

INSTRUCTIONS FOR USE

Important Information — Please Read Prior to Use



 **Manufacturer:**
Musculoskeletal Transplant Foundation
125 May Street
Edison, NJ 0837
1-800-433-6576

Distributed by:
Orthofix Inc.
3451 Plano Pkwy
Lewisville, Texas 75056 U.S.A.
214-937-3030

RX Only

System Name: **Trinity Evolution Strainer Cap**

Description: The Trinity Evolution Strainer Cap is a single-use sterile product used to decant the DMSO (dimethyl sulfoxide) solution once thawed. It is also subsequently used to decant or drain D5LR (5% dextrose in Lactated Ringer's) solution from the allograft matrix within the container jar prior to use.

Refer to Instructions for Use and package inserts provided with Trinity Evolution for information regarding: Description and Indications for Use, Cautions, Precautions, Contraindications, Adverse Effects and Sterility information.

Contraindications: Contraindications of the Trinity Evolution Strainer Cap include:

1. Metal sensitivity/allergies
2. Any contraindications identified in the package insert for Trinity Evolution

Operative Guidelines:

1. Once the Trinity Evolution Preparations for Use and Thawing Steps have been performed, the tissue will be ready for implantation. Refer to the Preparations for Use and Thawing Instructions documentation provided with Trinity Evolution.
Note: Trinity Evolution should be used within 2 hours of thawing. Do not allow Trinity Evolution to dry out.
2. Once the Trinity Evolution tissue is thawed, remove the cap from the jar.
3. Use standard aseptic/sterile technique to open the strainer cap package and make ready for use. Strainer cap and packaging have been terminally sterilized.
4. Peel open the outer tyvek pouch and pass the inner pouch into the sterile field.
5. Peel open the inner tyvek pouch and remove the strainer cap.
6. Place the strainer cap on the jar.
7. Tilt jar to decant the cryopreservation solution. If solution pours slowly, wet the strainer first.
8. Once the cryopreservation solution is decanted, remove the strainer cap. Add 5% Dextrose in Lactated Ringer's (D5LR) solution to the jar.
9. Replace the strainer cap on the jar.
10. Tilt to decant the D5LR.
11. Once the D5LR solution is decanted, remove the strainer cap and remove tissue from the jar.
Note: Only remove the D5LR solution once the tissue is ready to implant so as to not dry out the tissue.
12. After use, the Strainer Cap and packaging that has been in contact with the tissue should be properly disposed of in accordance with recognized procedures for discarding regulated medical waste materials.

Warnings and Precautions: This product must not be used under any of the following conditions:

1. If the container seal is damaged, or not intact
2. If the container or product has any physical damage
3. If the container label is severely damaged, not readable or is missing
4. If the expiration date shown on the container label has passed
5. Instruments should not be used for anything other than their intended use

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system), who has any complaints, or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Orthofix Inc, 3451 Plano Parkway, Lewisville, TX 75056, USA, Telephone at 1-888-298-5700 or 214-937-3030 or via email at complaints@orthofix.com.

Rx Only	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician		
	See Instructions for Use	REF	Catalogue Number
	Single Use Only Do Not Reuse		Do Not Resterilize
LOT	Lot Number		Manufacturer
STERILE	Sterilized by Radiation		Use By