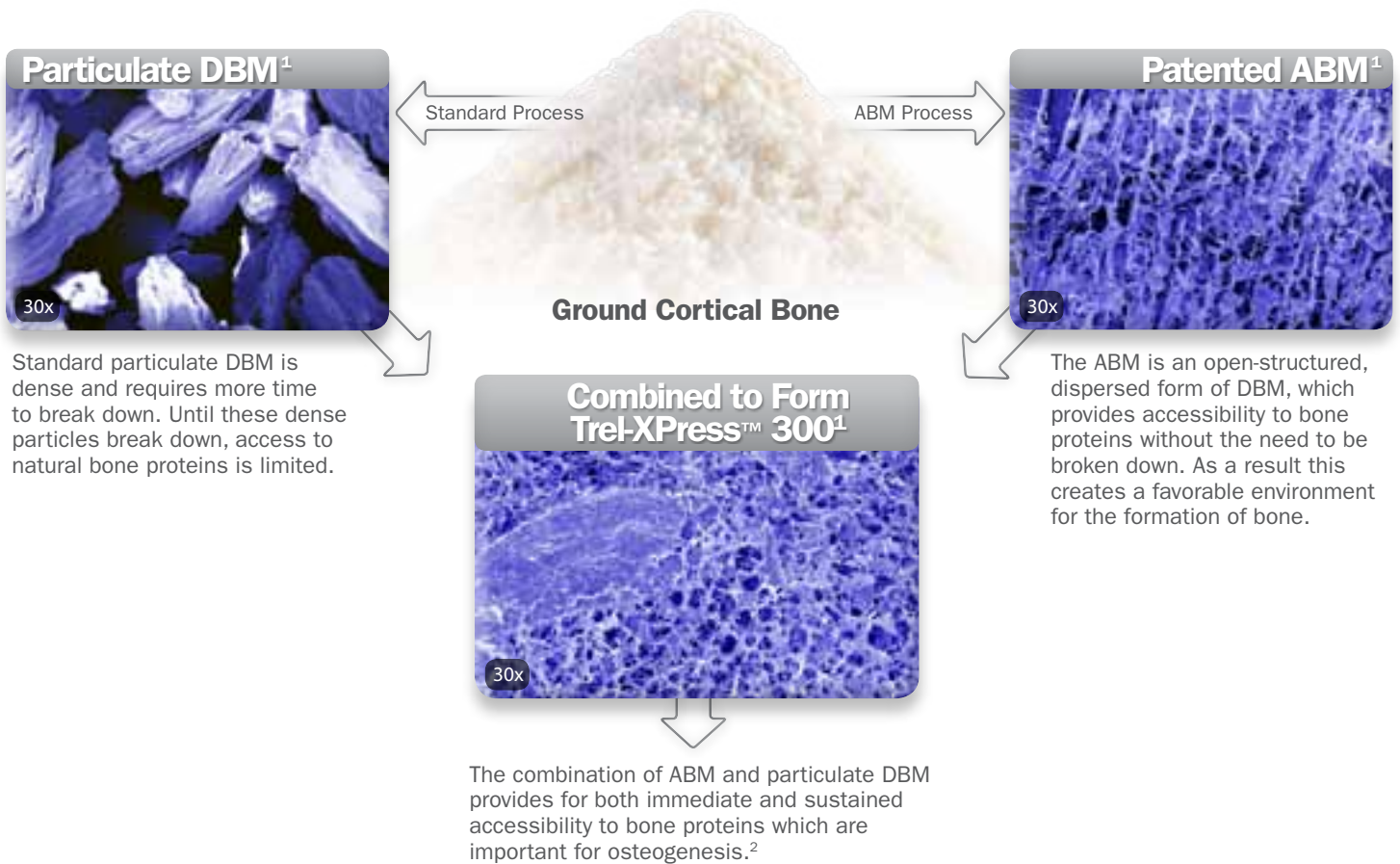
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The Trel-XPress™ 300 Advantage — What's the Difference?

Trel-XPress™ 300 Demineralized Bone Matrix combines Accell® Bone Matrix (ABM) and particulate DBM.



Optimized Bone Matrix

Trel-XPress™ 300 DBM consists of 3 parts Accell® Bone Matrix (ABM).

1st Generation



2nd Generation



3rd Generation **Trel-XPress™ 300**



This dispersed form of DBM offers significantly increased surface area, which provides access to natural bone proteins.



Trel-XPress™ 300 Demineralized Bone Matrix's increased surface area provides access to natural bone proteins.

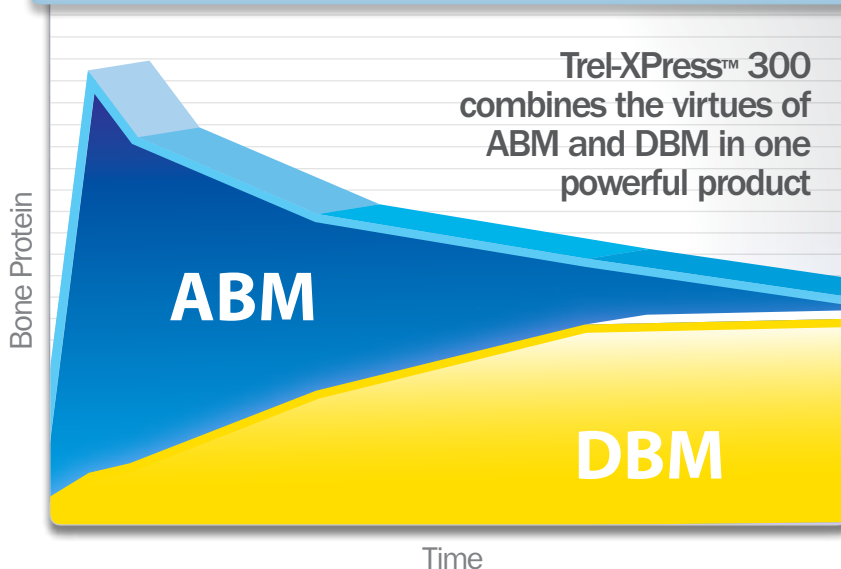
Natural bone protein content of ABM and particulate DBM was measured in vitro over time using an Enzyme Linked Immunosorbent Assay (ELISA). The results are shown graphically and indicate that bone protein was detectable in a saline solution containing ABM at earlier time points compared to that of particulate DBM.

The higher surface area and more open pore structure of ABM provides accessibility to the bone protein, without the need to be broken down.

This analysis shows that while ABM provided early accessibility of natural bone protein, particulate DBM provides for accessibility of natural bone protein at later time points.

Osteoinductive Potential – *In Vitro* Measurement³

Accell® Bone Matrix (ABM) vs. Particulate Demineralized Bone Matrix (DBM)



Superior Handling⁴

The optimized formulation of Trel-XPress™ 300 Demineralized Bone Matrix contains ABM and DBM combined with a unique poloxamer Reverse Phase Medium (RPM). The result is a graft material with exceptional handling and containment characteristics.

The unique RPM carrier becomes more viscous at body temperatures, while it is less viscous at room temperature. Because of the RPM's unique thermoreversible property, Trel-XPress™ 300 Demineralized Bone Matrix is:

- moldable at the time of application
- packable into virtually any size or shape defect
- mixable with other grafting materials
- irrigation-resistant

Ready to Use

Trel-XPress™ 300 Demineralized Bone Matrix is ready for implantation directly from the syringe. It does not require any cumbersome or time-consuming preoperative preparation such as thawing or mixing. The optimized formulation of Trel-XPress™ 300 Demineralized Bone Matrix results in a robust, moldable putty that does not stick to surgical gloves.



Custom Syringe

The new ergonomic syringe design facilitates easy handling and extrusion of the graft. The large diameter extrusion is ideal for graft mixing and placement.



Cancellous Bone

Trel-XPress™ 300c contains cancellous chips that compliment the osteoconductive scaffold by providing a natural porous structure that encourages tissue and vascular ingrowth. Cancellous bone is resorbed naturally by being incorporated into new bone during the remodeling process.



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<u>Description</u>	<u>Catalog Number</u>	<u>Description</u>	<u>Catalog Number</u>
2.5 cc syringe	XPRES325	2.5 cc syringe	XPRES3C25
5 cc syringe	XPRES305	5 cc syringe	XPRES3C05

References

1. Data on file
2. Lian J and Stein G, The Cells of Bone, (1999) Dynamics of Bone and Cartilage Metabolism (Ed Seibel J).
3. R&D Systems, Inc.: Quantikine(R)-BMP-2 Immunoassay, For the quantitative determination of bone morphogenetic protein 2 (BMP-2) concentrations in bone tissue extracts and cell culture supernates.
4. Compared to previous generations of Integra DBM products.

INDICATIONS FOR USE

Trel-XPress™ 300 Demineralized Bone Matrix is intended for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. Trel-XPress™ 300 Demineralized Bone Matrix is indicated for use as a bone graft extender in the spine, extremities and pelvis, or as a bone void filler in the extremities and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone.

WARNINGS AND PRECAUTIONS

Trel-XPress™ 300 Demineralized Bone Matrix is sterile during the stated shelf life in an unopened and undamaged package. The product must be used prior to the expiration date. Do not use if the packaging has been damaged and/or the product has been contaminated. In the event of contamination, discard the product. Damaged packaging should be returned to Integra LifeSciences Corporation. Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects. As with all biological products, the tissue in Trel-XPress™ 300 Demineralized Bone Matrix has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissue selection and laboratory tests. To date, there have been no reports of experimental or clinical viral serocon version using demineralized bone powder. When filling a closed defect, care must be taken while extruding Trel-XPress™ 300 Demineralized Bone Matrix from the syringe as possible pressurization of the device could result in fat embolization and/or embolization of the material into the blood stream. 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. Adverse outcomes potentially attributable to the product must be reported promptly to the manufacturer. If any dissatisfaction with the product performance or packaging occurs, notify Integra LifeSciences Corporation immediately and promptly return product and/or packaging. When introducing Trel-XPress™ 300, care must be taken to avoid excessive compaction. Overfilling the implantation site must be avoided to achieve a tension-free closure of the wound. For further information refer to the product insert.

INTEGRA™

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