

## A simply remarkable tissue!

Amnion is the placental tissue that surrounds and protects the fetus during development in utero. The properties of amnion that benefit the fetus also make it an effective material for protecting a wide variety of wounds, while at the same time creating an environment conducive to the regeneration of healthy tissue. Repurposing this versatile tissue to improve outcomes in wound management is supported by studies in published literature which describes its successful and safe clinical use.

Amnion consists primarily of fibrillar and membranous collagens, elastin, and a mix of growth factors and cytokines that provide the properties unique to placental tissues.

## The Benefits of Amnion

The scientific and peer reviewed literature describe a number of benefits from the clinical use of amnion tissues, including:

- Safe, natural covering that improves normal wound healing outcomes
- Reduced inflammation
- Reduced fibrosis and scarring at the surgical site
- Decreases pain
- Provides a substrate for stem cells

## Uses of Amnion

Specifically, amnion has been used to achieve the following outcomes:

- Inhibit fibrogenesis (scarring) when applied topically to dermal and subcutaneous wounds
- Prevent adhesions tethered to implanted hardware
- Reduce the occurrence of dural & nerve root adhesions
- Prevent adhesions in tendon grafts and repair

Amnion has been used successfully in many clinical applications:

- Spine / neurologic surgeries
- Ophthalmic procedures
- Podiatric surgery
- Cosmetic
- Bariatric surgeries
- Cranio maxillofacial surgery
- Sports medicine
- Wound care / burns
- Trauma
- Dental
- OB-Gyn

A close-up photograph of a hand wearing a blue nitrile glove, holding a piece of the SteriShieldII amnion patch. The patch is a translucent, textured material with a grid-like pattern. A black pen is visible in the background, pointing towards the patch.

*The versatile and powerful properties of amnion have been improving surgical outcomes for decades.*



For more information contact  
**Osseodent**  
 at 305-306-1000  
[www.osseodent.com](http://www.osseodent.com)



**SteriShield II has the following advantages:**

- Stores dry at room temperature
- Suitable for immediate use off the shelf
- Hydrates rapidly in wound environment
- Readily adheres to the wound surface
- Terminally sterilized with gamma radiation to SAL10<sup>6</sup> in accordance with ISO 11137
- Not chemically cross-linked
- Three year shelf life
- SteriShield II (Dual Layer) version processed with surface layer dimpling for ease of graft placement /handling
- SteriShield II (Dual Layer) version can be placed with either side in contact with wound surface

**Select IFUs**

- Maintain allograft in a clean, dry environment at room temperature (18° C/ 64° F to 34° C/ 93° F)
- No refrigeration is necessary
- Apply dry with forceps
- SteriShield II (Dual Layer) construction removes the requirement to apply with one side towards the wound (stromal layer) and a different side (epithelial layer) out
- If not initially placed properly during surgery, the SteriShield II (Dual Layer) graft can either be manipulated in place or removed; when placed in water or saline, the graft will unfold and can be repositioned

**Tissue Safety**

- Collection of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments
- Placentas are all from planned C-sections which helps minimize the potential for contamination during recovery
- Placental donors go through a rigorous pre-screening qualification
- Placental donors are tested to confirm they are free from disease
- Processed in accordance with the safety guide-lines provided by the U.S. Food and Drug Administration (FDA) - Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271)
- Processed in accordance with the standards from the American Association of Tissue Banks (AATB)

BB-SS2-101 0	SteriShield® II Dual Layer Amnion Patch, 10x10mm
BB-SS2-1013	SteriShield® II Dual Layer Amnion Patch, 10x13mm
BB-SS2-1025	SteriShield® II Dual Layer Amnion Patch, 10x25mm
BB-SS2-1520	SteriShield® II Dual Layer Amnion Patch, 15x20mm
BB-SS2-2020	SteriShield® II Dual Layer Amnion Patch, 20x20mm
BB-SS2-2030	SteriShield® II Dual Layer Amnion Patch, 20x30mm

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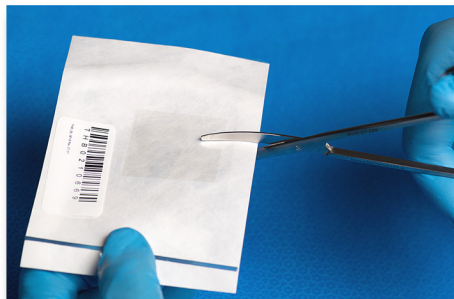
## INSTRUCTIONS FOR USE STERISHIELD II™ DUAL LAYER PROTECTIVE AMNION PATCH



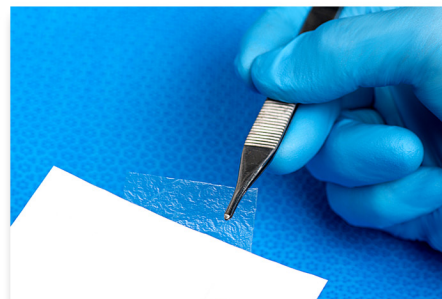
Stores at room temperature. No refrigeration necessary.



Wait to open inner package until ready to place graft.



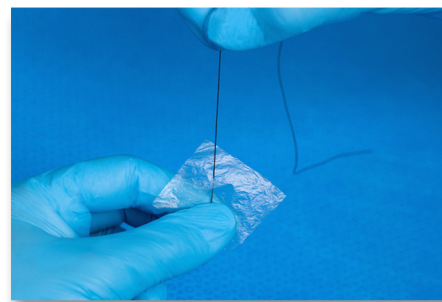
Trim through the sterile inner package if needed.



Take graft directly from package to surgical site.



Apply dry, ideally with forceps.



Sutures or adhesives may be used if indicated.

### Other Comments:

Apply in wound environment with either side facing the wound; dual layer version eliminates side specific placement issues of other amnion products. Can be manipulated when in the wound site; if graft becomes folded or difficult to handle, remove and place in saline (or any other sterile solution), as it will flatten out to original state.