Integra®

DuraSeal® Dural Sealant System
Assembly & Use

Limit uncertainty by using the quick and easy to use DuraSeal® dural sealant system to ensure a watertight closure.

INTEGRA®
LIMIT UNCERTAINTY

Dual Liquid Applicator

Kit Components

Powder Vial

Blue Precursor Syringe

Clear Precursor Syringe

Plunger cap

Syringe holder

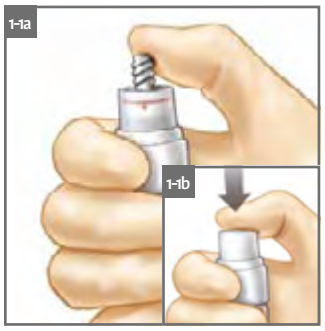
Spray Tips

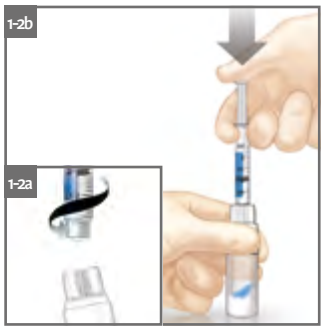
Dual liquid applicator

Step 1 • Preparation

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

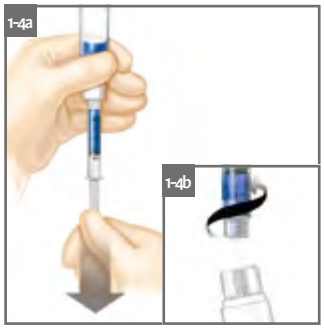
1-2 Remove syringe cap from blue precursor syringe. Screw blue precursor syringe onto powder vial (Figure 1-2a), then inject syringe contents into vial (Figure 1-2b).



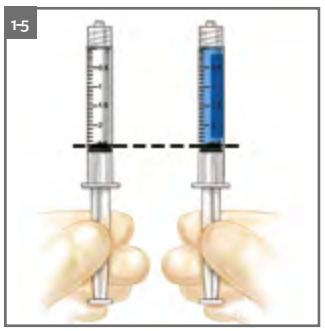


1-3 Gently shake vial/syringe assembly until powder is completely dissolved. The solution will turn blue (Figure 1-3).

1-4 Invert vial/syringe assembly, then draw vial contents back into syringe (Figure 1-4a). Unscrew syringe from vial and discard vial (Figure 1-4b).



1-5 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 1-5).

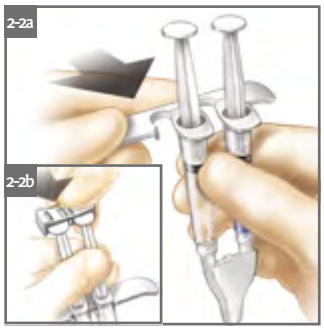


Step 2 • Assembly

2-1 Screw clear and blue precursor syringes onto applicator (Figure 2-1).

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

2-3 Attach a spray tip to the Dual Liquid Applicator (Figure 2-3).



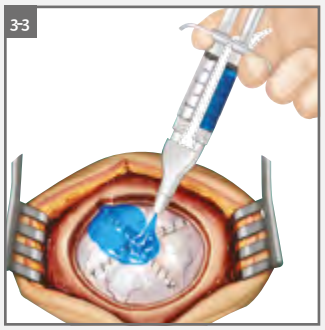
Final step • Application

3-1 Prepare application site by removing all blood clots and fluid.

3-2 Do not prime Dual Liquid Applicator prior to use, as plugging may result.

3-3 Position Dual Liquid Applicator tip (Figure 3-3) approximately 2 cm from target site. Rapidly depress syringes to ensure precursor mixing and spray-like application of gel.

3-4 Apply sealant to create 1-2 mm maximum thickness.



Extended Tip Applicator

Kit Components

Powder Vial

Blue Precursor Syringe

Clear Precursor Syringe

Plunger cap

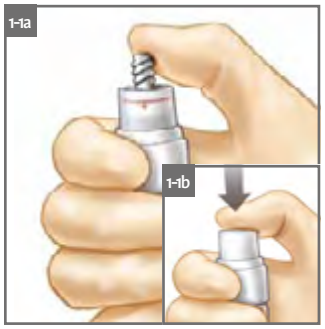
Syringe holder

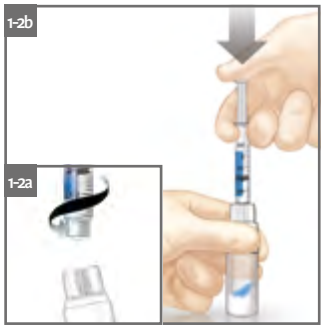
Extended Tip Applicator
(to be ordered separately)

Step 1 • Preparation

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

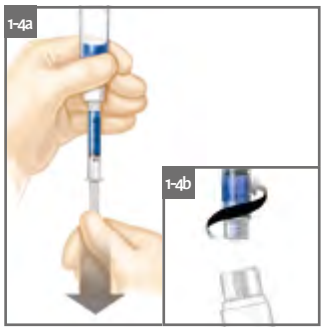
1-2 Remove syringe cap from blue precursor syringe. Screw blue precursor syringe onto powder vial (Figure 1-2a), then inject syringe contents into vial (Figure 1-2b).



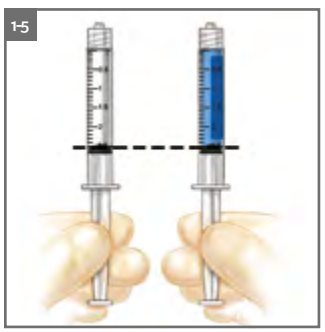


1-3 Gently shake vial/syringe assembly until powder is completely dissolved. The solution will turn blue (Figure 1-3).

1-4 Invert vial/syringe assembly, then draw vial contents back into syringe (Figure 1-4a). Unscrew syringe from vial and discard vial (Figure 1-4b).



1-5 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 1-5).

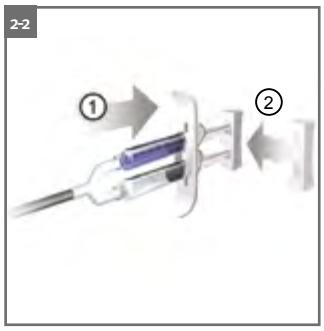


Step 2 • Assembly

2-1 Screw clear and blue precursor syringes onto applicator (Figure 2-1a).

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

2-3 Adjust malleable applicator shaft to improve access or visualization (Figure 2-3).

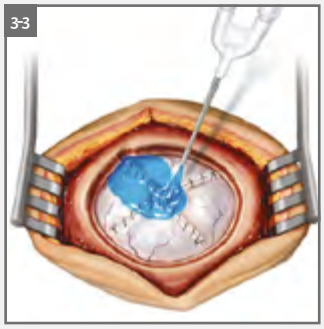


Final step • Application

3-1 Prepare application site by removing all blood clots and fluid.

3-2 While in surgical field, whenever anatomically possible, briefly spray sealant on gauze and without interrupting flow move to the target site (Figure 3-2).

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



MicroMyst® Applicator

Kit Components

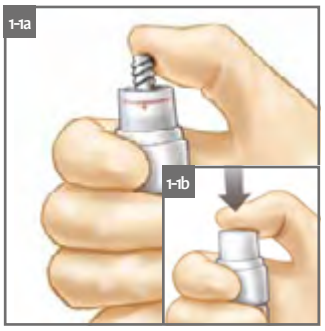
Powder Vial | Blue Precursor Syringe | Clear Precursor Syringe | Plunger cap | Syringe holder

MicroMyst® Applicator*
(to be ordered separately)

Step 1 • Preparation

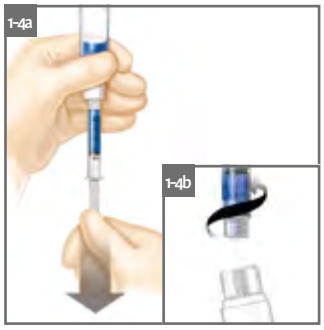
1-1 Depress threaded fitting of vial cap (Figure 1-1a). Ensure red line is no longer visible (Figure 1-1b).

1-2 Remove syringe cap from blue precursor syringe. Screw blue precursor syringe onto powder vial (Figure 1-2a), then inject syringe contents into vial (Figure 1-2b).

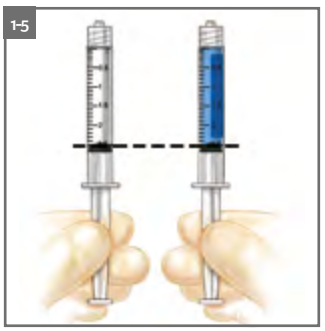


1-3 Gently shake vial/syringe assembly until powder is completely dissolved. The solution will turn blue.

1-4 Invert vial/syringe assembly, then draw vial contents back into syringe (Figure 1-4a). Unscrew syringe from vial and discard vial (Figure 1-4b).



1-5 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 1-5).



*MicroMyst® applicator requires an open air source to operate - used in conjunction with Flow Regulator
IMPORTANT: Please refer to package insert for complete instructions, contraindications, warnings and precautions.

Step 2 • Assembly

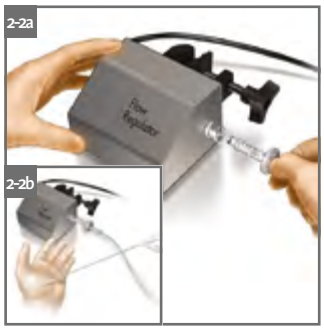
2-1 Ensure the Flow Regulator is connected to a compressed air or Nitrogen source (Figure 2-1). Confirm the nitrogen source is set to 50 - 200psi (3.45 - 13.8 Bar).

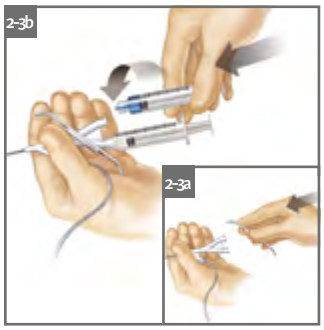
2-2 Connect MicroMyst® applicator line to Flow Regulator (Figure 2-2a). Ensure air is flowing through MicroMyst® applicator (Figure 2-2b).

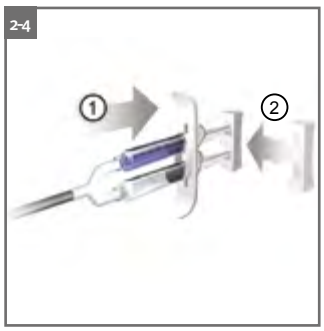
2-3 Position syringe holder over applicator fittings (Figure 2-3a). Screw clear and blue precursor syringes onto applicator (Figure 2-3b).

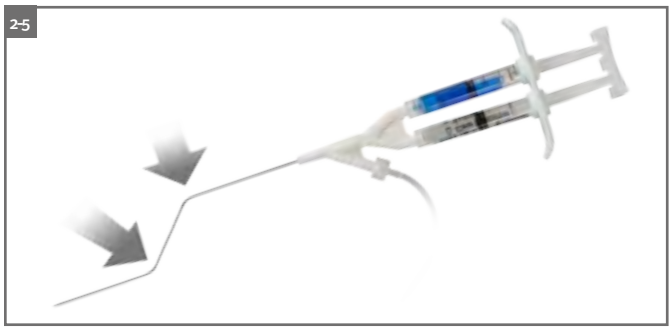
2-4 Slide syringe holder (Figure 2-4 ①) along syringe barrels until it fits snugly against syringe flanges. Attach plunger cap (Figure 2-4 ②) to syringe plungers.

2-5 Adjust malleable applicator shaft to improve access or visualization (Figure 2-5).







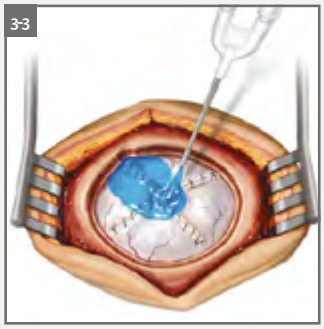


Final step • Application

3-1 Prepare application site by removing all blood clots and fluid.

3-2 While in surgical field, whenever anatomically possible, briefly spray sealant on gauze and without interrupting flow move to the target site (Figures 3-2).

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



DuraSeal® Dural Sealant System: the PEG* Hydrogel Technology for a Watertight Dural Closure

STRENGTH[2]	BIOCOMPATIBILITY[1,3]	VISIBILITY	SPEED[1,4]	CONVENIENCE
Tissue adherence and cohesive strength to withstand critical pressures.	Biocompatible PEG (polyethylene glycol) hydrogel.	Distinctive blue colorant provides visualization to assess sealant coverage and thickness.	Prepared in less than two minutes. When applied, forms a watertight seal in seconds.	Single kit, stored at room temperature.

Indications:

The DuraSeal® dural sealant system is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.
The Extended Tip Applicator is intended for use in the simultaneous delivery of two non-homogenous solutions onto a surgical site.
The MicroMyst® Applicator is intended for use in the delivery of two non-homogenous solutions onto a surgical site.
The Flow Regulator is intended to provide pressurized gas (air or nitrogen) to gas-assisted applicators.

Contraindications:

Do not apply **the DuraSeal® Dural Sealant** in abdominopelvic surgical procedures for use as a sealant or adhesion barrier.
Do not use **Extended Tip Applicator, MicroMyst® Applicator** and **Flow Regulator** for other indications than ones provided in the instructions for use.

1. **Cosgrove GR et al.** *"Safety and efficacy of a novel polytheylene glycol hydrogel sealant for watertight dural repair"*. J Neurosurg 106: 52-58, 2007
2. **In-vitro Product Comparison Study of Wound Healing Sealants.** Report no: R090417B (Cyanta Report)
3. **Safety Testing** for 4a20kSG-trilysine sealant with BHT. Report no: ER1105, page 2-9
4. **Delashaw JB. et al.** *"Reconstruction After Posterior Cranial Fossa Surgery: Application of a Synthetic Tissue Sealant to Augment Dural Closure."* Case Report 2009
* Polyethylene Glycol

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