CONFIDENTIAL	SIGNATURE PAGE
RECORD ID: PRA-LBL-0031	
TITLE: SpineSeal IFU Commercial (USA)	
AUTHOR: Shayla Som	
STATUS: EFFECTIVE	

User	Role	Revision	Decision	Date Signed
Alexandra Fontaine	Quality Approver(s)	A.0	Approve	19 Feb 2025 06:09 PM EST
Nick Svencer	Additional Approver(s)	A.0	Approve	18 Feb 2025 03:47 PM EST
David Giusti	Additional Approver(s)	A.0	Approve	18 Feb 2025 09:22 AM EST
Christina Young	Additional Approver(s)	A.0	Approve	18 Feb 2025 08:32 AM EST
Amanda Reid	Additional Approver(s)	A.0	Approve	18 Feb 2025 09:56 AM EST
Sima Bilge	Quality Approver(s)	A.0	Approve	18 Feb 2025 11:16 AM EST
Julia Doroshenko	Additional Approver(s)	A.0	Approve	18 Feb 2025 10:46 AM EST
Shayla Som	Additional Approver(s)	A.0	Approve	18 Feb 2025 08:24 AM EST

Title: Label Tracking and Proofing Form

Label Number	Revision	Description
PRA-LBL-0031	**A**	**SpineSeal IFU Commercial (USA)**

Change Request

CC#: PRA-CC-0316

Translation

☐ Required ☒ Not Required

Sent to: N/A **Date:** N/A

Quality Assurance Review: ☐ Yes ☒ No **By:** N/A **Date:** N/A

Proof Procurement

Is external vendor required? ☐ Yes ☒ No

Sent to (vendor): N/A **Date:** N/A

Should label be placed on Hold pending regulatory approval?* ☐ Yes ☒ No
Does the Label require a UDI number? ☐ Yes ☒ No

- If yes the UDI number is listed on **PRA-FRM-0039**

Release from Hold (if applicable): N/A **Date:** N/A

*Only recommended for changes to existing labeling of a saleable product. Pre-production and production labels are controlled by numeric/alpha revision of manufacturing documents (BOMs, DWGs, PRs) for the finished goods product code.

Completion of Label Tracking Form

Quality Assurance Approval: Alexandra Fontaine **Date:** Date Captured in ACE

Regulatory Approval: Julia Doroshenko **Date:** Date Captured in ACE

All persons listed on this approval page are required to sign in ACE Essentials.

See next page

Label Description	SpineSeal IFU Commercial (USA)		
Part Number	PRA-LBL-0031	**Rev**	A
Label Stock	Blank Paper	**Size**	8.5” x 11”

SPINESEAL™ SPINE SEALANT

(Product Code SS-2055)

INSTRUCTIONS FOR USE

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

Description:

The SpineSeal Spine Sealant consists of components for preparation of a synthetic absorbable sealant, and 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 buffer 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 sealant is absorbed in approximately 9-12 weeks.

The 5mL polymer device consists of the Dual Liquid Applicator in the tray. The polymer may also be used with the Pramand Air-Assisted Sprayer, which is provided separately. Please reference the Instructions for Use enclosed with the Pramand Air-Assisted Sprayer for directions on assembly and use.

The SpineSeal Spine Sealant is provided sterile.

Indication for Use:

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

Contraindications:

Do not apply the SpineSeal hydrogel to confined bony structures where nerves and spinal cord are present since neural compression may result due to hydrogel swelling. The hydrogel may swell up to 12% of its size in any dimension.

Warnings:

- Do not use if an active infection is present at the surgical site.
- Do not use as a hemostatic agent.
- The safety and effectiveness of the SpineSeal hydrogel 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 with a compromised immune system or autoimmune disease.

Precautions:

- Use only with the delivery system provided with the SpineSeal device or the Pramand Air-Assisted Sprayer (FS-2005).
- The SpineSeal Spine Sealant is provided sterile. Do not use if packaging or seal has been damaged or opened. Do not re-sterilize.
- The SpineSeal Spine Sealant is intended for single patient use only. Discard opened and unused product.
- Do not use if the PEG powder is not free flowing
- Use within 1 hour of preparation.
- 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.
- Prior to application of the hydrogel, ensure that adequate hemostasis has been achieved.
- Incidental application of hydrogel to tissue planes that will be subsequently approximated, such as muscle and skin, should be avoided.

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 SpineSeal Spine Sealant:

- Allergic reaction
- Blood and lymphatic system disorders
- Cardiac disorders
- Dermatologic events
- Gastrointestinal disorders
  - Nausea and/or vomiting
- General disorders
  - Delayed healing
  - Wound dehiscence
- Hematologic abnormality
- 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 hematoma
  - Headache
  - Seizure
  - Cerebral hemorrhage
  - CSF leak
  - Double vision
  - Hydrocephalus
  - Cerebral edema
  - Brain tumor
  - Severe neurological deficit post-op
  - Respiratory and thoracic disorders
  - Leakage of cerebrospinal fluid
- Renal compromise

Sterilization Method:

The SpineSeal Spine Sealant is sterilized with radiation.

Storage:

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

Clinical Experience:

The SpineSeal Spine 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 SpineSeal Spine Sealant to further update these Instructions for Use.

How Supplied:

The SpineSeal Spine Sealant is provided sterile and consists of the following components:

Polymer Kit Tray	
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 SpineSeal Spine Sealant Applicator
C. Hydrogel Application
D. Hydrogel Application when using the Pramand Air-Assisted Sprayer (FS-2005)

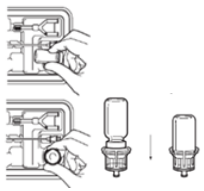
A. Preparing the Blue Precursor

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. Remove the polymer tray assembly and the applicator from the outer pouch and introduce to the sterile field.

2. Remove lid from polymer tray assembly.

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. Screw the Diluent Syringe (blue label) to the Powder Vial (blue label) and inject syringe contents into the vial.

6. Gently shake the vial/syringe assembly until the powder is completely dissolved. The solution will turn blue.

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

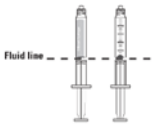
8. Unscrew the Syringe from the Powder Vial and discard the vial.

B. Assembling the SpineSeal Spine Sealant Applicator

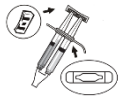
1. Remove and discard syringe cap from Clear Precursor Syringe (white end cap).

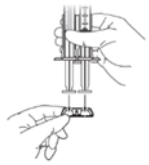
2. Prior to attaching the syringes to the applicator, remove excess air from both syringes.

3. Ensure syringe fluid levels are equal. If fluid levels are not equal, expel fluids out of syringes until equal.



4. Attach the syringe holder, which slides over both syringe barrels and the Plunger Cap to syringe plungers without dispensing precursors into the Applicator. Hold the syringes by the plungers while performing this operation so as to not deliver any of the precursors into the Applicator.





5. Attach one spray tip to the applicator.

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

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 with delivery.

C. Hydrogel Application when using the SpineSeal Spine Sealant Applicator

NOTE: While in surgical field, whenever anatomically possible briefly spray on gauze and without interrupting flow, move to the target site.

1. Dispense the solutions onto the target site by applying firm even pressure to the Plunger Cap. Rapid initial spraying, followed by a slower controlled rate is recommended.

2. SpineSeal hydrogel should only be applied when dural edges are well-approximated (~2mm) without a gap.

3. Continue applying the hydrogel until a thin (1 – 2 mm) uniform 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 SpineSeal hydrogel increases to 2 mm, the fine epidural vasculature becomes less visible.

4. Excess hydrogel may be removed with scissors or mechanical disruption.

D. Hydrogel Application when using the Pramand Air-Assisted Sprayer (FS-2005)

NOTE: Refer to Instructions for Use provided with the Pramand Air-Assisted Sprayer (FS-2005).

1. Remove Applicator assembly from inner pouch.
2. Remove and discard the protective sheath over the applicator shaft and tape from the Applicator line.
3. Connect the Applicator line to the Flow Source, and turn on Flow Source.
4. Place Syringe Holder over applicator fittings.
5. Screw the clear and blue precursor syringes onto the applicator.
6. Attach the Plunger Cap to the syringe plungers and slide the Syringe Holder along the syringe barrels until it fits snuggly against the syringe flanges.
7. Applicator metal shaft may be angled to improve access or visualization.

Hydrogel Application

- 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.
- Gel thickness should be limited to 1-2 mm. SpineSeal hydrogel can swell after application, it should not be used in areas where neural structures could be compressed.
- 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.

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

Manufacturer:
Pramand, LLC
201 Burlington Rd
Bedford, MA 01730 USA
PH: (781) 222-0081

Symbols Used on Labeling:

	**Consult Instructions for Use:** Indicates the need for the user to consult the instructions for use.
REF	**Catalogue or Model Number:** Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	**Lot Identification:** Indicates the manufacturer's batch code so that the batch or lot can be identified.
STERILE R	**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.
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner.