

# CONFORM<sup>®</sup> CUBE



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CONFORM Cube with Q-PACK<sup>®</sup> Zero Rehydration Technology is designed for use within allograft spacers and to fill bone voids. CONFORM Cube is 100% demineralized cancellous bone.\* It is conformable and may be compressed into the desired location.



Osteoinductivity<sup>1, 2</sup>  
Conformability  
Wickability

Q-PACK technology is an ambient temperature packaging method that allows CONFORM Cube to be offered in a hydrated state, eliminating the rehydration step required by competitive tissue forms.



- CONFORM Cube is a monolithic piece of cancellous bone designed to resist migration.
- CONFORM Cube readily absorbs and retains bone marrow aspirate, blood, or saline.
- CONFORM Cube can be osteogenic when combined with bone marrow aspirate.<sup>1</sup>

**Note: DePuy Synthes Spine offers ProCure<sup>™</sup> Bone Marrow Aspiration Kit for collecting bone marrow. Please see Product Information page for ordering information.**

\*CONFORM Cube is regulated as an HCT/P (Human Cells, Tissues, and Cellular and Tissue-Based Product), pursuant to 21 CFR 1271.

1. CONFORM<sup>®</sup> Cube: An Evaluation of a Fully Demineralized Cancellous Scaffold Seeded with Human Mesenchymal Stem Cells (white paper); Musculoskeletal Transplant Foundation. 2011. (00014 CI)
2. McLain RF, Fleming JE, Boehm CA, Muschler GF. *Aspiration of osteoprogenitor cells for augmenting spinal fusion: comparison of progenitor cell concentrations from the vertebral body and iliac crest.* J Bone Joint Surg Am. 2005;87(12):2655-2661..

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## CONFORM Cube is: Osteoinductive<sup>1,2</sup>

A unique demineralization process is used to expose the natural bone morphogenic proteins while maintaining a cell-friendly environment.

## Osteoconductive<sup>3</sup>

The cancellous bone structure provides a natural scaffold that allows for cellular ingrowth, attachment, and proliferation.

## Conformable

The cancellous tissue can be compressed for precise placement, and easily cut to accommodate irregular shapes and sizes.

## Wickable

The naturally occurring interconnectivity of the bone matrix provides optimal absorption and retention properties for bioactive fluids, such as bone marrow aspirate or blood.

Demineralized bone grafts provide a scaffold for attachment of mesenchymal stem cells. After attachment, the cells take on a preosteoblastic phenotype and eventually differentiate into osteoblasts, laying down a new organic bone matrix within the scaffold. Expression of alkaline phosphatase confirms osteoblastic differentiation. Histological analysis reveals direct attachment of cells to the demineralized bone matrix and proliferation with matrix deposition over time. (Figure 1, t=14 days).<sup>1</sup>

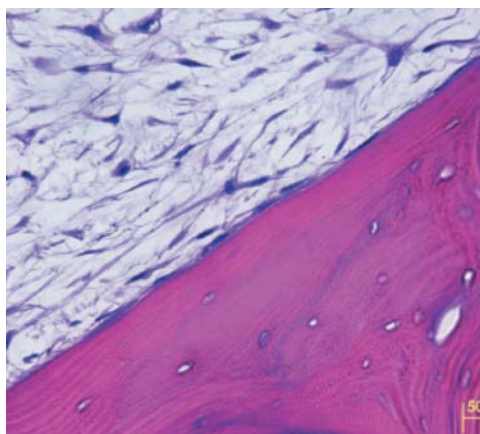


Figure 1.  
Histology of direct cell attachment to matrix

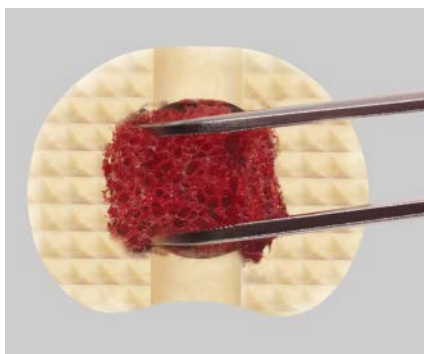


1. Data on file, MTF.

2. Urist MR. Bone: formation by autoinduction. *Science*. 1965;150(3698):893–899.

3. CONFORM® Cube: An Evaluation of a Fully Demineralized Cancellous Scaffold Seeded with Human Mesenchymal Stem Cells (white paper); Musculoskeletal Transplant Foundation. 2011. (00014 CI)

Features	Benefits
Demineralized cancellous tissue, organic matrix	Osteoinductive; promotes cellular ingrowth and vascularization.
Monolithic	Resists migration.
Conformable and customizable matrix	Compresses up to 50% of original size and can easily be cut to fit desired shapes and sizes.
Packaged in a hydrated form	Ready to use immediately out of the package.
Wickability	Naturally absorbs and retains various hydrating agents.
Neutral physiologic pH	Maintained for optimal cell viability and function.
Aseptically processed and passes USP <71> sterility tests	Maintains biological integrity.



CONFORM Cube can be customized via trimming, or placed directly into the desired location.

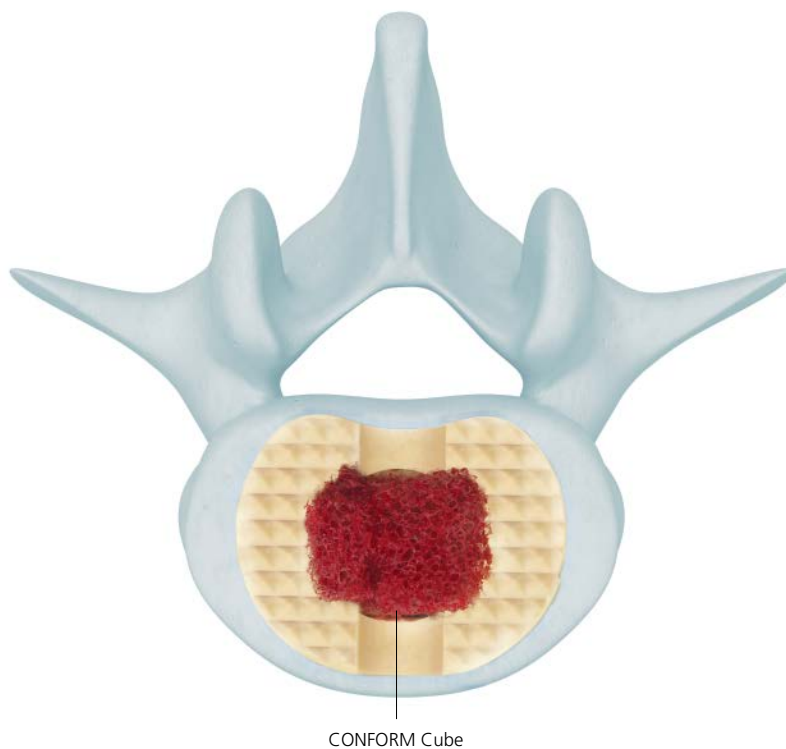


# PROCESSING INFORMATION

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## Processing Information

- CONFORM Cube is processed by the Musculoskeletal Transplant Foundation (MTF) and is available through *DePuy Synthes Spine*.
- The unique demineralization process allows conformability and exposes natural growth factors to provide CONFORM Cube with its osteoinductive properties.
- During the process, pH is restored to a neutral level that allows cell viability and function.
- Q-PACK Zero Rehydration Technology is employed to eliminate a rehydration step, providing ease of use while reducing preparation time.
- Processing and packaging are performed under controlled aseptic conditions—ISO Class 4 certified clean rooms are used to ensure the finished tissue form passes USP <71> sterility tests.



# MUSCULOSKELETAL TRANSPLANT FOUNDATION (MTF)

DePuy Synthes Spine has partnered with the Musculoskeletal Transplant Foundation (MTF) for over 10 years to provide high quality tissue for patients. Although there are national standards for tissue banks, they only set a baseline for the industry. Beyond that, regulations leave a lot to interpretation, so standards vary significantly from tissue bank to tissue bank. MTF offers safe allografts processed from among the most carefully selected donors.

## Directed by Surgeons

MTF utilizes a Medical Board of Trustees comprised of more than 40 surgeons from world-renowned academic institutions. MTF's board sets standards which are among some of the most stringent in the industry.

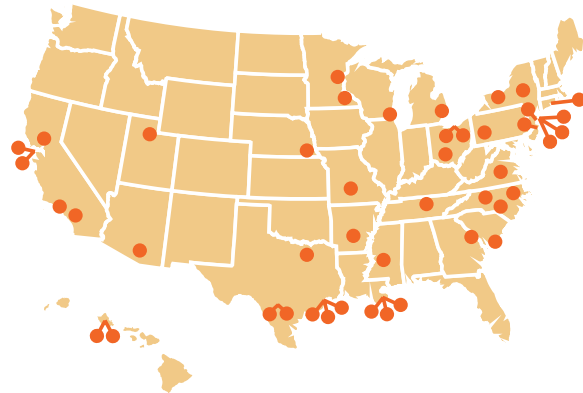
## Selecting the Ideal Donor

MTF's extensive network of participating organ procurement organizations ensures that MTF has access to a broad selection of qualified donors. MTF holds itself to stringent standards for donor selection and processing criteria. MTF defers more donors than they accept.

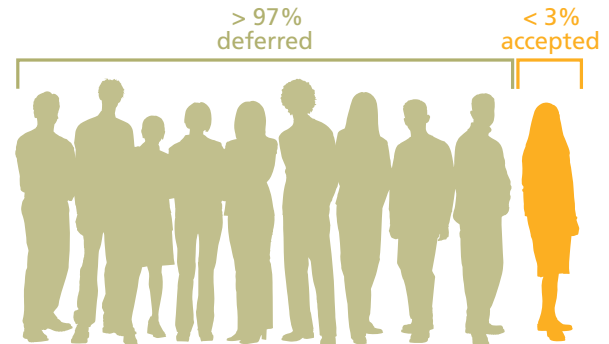
## Preserving and Protecting Tissue Integrity

MTF's approach ensures a high level of safety, without compromising biological and mechanical integrity. MTF has developed and validated several tissue cleaning technologies to provide safe and high quality allograft bone. Allograft bone processed by MTF may result in improved incorporation in humans when compared to allograft bone processed from other sources based on results of *in vivo* testing.\* Since MTF's inception, MTF has maintained an exemplary safety record distributing more than 5 million allografts from over 100,000 donors.

MTF's standards are set by their Medical Board of Trustees — more than 40 surgeons from world-renowned academic institutions.



## MTF Donor Deferral Rate



\* Dunn M.G., 2008. "Effect of Allograft Bone Processing on Structural Cortical Grafts: A Comparison of three proprietary processing Methods."

# ORDER INFORMATION

**CONFORM Cube**

Item Number	Dimensions	Volume
0W1009	9 mm x 9 mm x 9 mm	0.7 cc
0W1011	11 mm x 11 mm x 11 mm	1.3 cc
0W1013	13 mm x 13 mm x 13 mm	2.2 cc
0W1015	15 mm x 15 mm x 15 mm	3.4 cc
0W1017	17 mm x 17 mm x 17 mm	4.9 cc



**PROCURE Bone Marrow Aspiration Kits, sterile**

Item Number	Description
710.111.99S	11 gauge, 11 cm multi-port needle (side holes)
710.151.99S	11 gauge, 15 cm multi-port needle (side holes)
710.150.99S	11 gauge, 15 cm single-port needle (without side holes)



**Limited Warranty and Disclaimer:** DePuy Synthes Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

**WARNING:** In the USA, this product has labeling limitations. See package insert for complete information.

**CAUTION:** USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

**Some devices listed in this brochure may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.**



*Manufactured by (United States):*

**Synthes USA Products, LLC**  
1302 Wrights Lane East  
West Chester, PA 19380  
Telephone: (610) 719-5000  
To order: (800) 523-0322  
Fax: (610) 251-9056

[www.depuysynthes.com](http://www.depuysynthes.com)