

# Avalon Medical

## Innovative Veterinary Surgical Products

### ***PeriSeal™ Tissue Patch***

*PeriSeal™ stabilized pericardium is intended for use in all veterinary applications requiring soft tissue buttressing.*

#### **Indications for Use**

- *PeriSeal™* is indicated for use in the repair of soft tissue deficiencies and fascial defects.
- *PeriSeal™* is useful in the repair of abdominal and thoracic wall defects, muscle flap reinforcement, pelvic floor reconstruction as well as herniation and biopsy wound repair.
- *PeriSeal™* is intended for veterinary applications in canine, feline, porcine, equine and bovine species only and is not for use in human implant.
- *PeriSeal™* is for internal use only and is not intended for dermal applications.

#### **Product Description**

*PeriSeal™* is a durable, non-absorbable, stabilized pericardium patch. Proprietary processing yields an acellular, crosslinked tissue with exceptional handling, elasticity and biocompatibility. *PeriSeal™* will readily support tissue ingrowth and allow remodeling of the implant site.

#### **Warnings**

- *PeriSeal™* is supplied sterile in a 0.65% phosphate buffered glutaraldehyde solution. It is highly recommended gloves are worn when handling this product.
- The use of strict aseptic technique is required when implanting *PeriSeal™*. If an infection develops it must be treated aggressively. Removal of the biomaterial may be required.
- Use of the device in applications that expose the tissue to increased level of microbial flora such as transvaginal techniques increase the risk of microbial contamination of the material.
- Possible adverse reactions to *PeriSeal™* include those noted for any tissue implant material. These include infection, seroma formation, inflammation, adhesions, hematoma and fistula formations.

#### **Contradictions**

- Implantation of *PeriSeal™* into an infected operative field should be avoided. Postoperative infection should be aggressively treated at the earliest possible time. Unresolved infections may require the removal of the material.

#### **Shelf Life and Storage**

*PeriSeal™* should be stored at room temperature. Do not allow the tissue to freeze. *PeriSeal™* has a shelf life of 18 months from date of processing.

#### **Sterility**

*PeriSeal™* is supplied sterile in a 0.65% phosphate buffered glutaraldehyde solution. Provided that the package has not been compromised the product will remain sterile until the expiration date on the jar has elapsed. *PeriSeal™* cannot be resterilized once it has been removed from its container. Excess tissue remaining post-procedure should be discarded. The solution *PeriSeal™* is supplied in may be safely poured down any drain.

#### **Orientation**

No orientation of the tissue is required. The upper and lower surfaces are similarly porous.

#### **Recommended Implant Technique**

- Use atraumatic, sterile tools when handling *PeriSeal™*. When removing the tissue from the packaging solution care must be taken to avoid contact with the edges of the container.
- *PeriSeal™* should not be allowed to dry at any time.
- Do not suture closer than 2mm from any edge.

#### **Rinsing**

- To rinse *PeriSeal™* remove from the original packaging solution. Place *PeriSeal™* into a sterile basin and completely submerge in saline solution. Gently swirl the solution for a period of three minutes and then discard the solution.

**Trimming**

Trimming *PeriSeal*<sup>™</sup> to size is readily accomplished using standard, sharp surgical instruments. Proper sizing of the tissue is critical to the surgical outcome. Tissue that is excessively undersized may place undue tension on the suture line causing adjacent tissue failure.

**Suturing/stapling**

*PeriSeal™* should be sutured using taper point, non-absorbable sutures. Cutting edge needles should be avoided for use on *PeriSeal™*. Use of absorbable sutures may lead to inadequate tissue fixation and product failure. When suturing *PeriSeal™*, care should be taken to avoid placing the suture line excessively close to the tissue edge. The ratio of suture length in the autologous tissue and *PeriSeal™* should be 1:1. Similarly a bite ration of 1:1 should be observed at all times. Staples can be used as an alternative to sutures.

**Distributed by:**

Veterinary distributors or contact Avalon Medical Ltd at (888) 289-1890 or [www.avalonmed.com](http://www.avalonmed.com).

**Presentation:**

*PeriSeal™* is available in three sizes: 6cm x 8cm patch (#25-01), 8cm x 8 cm patch (#25-02) and 10cm x 10cm patch (#25-03).

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