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**01-50-1464**  
Date: 2010-06



## CoAxial Applicator System

### ATTENTION OPERATING SURGEON

**NOTE: FOR SINGLE USE ONLY. Discard the entire disposable system after one use using an acceptable method for material potentially contaminated with blood products.**

#### DESCRIPTION

The CoAxial Applicator System consists of the CoAxial Spray Kit and the CoAxial Cannula Tip. Within the CoAxial Spray Kit is a sterile, single-use syringe-type device (CoAxial Applicator), a Y-connector, and Spray Tip. The CoAxial Applicator is comprised of an inner, smaller chamber and an outer, larger chamber designed to simultaneously hold, and keep separate, two non-homogeneous liquids. The Y-connector facilitates loading of the liquids into the separate chambers of the CoAxial Applicator. The two liquids can subsequently be applied simultaneously by attaching an applicator tip and actuating the CoAxial Applicator plunger. While the Spray Tip is included in the CoAxial Spray Kit as one application option, the Cannula Tip is sold separately.

#### INDICATIONS FOR USE

The CoAxial Applicator System is designed to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials for application to an orthopedic surgical site with autologous blood, plasma, platelet rich plasma, or other specific blood component(s) as deemed necessary by the clinical use requirements.

In addition, the CoAxial Applicator System is intended for the application of autologous blood, plasma, platelet-rich plasma, or other specific blood component(s), as deemed necessary by the surgeon's determination of the clinical use requirements to facilitate the preparation of soft tissue autograft or allograft material prior to the application of the graft material to a repair site.

#### MATERIALS

Applicator Syringe	Acrylic Polymer, Polycarbonate
Applicator Plunger	Acrylonitrile Butadiene Styrene (ABS), Thermoplastic Elastomer, Silicone Lubricant
Cannula Tip	Polycarbonate, Stainless Steel, Silicone, ABS
Y-Connector	ABS, Silicone
Spray Tip	ABS, Silicone

All components in this kit are latex-free.

#### CONTRAINDICATIONS

None known.

#### WARNING AND PRECAUTIONS

1. Single use device. Do not reuse. Do not resterilize.
2. Do not use after expiration date.
3. Do not use if package is opened or damaged.
4. The end user is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
5. Not for intravascular use.
6. Only intended for final application of a 10:1 ratio.
7. Device is single use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.

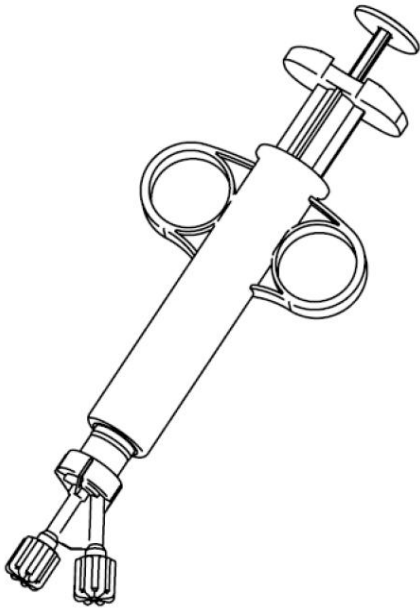
#### STERILITY

The CoAxial Applicator System is sterilized by exposure to a minimum dose of 25 kGy of gamma irradiation. Single Use Only. Do not use any component from an opened or damaged package. Do not re-sterilize. Do not use past expiration date.

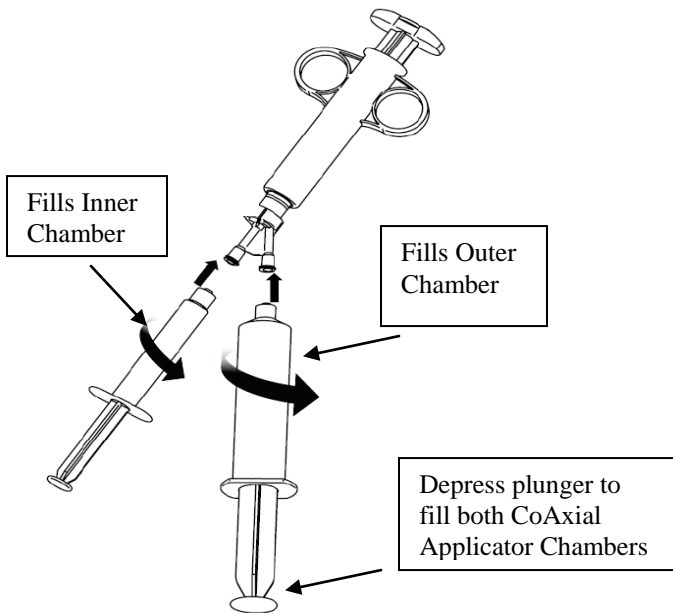
#### INSTRUCTIONS FOR USE

**NOTE: Use standard aseptic technique throughout the following procedure.**

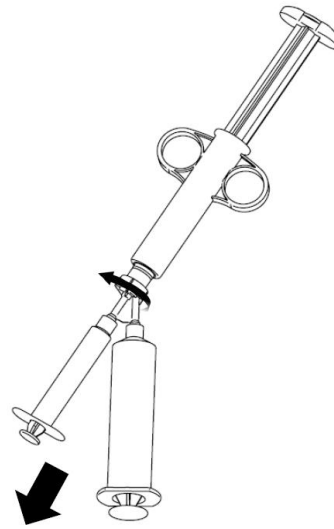
1. **TRANSFER:** Sterile Inner Package, containing the CoAxial Applicators, Y-connectors, and Spray Tips to the sterile field.
2. **REMOVE:** CoAxial Applicators, Y-connectors, and Spray Tips from the sterile packages.
3. **ATTACH:** Y-connector to CoAxial Applicator (Figure1).
4. **ATTACH:** Syringe with liquid component of greater volume to Y-connector by first removing the red cap, then twisting the syringe onto the threaded port. This will connect the syringe to the outer chamber of the CoAxial Applicator. (Figure 2).
5. **ATTACH:** Syringe with liquid component of lesser volume to Y-connector by first removing the clear cap, then twisting the syringe onto the threaded port. This will connect the syringe to the inner chamber of the CoAxial Applicator. (Figure 2).
6. **FILL CoAxial Applicator:** By depressing the plunger of the syringe used to fill the outer chamber. Both chambers of the CoAxial Applicator will fill. (Figure 2 )  
**NOTE: Filling is complete when either the smaller or larger syringe is void of liquid. At this time, stop depressing plunger to ensure a 10:1 ratio.**
7. **REMOVE:** Y-connector and attached syringes and discard. (Figure 3).
8. **ASSEMBLE:** Applicator Tip (i.e. Spray Tip or Cannula Tip) to CoAxial Applicator by twisting onto the threaded hub. (Figure 4).  
**NOTE: Ensure tip is tightened before use.**
9. **Applicator is ready for use.**



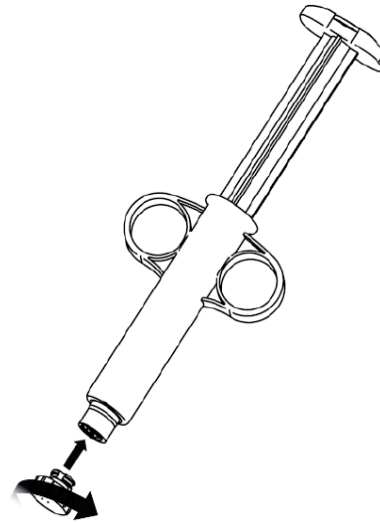
**Figure 1:** CoAxial Applicator with attached Y-connector



**Figure 2:** Syringes being assembled to the Y-connector



**Figure 3:** Removal of the Y-connector with attached syringes



**Figure 4:** Spray Tip being attached to the CoAxial Applicator

**Caution:** Federal Law (USA) limits this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968

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## Symbol Legend



Manufacturer



Date of Manufacture



Do Not Reuse



Caution



Sterilized using Ethylene Oxide



Sterilized using Irradiation



Sterile



Sterilized using Aseptic Processing Techniques



Sterilized using Steam or Dry Heat



Use By



WEEE Device



Catalogue Number



Batch Code



Flammable



Authorized Representative in the European Community