INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

℞ Only

Orthofix Inc.
3451 Plano Parkway
Lewisville, Texas 75056-9453 U.S.A.
1-214-937-3199
1-888-298-5700
www.orthofix.com

Device System Name:

O-GENESIS™ Graft Delivery System

Click directory below for desired language

AW-35-9903 Rev.AC

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English EN

Device System Name:

O-GENESIS™ Graft Delivery System

Description:
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.

Indications for Use:
The O-GENESIS Graft Delivery System is intended to be used for the delivery of allograft, autograft or synthetic bone graft material to an orthopedic surgical site.

Contraindications:
The O-GENESIS Graft Delivery System is not designed for any use except as indicated. The physician should be familiar with any contraindications of the bone graft material being delivered. For a full list of contraindications, please refer to the package insert of the specific bone graft material. Contraindications specific to the delivery system include, but are not limited to:

1. Allergies to biocompatible polymer materials; High Density Polyethylene (HDPE)

Potential Adverse Events:
For a complete list of potential adverse events, please refer to the package insert of the specific bone graft material being used. A list of the possible adverse events associated with this device includes but is not limited to:

1. Neurological injury; pain, paralysis
2. Allergic reaction to foreign materials
3. Infection

Note: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

Warnings and Precautions:

1. The O-GENESIS Graft Delivery System is for single patient use only.
2. The O-GENESIS Graft Delivery System is sold STERILE and therefore must NOT be re-sterilized before use.
3. The O-GENESIS Graft Delivery System must be used within the STERILE shelf-life as indicated on the packaging.
4. The use of a surgical instrument for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
5. Extreme care must be taken when using instruments near vital organs, nerve and vessels.
6. For use only by qualified staff and physicians in accordance with the operative technique provided by Orthofix.
7. Federal law (USA) restricts this device to sale by or on the order of a physician.

Cleaning and Sterilization:
The O-GENESIS Graft Delivery System is provided STERILE. The components of the system are sterilized using gamma irradiation sterilization. Do not re-sterilize. Please discard all opened and unused components.

Packaging:
Packages should be intact upon receipt. The O-GENESIS Graft Delivery System should be carefully checked for completeness and all components should be carefully checked for damage prior to use. If the package is opened, damaged, or if the expiration date has passed, products should not be used and should be returned to Orthofix.

Product Complaints:
Any Health Care Professional (e.g., customer or user of this system of products) 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, by telephone at 1-214-937-3199 or 1-888-298-5700 or by e-mail at complaints@orthofix.com.

Further Information:
A recommended operative technique for the use of this system is available upon request from Orthofix at the phone numbers provided above.

Latex Information:
The implants, instruments and/or packaging material for the O-GENESIS Graft Delivery System are not formulated with and do not contain natural rubber. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

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

℞ 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 Manufacture
2	Single Use Only Do Not Reuse		Use By Date
REF	Catalogue Number	LOT	Lot Number
STERILE R	Sterilized Using Irradiation	2 STERILIZE	Do Not Resterilize
	Do Not Use if Package is Damaged		

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