acellular allograft amniotic membrane

distributed by

the definitive choice for better biologics

aril®

acellular allograft amniotic membrane

aril® is a room-temperature stable allograft derived from human placental tissue collected from consenting donors. Post-decellularization & stabilization, aril™ is packaged in a double pouch packaging system and subjected to low-dose gamma irradiation. aril® is an allograft tissue intended for homologous use regulated by 21 CFR Part 1271 and Section 361 of the PHS Act.

aril® is configured as a precision-cut single layer of amnion shaped as an ellipse or disc. The configuration was selected and designed to maximize clinical usable surface area and limit necessary pre-operative manipulation of the graft. Seed Biotech, Inc. has shown a **greater than 95% reduction in DNA** using their proprietary decellularization process[9]. As a single layer of amnion, it is not necessary to emboss aril® as there is no side-specific orientation to the graft.

These images depict the revision of an epithelial scar defect and real-time healing post-treatment with aril®

Medical use of Amniotic Membrane

The amniotic membrane is a graft used to protect and help initiate the healing process for a variety of corneal diseases and defects.[7] Its anti-inflammatory and antimicrobial properties make it ideal for use in ophthalmology. Amniotic membrane has been shown to reduce the formation of adhesions and scar tissue, as well as accelerate healing.[2,3,4,5,6,7,8]

Seed Biotech® utilizes the natural protective qualities of the amniotic membrane, combined with proprietary processing technology, to create an acellular amniotic membrane allograft with clinically proven safety and efficacy.

Clinical Advantages

Prepared in a U.S. Food and Drug Administration (FDA) registered and American Association of Tissue Banks (AATB) accredited tissue establishment. This establishment's operations are focused on innovative biological material manufacturing, and it adheres to high standards of quality and safety. Decades of experience in biologics have informed the development of processing technology designed to remove unwanted material, such as cells, intracellular genetic material, and antigens, without altering the material structure and beneficial bioactive properties of amniotic membranes. This process used to prepare aril® for clinical use has been shown to reduce donor DNA by greater than 95%.[9] Seed Biotech's amniotic membrane is uniquely decellularized and configured to promote maximized patient care and benefit.

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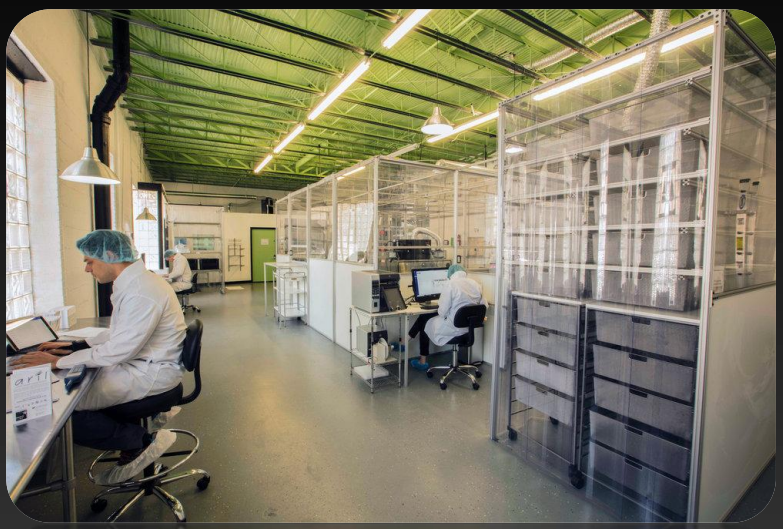

Ophthalmic Procedures:
- Corneal Defects[10]
- High-risk Trabeculectomies[11]
- Chemical burns[12]
- Stevens-Johnson Syndrome[13]
- Pterygium[14]

Surgical
- Orthopedic[15]
- General[16]
- Neurosurgery[17]
- Gynecological[18]

Wound
- Chronic[19]
- Surgical / Reconstruction[20]
- Burns[21]
- Traumatic[22]

Amniotic Tissue Properties:
- Anti-Inflammatory[2,3]
- Anti-microbial[4]
- Reduces scarring[2]
- Reduces adhesion[5]
- Promotes healing[6]
- Speeds fibrogenesis and angiogenesis[6]

Allograft tissues are intended for homologous use and are regulated by 21 CFR Part 1271 and Section 361 of the PHS Act They can be used in various orthopedic, surgical, ophthalmology, spinal, and wound-covering applications. The potential for clinical benefit has been demonstrated in numerous applications.

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Coding and Reimbursement Guide Eye Care

Amniotic Membrane(AM) can be used as a graft to facilitate ocular tissue repair or as a biological dressing to protect the ocular surface. As a graft, it provides a natural substrate that is conducive for migration and attachment of the patient's own epithelial cells.

Some common indications for AM as a surgical graft include:
- Pterygium and pinguecula surgery
- Conjunctivochalasis and conjunctival lesion surgery
- Superior limbic keratoconjunctivitis
- Leaking bleb repair
- Descemetocele or perforation
- Fornix and socket reconstruction

Q. What CPT codes describe the placement of AM?

A. There are several depending on how the AM is used: 65778 – Placement of amniotic membrane on the ocular surface; without sutures 65779 – Placement of amniotic membrane on the ocular surface; single layer, sutured 65780 – Ocular surface reconstruction; amniotic membrane transplantation; multiple layers

Q. What does Medicare allow for these procedures?

A. Physician payment rates vary depending on the site of service. There is a large site-of-service differential between physician reimbursement in-office and in-facility due to the supply. Payment for the supply of AM is not made to the physician when the procedure is performed in a facility. The 2024 Medicare allowable amounts are below. These amounts are adjusted in each locality by local indices. Other payers set their own fee schedules, which may differ considerably from Medicare rates.

CPT® Codes	65778	65779	65780
Physician in Office	$1217.32	$1066.03	$567.17
Physician in Facility	$41.85	$100.16	$567.17

Q. Does Medicare pay separately for the supply of AM?

A. No. HCPCS code V2790, Amniotic membrane for surgical reconstruction per procedure, is no longer eligible for discrete Medicare payment in any setting. Reimbursement for the supply is included with payment for the procedure.

Q. Are there any restrictions on Medicare reimbursement?

A. Yes. Medicare's National Correct Coding Initiative (NCCI) edits bundle AM transplantation procedures with pterygium removal (65420, 65426) and with the keratoplasty codes (65710, 65730, 65750, 65755, 65756). Use of a bandage contact lens (92071) is bundled with 65778. NCCI edits change quarterly, so check them periodically. The reimbursement information is provided by based on publicly available information from CMS, the AMA, and other sources. The reader is strongly encouraged to review federal and state laws, regulations, code sets, and official instructions promulgated by Medicare and other payers. This document is not an official source nor is it a complete guide on reimbursement. Although we believe this information is accurate at the time of publication, the reader is reminded that this information, including references and hyperlinks, changes over time, and may be incorrect at any time following publication.

Product Code	Configuration
M1002BR	15mm disc
M1005BR	2x3cm ellipse
M1012BR	3x5cm ellipse
M1017BR	3x7cm ellipse
M1027BR	5x7cm ellipse
M1063BR	8x10cm ellipse

allogeneic solutions

Allogeneic Solutions provides safe, high-quality acellular allograft amniotic membrane from Seed Biotech to meet the needs of physicians and their patients.

Partnership

Allogeneic Solutions and Seed Biotech have partnered, making Allogeneic Solutions an authorized distributor. Through our partnership with Seed Biotech, Allogeneic Solutions provides aril® (acellular allograft amniotic membrane), which can be used in a variety of orthopedic, surgical, ophthalmology, spinal, and wound-covering applications.

Allograft tissues are intended for homologous use and are regulated by 21 CFR Part 1271 and Section 361 of the PHS Act.

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