Handling Instructions

RegenaVate® DBM

**RegenaVate Formable DBM, Frozen**

1. **OPEN** outer pouch only using sterile technique. Introduce inner pouches to sterile field.
2. **WARM** sterile water or saline to 43-49°C, (109.4-120.2°F). Do NOT use fluid hotter than 49°C (120°F).
3. Place sealed pouch containing frozen RegenaVate Formable DBM in heated water.
4. **REMOVE** softened graft from warm bath. Open package using sterile technique.
5. **MOLD** graft to final shape. DO NOT heat paste for more than six hours.
6. **MONITOR** softness of graft in pouch after 5 minutes by squeezing gently. If graft hasn’t reached desired consistency return to the warm bath.

**RegenaVate DBM Fill**

1. **OPEN** outer pouch using sterile technique. Introduce inner pouches to sterile field. Open inner pouches and place contents in sterile field.
2. **SHAKE** contents after pulling back plunger of powder dispenser to approximately 3/4 of full extension until dry powder is homogenous. Gently push plunger back in to its original position.
3. **FILL** using the fluid dispenser-draw fluid to the appropriate line.
   - **Black line**: Sterile water or saline (19°-49°C; 66.2°-120.2°F)
   - **Red line**: Patient’s blood
4. **CONNECT** the two leur lock syringes ensuring that air is not introduced. Holding the dispensers vertically with the powder dispenser on the bottom, slowly push the fluid into the powder dispenser until it is thoroughly moistened (hold for a minimum of 10 seconds).
5. **MIX** by slowly injecting fluid into powder. Injecting fluid too quickly may cause improper mixing. Push plunger back and forth for 10 cycles (back and forth equals one cycle.)
6. **DISPENSE** by pushing all paste into small fluid syringe. Place tip on delivery syringe, if necessary, for graft placement.
**RegenaVate DBM Handling Instructions**

**RegenaVate Formable DBM, RT (Room Temperature)**
Sterile, powder-free gloves are required for proper manipulation of the graft. For best results, all grafts should be used immediately after preparation.

1. **OPEN** outer pouch using sterile technique. Introduce inner pouches to sterile field.
2. **SHAKE** jar until RegenaVate DBM Powder is homogenous.
3. **FILL** dispenser to appropriate line.
   - **Blue Line**: Warm sterile water or saline (43-49°C; 109.4-120.2°F).
   - **Red Line**: Room temperature sterile water or saline (19-25°C; 66.2-77°F), or patient’s blood.
4. **ADD** the fluid to the jar containing the RegenaVate DBM Powder.
5. **MIX** thoroughly using spatula until all contents are completely blended.
6. **FORM** into desired shape using wet gloves and pack into place. **Please note**: sufficient kneading of the material is required to prevent crumbling.
   - **DO NOT** heat paste for more than six hours.

**RegenaVate DBM RT Re-Warming Technique:**

1. Warm sterile water or saline in a warmer to a temperature of 43°-49°C (109.4°-120.2°F). **Do NOT** use fluid hotter than 49°C (120.2°F).
2. Re-seal Mixing Container
   - **Syringe**: Place the dispenser cap (included) on the syringe and submerge in the warmer.
   - **Jar**: Re-seal mixing container and submerge in the warmer.
3. Leave syringe/jar in the warmer for approximately 5 minutes.
4. If paste does not have desired consistency after the 5 minutes, re-warm.
   - **DO NOT** heat paste for more than six hours.

These are abbreviated instructions. See accompanying instructions for use for complete instructions for use.

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