

# iPatch™

Amniotic Membrane Allograft



a **FORMULA/5™**  
processed product

## What is iPatch™?

A safe, easy-to-apply amniotic membrane allograft derived from human placental tissue and processed using the proprietary Formula/5™ method.

### Source | Quality | Safety

Our quality process starts with carefully screened and tested mothers who donate tissue resulting from healthy live births.

Every donor is screened thoroughly and lab tested for ten infectious diseases.<sup>1</sup>

Robust manufacturing process controls ensure that before leaving our facility, every iPatch™ is confirmed to meet the highest internal standards and industry specifications.<sup>2</sup>

### Process | Facility

iPatch™ is manufactured in a facility designed to consistently deliver safe, standard-setting amniotic membrane allografts that meet the needs of clinicians and the patients they treat.

Our proprietary **FORMULA/5™** process:



Ensures minimal manipulation



Uses no harsh chemicals



Provides the most gentle drying process in the industry

Our process is engineered to meet stringent FDA regulations and AATB standards and deliver a product that stores easily, transports safely, rehydrates quickly, and handles well at application.

### iPatch™ with FORMULA/5™

FORMULA/5™ preserves the natural ECM structure, including collagen, glycoproteins, and elastin.



**Bioresorbable**



**Naturally non-immunogenic**



**Retains growth factors**



**Reduced scar tissue formation**



**Semi-permeable protective barrier**



**No preparation required**



**Bi-directional application**



**Air-dried processing**



**Stores at room temperature**

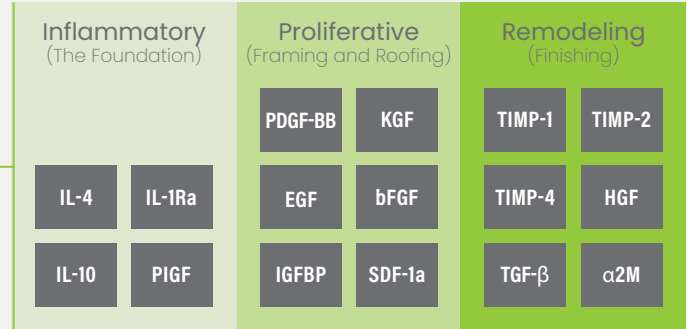


## Common clinical applications

Human amniotic membrane is a biocompatible allograft shown to provide substantial benefit in treating conjunctival and corneal disease.<sup>3</sup>

- Keratitis
- Corneal ulcers
- Neurotrophic keratopathy
- Chemical burns
- PCED
- Chronic dry eye

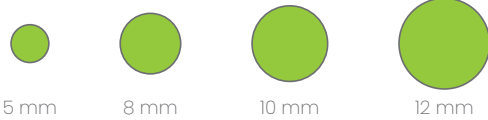
The FORMULA/5™ processing method is designed to retain natural growth factors and other regulatory proteins to support the full healing cascade.<sup>4,5,6,7,8</sup>



## Products | Sizes

iPatch™ allografts are available in multiple sizes and layer configurations.

Standard sizes include 5, 8, 10, and 12 millimeters (mm).



Item Description	SKU
5 mm Amnion Single Layer Disc	iPatch-105
8 mm Amnion Single Layer Disc	iPatch-108
10 mm Amnion Single Layer Disc	iPatch-110
12 mm Amnion Single Layer Disc	iPatch-112
5 mm Amnion Double Layer Disc	iPatch-205
8 mm Amnion Double Layer Disc	iPatch-208
10 mm Amnion Double Layer Disc	iPatch-210
12 mm Amnion Double Layer Disc	iPatch-212



## Placing the allograft

- 1 Remove allograft from the inner pouch using dry toothless forceps.
- 2 Place the dry allograft directly on the ocular surface. Avoid exposing the allograft to moisture or humidity until it has been placed. Gently flatten the allograft over the defect using toothless forceps or a sterile eye spear sponge.
- 3 If needed, hydrate using sterile isotonic solution once placed on the defect.
- 4 Cover with a bandage contact lens.

iPatch™ is a product of focus.

C5 does one thing: manufacture safe, effective human amniotic membrane products that meet or exceed every relevant standard.

NOTES/REFERENCES: 1. Testing is done at an FDA registered, CLIA certified laboratory, and in accordance with FDA's regulations and guidance documents, as well as the American Association of Tissue Banks' Standards for Tissue Banking. Testing includes: HIV-1/HIV-2 Ab, HBsAg, HCV Ab, HbCAb HTLV-1/II Ab, SRPR or TPA, HBV NAT, HCV NAT, HIV-1 NAT, WNV NAT (when relevant). 2. C5 Biomedical's quality management system is designed to meet FDA's 21 CFR 1271 regulations and the American Association of Tissue Banks' Standards for Tissue Banking. 3. Malhotra C, et al. World J Transplant. 2014; 4(2):111-21. 4. Partial list of regulatory proteins. 5. Data on File. C5 Biomedical. 6. Koizumi N, et al. Current Eye Research. 2000; 20(3): 173-77. 7. Koob TJ, et al. J Biomed Mater Res Part B 2015; 103B: 1133-40. 8. Li JF, et al. HGF accelerates wound healing by promoting the dedifferentiation of epidermal cells through β1-integrin/ILK pathway. Biomed Res Int. 2013;2013:470418. doi: 10.1155/2013/470418. Epub 2014 Jan 15. PMID: 24490163; PMCID: PMC3899705.

