Mixing and Delivery System

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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, 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 a 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 & DELIVERY INSTRUCTIONS
Refer to the Mixing Usage Guide for Mixing, Delivery and Setting times.

SYMBOLS GLOSSARY

Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EC, 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	Indicate 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	Indicate 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 sterilized.
	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 the sale by or on the order of a physician
	21 CFR 801.109(b)(1)	Prescription only	Requires prescription in the United States
	Fig. 1 ASTM F2503-23	MR Safe	An an item that poses no known hazards resulting from exposure to any MR environment.
With the exception of the RX symbol & MR, all information is from ISO 15223-1:2016, Medical Devices - Symbols to be used with medical device label, labeling and information to be supplied - Part1: General requirements, FR recognition number 5-117.			

PRODUCT COMPLAINTS
Any healthcare professional who has any complaints or is dissatisfied with this product should notify Bone Solutions Inc, 5712 Colleyville Blvd., Colleyville, TX 76034, USA.
Telephone: 817 809-8850 Email: customerservice@bonesolutions.net

FURTHER INFORMATION
For product information, sales inquiries, customer service, or to obtain a surgical technique, please contact your sales representative or Bone Solutions Inc. Customer Service at Email: customerservice@bonesolutions.net