Arthrex DX Reinforcement Matrix

Acellular Dermal Matrix

For safe, superior strength and support of cellular migration

Arthrex®
ORTHOBIOLOGICS

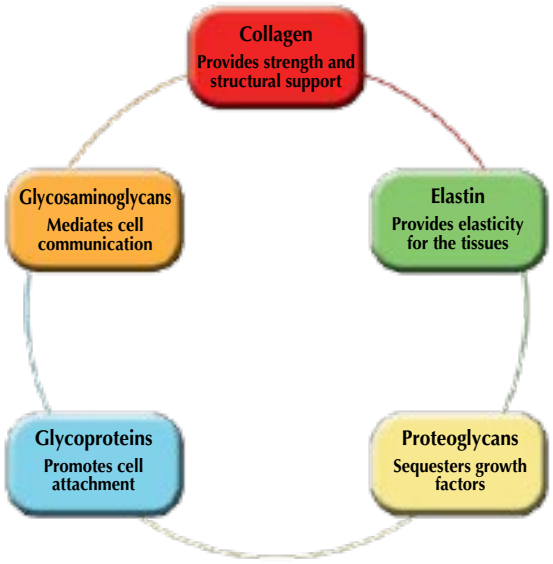
http://biologics.arthrex.com

Arthrex DX Reinforcement Matrix

Introduction

The Arthrex DX Reinforcement Matrix is a dermal Extracellular Matrix (ECM) that has been created as a biomechanically strong and biocompatible scaffold for the reinforcement and repair of soft tissues. By maintaining the natural 3D structure and natural vascular channels through the OPTRIX™ processing technology, Arthrex is providing a sterile, ready to use, biologically intact scaffold while maintaining essential matrix components such as collagen, elastin, glycoproteins, glycosaminoglycans, and proteoglycans.

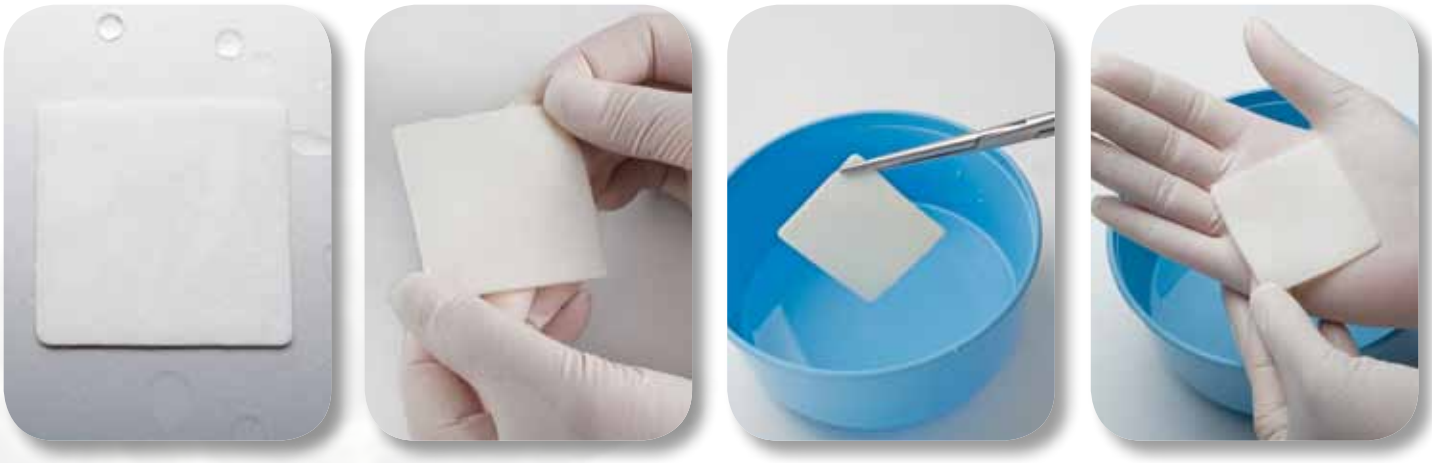
Arthrex DX Reinforcement Matrix Components



Features and Benefits:

- Retains native matrix structure for superior strength and support for cellular migration
- Removes antigenic components, while maintaining high level of collagen structure
- Porous, open structure providing a scaffold for cell ingrowth
- Excellent strength without crosslinking
- Higher modulus than competitive products[1]
- Validated preservation of ECM proteins and growth factors[1]
- Convenience
  - Room temperature storage
  - Prehydrated
  - No preparation time
  - Two-year shelf life
- Safety
  - Sterile
  - Reduced α-Gal antigen
  - Biocompatible
  - OPTRIX™ process
  - Every lot tested to confirm DNA and cellular removal
  - Retains biologic integrity

The Arthrex DX Reinforcement Matrix is supplied sterile and comes prehydrated, with saline already in the package, and ready to use.



Indications

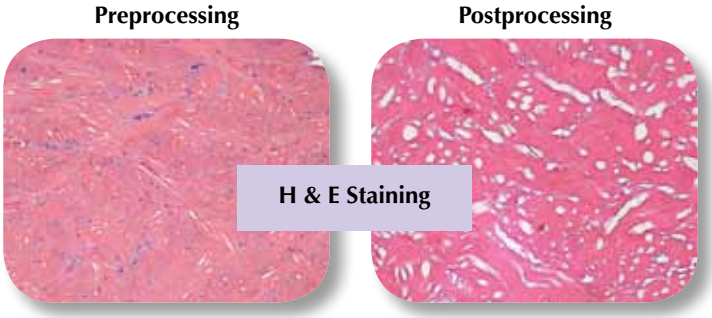
Arthrex DX Reinforcement Matrix is indicated for the reinforcement and repair of soft tissue where weakness exists including, but not limited to, suture line reinforcement, and muscle flap reinforcement; and for reinforcement of the soft tissues which are repaired by suture or suture anchors including, but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons.

Arthrex DX Reinforcement Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures, used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone, provide biomechanical strength for the tendon repair. Arthrex DX Reinforcement Matrix is intended for one time use. The device is provided sterile and cannot be resterilized.

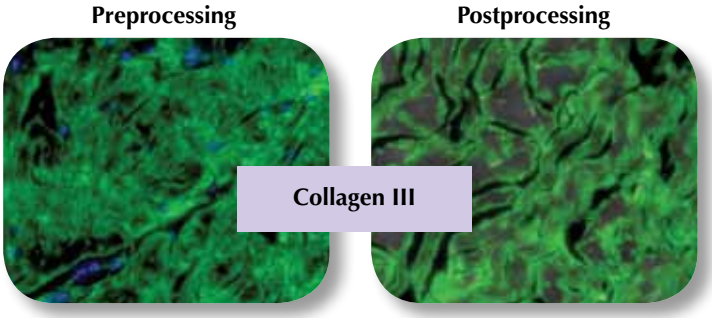
The Science

OPTRIX™ Tissue Processing Technology

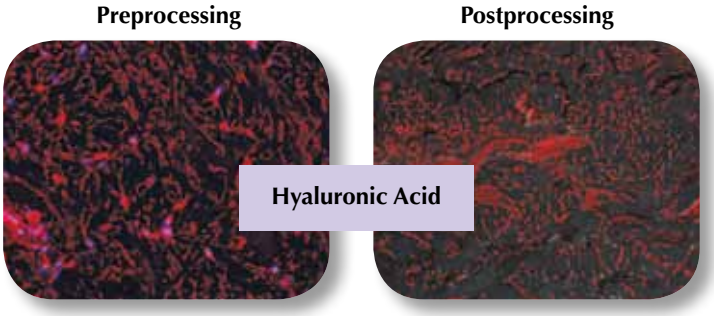
The OPTRIX™ process gently disinfects tissues, inactivates viruses, and removes cells while preserving the natural, open-pore structure of the collagen matrix and maintaining the ECM components. The gentle and selective nature of the process results in products with strength and durability, a porous scaffold structure amenable to cell ingrowth, and retention of ECM components that facilitate rapid cell infiltration and revascularization.



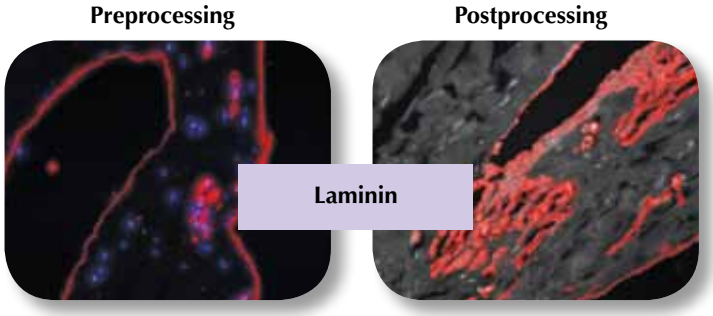
Hematoxylin and eosin staining of native and decellularized dermis tissue demonstrate elimination of the nuclear staining material after decellularization but preservation of the decellularized ECM. Scale = 100 um



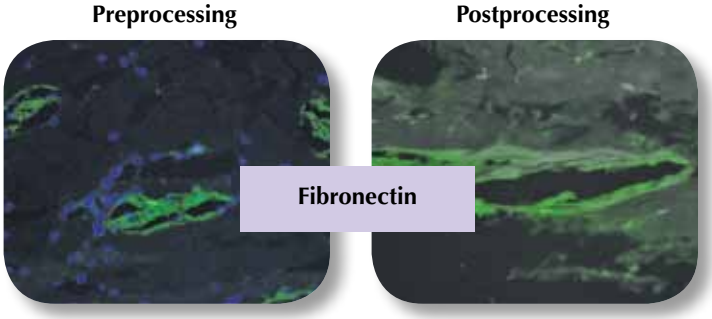
Staining for Collagen III, pre- and post-OPTRIX shows removal of cellular components (blue stain) and retention of collagen proteins. Residual Collagen III is dispersed throughout the tissue.



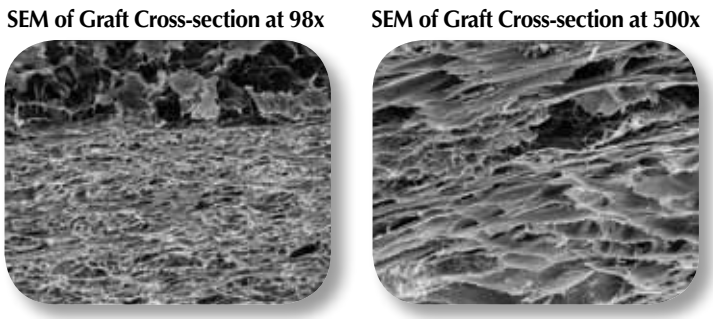
Staining for Hyaluronic acid pre- and post-processing with OPTRIX. Hyaluronic acid is present most strongly near the surface of the decellularized dermis but also throughout, to a degree.



Staining for Laminin in pre- and post-processed tissue shows removal of cellular components (blue stain) and preservation of Laminin dispersed throughout the tissue.



Staining for Fibronectin pre- and post-Optrix shows removal of cellular components and retention of ECM protein. Fibronectin has patchy distribution throughout, more concentrated in areas that may be decellularized vascular structures.

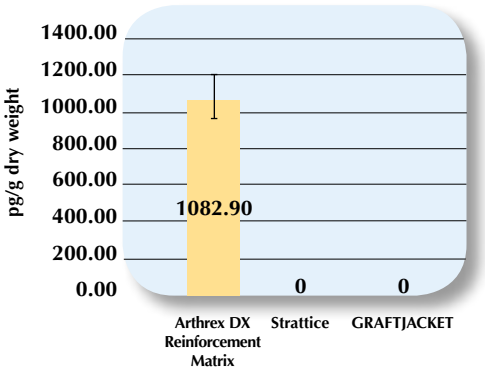


Scanning electron micrograph images of Arthrex DX Reinforcement Matrix. Shown are lower magnification (98x) and higher magnification (500x) cross-sectional images, demonstrating the morphology interconnected fibrous bundles, that may contribute to the strength of the material.

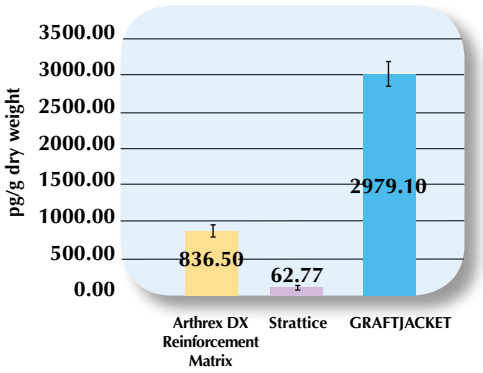
In Vitro Studies

Growth factors are studied to identify the roles they play in regulation of cellular activity. Retaining growth factors in the Arthrex DX Reinforcement Matrix may assist in the integration to and repair of the surgical site. Hoganson, et al,[1] described testing to measure the levels of vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF), and transforming growth factor beta (TGF-β) within the Arthrex DX Reinforcement Matrix and competitive products. VEGF is beneficial for stimulating angiogenesis, FGF plays a key role in angiogenesis and wound healing, and TGF-β is important for controlling proliferation. Graphs A and C show that VEGF and TGF-β, respectively, are retained within the Arthrex DX Reinforcement Matrix compared to competitive products. Graph B identifies more FGF in the Arthrex DX Reinforcement Matrix compared to Strattice ($p < 0.05$), but much less FGF compared to GRAFTJACKET ($p < 0.05$).

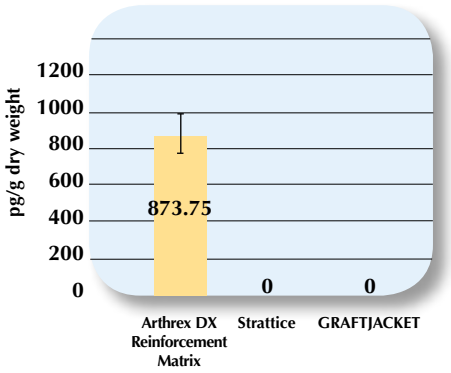
Graph A - *VEGF*



Graph B - *FGF*



Graph C - *TGF*β



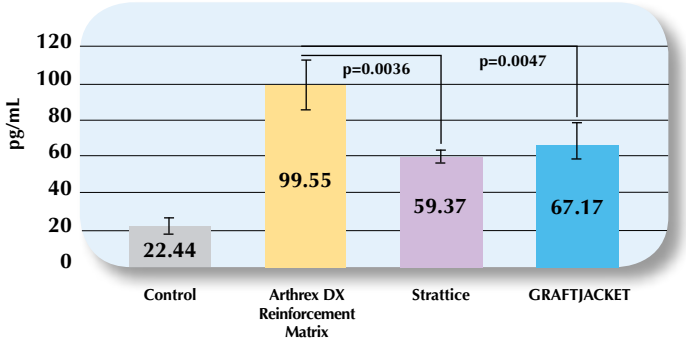
*The growth factor values are typical of results seen in Arthrex DX Reinforcement Matrix. Actual amounts may vary lot-to-lot.

Growth Factors Released in Cell Culture Media After Matrix Conditioning

Cell culture medium was either left untreated as a control, or treated with Arthrex DX Reinforcement Matrix, Strattice, or GRAFTJACKET for 24 hours. After the matrices were removed, human fibroblasts were cultured in the conditioned media for 24 hours; the media was then measured for VEGF content. Arthrex DX Reinforcement Matrix-conditioned medium stimulated fibroblasts to produce significantly higher levels of VEGF than Strattice-conditioned, GRAFTJACKET-conditioned, and control media.

*Bench test results may not be indicative of human clinical performance.

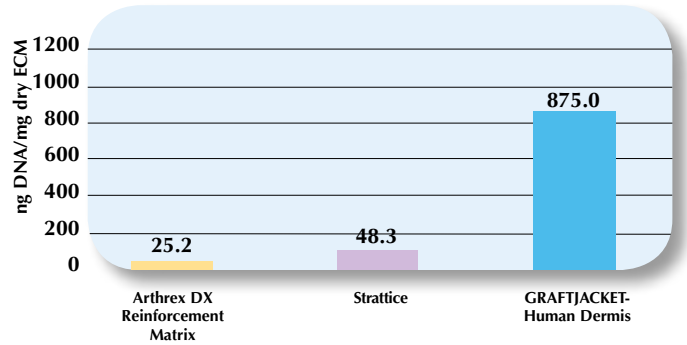
VEGF Concentration



Residual DNA Content

Residual DNA content, measured by Pico Green, demonstrates the effectiveness of processing methods to remove cellular materials. A quantitative Pico Green analysis for residual DNA was performed on the Arthrex DX Reinforcement Matrix and other commercially available patches to compare the effectiveness of their processing methods. The OPTRIX processed Arthrex DX Reinforcement Matrix exhibited >94% removal of the DNA, much better than for other commercially available matrices.

Residual DNA Content[1]



In Vivo Testing

To evaluate the reincorporation of the Arthrex DX Reinforcement Matrix, the ECM was evaluated in an *in vivo* fascial defect model in sheep. Defects were created either adjacent to the abdomen or the thigh and then repaired without additional augmentation (empty negative control, n = 4) or with the DX Matrix (n = 12). The surgical sites were evaluated grossly, histologically and biomechanically at six and twelve weeks. The DX Matrix performed favorably compared to empty negative controls, with minimal gross adhesion, low inflammatory scores and greater tensile strength of the healing surgical site when compared with the empty control.[2]

Empty Control -12 Weeks **Arthrex DX Reinforcement Matrix -12 Weeks**

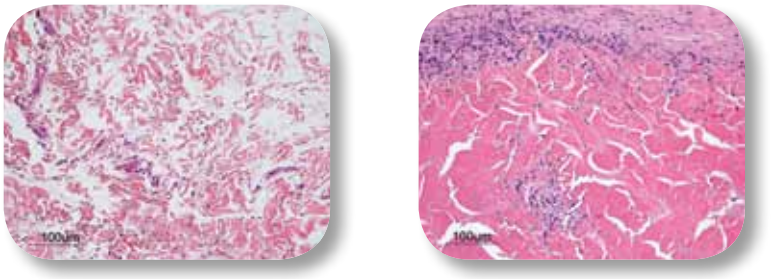


Figure 1

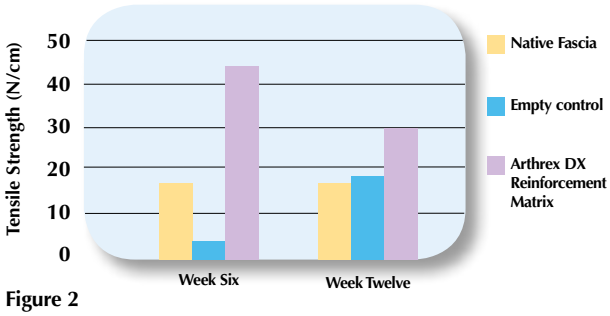
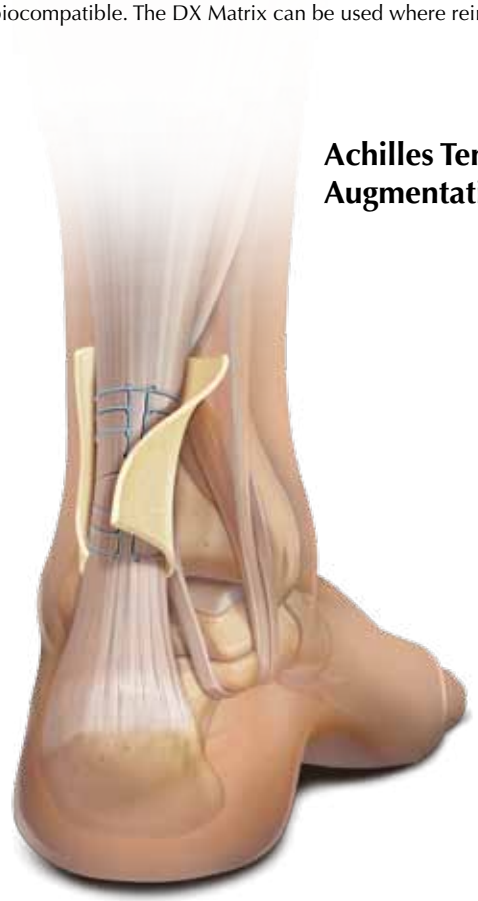


Figure 2

Figure 1. Histologic images of the empty control and Arthrex DX Reinforment Matrix fascial repair sites from explanted tissues harvested at twelve weeks post-operatively. Tissues were stained with hematoxylin and eosin (H & E). The images demonstrate good cell infiltration (purple elongated structures within pink tissue) at both defect sites with a minimal amount of circular-shaped macrophages demonstrating a minimal inflammatory response. Images at 20X magnification.[2]

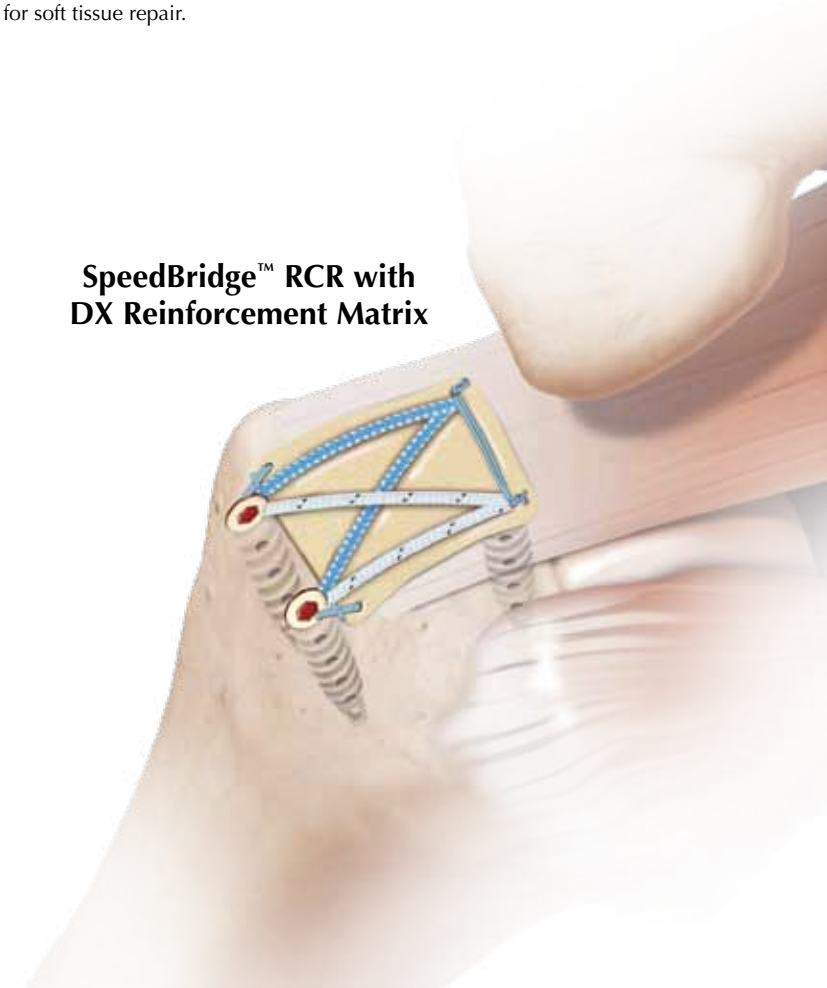
Figure 2. Strength of the surgical site at six and twelve weeks compared to native fascia. The Arthrex DX Reinforcement Matrix consistently maintains strength greater than native fascial tissue and the empty control throughout the healing process. As the DX Matrix is incorporated into the fascia, its strength adjusts towards the levels of the native fascia.[2]

The Arthrex DX Reinforcement Matrix is an acellular dermal matrix product that provides excellent mechanical strength and is completely biocompatible. The DX Matrix can be used where reinforcement is necessary for soft tissue repair.



Achilles Tendon Augmentation

SpeedBridge™ RCR with DX Reinforcement Matrix



References:

1 Hoganson DM, O'Doherty EM, Owens GE, Harilal DO, Goldman SM, Bowley CM, Neville CM, Kronengold RT, Vacanti JP, *The retention of extracellular matrix proteins and angiogenic and mitogenic cytokines in a decellularized porcine dermis*, Biomaterials, 2010; 31(26): 6730-7.

2 Hackett ES, Harilal DO, Bowley CM, Hawes M, Turner AS, Goldman SM, *Evaluation of porcine hydrated dermis augmented repair in a fascial defect model,* Journal of Biomedical Materials Research Part B: Applied Biomaterials, 2011; 96(1): 134-8.

Ordering Information

5 cm x 5 cm, Hydrated	ABS-30001S
6 cm x 8 cm, Hydrated	ABS-30002S

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