

2009-4437b1-10

Direction of Use

The Sponsor did not define a separate surgical technique during the investigation of the DuraSeal Spine Sealant. For your convenience, the instructions provided in the Package Insert are translated below.

DIRECTIONS FOR USE

Device Preparation – 2 mL Configuration REF 20-4300

A. Preparing the Blue Precursor

1. Remove the polymer kit tray and the MicroMyst Applicator from their respective outer pouches and introduce into the sterile field.
2. Remove lid from polymer kit tray.
3. Remove and discard syringe cap from Diluent Syringe (blue label).
4. Attach the Diluent Syringe to the Powder Vial.
5. Without depressing the syringe plunger, pierce the vial seal until it is fully depressed (twisting is not required). The entire threaded portion of the vial cap should be depressed bellow the level of the surrounding plastic vial rim.
 
6. Inject syringe contents into the vial.
7. Gently shake the vial/syringe assembly until the powder is completely dissolved.
 
8. Invert the vial/syringe assembly, and draw the vial contents back into the syringe.
 
9. Unscrew the syringe from the vial and discard the vial.
10. Remove syringe cap from Clear Precursor Syringe.
11. Ensure that the

precursor volume in each syringe is equal.

B. Assembling the MicroMyst Applicator

1. Remove Applicator assembly from inner pouch.
2. Remove and discard the protective sheath over the Applicator shaft and tape from the Applicator air line.
3. Connect the Applicator air line to the compressed air source (Confluent Surgical Flow Regulator or Confluent Surgical Air Pump), and turn on air source.
4. Attach the Clear and Blue precursor syringes to the Applicator. 
5. Attach the Syringe Holder (A) to syringe barrels and the Plunger Cap (B) to syringe plungers. 
6. Applicator metal shaft and flexible tip may be angled to improve access or 

Device Preparation – 5 mL Configuration REF 20-4004

A. Preparing the Blue Precursor

12. Remove the polymer kit tray from its outer pouch and introduce into the sterile field.
13. Remove lid from polymer kit tray.
14. Remove and discard syringe cap from Diluent Syringe (blue label).
15. Attach the Diluent Syringe to the Powder Vial.
16. Without depressing the syringe plunger, pierce the vial seal until it is fully depressed (twisting is not required). The entire threaded portion of the vial cap should be depressed below the level of the surrounding plastic vial rim. 
17. Inject syringe contents into the vial.

18. Gently shake the vial/syringe assembly until the powder is completely dissolved.



19. Invert the vial/syringe assembly, and draw the vial contents back into the syringe.



20. Unscrew the syringe from the vial and discard the vial.
21. Remove syringe cap from Clear Precursor Syringe.
22. Ensure that the precursor volume in each syringe is equal.

B. Assembling the Dual Liquid Applicator

1. Attach the Clear and Blue precursor syringes to the Y-Applicator.
2. Attach the Syringe Holder (A) to syringe barrels and the Plunger Cap (B) to syringe plungers.



Note:

Avoid touching the plunger cap before application to avoid inadvertent precursor injection and tip plugging

3. Attach one Spray Tip to the Y-Applicator.

Hydrogel Application **REF 20-4300, REF 20-4004**

Note:

- Achieve hemostasis and minimize fluid (CSF, blood) outflow from the target site.
- Ensure that 2-3 mm margins around the defect edge are clear of blood clots, hemostatic reagents and/or loose connective tissue.

When using the MicroMyst Applicator:

1. Prime the Applicator by dispensing a small amount of hydrogel outside the target site until both precursors flow evenly.
2. Paint the target site with a thin coating of hydrogel by gently pressing the Plunger Cap until a thin layer, approximately 1 -2 mm in thickness, is formed.

Note: Excess gel thickness should be avoided due to hydrogel swelling. Gel thickness should be limited to 1-2 mm. [do we really want to say this?

Note: The blue color of the hydrogel aids in gauging thickness. As the thickness of the hydrogel increases to 2 mm, the fine epidural vasculature becomes less visible.

When using the Dual Liquid Applicator

3. Position the applicator 2-4 cm from the target site. Apply firm even pressure to the center of the plunger cap to dispense the precursors. Rapid initial spraying, followed by a slower controlled rate is recommended.
4. Continue applying the hydrogel until a thin (1 – 2 mm) coating is formed.
Note: If delivery is interrupted and the spray tip is plugged, remove the spray tip, wipe the applicator tip, attach a new spray tip and continue delivery.
Note: The blue color of the hydrogel aids in gauging thickness. As the thickness of the DuraSeal hydrogel increases to 2 mm, the fine epidural vasculature becomes less visible.
5. Hydrogel application beyond the defect edges may be removed with scissors or mechanical disruption. Irrigation immediately after the sealant has solidified is permitted.

STORAGE

The DuraSeal Xact Sealant System should be stored at or below 77 °F (25°C).