



# AcuPatch™

AMNION TISSUE PATCH



AcuPatch™ is a protective amnion tissue patch. **Amniotic tissues are allografts, regulated by the FDA as a human cell, tissue, and cellular and tissue based product** (HCT/P) under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. Tissues and fluids are minimally manipulated and intended for homologous use only. Homologous **use is defined as repair, reconstruction, replacement, or supplementation of a tissue** with an HCT/P that performs the same basic function in the recipient as in the donor. **Final products are tested for sterility and indicated usage is for a single patient, one-time use.**

## BENEFITS

<b>Processing</b>	Tissue is procured through voluntary donation from scheduled Cesarean procedures of full-term healthy births. Maternal donors are screened per FDA and AATB guidelines for a panel of infectious diseases at an FDA registered and CLIA Certified laboratory and against established medical-social risk factors. Once received, the membrane is minimally processed to preserve the native structure of the tissue, dehydrated, and terminally sterilized with gamma irradiation with sterility assurance level (SAL) 10 <sup>-6</sup> to ensure recipient safety. A final quality control review is conducted by dedicated quality associates to ensure only grafts meeting the highest quality and safety standards are released for distribution.
<b>Natural Covering For Wounds</b>	Constructed from the natural layer surrounding the fetus in the womb, AcuPatch™ can provide a safe, natural covering for wounds, providing a physical defense barrier inside the surgical site. The layers of the membrane provide a protective barrier adept at remodeling to accommodate the growing fetus. This protective feature makes amniotic membrane ideal for homologous use as a barrier in a variety of applications.
<b>Ideal For Transplantation</b>	AcuPatch™ utilizes placental tissues from living donors and captures its benefits. The ability of the amniotic membrane to protect the delicate fetus in utero creates an ideal biocompatible tissue and does not lead to adverse immune responses.
<b>Resorbable Host Tissue</b>	Amnion is also resorbed by the body, making it well-suited for use in surgical procedures. Literature also highlights amnion as a rich source of collagen (types IV, V, and VII), and an extracellular matrix containing growth factor proteins EGF, TGF-β, FGF, and PDGF, which may reduce inflammation and scarring at the surgical site. Amnion has also been cited in published articles to decrease pain and serve as a host for stem cells to attach and multiply.

## VERSATILE SURGICAL APPLICATIONS IN ORTHOPEDICS

Usage in various procedures including spine/neurology surgery, bariatric surgery, sports medicine, ophthalmology procedures, craniomaxillofacial and dental surgery, podiatry, bladder sling/hysterectomy procedures, trauma, and wound care/burns/cosmetic surgery.

## HANDLING AND STORAGE

AcuPatch™ is **processed with the membrane intact, preserving the spongy layer between the amnion and the chorion.**

The graft may be anchored to the surgical site by the method of choice and rapidly rehydrates once affixed.

The dual-sided version can be placed with either side in contact with the wound surface.

AcuPatch™ is desiccated to **allow for storage at room temperature and immediate use off the shelf (no preparation required).**

The reduced moisture in the graft makes the tissue easy to handle and hydrates when placed in the wound environment to readily adhere to the wound site. **Terminally sterilized grafts come in multiple rectangle shapes and have a 5-year shelf life stored at ambient temperature.**

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PRODUCT CODE	VOLUME
90-00A01520	AcuPatch™ DS 1.5cm x 2cm
90-00A02020	AcuPatch™ DS 2cm x 2cm
90-00A02040	AcuPatch™ DS 2cm x 4cm
90-00A04040	AcuPatch™ DS 4cm x 4cm
90-00A04060	AcuPatch™ DS 4cm x 6cm