



O-GENESIS™
GRAFT DELIVERY SYSTEM

Operative Technique



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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.



INTRODUCTION

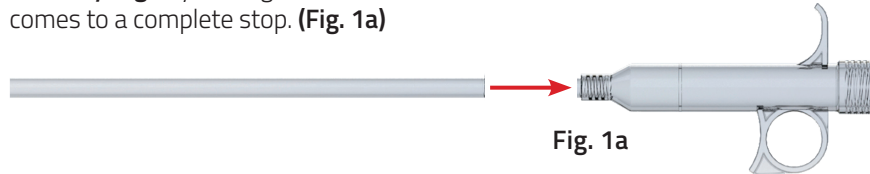
The O-GENESIS Graft Delivery System is designed to deliver allograft, autograft or synthetic bone graft material to an orthopedic surgical site. The system consists of a loading syringe, a loading plunger, a loading funnel, a delivery cannula and a delivery gun with an actuating trigger handle. The system is provided sterile and is for single-use only.



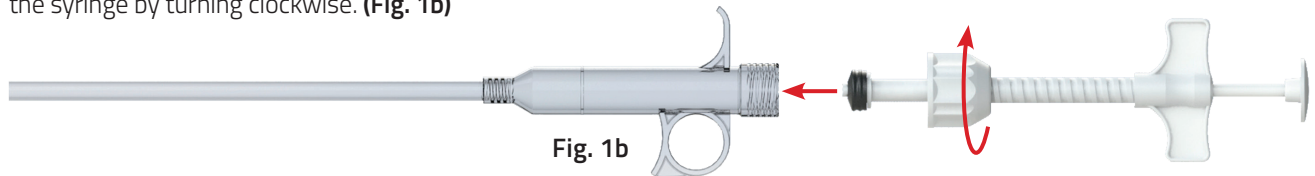
OPERATIVE TECHNIQUE

Loading of Bone Graft Material Using Syringe: If using hydrated and flowable bone graft material (ie, DBM, putty mixed with morselized autograft, synthetic putty), the syringe option should be used to load bone graft into the cannula.

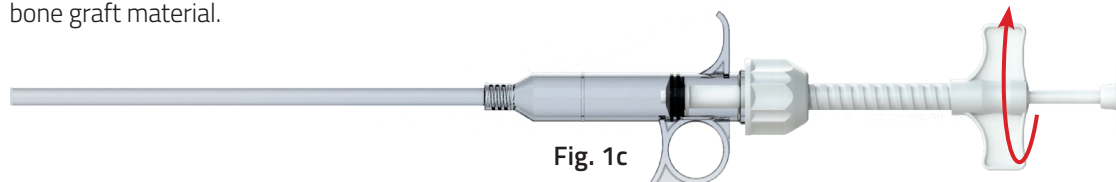
Thread the **Cannula** into the threads on the distal end of the **Syringe** by turning the cannula clockwise until it comes to a complete stop. (**Fig. 1a**)



Load the bone graft material into the syringe opening. Insert the **Plunger** and tighten the threaded cap onto the syringe by turning clockwise. (**Fig. 1b**)



Turn the **Plunger T-Handle** clockwise until the bone graft material has filled the cannula. (**Fig. 1c**) The cannula is capable of holding approximately 10cc of bone graft material.



NOTE: There is an indicator line on the syringe. If a substantial increase in resistance is felt before the stopper hits this line, rotate the T-Handle counterclockwise to relieve pressure. Push the push rod on the top of the T-handle to release pressure in the syringe. Rotate T-Handle quarter turn clockwise, and push the push rod. Repeat until bone graft is loaded into the cannula.

NOTE: Do not apply excess torque when the plunger stopper reaches the distal end of the syringe.

NOTE: If bone graft material is too dry or the size of the bone graft materials are too large, they may become lodged in the loading device or cannula, limiting the ability to load the bone graft.

NOTE: If loading of bone graft material using the syringe and plunger is unsuccessful, the funnel attachment can be used as an alternative.

Once the bone graft has been loaded into the cannula, unthread the cannula from the distal end of the syringe. **Cannula Caps** are provided to place on either ends of the cannula until ready to use. **(Fig. 1d)**



Fig. 1d

Loading Additional Cannulas with Bone Graft Material:

After removing the cannula from syringe or funnel, unscrew the threaded cap from the syringe by turning counterclockwise. **(Fig. 2a)**

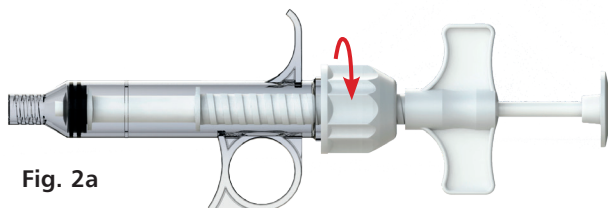


Fig. 2a

Turn the threaded cap towards the stopper until it hits the stop and is positioned furthest away from the T-handle. **(Fig. 2b)** Repeat steps as shown in Fig. 1a - Fig 1d.



Fig. 2b

NOTE: Additional cannula and caps are available if bone graft material for the orthopedic surgical site requires more than one cannula.

NOTE: Remove any residual bone graft material from the syringe prior to loading additional cannulas. Do not use the same cannula for multiple deliveries.

Loading of Bone Graft Material Using the Funnel: The funnel option should be utilized to load granular autograft and allograft as well as any dry bone graft material.

Thread the **Funnel** onto the threads of the cannula by turning clockwise until it comes to a complete stop.
(Fig. 3a)



Fig. 3a

Use a blunt-tip surgical instrument (e.g. small tamp) to push the bone graft material through the funnel and into the cannula.

NOTE: Do not over pack the cannula.

Once the bone graft has been loaded into the cannula, unthread the cannula from the funnel. Cannula caps are provided to place on either ends of the cannula until ready to use. **(Fig. 3b)** Repeat steps as shown in Fig. 3a - Fig. 3b for additional cannulas.



Fig. 3b

Delivery of Bone Graft Material Utilizing the Delivery Gun:

Lift and hold the actuator of the **Graft Delivery Gun**, pull the ring of the ratchet plunger away from the gun until it stops. **(Fig. 4a)**



Remove the caps from the cannula, thread the proximal end of the cannula to the adapter of the graft delivery gun until it comes to a complete stop. **(Fig. 4b)**



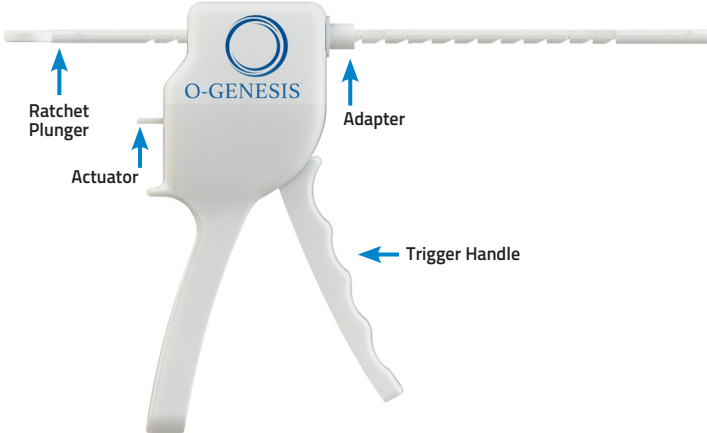
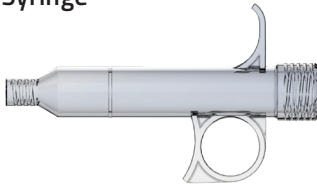
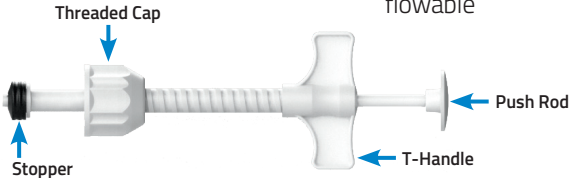



Place the distal end of the cannula into the surgical site. Squeeze the trigger handle of the graft delivery gun to deliver the bone graft material. **(Fig. 4c)**



NOTE: Variability in the bone graft material could lead to variable loads applied to deliver bone graft.












NOTE: Excessive force should not be applied during delivery as it may result in disengagement of the cannula.

System Components

Component	Description	Qty
Graft Delivery Gun	Delivery gun with ratchet plunger, actuator and trigger handle	1
		
Syringe	Syringe for use when loading bone graft material that is hydrated and flowable	1
		
Plunger	Plunger for use when loading bone graft material that is hydrated and flowable	1
		
Cannula	Length: 200mm, Outer Diameter: 8mm, Inner Diameter: 6.5mm	1
		
Cannula Caps	Cannula Caps: optional to maintain hydration of bone graft material in the cannula	2
		
Funnel	Funnel for use when loading granular autograft or allograft, and dry bone graft material	1
		

The O-GENESIS Graft Delivery System is provided STERILE and intended for SINGLE USE ONLY. Do not re-sterilize. Do not use if the package is opened, damaged, or if the expiration date has passed. Please discard all opened and unused components.

Caution: Extreme care must be taken when using instruments near vital organs, nerve and vessels.

Rx Only Federal (U.S.A.) law restricts this device to sale by or on the order of a physician	
 See Instructions for Use	 Manufacturer
 Orthofix.com/IFU	 Date of Manufacturer
 Single Use Only Do Not Reuse	 Use By Date
 Catalog Number	 Lot Number
 Sterilized Using Irradiation	 Do Not Resterilize
 Do Not Use if Package is Damaged	

Part Numbers	Description
35-6000SP	O-GENESIS Graft Delivery System
35-6001SP	O-GENESIS Cannula and Caps

Please visit [Orthofix.com/IFU](https://www.orthofix.com/IFU) for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



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