Mixing and Delivery System

ORTHOFIX®

STERILE - Single Use Only

CAUTION: ***Federal (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.***

IMPORTANT INFORMATION FOR PHYSICIANS, SURGEONS, AND/OR STAFF

DESCRIPTION:
The Mixing and Delivery System is used to mix graft material such that it can be delivered to the patient. The system is comprised of the mixing/delivery syringe and auxiliary components including a threaded spindle with nut, open bore luer cap, pusher, cannulae and bead mat which provide alternative methods of delivery for the mixed material.

MATERIALS:
The Mixing and Delivery System components are manufactured from medical grade polymers including polyamide (PA), polypropylene (PP), Polybutylene terephthalate (PBT) and Medical Grade Silicone (DC QP1-250)

INDICATIONS:
The Mixing and Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site

PRECAUTIONS:

Surgeons are advised to review the product specific surgical technique prior to performing any surgery.
General use instructions are below.
Contact your Bone Solutions representative for an onsite demonstration.

WARNINGS:
1. Prior to use, thoroughly read these instructions for use. Follow the instructions outlined in this document for successful mixing of the graft material.
2. Before use, inspect the instrument carefully for damage, wear and / or non-functioning parts.
3. Keep the instructions for use accessible to all staff.
4. Never use or process damaged or defective devices. Contact your local sales representative or Bone Solutions for replacement.
5. **DO NOT RESTERILIZE:** The Mixing & Delivery System is intended for single use only.
6. **DO NOT REUSE:** The Mixing & Delivery System is intended to be used for mixing one time only - to only mix one mixture of materials. Repeated use could result in device failure and/or contamination of graft materials from previous use debris.
7. Only mix with the specified volumes of materials as directed by the IFU of the graft materials.
8. **DO NOT OVERFILL:** Do not overfill mixing syringe with materials. Overfilling syringe could result in device failure and/or ineffective mixing of the graft material.
9. If the Mixing & Delivery System does not function correctly as outlined in the instructions of this document, **DO NOT USE.** Discard the Mixing & Delivery System and graft materials contained in it.
10. 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.
11. Make sure the product is only used by qualified or trained staff.
12. Follow the general guidelines and aseptic principles when handling sterile items.

CONTRAINDICATIONS:
Contraindications include, but are not limited to:
1. Blood supply limitations and previous infections, which may retard healing.
2. Any active infection or blood supply limitations.
3. Do not use for kyphoplasty or vertebroplasty procedures.

STERILIZATION
This device is provided sterile (gamma radiation).
Contents are **STERILE** unless the barrier packaging is open or damaged; **DO NOT USE** if the package is open or damaged.
STORAGE CONDITIONS
Sterile devices must be stored in the original unopened packaging, and should not be used after the expiration date.
Store at room temperature.

MIXING INSTRUCTIONS:

Step 1:
Remove the preassembled white syringe cap and winged female luer cap at the distal end of syringe by unscrewing counter clockwise. Pull the plunger all the way back.

Step 2:
Attach funnel on the open bore of syringe. Pour contents of powder into syringe. Open vial of premeasured liquid solution and pour into syringe and remove the funnel.

Step 3:
Replace white syringe cap by screwing clockwise onto the open bore. Make sure the winged female lure cap is connected to the end of the white syringe cap.

Step 4:
Remove the support rod from the mixing stick by gently pushing the internal mixing stick out of the support rod. Vigorously push and pull the mixing stick for a minimum of 2 minutes with a twisting motion until the powder and liquid solution are thoroughly mixed and have a slurry consistency.
*****Technique Tip: Increased ambient temperature of the operating room will accelerate the curing time.**

Step 5:
Pull the mixing stick back until plunger is at the base of the syringe and reinstall the support rod on the mixing stick (See step 4).

Step 6, Plunger delivery:
Remove winged female cap from the white syringe cap. Then, purge the excess air in the syringe by carefully pressing on the plunger. Now, the material is ready to be injected.
*****If a moldable product is desired, remove the white syringe cap on the distal end of the syringe to extrude the material.**

Step 7, Optional spindle drive delivery:

Remove the support rod from the mixing stick by gently pushing the internal mixing stick out of the support rod (See step 4). Snap off the wedge-shaped end of the mixing stick. Attach the spindle nut to the base of the syringe. Ensure both sides of the nut are attached. Insert the threaded spindle over the mixing stick and rotate clockwise to advance the spindle through the spindle nut. Remove the winged female cap from the white syringe cap. Purge the excess air in the syringe by slowly turning the spindle handle clockwise. Now, the material is ready to be injected.

DELIVERY INSTRUCTIONS:

Option 1, Luer cannula:
Attach the open luer cannula to the preassembled white syringe cap by threading its end into the luer of the white syringe cap.

Option 2, Open bore cannula:
Step 1. Remove the preassembled white syringe cap on the distal end of the syringe. Attach the open bore syringe cap by threading it clockwise onto the syringe barrel. Attach the open threaded cannula to the syringe cap by threading it clockwise onto the open bore syringe cap.
Step 2. Material that is trapped within the open threaded cannula can be fully extruded. Detach the open bore syringe cap and open threaded cannula assembly from the syringe barrel by threading it counterclockwise. Insert the pusher tip into the underside of the open bore syringe cap until all material is removed.

Option 3, Bead Mat:
Apply hydrated allograft, autograft, or synthetic bone graft material to the bead mat for a uniform bead shape.

Refer to STI for setting times.

SYMBOLS GLOSSARY:

Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard[1]
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	5.4.4	Caution	Caution: Federal Law restricts this device to sale by or on the order of a physician
	21 CFR 801.109(b)(1)	Prescription only	Requires prescription in the United States

[1]With the exception of the Rx Only symbol, all information is from ISO 15223-1:2016, Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements, FR recognition number 5-117.

PRODUCT COMPLAINTS:

Any healthcare professional who has any complaints or is dissatisfied with this product should notify Orthofix US LLC,
3451 Plano Pkwy, Lewisville, TX 75056
Phone: (214) 937-2000
Fax: (800) 445-1923
Email: OSI-CustomerService@Orthofix.com

FURTHER INFORMATION:

For product information, sales inquiries, customer service, or to obtain a surgical technique, please contact your sales representative or Orthofix US LLC Customer Service at Email: OSI-CustomerService@Orthofix.com

ORTHOFIX®

Distributed by:
Orthofix US LLC
3451 Plano Pkwy,
Lewisville, TX 75056
Phone: (214) 937-2000
Fax: (800) 445-1923

Manufactured by:
Bone Solutions Inc.
5712 Colleyville Blvd. Suite 210
Colleyville, Texas 76034
Phone: 817-809-8850
Fax: 866-673-0111