

Avalon Medical

Innovative Veterinary Surgical Products

PoliPhase™ Sealant

(formerly *PoliPhase™ Surgical Sealant* or *PoliPhase™ Sealant Dental Extraction Packing*)

PoliPhase™ Sealant is a resorbable, two component biopolymer consisting of a liquid biological substrate and crosslinker. When combined, the substrate and crosslinker will form a leak tight seal with minimal inflammatory response.

Indications for Use

- *PoliPhase™ Sealant* is intended for use in internal applications where bleed control is key. This includes suturing and stapling in the control of fluid leaks during surgical procedures, as well as dental extractions and oral applications.
- *PoliPhase™ Sealant* is indicated for use in canine, feline, equine, porcine and bovine species.
- *PoliPhase™ Sealant* is for internal use only.

Product Description

PoliPhase™ Sealant is a phase change polymer that forms an adhesive for control of fluid in both dry and relatively wet fields. The *PoliPhase™ Sealant* system consists of a double-barreled syringe, a plunger, and mixing / applicator tips. One syringe barrel includes a plasticized proteinaceous substrate and tacking agents. The other syringe barrel contains a modified aldehyde crosslinker. Mixing of the contents of the two barrels takes place in the mixing / applicator tip and will cause the components to crosslink yielding the sealant properties desired. The application of *PoliPhase™ Sealant* will immediately present fluid control. The application time for *PoliPhase™ Sealant* is approximately 20 seconds after mixing, and full crosslinking and polymerization is achieved in less than two minutes. In general, maximum fluid control (sealing) is achieved when the surface has been properly prepared, although the sealant will control mild oozing surfaces without any prior fluid control. *PoliPhase™ Sealant* will hydrolyze *in situ*. Complete hydrolysis will occur in approximately four to six months.

Cautions

- For veterinary use only. *PoliPhase™ Sealant* is not intended for human use.
- All components are sterile and should be assembled using aseptic technique.
- Do not pre-mix the components in anticipation of future use.
- Store at room temperature. Do not freeze. Refrigeration is not required or recommended.

Warnings

- *PoliPhase™ Sealant* is intended for single-use only.
- *PoliPhase™ Sealant* contains a bovine-derived component.
- As with the use of any implantable medical device, serious complications may lead to injury or death. Complications associated with *PoliPhase™ Sealant* include continued leakage through the sealed site, inflammatory response, surgical site infection, calcification, and immune response.

1052 Curve Crest Blvd. • Stillwater, MN 55082

Contraindications

- *PoliPhase™ Sealant* should not be used where the patient has demonstrated sensitivity toward bovine-derived products.
- *PoliPhase™ Sealant* is not intended to control bleeding in a fatty field.
- *PoliPhase™ Sealant* is not intended for use in which the wound is subjected to long-term exposure to air following surgical intervention.
- *PoliPhase™ Sealant* is not intended to be dehydrated.

Shelf Life & Storage

- *PoliPhase™ Sealant* should be used within 12 months from the date indicated on the package.
- The product should be stored at room temperature, not to exceed 30°C.

Preparation of the Site (Surgical & Dental Applications)

PoliPhase™ Sealant works best when applied to autologous tissues that have been properly prepared to receive the sealant. To properly prepare for use of *PoliPhase™ Sealant*:

- Remove any fatty tissue from the site to be sealed.
- Remove surrounding fluid from the site such that the area remains moist but not immersed in fluid. Continued fluid control of the site while sealing may be necessary.

In general, maximum fluid control (sealing) is achieved when the surface has been properly prepared, although the sealant will control mild fluid secreting surfaces without prior control required.

Preparation of the Sealant

1. Using aseptic technique, open the outer package and allow the inner package to drop into the sterile field.
2. Open the inner package and remove all contents.
3. Attach mixing tip to syringe.
4. Attach plunger.
5. Apply *PoliPhase™ Sealant* to site by slowly depressing plunger.
6. Reapply cap if useable material remains in the syringe. Care should be taken to prevent contamination of the cap and remaining material.

NOTE: You should have about 30 seconds to work the sealant out of the syringe before polymerization and solidification advances to a state where application is difficult. Full crosslinking of the material will be achieved in approximately two minutes.

Distribution

PoliPhase™ Sealant is available from veterinary distributors, or contact Avalon Medical at (888) 289-1890 or www.avalonmed.com.

Presentation

PoliPhase™ Sealant is available in a single-use, 2.5mL syringe with two dental or three surgical mixing tips.

Successful use of this product is dependent upon the use of an aseptic technique, proper material preparation and good surgical practices. Avalon Medical guarantees that reasonable care was taken in the preparation and processing of PoliPhase™ Sealant. No other warranty, expressed or implied, applies to sale or use of PoliPhase™ Sealant.

1052 Curve Crest Blvd. • Stillwater, MN 55082