

# CONFORM SHEET®

Demineralized cancellous bone



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# CONFORM SHEET



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CONFORM SHEET with Q-PACK™ technology is designed for use in the posterolateral gutters and for filling bone voids. CONFORM SHEET is 100% demineralized cancellous bone.\* It is pliable with shape memory and may be compressed into the desired location.

Q-PACK technology is an ambient temperature packaging method that allows CONFORM SHEET to be offered in a hydrated state, eliminating the rehydration step required by competitive tissue forms. CONFORM SHEET is prehydrated, however a quick saline rinse is recommended prior to use.

- CONFORM SHEET readily absorbs and retains bone marrow aspirate, blood, or saline.
- CONFORM SHEET provides a scaffold for cellular ingrowth, attachment and proliferation.
- CONFORM SHEET is osteogenic when combined with bone marrow aspirate.<sup>1</sup>



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

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CONFORM SHEET is:

### Osteoinductive<sup>2, 3</sup>

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

### Osteoconductive<sup>4</sup>

The cancellous bone structure provides a natural scaffold for new bone formation.

Demineralized bone grafts provide a favorable scaffold for attachment of mesenchymal stem cells. After attachment, the cells then take on a pre-osteoblastic 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>2</sup>

### Conformable

The resilient 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.

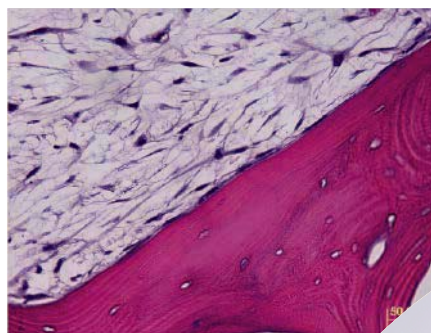


Figure 1: Histology of direct cell attachment to matrix



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1. R. McLain, J. Fleming, C. Boehm and G. Muschler. "Aspiration of Osteoprogenitor Cells for Augmenting Spinal Fusion: Comparison of Progenitor Cell Concentrations from the Vertebral Body and Iliac Crest", *Journal of Bone and Joint Surgery*, 2005; 2655–2661.  
2. Data on file, MTF.  
3. M. Urist. "Bone Formation by Autoinduction." *Science*. 1965; 150: 893–899.  
4. 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 AND BENEFITS

| <b>Features</b>  | <b>Benefits</b>  |
|--|--|
| Demineralized cancellous tissue, organic matrix            | Osteoinductive, promotes cellular ingrowth and vascularization             |
| Conformable and customizable matrix                        | Compresses and can be easily cut to accommodate irregular shapes and sizes |
| Packaged prehydrated                                       | Ready to use immediately out of the package                                |
| Wickable   | 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   |



# HYDRATION INFORMATION



## CONFORM SHEET

CONFORM SHEET is offered prehydrated. The following rinse procedure is recommended prior to use of CONFORM SHEET.

1. While maintaining sterility, saturate CONFORM SHEET with sterile saline.
2. Wring out the saline by manually compressing the tissue. This will allow for the maximum absorption of the preferred biologic fluid.

Hydrate with the preferred biologic fluid. CONFORM SHEET can be hydrated with blood or bone marrow aspirate.



Note: DePuy Synthes offers ProCure™ Choice Marrow Aspiration Kit for collecting bone marrow. Please see Ordering Information.

# PROCESSING AND PACKAGING INFORMATION

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- CONFORM SHEET is processed by the Musculoskeletal Transplant Foundation (MTF) and is available exclusively through *DePuy Synthes Spine*.
- The unique demineralization process exposes natural growth factors that provide CONFORM SHEET with its osteoinductive properties and conformability.
- During processing, pH is restored to a normal physiologic range that allows optimal cell viability and function.
- Q-PACK packaging 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 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 forty surgeons from world-renowned academic institutions. MTF's board sets standards, which are among some of the most stringent in the industry.

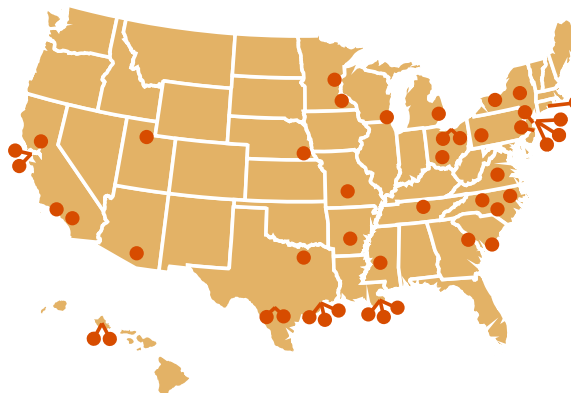
## Selecting the Ideal Donor

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 more than 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."

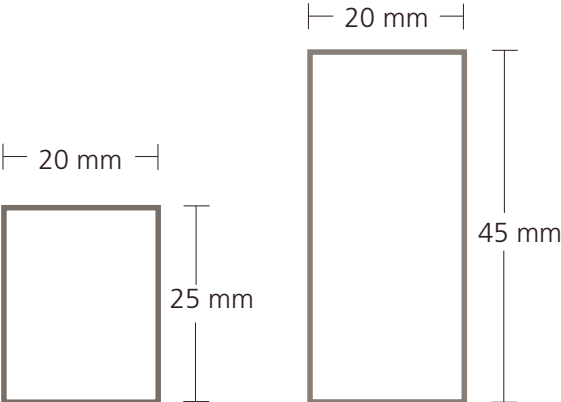


# ORDERING INFORMATION

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## CONFORM SHEET

| Item Number | Dimensions           |
|-------------|----------------------|
| 0W1025      | 25 mm x 20 mm x 5 mm |
| 0W1027      | 25 mm x 20 mm x 7 mm |
| 0W1045      | 45 mm x 20 mm x 5 mm |
| 0W1047      | 45 mm x 20 mm x 7 mm |



PROCURE™ Choice Marrow Aspiration Kits, sterile

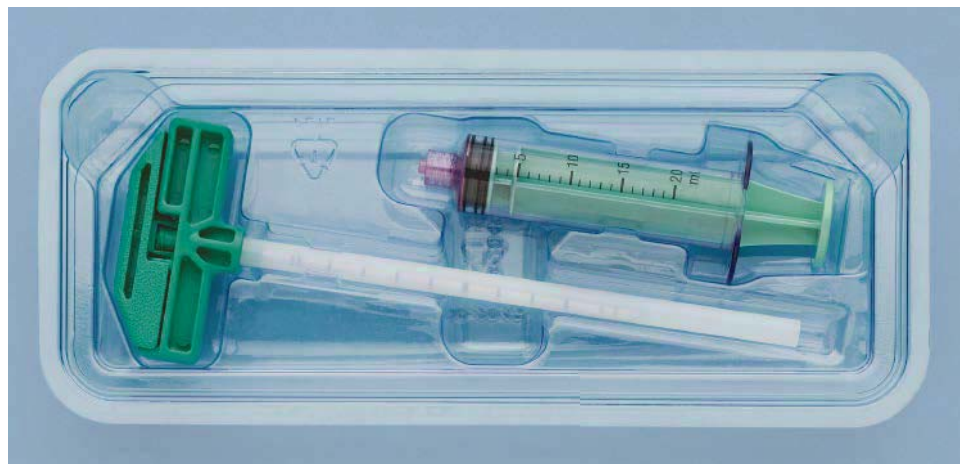
| Item Number | Description   |
|-------------|---|
| 710.111.99S | 11 gauge, 11 cm multi-port needle (side holes)          |
| 710.151.99S | 11 gauge, 15 cm multi-port needle (side holes)          |
| 710.150.99S | 11 gauge, 15 cm single-port needle (without side holes) |



11 gauge multi-port needle  
710.111.99S 11 cm  
710.151.99S 15 cm



11 gauge single port (distal hole) needle  
710.150.99S 15 cm



**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.



COMPANIES OF *Johnson & Johnson*

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