

# NOVOMEDICS

MODERNE MEDIZINTECHNIK



BioAdapt<sup>®</sup>  
DEMINERALIZED BONE MATRIX



A HIGHER STANDARD™

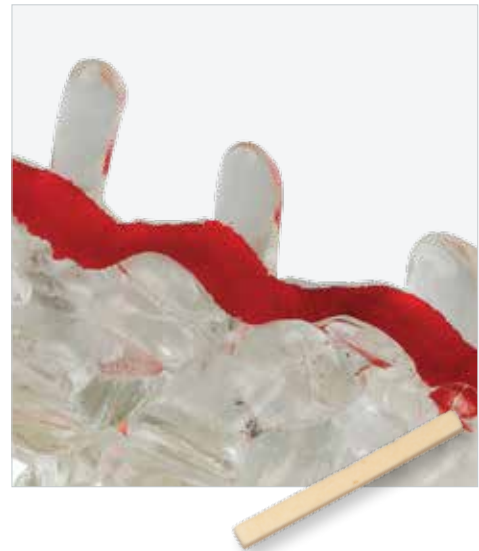
## GRAFT OVERVIEW

BioAdapt® is a pre-formed demineralized bone matrix (DBM) comprised of 100 percent donated human musculoskeletal tissue. BioAdapt DBM provides an open matrix which allows for bony ingrowth, as well as exposure of a full range of proteins known to induce the signal for bone formation.<sup>1</sup> The flexibility and malleability of BioAdapt DBM provides a contoured fit, making it an ideal bone grafting option for various types of defects, particularly irregular bony defects.

BioAdapt DBM may be rehydrated with various types of fluid including, patient's blood, sterile water, sterile saline, or bone marrow aspirate (BMA). Upon rehydration, the graft exhibits cohesive, yet flexible handling properties allowing optimal and precise placement of the grafting material.



**BioAdapt DBM Medium Strip**



**BioAdapt DBM Skinny Strip**

## Safety

The highest level of safety is provided through redundant safeguards, including stringent donor screening, laboratory testing and validated tissue processing (including viral inactivation and terminal sterilization).

The tissue sterilization processes applied to BioAdapt DBM achieve a Sterility Assurance Level (SAL) of  $10^{-6}$ . The carrier component is sterilized through the BioCleanse<sup>®</sup> Tissue Sterilization Process and the DBM component is sterilized through the Canceled<sup>®</sup> SP DBM Sterilization Process, which was specifically designed to preserve protein activity.

## Quality

In order to consistently provide the highest quality DBM implants, RTI performs a series of in-process and post-process quality checks.

Osteoinductive\* (OI) potential is verified by 100 percent lot testing after sterilization.

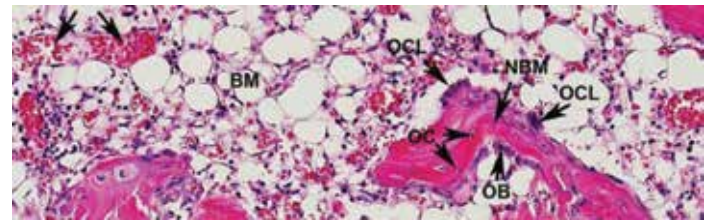


Fig. 1: H&E stain of Urist in vivo model<sup>2</sup> at 28 days. Note the presence of osteocytes (OCL), osteoclasts (OC), osteoblasts (OB), and new bone matrix (NBM) indicating new bone formation.<sup>2</sup>

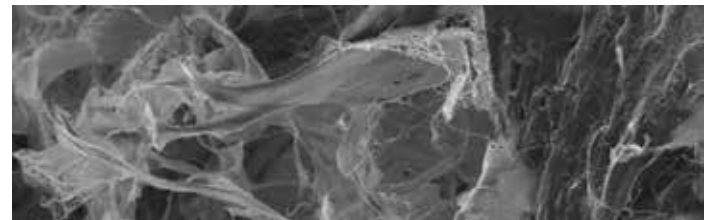


Fig. 2: BioAdapt DBM's open matrix viewed through Scanning Electron Microscope

\*DBM or representative finished implant is either assayed in vivo in the modified athymic nude rat for bone formation or in vitro for endogenous BMP-2 as a surrogate test marker for osteoinductive potential. Because the combination of various proteins is responsible for osteoinductive potential, DBM when assayed in vitro, is also screened for the presence of BMP-7. Findings from an in vitro assay or animal model are not necessarily predictive of human clinical results.

## GRAFT FEATURES

- Absorbs over 5x total dry weight in fluid, allowing the fluid to fully penetrate the graft
- 70 percent DBM by weight
- Osteoinductive Potential\*
- Expands with rehydration to provide a contoured fit to the bony defect
- Retains fluid at the surgical site
- Adjust scaffold's consistency with shorter or longer hydration time
- Easily mixed with autograft or allograft to provide an osteoconductive scaffold
- Water insoluble allowing the graft to maintain its structural integrity once implanted
- Offered in a variety of sizes for added convenience
- Three year shelf life
- Flexible yet cohesive handling characteristics make it easy to cut, shape and mold to fit the defect.

## BONE VOID FILLER APPLICATIONS

### SPINE

- Cervical fusion procedures
- Lumbar fusion procedures
- Deformity

### TRAUMA & ONCOLOGY

- Fresh fractures
- Non-union fractures

### EXTREMITY

- Fusion procedures
- Primary joint surgery
- Revision joint surgery

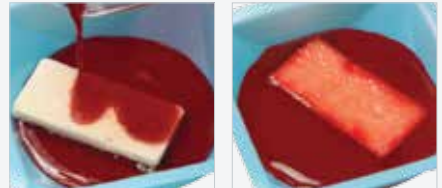
### LARGE JOINT RECONSTRUCTION

- Primary joint surgery
- Revision joint surgery



## Hydrate

- Stored dried but can be rehydrated with sterile water, saline, blood or BMA
- Rehydrate by completely covering it with the appropriate amount of fluid
- Can be rehydrated multiple times
- Adjust scaffold's consistency with shorter or longer hydration time
  - Rehydrate 1-2 minutes: firmer graft handling
  - Rehydrate 3+ minutes: softer, more pliable handling



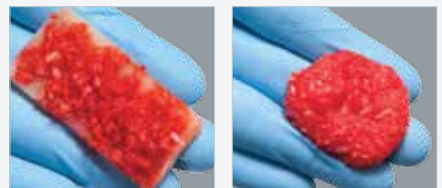
## Absorb

- Can absorb over 5x total dry weight in fluid and is water insoluble, allowing the graft to maintain its structural integrity once implanted
- Graft continues to absorb fluid once implanted in surgical site







## Adapt

- Comes in various sizes to fill a variety of bony defects
- Flexible, yet cohesive handling characteristics make it easy to cut, shape, and mold to fit defect
- Can be easily mixed with autograft or allograft to provide an optimized osteoconductive scaffold



*Note: light compression of the graft during rehydration will result in faster absorption of fluid.*

## Ordering Information - Room Temperature Storage

Code	Description	LxWxH	Grafts/Pack	
DU0110	BioAdapt® DBM, Skinny Strips, 16cc	100 x 10 x 8mm	2	
DU0125	BioAdapt® DBM, Large Strip, 12cc	100 x 25 x 5mm	1	
DU0025	BioAdapt® DBM, Medium Strip, 6cc	50 x 25 x 5mm	1	
DU0015	BioAdapt® DBM, Small Strip, 2cc	15 x 15 x 8mm	1	

<sup>1</sup> Landesman, R.; Reddi, A.H., *Chemotaxis of muscle derived mesenchymal cells to bone-inductive proteins of rat*. Calcified Tissue International, 39: 259-262, (1986).

<sup>2</sup> Data on file at RTI.

### Distributed by

Novomedics GmbH  
Bahnhofstrasse 104  
CH 8001 Zürich  
Tel. +41 43 497 39 80  
Fax. +41 43 497 39 82

**NOVOMEDICS**

info@novomedics.ch  
www.novomedics.ch

UBS Switzerland AG  
CH 8098 Zürich  
BIC: UBSWCHZH80A  
IBAN: CH61 0020 6206 1720 5901 H  
Mwst-Nummer: CHE-116.303.292

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