

The DuraSeal Dural Sealant System is intended for use as an adjunct to sutured dural repair during cranial surgery to provide watertight closure.

The DuraSeal Exact Spine Sealant System is indicated for use as an adjunct to sutured dural repair during spinal surgery to provide watertight closure.

Kit Components



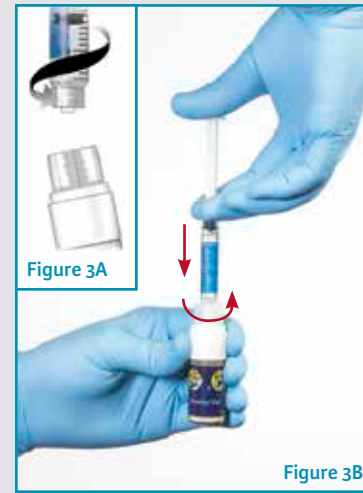
Extended Tip Applicator

The Extended Tip Applicator combines the versatility of a malleable manual applicator with extended reach and added visibility. A special tip allows users to pause and resume spraying of the sealant during application.

Step 1: Preparation



Depress threaded fitting of vial cap (Figure 1). Ensure red line is no longer visible (Figure 2).



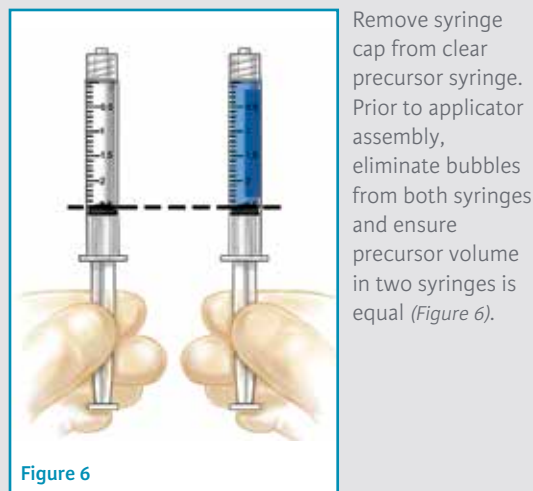
Remove syringe cap from blue precursor syringe. Screw blue precursor syringe onto powder vial (Figure 3A), then inject syringe contents into vial (Figure 3B).



Gently shake vial/syringe assembly until powder is completely dissolved. The solution will turn blue (Figure 4).



Invert vial/syringe assembly, then draw vial contents back into syringe (Figure 5A). Unscrew syringe from vial and discard vial (Figure 5B).

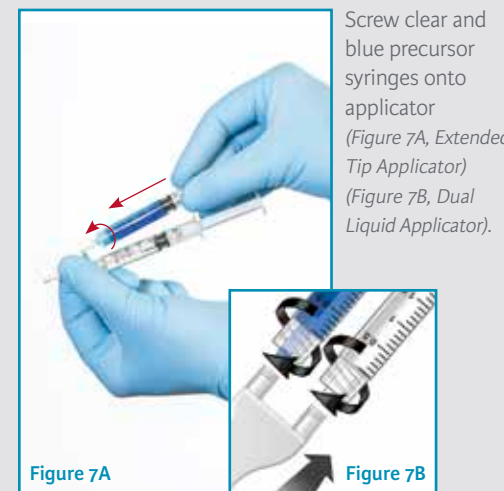


Remove syringe cap from clear precursor syringe. Prior to applicator assembly, eliminate bubbles from both syringes and ensure precursor volume in two syringes is equal (Figure 6).

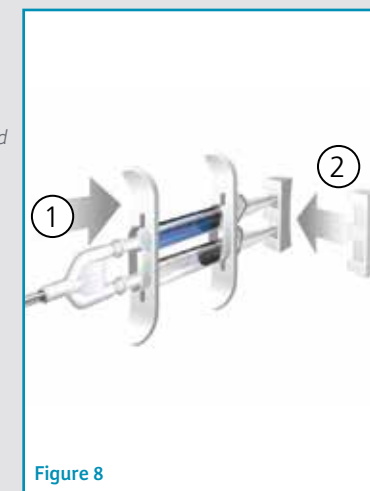
Step 2: Assembly for Extended Tip Applicator or Dual Liquid Applicator

(Figures 7, 8, 9)

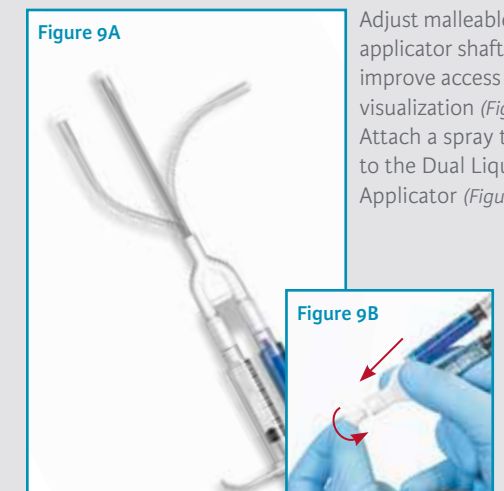
(Figures 7A, 8, 9A)



Screw clear and blue precursor syringes onto applicator (Figure 7A, Extended Tip Applicator) (Figure 7B, Dual Liquid Applicator).



Slide syringe holder (Figure 8-1) along syringe barrels until it fits snugly against syringe flanges. Attach plunger cap (Figure 8-2) to syringe plungers.




Adjust malleable applicator shaft to improve access or visualization (Figure 9A). Attach a spray tip to the Dual Liquid Applicator (Figure 9B).



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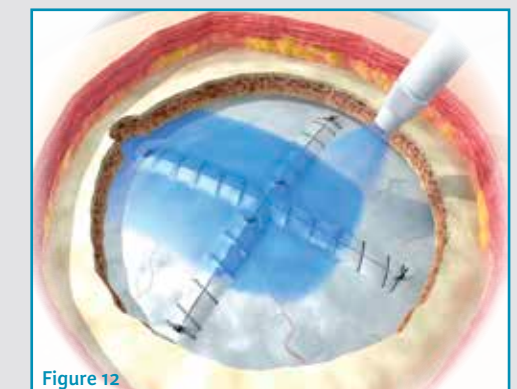
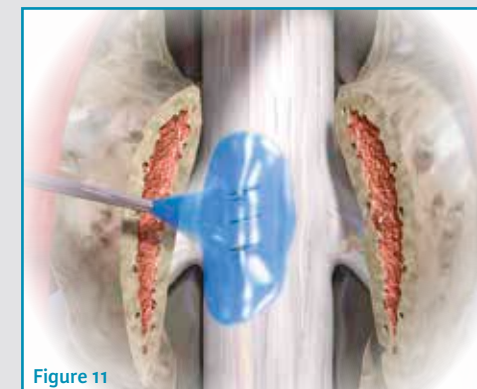
 Integra LifeSciences Corporation
 311 Enterprise Drive
 Plainsboro, NJ 08536 ■ USA

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Final Step: Application



1. Prepare application site by removing all blood clots and fluid.
2. While in surgical field, whenever anatomically possible, briefly spray sealant on gauze and without interrupting flow move to the target site (Figure 10).



3. Position applicator tip 2-4 cm from the target site, depress syringes using strong, even pressure (Figure 11, 12).
4. Using a continuous motion, apply an even, approximately 1-2 mm thin coating of hydrogel.

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The DuraSeal Exact Spine Sealant System is indicated for use as an adjunct to sutured dural repair during spinal surgery to provide watertight closure.

Kit Components



For Precise, Controlled Delivery

The MicroMyst® applicator is a multi-lumen cannula with a filtered air line that is used in conjunction with the Flow Regulator for controlled, air-assisted application.

- Provides a fine mist for a precise application
- 14 cm - provides extended reach
- Shaft can be bent to improve visualization
- 3.3 mm cannula diameter



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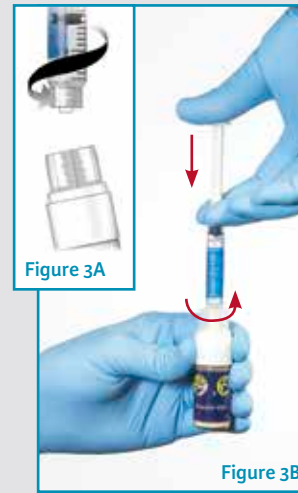
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Step 1: Preparation



Depress threaded fitting of vial cap (Figure 1). Ensure red line is no longer visible (Figure 2).



Remove syringe cap from blue precursor syringe. Screw blue precursor syringe onto powder vial (Figure 3A), then inject syringe contents into vial (Figure 3B).

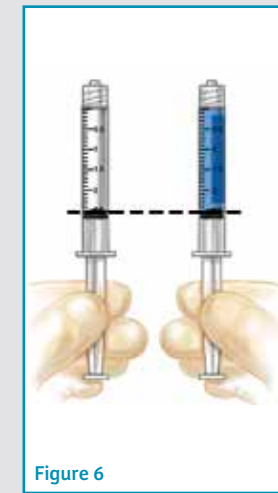


Gently shake vial/syringe assembly until powder is completely dissolved. The solution will turn blue (Figure 4).



Invert vial/syringe assembly, then draw vial contents back into syringe (Figure 5A).

Unscrew syringe from vial and discard vial. (Figure 5B).



Remove syringe cap from clear precursor syringe. Prior to applicator assembly, eliminate bubbles from both syringes and ensure precursor volume in two syringes is equal (Figure 6).

Step 2: MicroMyst® Applicator Assembly



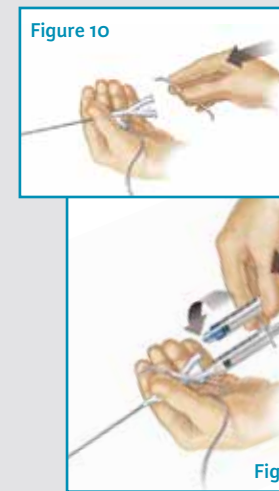
Ensure the Flow Regulator is connected to a compressed air or Nitrogen source (Figure 7).

Confirm the nitrogen source is set to 50 - 200psi.



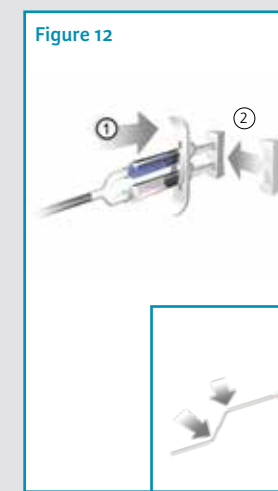
Connect MicroMyst applicator line to Flow Regulator (Figure 8).

Ensure air is flowing through MicroMyst applicator (Figure 9).



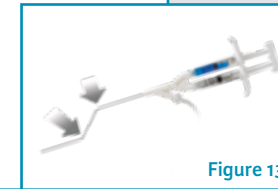
Position syringe holder over applicator fittings (Figure 10).

Screw clear and blue precursor syringes onto applicator (Figure 11).



Slide syringe holder (Figure 12-1) along syringe barrels until it fits snugly against syringe flanges. Attach plunger cap (Figure 12-2) to syringe plungers.

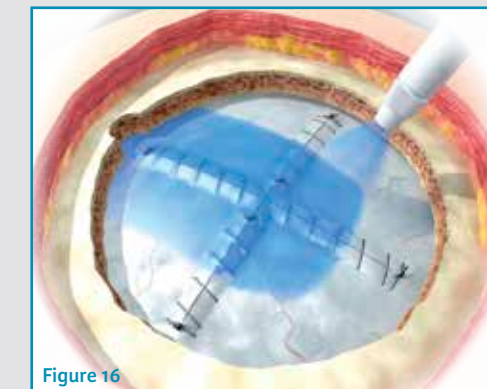
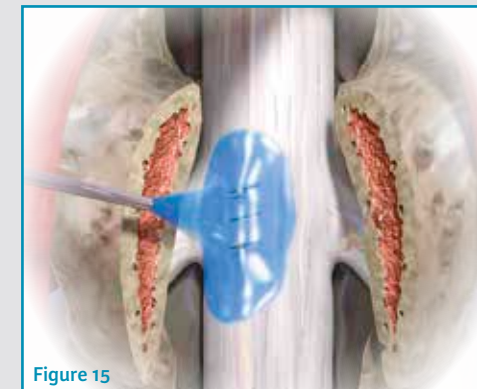
Adjust malleable applicator shaft to improve access or visualization (Figure 13).



Final Step: Application



1. Prepare application site by removing all blood clots and fluid.
2. While in surgical field, whenever anatomically possible, briefly spray sealant on gauze and without interrupting flow move to the target site (Figure 14).



3. Position applicator tip 1-4 cm from the target site, depress syringes using strong, even pressure (Figure 15, 16).
4. Using a continuous motion, apply an even, approximately 1-2 mm thin coating of hydrogel.