CRANISEAL™ DURAL SEALANT

(Product Code CS-2051)

INSTRUCTIONS FOR USE

Description:

The CraniSeal Dural Sealant consists of components for preparation of a synthetic, absorbable sealant and an applicator for delivery of the sealant to the target site.

The sealant is composed of two solutions, a polyethylene glycol (PEG) ester solution and a trilysine amine solution (referred to as the 'blue' and 'clear' precursors, respectively). When mixed together, the precursors cross-link to form the hydrogel sealant. The mixing of the precursors is accomplished as the materials exit the tip of the applicator.

The hydrogel implant is absorbed in approximately 4 to 8 weeks, sufficient time to allow for healing.

Indications for Use:

The CraniSeal Dural Sealant is indicated for use in patients ≥ 18 years of age as an adjunct to sutured dural repair during cranial surgery to provide watertight closure.

Contraindications:

Do not apply the CraniSeal Dural Sealant in any surgical procedures other than those specified in the indications for use as a sealant or adhesion barrier.

Do not apply the CraniSeal Dural Sealant to confined bony structures where nerves are present since neural compression may result due to hydrogel swelling. The hydrogel may swell up to 50% of its size in any dimension.

Warnings:

The safety and effectiveness of the CraniSeal Dural Sealant has not been studied in:

- Patients with a known allergy to FD&C Blue #1 dye.
- Patients with severely altered renal or hepatic function.
- Patients who are pregnant or lactating.
- Patients undergoing a cranial procedure involving a translabyrinthine, transsphenoidal, or transoral approach, or any procedure that non-superficially penetrates the air sinus or mastoid air cells.
- Patients with a compromised immune system or autoimmune disease.
- Patients undergoing cranial procedures involving petrous bone drilling.
- Patients with traumatic injuries to the head.
- Patients undergoing cranial procedures involving non-autologous duraplasty materials that are not collagen based.

Do not use the CraniSeal Dural Sealant if an active infection is present at the surgical site.

Do not use the CraniSeal Dural Sealant as a void filler in confined spinal canal or nerve root spaces.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or resterilize this device.

Precautions:

- Use only with the delivery system provided with the polymer kit.
- The CraniSeal Dural Sealant is provided sterile. Do not use if the packaging or seal has been damaged or opened. Discard opened and unused product.
- Do not use if the PEG powder is not free flowing.
- Use within 1 hour of preparing the blue precursor.
- Prior to application of the CraniSeal hydrogel, ensure that adequate hemostasis has been achieved.
- CraniSeal should only be applied when dural edges are well-approximated without a gap to mitigate the risk of cerebral spinal fluid (CSF) leak, CSF cutaneous fistula, or pseudomeningocele formation.
- Incidental application of the CraniSeal hydrogel to tissue planes that will be subsequently approximated, such as muscle and skin, should be avoided.
- Do not use in combination with other sealants or hemostatic agents.
- Do not use in patients younger than 18 years of age or in pregnant or breast-feeding females.

Adverse Reactions:

Comprehensive review of the published literature and labeling for dural sealant devices available in the United States showed the following adverse events that are applicable to the CraniSeal Dural Sealant:

- Allergic reaction
- Bleeding
- Blood and lymphatic system disorders
- Cardiac disorders
  - Arrhythmia
- Dermatologic events
- Electrolyte imbalance
- Elevated liver enzymes
- Gastrointestinal disorders
  - Nausea and/or vomiting
- General disorders
  - Delayed healing
  - Wound dehiscence
- General malaise
- Hematologic abnormality
- Hypertension
- Infections and infestations
  - Deep incisional surgical site infections
  - Superficial surgical site infections
  - Meningitis (aseptic or bacterial)
  - Late incisional surgical site infections
- Inflammatory reaction
- Musculoskeletal events
- Neoplasms benign and malignant, including cysts and polyps
- Nervous system disorders
  - Acute gait dysfunction
  - Epidural or subdural hematoma
  - Headache
  - Dizziness
  - Fever
  - Seizure
  - Stroke
  - Cerebral hemorrhage
  - CSF leak (incisional, pseudomeningocele)
  - Cranial nerve deficit
  - Motor deficit
  - Speech difficulty
  - Double vision or visual disturbance
  - Hydrocephalus
  - Cerebral edema
  - Brain tumor
  - Severe neurological deficit post-op
  - Respiratory and thoracic disorders
- Pain
- Pneumonia
- Renal compromise
- Ureterolitithiasis
- Urinary difficulty

Sterilization Method:

The CraniSeal Dural Sealant is sterilized with radiation.

Storage:

The CraniSeal Dural Sealant should be stored at or below 77 °F (25 °C).

Clinical Experience:

The CraniSeal Dural Sealant has not been clinically evaluated but is subject to a post-approval study to gather clinical performance data on the safety and effectiveness of the CraniSeal Dural Sealant to further update these Instructions for Use.

How Supplied:

The CraniSeal Dural Sealant is provided sterile and consists of the following components:

Powder Vial, with blue label (1)	
Vial Adapter (1)	
Diluent Syringe, with blue label (1)	
Clear Precursor Syringe with white cap (1)	
Applicator (1)	
Syringe Holder (1)	
Plunger Cap (1)	

Spray Tip (3)	

Directions For Use:

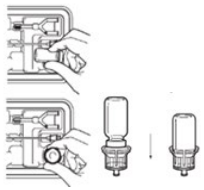
The application procedure consists of three steps:

A. Preparing the Blue Precursor
B. Assembling the CraniSeal System Applicator; and
C. Hydrogel Application

A. Preparing the Blue Precursor

Note: Inspect the PEG powder vial to ensure the powder is free flowing or can be loosened up by shaking. If the powder remains not free flowing, discard the entire kit.

1. Open the pouch and introduce the polymer kit tray into the sterile field.
2. Once in the sterile field, remove the lid from the polymer kit tray.
3. Use one hand to stabilize tray. Use the other hand to pick up the Powder Vial with blue label, invert it, and attach to the Vial Adapter. Push downward until the Powder Vial is fully seated.



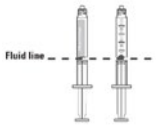
4. Remove and discard syringe cap from Diluent Syringe (blue label).
5. Attach the Diluent Syringe to the Powder Vial.
6. Remove the blue cap from the Diluent Syringe and discard.
7. Attach the Diluent Syringe (blue label) to the Powder Vial (blue label).

8. Inject syringe contents into the vial.
9. Gently shake the vial/syringe assembly until the powder is completely dissolved. The solution will turn blue.
10. Invert the vial/syringe assembly and draw vial contents back into the syringe.

11. Unscrew the Syringe from the Powder Vial and discard the vial.

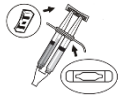
B. Assembling the CraniSeal System Applicator

1. Prior to attaching the syringes to the applicator, ensure syringe fluid levels are equal. If fluid levels are not equal, expel fluids out of syringes until equal.

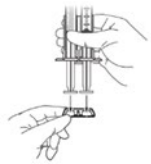


2. Attach blue and clear precursor syringes to the applicator.

3. Attach the syringe holder to syringe barrels.



4. Carefully attach the Plunger Cap to the plungers of both syringes without dispensing precursors into the Applicator. Hold the syringes by the plungers while performing this operation to prevent the delivery of the precursors into the Applicator.



5. Attach a spray tip to the applicator.

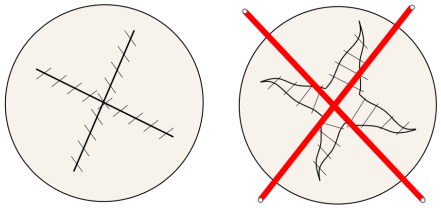
NOTE: Avoid touching the plunger cap before application to avoid inadvertent precursor injection and tip plugging.

C. Hydrogel Application

Note: Achieve hemostasis and minimize CSF outflow. Ensure that there are 2-3 mm margins around the durotomy edge and that the margins are clear of clots and fluids, hemostatic agents and loose connective tissue.

1. 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.

2. CraniSeal should only be applied when dural edges are well-approximated (~2mm) as reflected in the figures below.



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 CraniSeal hydrogel increases to 2 mm, the fine epidural vasculature becomes less visible.

3. Hydrogel application beyond the edges of the dural margin may be removed with scissors or mechanical disruption. Irrigation immediately after the sealant has solidified is permitted.

For more surgical information, or to obtain Pramand, LLC documents or references, contact:

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Symbols Used on Labeling:

Consult Instructions for Use: Indicates the need for the user to consult the instructions for use.

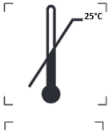
Catalogue or Model Number: Indicates the manufacturer's catalogue number so that the medical device can be identified.

Lot Identification: Indicates the manufacturer's batch code so that the batch or lot can be identified.

Sterilized Using Radiation: Indicates medical device has been sterilized using irradiation.

Use by: Indicates the date after which the medical device is not to be used (YYYY-MM-DD).

Single Use only: Indicates medical device that is intended for single use only.



Storage temperature range: Indicates range of temperature the medical device can be safely exposed.

Double sterile barrier system: Indicates two sterile barrier systems.

Non-pyrogenic: Indicates that the product is non-pyrogenic.

Manufacturer: Indicates the medical device manufacturer.

℞ **ONLY** **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner.