



Device System Name:

Trinity Evolution Delivery System

Description: Trinity Evolution Bone Graft Delivery System

The Trinity Evolution Bone Graft Delivery System includes a funnel and a plunger. The funnel is the instrument that will contain the tissue form and is capable of accepting all size options of Trinity Evolution, including the largest container. The funnel's long narrow tube is designed for both minimally invasive as well as for open surgeries. The plunger helps slide Trinity Evolution down the narrow tube.

Refer to Instructions for Use and package inserts provided with the Trinity Evolution material for information specific to the product, including: indications for use, contraindications, warnings, precautions, adverse reaction information and sterilization information.

Contraindications:

Contraindications of the Trinity Evolution Delivery System instrumentation include:

1. Instruments should not be used for anything other than their intended use
2. Metal sensitivity/allergies
3. Patients unwilling or unable to follow post-operative care instructions
4. Active infection
5. Any contraindications identified in the package inserts for the Trinity Evolution product

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 documents provided with the Trinity Evolution product.
Note: Trinity Evolution should be used within 2 hours of thawing. In order to provide optimal cell viability, do not allow Trinity Evolution to dry out.
2. Right before placing Trinity Evolution into the funnel instrument, flush 5% Dextrose in Lactated Ringer's solution (saline is also acceptable) into the funnel for optimal expression of Trinity Evolution. Use a sterile spatula or spoon to gather and transfer the tissue into the Delivery System funnel instrument. Do not allow Trinity Evolution to sit in the funnel for an extended period of time and do not preload the instruments prior to use.
Note: The use of excessive packing force during this step may affect the viability of the cells within Trinity Evolution.
3. Once the tissue is placed into the funnel, use the Delivery System plunger instrument to gradually push the tissue form through to the distal end where it will enter the surgical site for application. When tamping the bone graft into the surgical site, variable force may be used for the proper flow through the funnel. When the plunger enters the narrow portion of the funnel, it should go all the way to the end without leaving any tissue in the narrow portion.
Note: In order to provide optimal cell viability, do not use excessive force in the delivery of Trinity Evolution to the surgical site.

Potential Adverse Effects:

As with any major surgical procedure involving instrumentation, infrequent possible adverse effects include, but are not limited to:

1. Neurological injury
2. Vascular or visceral injury
3. Foreign body (allergic) reaction to instruments, debris, corrosion products, including metallosis, straining, tumor formation, and/or autoimmune disease
4. Infection can result if instruments are not properly cleaned and sterilized
5. Hemorrhage
6. Cessation of any potential growth of the operated portion of the spine
7. Death
8. Potential complications associated with the Trinity Evolution product are described in the Package Insert or Instructions for Use provided with the implantable product.
9. Loss of cell viability within the Trinity Evolution material may occur with use of insertion force during insertion into the surgical site.

Warnings and Precautions:

The Trinity Evolution Delivery System should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with the device. The surgeon should be aware of the following when using the instrumentation:

1. The Trinity Evolution Delivery System instruments must be cleaned and sterilized prior to use
2. Use the instruments as intended and not under impaction unless specifically designed for this purpose

3. If used around the spinal cord and nerve roots, extreme caution should be taken
4. Care should be exercised in the handling and storage of instruments. Instruments should not be scratched, notched, or otherwise damaged since such actions may reduce functional performance. Store away from corrosive environments.
5. Instruments should be carefully placed in the cases and stored in a cool dry place when not in use.
6. Instruments should be examined for functionality or damage prior to use and any damaged instruments should not be used to implant devices.
7. Improper handling of instruments may result in malfunction during surgery.
8. Damage to implants from instruments must be avoided, or device failure could occur.
9. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not attempt to re-sterilize single-use implants that come in contact with body fluids.
10. Do not use excess force to deliver the Trinity Evolution material as it may impact the viability of the cells within the product
11. Do not store the Trinity Evolution material within the delivery system for extended periods of time as this may impact the viability of the cells within the product.

Cleaning:

After each use, ensure that no Trinity Evolution is left within the narrow tube of the funnel. All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization: The Trinity Evolution System components are supplied NON-STERILE. Prior to use, all components should be steam sterilized by the hospital using the recommended cycle:

Method: Steam	Or:	Method: Steam
Cycle: Gravity		Cycle: Prevac
Temperature: 270° F (132° C)		Temperature: 270° F (132° C)
Exposure time: 15 minutes		Exposure time: 4 minutes
Drying time: 30 minutes		Drying time: 30 minutes

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. at: complaints@orthofix.com.

Further information: A recommended surgical technique for the use of this system is available upon request from: Orthofix Inc.



Manufacturer:
 Orthofix Inc.
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GRAPHICAL SYMBOLS	
	Read Instructions Before Use
	Provided Non-Sterile
	Lot Number
	Catalog Number
	Manufacturer

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.