

NOVOMEDICS

MODERNE MEDIZINTECHNIK



BIOset[®]
DEMINERALIZED BONE
MATRIX



A HIGHER STANDARD[®]

Mixing Information

IMPORTANT: Read the entire package insert (provided with the implant) before using the following quick reference guide.

Flowable: BioSet[®] DBM



Shake

Pull back the plunger of the powder dispenser to approximately $\frac{3}{4}$ of full extension. Shake contents until dry powder is homogenous. Gently push the plunger back in without compacting the DBM powder.



Fill

Using the fluid dispenser, draw fluid to the appropriate line.

Fill To

Black line

If Using

Sterile (19°C-49°C) water/saline

Red line

Patient's blood



Connect

Holding the dispensers vertically with the powder dispenser on the bottom, connect the dispensers. Slowly push the fluid into the powder dispenser until it is thoroughly moistened (hold for a minimum of 10 seconds).



Mix

Holding the dispensers horizontally, push paste mixture back and forth between the two dispensers, emptying each side between strokes. Repeat cycle 10 times until contents are completely blended.



Dispense

Push the contents into the fluid dispenser and disconnect powder dispenser. Attach desired tip onto the fluid dispenser. Dispense as needed.

Moldable: BioSet[®] IC DBM



Shake

Shake jar until dry mixture is homogenous.



Fill

Fill the dispenser (provided) to the appropriate line.

Fill To

Blue line

If Using

Warm (43°C-49°C) sterile water/saline

Red line

Room temperature sterile water or saline (19°C-25°C), or patient's blood



Mix

Deliver fluid into jar and mix thoroughly using spatula until all contents are completely blended.



Apply

Using wet gloves, form into shape and pack it in place.

SETS TO MAINTAIN SHAPE & CONSISTENCY

BioSet[®] Demineralized Bone Matrix (DBM) provides a natural scaffold to support cellular ingrowth and provides osteoinductive* potential.

Handling Characteristics

BioSet DBM is composed of demineralized bone from human donors, a highly purified porcine gelatin carrier, and is available with or without cortical cancellous chips. When combined with fluid (patient's blood, sterile saline or sterile water) the graft becomes pliable and moldable allowing easy placement of the grafting material. A range of options including dried and pre-hydrated grafts are available to meet your surgical needs.

Firming of the Graft

In addition to its ease of use, BioSet DBM firms at body temperature. Not all DBMs have this characteristic. Once fluid is added, the graft will begin to firm up. *(Note: This excludes frozen forms of BioSet DBM.)* This enables the graft to maintain a very robust and stable consistency allowing it to stay in place during irrigation limiting the risk of migration or wash out.

Implanting the graft immediately after it has been completely mixed with fluid prevents it from hardening and becoming too difficult to work with. However, if the graft becomes too difficult to manipulate, the graft may be re-warmed using the re-warming technique (described in the package insert) to loosen the graft and bring it to a more pliable consistency. (Graft consistency may vary depending on hydration time. As the graft begins to firm, the consistency will become more robust.)

GRAFT FEATURES

- Provides an osteoconductive scaffold with osteoinductive* potential to support bone incorporation
- Available with and without cortical-cancellous chips (CCC)
- Graft should be rehydrated with patient's blood, sterile saline or sterile water.
- Sets at body temperature providing a robust and stable graft consistency
- Water insoluble allowing the graft to resist migration once implanted
- 24 percent DBM by weight**
- Easy to shape
- Sterilized using low temperature, low dose gamma irradiation
- Offered in syringe for easy extrusion into the surgical site
- Offered in a jar for easy mixing
- Offered in pre-formed shapes for adaptability of the defect site (pre-formed shapes are only available frozen)
- Has gel, paste, or putty-like handling characteristics depending on hydration stage (applies only to grafts without CCC)

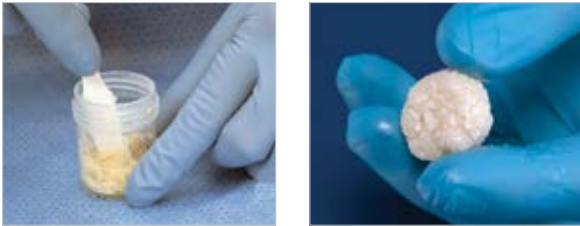
*These products induced bone formation when evaluated using the modified athymic nude rat assay. Findings from an animal model are not necessarily predictive of human clinical results.

**Applies to a single formulation.

Select Your DBM Option

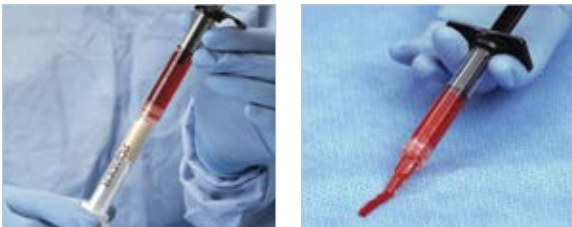
BioSet® IC, RT DBM in a Jar

- A DBM paste with chips that sets once implanted
- A more robust DBM paste that handles like a putty
- Has an osteoconductive scaffold comprised of cortical-cancellous chips
- Easily molded to fill the bone void



BioSet® RT DBM in a Syringe

- A DBM paste that sets once implanted
- Has gel, paste, or putty-like handling characteristics depending on stage in hydration
- Easily extruded into the surgical site



**Note: BioSet DBM is also available frozen in a syringe with and without chips*

BioSet® DBM in Preformed Shapes (only available frozen)

- The graft's flexibility allows it to conform and adapt to the defect site



Bone Void Filler Applications

Spinal Fusion

- Posterolateral gutters
- Deformity

Trauma & Oncology

- Fresh fractures
- Non-union fractures



BioSet® IC, RT DBM

Extremity

- Fusion procedures
- Primary joint surgery
- Revision joint surgery

Large Joint Reconstruction

- Primary joint surgery
- Revision joint surgery



BioSet® IC, DBM
Partial & Full Discs



BioSet® RT DBM

MIXING & HANDLING OVERVIEW

Thawing for frozen BioSet, BioSet IC, and BioSet Pre-Shaped Discs and Strips:

1. Warm sterile water or saline to a temperature of 43-49°C (110-120°F). Do NOT use fluid hotter than 49°C (120°F).
2. Remove outer packaging, leaving only the inner most pouch, dispenser or jar. If using dispenser, ensure watertight seal between dispenser and cap.
3. Submerge container into heated fluid.
4. Warm in five minute intervals until paste is completely thawed.
5. Remove container from fluid. Open container and apply as needed. Paste may be delivered directly into the graft site or molded into shape. DO NOT heat paste for more than six hours.

Rewarming Technique

1. Warm sterile water or saline to a temperature of 43-49°C (110-120°F). Do NOT use fluid hotter than 49°C (120°F).
2. Re-Seal Mixing Container.
 - a. Flowable: Place the dispenser cap (included) on the fluid dispenser and submerge in the warming fluid.
 - b. Moldable: Place the lid on the jar and submerge in the warming fluid.
3. Leave dispenser or jar in the warming fluid for approximately five minutes.
4. If paste does not easily extrude, re-warm. DO NOT heat paste for more than six hours.

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).

BioSet DBM implants are sterilized through the Cancell® SP DBM Sterilization Process, which is 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.

Quality Control Release Criteria

The following tests are performed on every lot before release:

- Osteoinductivity of representative finished implant
- Residual calcium
- Residual moisture
- Dissolution of finished implant (only flowable)
- Consistency of finished implant (only moldable)

Ordering Information

Code	Description	Storage	
006702	BioSet® IC, RT Allograft Paste, 2cc	RT	
006705	BioSet® IC, RT Allograft Paste, 5cc	RT	
006710	BioSet® IC, RT Allograft Paste, 10cc	RT	
006720	BioSet® IC, RT Allograft Paste, 20cc	RT	
005701	BioSet® RT Allograft Paste, Syringe, 1cc	RT	
005705	BioSet® RT Allograft Paste, Syringe, 5cc	RT	
007890	BioSet® IC Allograft Full Disc, 90 x 5mm, 32cc	FZ	
007875	BioSet® IC Allograft Partial Disc, 75 x 5mm, 15cc	FZ	
007891	BioSet® IC Allograft Partial Disc, 90 x 5mm, 22cc	FZ	
008850	BioSet® IC Moldable Strip, 50mm (2 each), 6cc	FZ	
008890	BioSet® IC Moldable Strip, 90mm (2 each), 10cc	FZ	

RT=Room Temperature | FZ=Frozen

See implant labeling for complete instructions for use.

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