MiMedx GROUP

AmnioFix

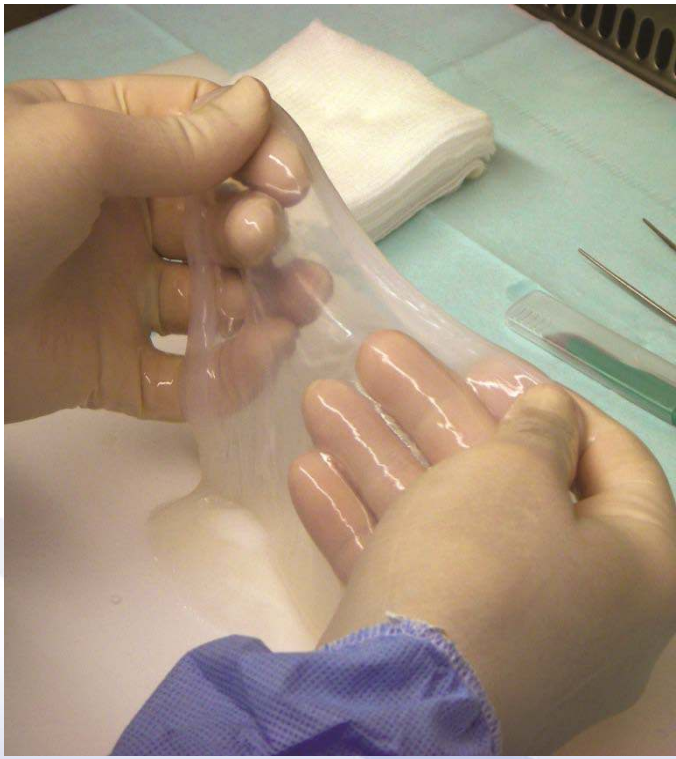
Training

Amniotic Membrane

AmnioFix

Why Amnion?

- History shows human amniotic membrane has been used in a clinical setting since the early 1900s.
- *In vivo* studies show the barrier properties of amniotic membrane help reduce scar tissue formation and scar attachment to the dura[1]
- Studies show amniotic membrane enhances the wound healing process.
  - It is non-immunogenic
  - It reduces inflammation
  - It reduces scar tissue
  - Contains essential growth factors



[1]Tao H and H. Fan. Implantation of Amniotic Membrane to Reduce Postlaminectomy Epidural Adhesion, *Eur Spine J.* 2009 Aug; 18(8): 1202-12

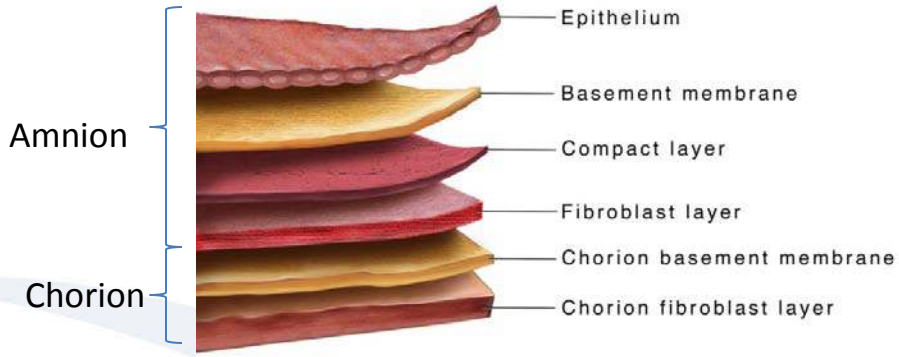
AmnioFix

Anatomy and Physiology

Collagen types: IV, V and VII

Presence of Growth Factors[1]*:

- Epidermal Growth Factor (EGF)
- Transforming Growth Factor Beta (TGF-β)
- Fibroblast Growth Factors (FGFs)
- Platelet Derived Growth Factors (PDGF) A&B

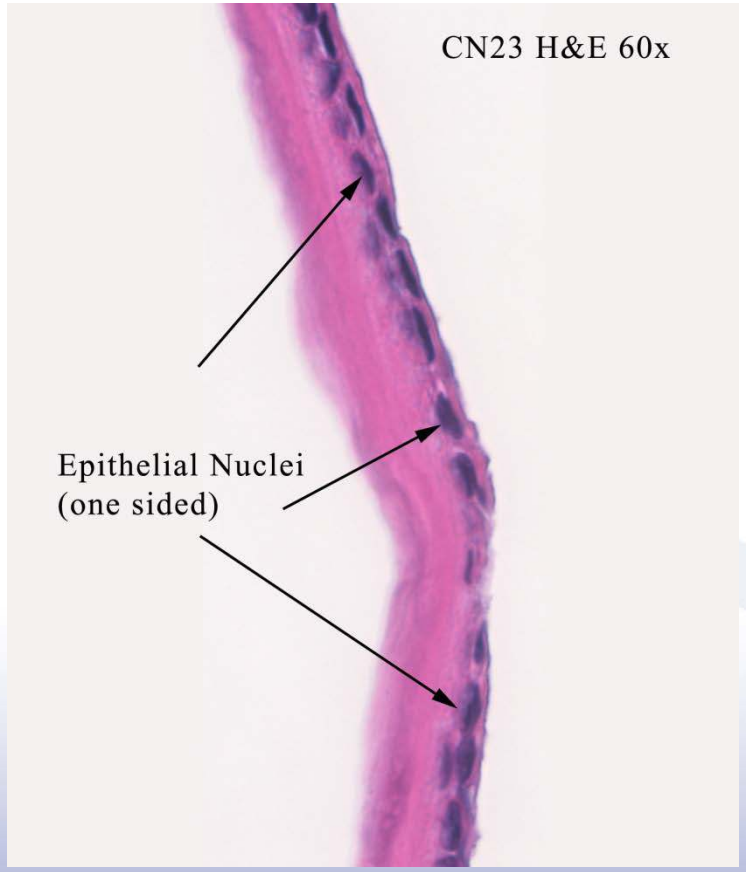


[1]*Hopkinson A. et al Proteomic Analysis of Amniotic Membrane Prepared for Human Transplantation: Characterization of Proteins and Clinical Implications. Journ Proteome Res 2006, 5, 2226-2235.*

*Confirmed by HPLC tests of sterilized AmnioFix

AmnioFix

H&E Stain of Amnion after Purion® Process



AmnioFix

- Efficacy
- Applications
- Safety

AmnioFix

- Efficacy
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AmnioFix

Efficacy

1. Overview of Healing Process
2. Anti- Inflammatory Properties
3. Reduction of Scar Tissue Formation
4. Enhance Healing Process

AmnioFix

Healing Process

Step 1: Inflammatory Phase (Immediate to 2-5 days)

- Hemostasis
- Inflammation

Reduction in Inflammation

Provides Collagen and growth factors

Step 2: Proliferative Phase (2 days to 3 weeks)

- Granulation- Fibroblasts lay bed of collagen
- Contraction- wound edges pull together to reduce defect, Epithelialization

Step 3: Remodeling Phase (3 weeks to 2 years)

- New Collagen forms which increases tensile strength to wound

AmnioFix

Anti-Inflammatory Properties

"Amniotic membrane reduces inflammation through entrapment of inflammatory cells"[1]

Amniotic membrane contains anti-inflammatory growth factors that can enhance wound healing.[2]

"HAM (Human Amniotic Membrane) cells express various anti-angiogenic and anti inflammatory proteins such as interleukin (IL)-1… and IL-10"[3]

[1] *Baradaran-Raffi et al Amniotic Membrane Transplantation. Iran J Ophthalmic Res 2007;2 (1):58-75.*

[2] *John T. et al Human amniotic membrane transplantation: Past, present, and future. Ophthalmology Clinic of North Am. 16 (2003) 43-65*

[3] *Toda A. et al The Potential of Amniotic Membrane/Amnion-Derived Cells for Regeneration of Various Tissues. J. Pharmacol Sci 105 (2007), 215-228*

AmnioFix

Reduction of Scar Tissue Formation and Enhancing Healing Process

Contains Collagen types, IV, V, and VII

- May inhibit fibrosis when used as a anatomic barrier.[1]
- Epidermal Growth Factor (EGF), Transforming Growth Factors-β (TGF-β), and Fibroblast Growth Factors (FGFs).

[1]*John T. et al Human amniotic membrane transplantation: Past, present, and future. Ophthalmology Clinic of North Am. 16 (2003) 43-65*

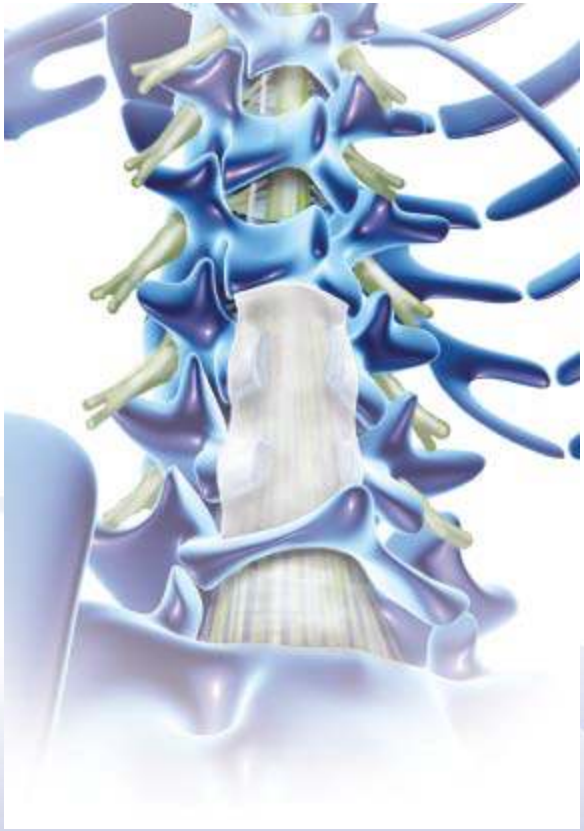
AmnioFix

- Efficacy
- **Applications**
- Safety

AmnioFix

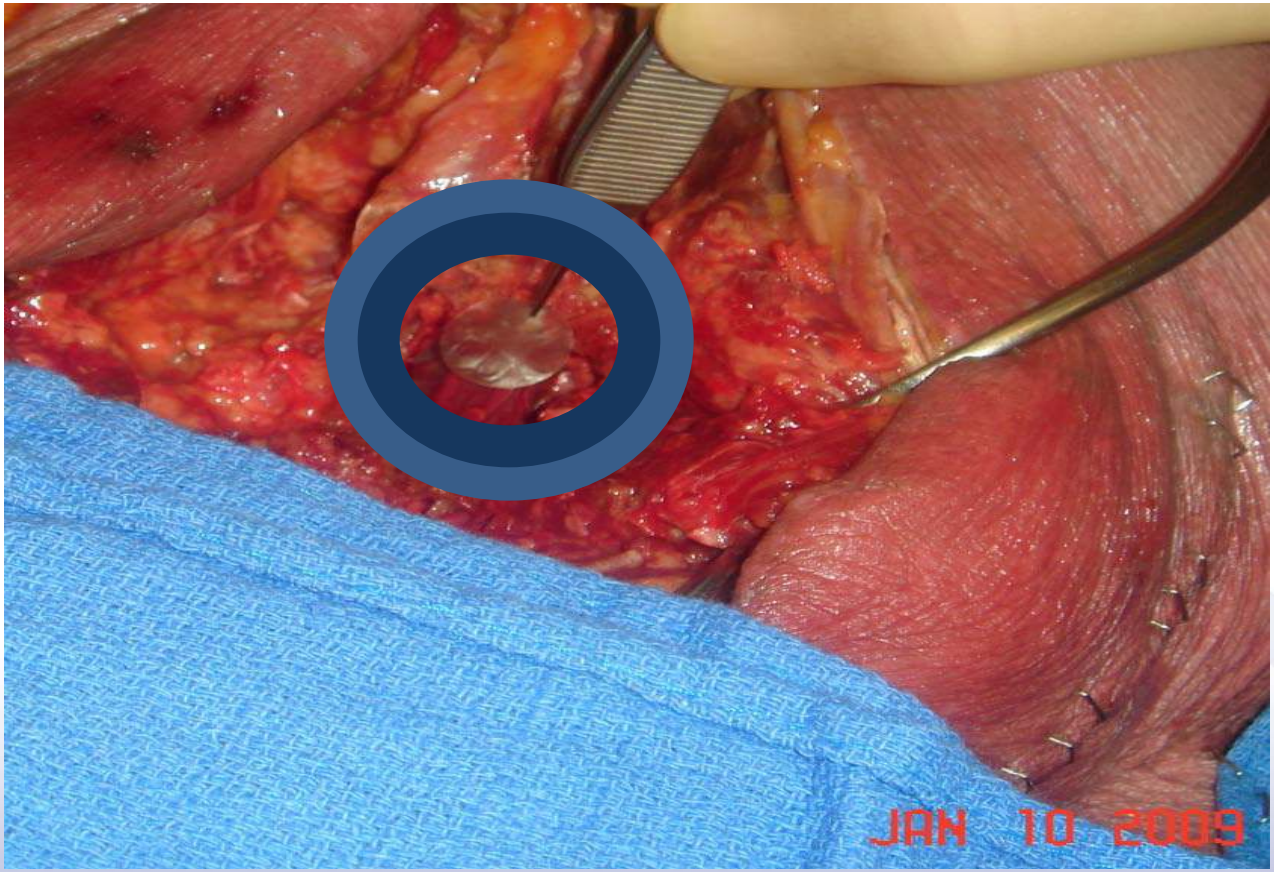
Applications

- Posterior
  - Laminectomy
  - Posterior Decompression
- Anterior
  - ACDF



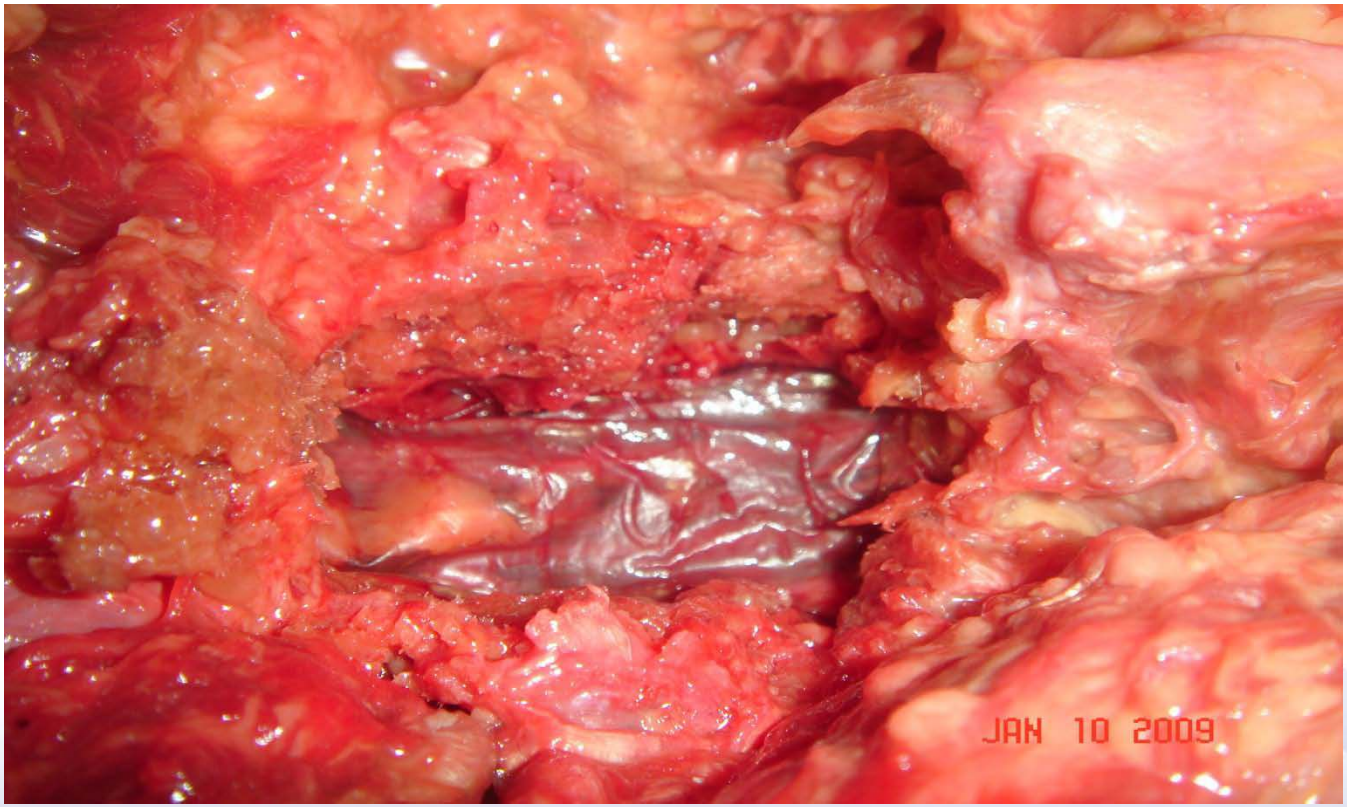
AmnioFix

Posterior Laminectomy Open or MAST Approach



AmnioFix

Posterior Spinal Approach



How to Apply on Posterior Approach

Dry Application:

1. Cut the AmnioFix to the appropriate size, larger is better.
2. Ensure all excess blood /fluid is removed from the surgical site.
3. Lay the AmnioFix so you can read the SB on the affected area, dura or exiting nerve root.
4. The AmnioFix will become tacky to the site. If surgeon needs to reposition just add a couple drops of sterile saline or water.
5. To make the tissue more malleable, add a couple drops of saline to hydrate the graft. The AmnioFix may be wrapped around corners and edges.
6. Do not suction near the AmnioFix once it is place.
7. Complete surgical procedure and close.

AmnioFix may be applied dry or wet, preferably dry

Reasons for using AmnioFix on a Laminectomy or Posterior decompression

1. Reduce scar tissue or “fibrosis” formation near or on dura
   - Fibrosis may lead to adhesions and could contribute to post-op pain

2. Reduce inflammation in the surgical site

3. “Enhances Healing”
   - Provides a scaffold for native connective tissues to penetrate, leaving a dissection plane of native tissue

1 and 3 should aid if surgeon needed to do a revision

relative light units per second (RLU/s).
Results: Results showed that the average RLU/s values from rats with 5x10^6 Ad-HMSCs engineered with 0.003 mg/ml rhBMP-2 on ACS were the highest, followed by the 5x10^6 Ad-HMSCs exposed to rhBMP-2 on ACS, then the 5x10^6 Ad-HMSCs/ACS (no rhBMP-2), and finally the rhBMP-2/ACS only (no cells, control) ($p < 0.05$). *In vitro* results were similar to *in vivo* study findings, wherein *Gluc* expression was only observed during the first 2-3 weeks after infection. Data suggest that decreased *Gluc* expression was possibly due to deletion of Gluc (target DNA), cell mutation, limited integration, or unstable infection rather than cell death.
Conclusion: *Gluc* urine-based assays facilitate frequent interval measurements in longitudinal studies and avoid the invasive procedure of terminal tissue harvest to evaluate the stem cells.

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Preclinical Study of Human Allograft Amniotic Membrane as a Barrier to Epidural Fibrosis in the Early Wound of a Postlaminectomy Rat Model
R.T. Allen[1], J. Massie[2], A. Mahar[1], F. Phillips[3]
[1]University of California - San Diego, Department of Orthopaedic Surgery, San Diego, CA, USA, [2]Alphatec Spine, Biomechanical and Clinical Research, Carlsbad, CA, USA, [3]Rush University Medical Center, Department of Orthopaedic Surgery, Chicago, IL, USA

Purpose: Epidural fibrosis and adhesive dural scarring poses potential problems in lumbar spine revision cases and may in part be responsible for recurrent post-operative pain. The purpose of the current study is to evaluate the use of human amniotic membrane for prevention of dural adhesions in a well established post-laminectomy animal model.
Methods: Thirty two mature male Harlan Sprague-Dawley rats had bilateral laminectomies (L5 and L6) and a right unilateral "joystick" disc injury (L5-6). Sixteen rats received no treatment (control group) whereas the other sixteen animals received the human amniotic roofing barrier (Amnioshield™, Alphatec Spine, Carlsbad, CA) over the entirety of the laminectomy site. Animals survived for 8 weeks. For each group, 8 animals were dedicated to histological analysis. The other 8 animals were allocated to biomechanical testing with dissection and exploration of the scar-dura interface post-testing. Histology analysis involved formalin fixation, ethanol dehydration, polymethylmethylacrylate embedding, milling to approximately 100-micron axial sections and staining with Masson-Goldner Trichrome (collagen). Intervertebral foramen fibrosis of the right L5 spinal nerve was quantified using a biomechanical methodology measuring the load-to-failure of the nerve as it is pulled free from the intervertebral foramen. The segmental L5 spinal nerve proximal and distal to the intervertebral foramen were freely dissected, isolating the segment of the nerve within the intervertebral foramen. The nerve was displaced distally at a constant velocity of 1cm/min along the axis of the spinal nerve and load-to-failure (grams) was measured for each animal. Behavioral changes to assess pain were monitored daily during the post-operative period for all animals. Tactile allodynia (behavioral changes) was evaluated utilizing von Frey hairs of logarithmically increasing stiffness to assess the withdrawal response at specific forces (grams) (indicative of pain).
Results: Histological analysis demonstrated clearly demarcated borders of the amniotic barrier separating the epidural fibrosis from the dura while the group with no barrier demonstrated epidural scar directly on the dura with visual obstruction of the dural sac (Figure 1). The axial pullout force required to remove the right L5 nerve root for the no barrier group (194.5±154.2g) demonstrated an approximately 50% greater force required than for the group with a barrier (98.1±98.4g). The barrier group also demonstrated significantly greater tolerance to pain (14.4±1.2g) than the no barrier group (11.1±5.4g) during behavioral testing (30% difference). Dissection of each specimen found that the scar could not be separated from the dura in the no barrier group while the barrier group demonstrated a clear tissue plane and the scar was easily removed without disruption to the dura.
Conclusion: The barrier group consistently demonstrated evidence that the dura was not as affected/adhesed to the epidural scar as the no barrier group when evaluated via histology, biomechanical evaluation of foraminal adhesions, tissue dissection/exploration and pain tolerance.

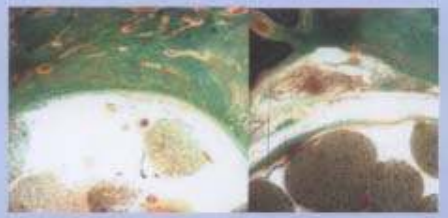
[barrier3]

Figure 1: Histology of no barrier (left) and barrier (right) groups demonstrating scar formation and location.

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Intradiscal Injections of Autologous Conditioned Serum (ACS) for Lumbar Disc Pain
C. Moser[1], D.W. Groenemeyer[2], T. Paduch[3], J. Becker[3], J. Hartmann[3], P. Wehling[1,3]
[1]Groenemeyer Institute for Microtherapy, University Witten/Herdecke, Bochum, Germany, [2]Private Group Practice Professor Wehling, Dr. Hartmann, Duesseldorf, Germany, [3]University of North Carolina, Comprehensive Center for Inflammatory Disorders, Chapel Hill, NC, USA

Background: Biology offers several strategies for restoring the degenerating disc, including the use of natural proteins that increase matrix accumulation and assembly, enhance the number of disc cells, or in other ways lead to restoration of the native healthy disc. This is the basis for administering Autologous Conditioned Serum (ACS). When peripheral blood is withdrawn and incubated with etched glass beads, leukocytes within the aspirate enrich the plasma with anti-inflammatory cytokines,

AmnioFix

Preclinical Study of Human Allograft Amniotic Membrane as a Barrier to Epidural Fibrosis in the Early Wound of a Postlaminectomy Rat Model

SAS 2011 Poster

Model

- Laminectomy Model- Rat (32)

Groups

- Human Amnion (16)
- Control (16)

Timepoints

8 weeks

Outcome Measurement

Epidural fibrosis

- Histological analysis to demonstrate a separation of epideral fibrosis from dura
- Adhesion tenacity via a nerve pull-out
- Pain

AmnioFix

Preclinical Study of Human Allograft Amniotic Membrane as a Barrier to Epidural Fibrosis in the Early Wound of a Postlaminectomy Rat Model

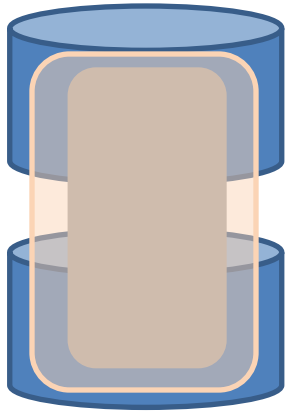
SAS 2011 Poster

Results

- Clear demarcated borders of the amniotic barrier separating the epidural fibrosis from the dura while control group with no barrier demonstrated epidural scar directly on the dura with visual obstruction of the dura
- Axial pull-out force was 50% reduced with the amniotic barrier group
- Barrier group demonstrated a significantly greater tolerance to pain (30% difference)

AmnioFix

How to Apply on Anterior Approach



Dry Application:

1. Cut the AmnioFix to the appropriate size, larger is better.
2. Ensure all excess blood /fluid is removed from the surgical site.
3. Lay the AmnioFix so you can read the SB on the affected area, dura or exiting nerve root.
4. The AmnioFix will become tacky to the site. If surgeon needs to reposition just add a couple drops of sterile saline or water.
5. To make the tissue more malleable, add a couple drops of saline to hydrate the graft. The AmnioFix may be wrapped around corners and edges.
6. Surgeon may choose to tack the tissue down, but does not have to
7. Do not suction near the AmnioFix once it is place.
8. Complete surgical procedure and close.

AmnioFix may be applied dry or wet, preferably dry

AmnioFix

Reasons for using AmnioFix on a ACDF

1. Provides a gliding surface for the esophagus and trachea to move over the plate
   - Slower resorption time of the AmnioFix Anterior than Posterior grafts

2. Reduce scar tissue or “fibrosis” formation onto the plate
   - Anterior fibrosis may contribute to dysphasia

3. Reduce inflammation in the surgical site

4. “Enhances Healing”
   - Provides a scaffold for native connective tissues to penetrate, leaving a dissection plane of native tissue

2 and 4 should aid if surgeon needed to do a revision

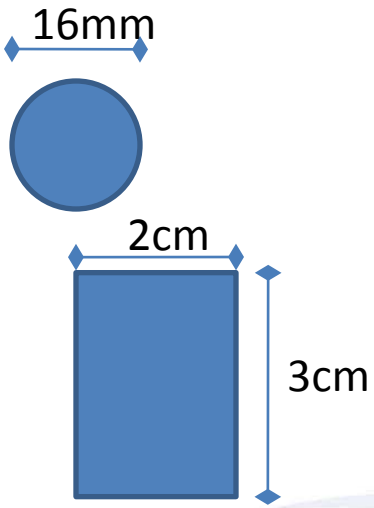
AmnioFix

Sizes and Potential Applications

- APS-5160

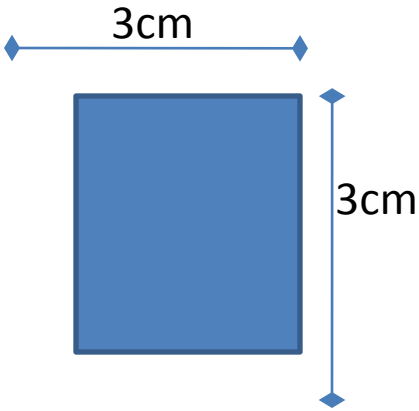
  or

- APS-5230



  - Posterior Laminectomy
  - Micro-disc
  - TLIF
  - PLIF
  - Over a Dural Repair

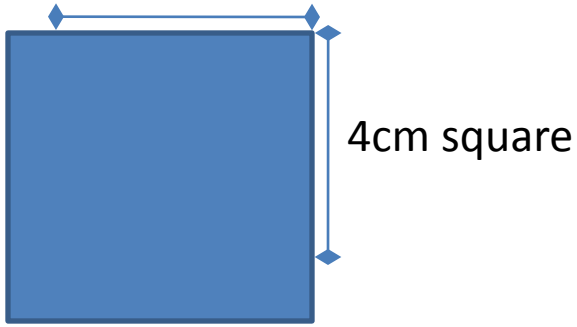
- AAS-5330
  - TLIF
  - PLIF
  - Single Level Posterior Fusion
  - Over a Dural Repair



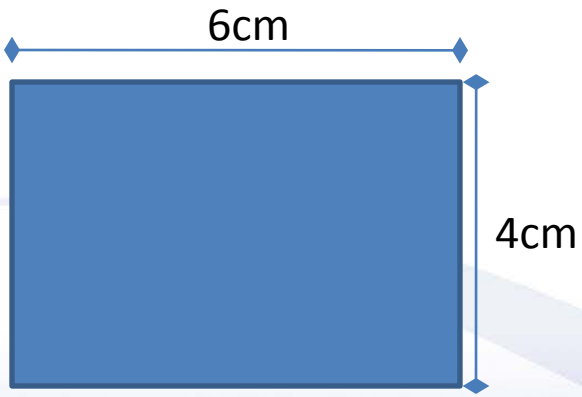
AmnioFix

Sizes and Potential Applications

- AAS-5440



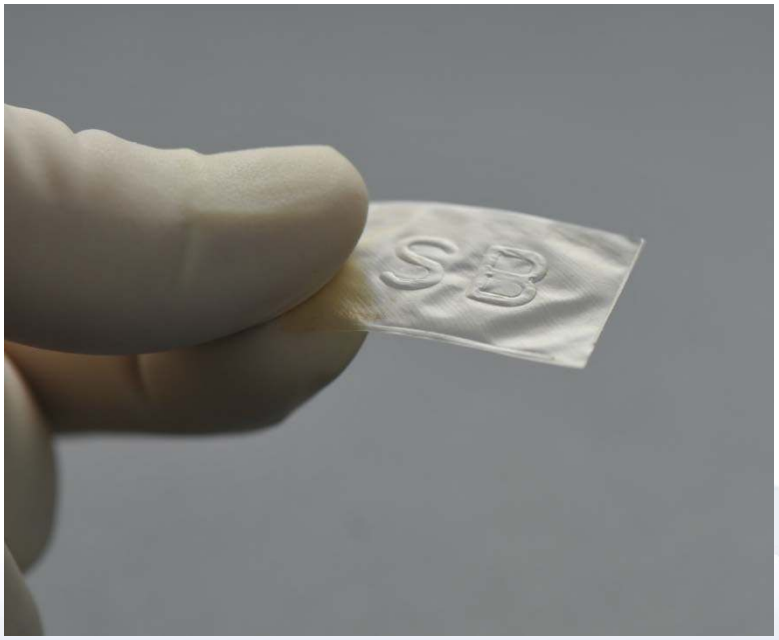
- AAS-5460
  - Single Level ACDF
  - Single Level Anterior Lumbar Fusion
  - Multilevel ACDF



AmnioFix

Handling Considerations

- Orientation of the Tissue Graft



- There is an up and a down. The surgeon should be able to read the SB embossment when placed on surgical site

AmnioFix

Resorption/ Remodeling of AmnioFix

- Depends on the anatomic location
- Depends on the patient
- Depends on the AmnioFix configuration

- Usually 3-4 weeks
- Scar tissue typically forms up to 2-3 weeks

AmnioFix

- Efficacy
- Applications
- Safety

AmnioFix

Safety

- What is the Regulatory Status of AmnioFix?
- How do we get and process Amniotic Tissue?
- Is there a possible host/patient reaction like other tissues?
- How and how long has been amniotic tissue been used?

AmnioFix

Regulatory Status

- AmnioFix products are regulated by the FDA under Section 361 of the PHS Act as tissue products (HCT/Ps).*
- This regulatory pathway allows for homologous use (i.e. the tissue performs a similar function in the recipient) in patients requiring wound healing and tissue protection from scar adhesions.
- FDA 510(k) clearance and approval are not needed.

**Surgical Biologics has pipeline products that will be regulated outside of Section 361 of the PHS Act.*

AmnioFix

Regulatory Compliance

Licensure and Accreditation

- Compliant with FDA, AATB, State and Local Regulations.
- Registered with the FDA as a Tissue Establishment.
- Accredited by the American Association of Tissue Banks (AATB) for the recovery, processing and distribution of amnion-based products.
- Licensed in the states of New York, Maryland and California.
- Copies of pertinent licensure and registration are available.

Regulatory Status

- Products regulated by the FDA as 361 tissue products (HCT/Ps).

About Surgical Biologics and MiMedx

- MiMedx Group acquired Surgical Biologics January 5, 2011
  - Surgical Biologics is now a MiMedx Group company
  - MiMedx tissues, AmnioFix will focus on Spinal applications

- Control largest amnion supply network in the nation
  - Unequalled ability to meet current product demand
  - Well-positioned for product growth
  - Vertically integrated

- Operate a state-of-the-art processing facility in Atlanta, GA
  - All products are processed, packaged and quality checked before final release – in one facility
  - Product chain-of-custody is maintained throughout process

- Maintain a strong product pipeline
  - Poised to introduce more sophisticated amnion-based tissues and products
  - Directed indications to optimize therapeutic benefits of amniotic membrane

AmnioFix

The Donation Process

- Prospective donors are referred from OB/GYN physicians.
- Only scheduled cesarean section births are used for transplant.
- Obviously, all live donors
- Surgical Biologics attends each donation.
- Nearly 100% of donations are from the Atlanta area.

AmnioFix

The Tissue Process

The *Purion*® process is validated to ensure safety, promoting surgical confidence.

- Effective decontamination step to reduce microbial contamination
- Terminal sterilization using E-Beam, which does not harm the product or matrix structure
- Products are presented dry for a simple application; unique embossment ensures proper orientation
- Five year shelf life

Purion processed Tissues are easy…

…to store

…to ship

…for the clinician to handle

…to orient prior to placement at the surgical site

AmnioFix

Why use the Purion® Process?

- The Purion process
  - provides increased surgical confidence.
  - yields a reliable graft which ensures patient safety.
  - has been validated for effective bioburden reduction.

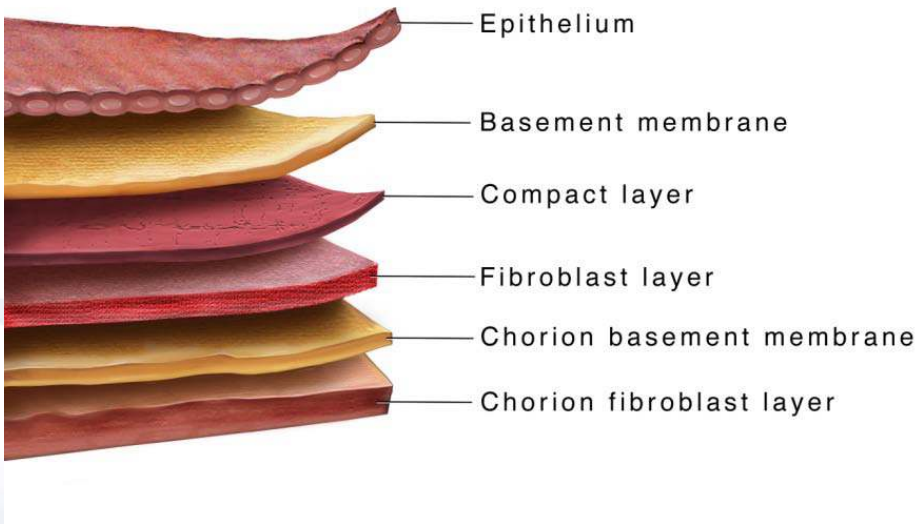
- The Purion process
  - has been specifically developed for the unique characteristics of amniotic membrane.
  - minimal graft manipulation maintains structural integrity.

AmnioFix

Anatomy and Physiology

Immunoprivileged Tissue

- No Immune response to the tissue
- Lack of HLA-A, B, C antigens or β2 microglobulin
- Immunosuppressive cytokines IL-4, IL-10, TGF



AmnioFix

Immunoprivileged Characteristics

- Amniotic membrane tissues are immunopriviledged and have negligable antigens on the tissue

Mothers and Babies can have different blood types but don't react to eachother. Typically the only difficulty could be during the birth where the bloods could mix

AmnioFix

Publication History

- Since 1913, ninety-two studies have concluded that amniotic tissue provides:
  - Scar Reducing
  - Adhesion Reducing
  - Inflammation Reducing

Peer reviewed journals include:

JBJS
Transplantation Journal
Canadian Medical Assoc Journal
Journal of Surgical Research
Nature
Journal of Wound Care
American Journal Clinical Pathology
European Journal Clinical Invest
Chinese Journal Tramatology
Blood
Toxicol Appl pharacol

Science
Lancet
Journal of Neuroendocrinology
American Plastic Surgery
British Journal Plastic Surgery
American Journal Opthalmics
Journal Indian Medical Assoc
Jnl Musculoskeletal Neuronal Int
Current Stem Cell Research
Journal Tissue Eng Regen Med
Nat Biotechnology

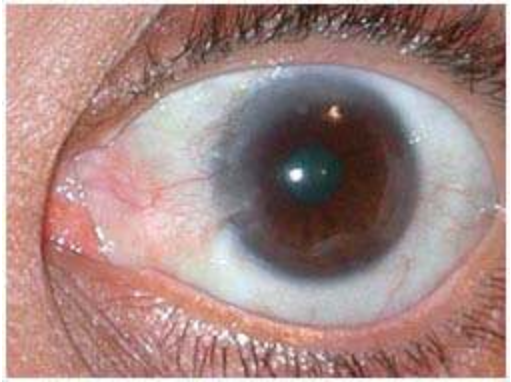
JAMA
Medical Journal of Australia
Journal of Wound Care
Medical Record Journal
Wound Repair and Regeneration
Japan Journal of Surgery
Stem Cells
Journal Orthopedic Research
Tissue Engineering
Haematologica

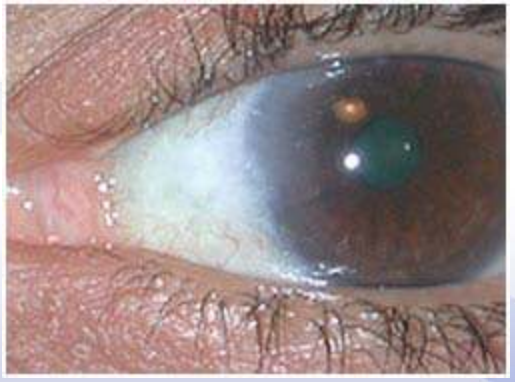
AmnioFix

Implant History

Over 30 Thousand implants in Ophthalmology Clinical Application

- Amnion is used to treat pterygium and chemical burns.
- Amnion closely mimics the natural properties of conjunctiva tissue.
- Amnion helps comfort the surgical site and guide healing.





<u>Supports the anti-inflammatory and scar reduction properties of AmnioFix.</u>

Sterilization, Shelf Life and Safety

- AmnioFix is terminally sterilized using e-beam radiation.
  - Target radiation level is <2.7 Mrads
- AmnioFix has a 5 year shelf-life

AmnioFix

Handling Considerations

- Temperature Restrictions
  - 32°F to 100°F
- Distributor Tissue Tracking
- Hospital Tissue Tracking
- Graft Preparation
  - Double Foil Pouch
  - Dry

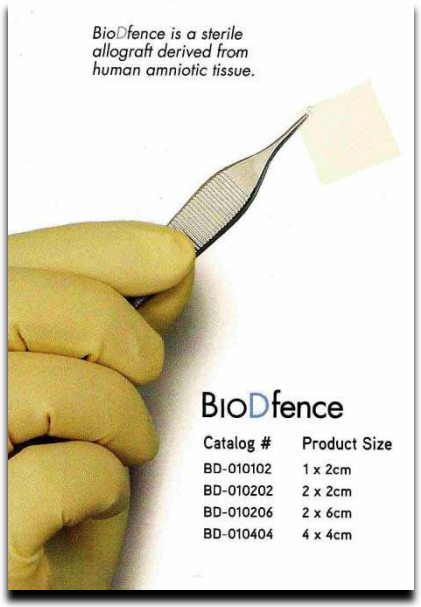
AmnioFix

Competition

- NuTech- NuShield
- AF Cell/Alphatec-AmnioShield
- BioD/ US Spine, Amedica- BioDfence

AmnioFix

Competition



Bio D-logics

- Single Layer Amnion
  - Thin, Difficult to place
  - Provided Hydrated
  - Cross-linked with Gluteraldehyde
- Distributed by Amedica/US Spine, plus other regional distributors

NuTech

Our Tissue, Purion Processed

AF Cell/ Alphatec

Our Tissue(most recent) there were previous suppliers that had more difficult to handle Amniotic tissue (BioD)

AmnioFix

Dried vs. Freeze Dried vs. Cross-linked

Freeze Dried-

- Goes through a freeze process, ice crystal formation, damage collagen structure

Cross-linked-

- Uses a chemical to make stronger
- Changes the structure of the collagen molecule
- Residual chemical agents (Gluderaldehyde)

Dried-

- Minimal damage to collagen structure
- No residual chemicals to damage tissue

AmnioFix

Autologous Free Fat Grafts

"The hypertrophic epidural scarring occurred in these three cases despite the presence of autologous fat grafts"[1]

"This study suggests that the use of free fat grafts during lumbar disc surgery was clinically ineffective"[2]

[1] *Martin-Ferrer S. Failure of autologous fat grafts to prevent postoperative epidural fibrosis in surgery of the lumbar spine. Neurosurgery. 1989 May;24(5):718-21.*

[2] *Gorgulu A. The effect of epidural free fat graft on the outcome of lumber disc surgery. Neurosurg Rev. 2004 Jul;27(3):181-4.*

AmnioFix

Key Points

AmnioFix

Key Selling Points

Effective

Contains growth factors unique to placental tissue:

Collagen Types IV, V, and VII

- Enhance wound healing
- Reduces Inflammation
- Barrier Protection
- Reduces Scar Tissue Formation
- Non-immunogenic

AmnioFix

Key Competitive Points

AmnioFix is not a single layer of Amnion, it is a composite graft

Purion Process® protects the scaffold leaving the collagen matrix intact, terminally sterilized

Dehydrated

- Simple application
- Embossed to facilitate ease of orientation
- Doesn't damage the collagen
- 5 year shelf life

AmnioFix is not cross-linked, leaving no residual Gluderaldehyde

AmnioFix

Sizes and Potential Applications

Offering	Dimensions
• APS-5160	16mm disc
• APS-5230	2x3cm
• AAS-5330	3x3cm
• AAS-5440	4x4cm
• AAS-5460	4x6cm

AmnioFix

Frequently Asked Questions

Q: What is Amniotic Tissue (or Amniotic Membrane)?

A: The amniotic membrane is the innermost layer of the placenta which lines the amniotic cavity. The membrane itself is made up of layers of tissue containing specialized cells. These cells allow the membrane to provide specific functions which aid in healing.

Q: What are the specialized cells and growth factors that make Amniotic Membrane a good barrier and wound healing agent?

A: The amniotic membrane has a structure or Extra Cellular Matrix (ECM) that is constructed of collagen types IV, V and VII, plus specialized proteins (fibrillin, fibronectin and laminins). In addition, amniotic membranes have growth factors that signal to elicit a specific cellular response. In vivo studies show that the properties of amniotic membrane help reduce scar tissue formation and scar attachment to the dura.[1]

Q: What growth factors are present in Amniotic Tissue?

Epidermal Growth Factor (EGF)

Transforming Growth Factor Beta (TGF-**β)**

Fibroblast Growth Factor (FGF)

Platelet Derived Growth Factor (PDGF)

AmnioFix

Q: How does AmnioFix both reduce scar formation and heal at the same time?

A: AmnioFix reduces scar tissue formation by down regulating or inhibiting expression of TGF-b receptors in migrating fibroblast cells. These migrating cells are now stimulated by other growth factors where granulation tissue is minimized and a native connective tissue matrix is generated at the wound site. AmnioFix also reduces inflammation by entrapment of T lymphocytes and the expression of IL-4 and IL-10 (interleukins).

Q: What kind of publications are there on Amniotic Tissue?

A: There are over 90 publications on Amniotic Tissue. Publications on ophthalmic, wound care, spine and orthopedic uses of the tissue describing the anti-inflammatory properties, scar reduction and wound healing.

Q: How safe is AmnioFix?

A: MiMedx uses the patent pending Purion® process for the processing of amniotic membrane tissue. The process technology and donor screening follow strict guidelines as set forth by both the Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). Eligible donors are all living mothers which have given full consent and must have delivered a live birth via cesarean section. Serologic blood tests are then performed to rule out the potential for infectious disease transmission. The complete process concludes with validation by an outside source to ensure that the procedural process results in a safe and effective implant.

AmnioFix

Q: Are there differences between the tissues being used for different applications?

A: Yes, there are difference between the tissues for each of the applications. Each tissue has been specifically processed for the application it is promoted for.

Q: What is the "SB" that I see on the tissue?

A: "SB" stands for Surgical Biologics, the founder and processor of the amniotic tissue and Wholly owned subsidiary of MiMedx Group, Inc.

Q: Is amniotic tissue permanent or resorbable?

A: AmnioFix is resorbable and will resorb depending on the specific application, patient, and location it is placed, typically 4-6 weeks.

Q: Do I need to suture the Amniotic Tissue?

A: Suturing is not required.

AmnioFix

Q: What is the technique to apply AmnioFix?

A: 1. Cut the AmnioFix to the appropriate size, if clinically necessary.

2. Ensure all excess blood/fluid is removed from the surgical site.

3. Lay the AmnioFix so the SB can be read on the desired surgical site. ("SB" side up)

4. The AmnioFix will become tacky to the site. If surgeon needs to reposition, just add a couple drops of sterile saline or water.

5. Suture the AmnioFix (optional based on surgeon preference)

6. To make the AmnioFix more malleable, add a couple drops of saline to hydrate the graft. The AmnioFix may be contoured to the underlying anatomy.

7. Do not suction near the AmnioFix.

8. Complete surgical procedure and close.

Q: Is this product freeze dried? I heard the freeze dried process destroys cell structure.

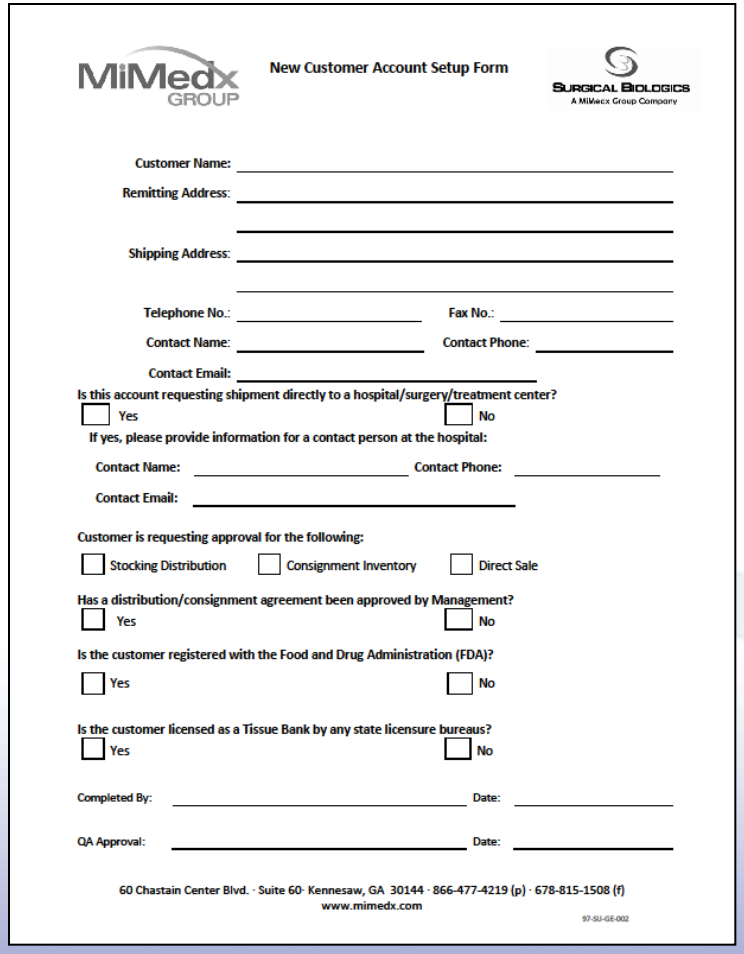
A: No, this product is not freeze dried.

Q: How is this more effective than the liquid versions on the market?

A: The injectable liquid versions on the market are in early stages of development. We are working on an injectable that we think will clinically relevant soon. There is room on the market for both treatments.

AmnioFix

Forms



MiMedx GROUP

New Customer Account Setup Form

SURGICAL BIOLOGICS
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Customer Name: _____

Remitting Address: _____

_____

Shipping Address: _____

_____

Telephone No.: _____ Fax No.: _____

Contact Name: _____ Contact Phone: _____

Contact Email: _____

Is this account requesting shipment directly to a hospital/surgery/treatment center?

☐ Yes ☐ No

If yes, please provide information for a contact person at the hospital:

Contact Name: _____ Contact Phone: _____

Contact Email: _____

Customer is requesting approval for the following:

☐ Stocking Distribution ☐ Consignment Inventory ☐ Direct Sale

Has a distribution/consignment agreement been approved by Management?

☐ Yes ☐ No

Is the customer registered with the Food and Drug Administration (FDA)?

☐ Yes ☐ No

Is the customer licensed as a Tissue Bank by any state licensure bureaus?

☐ Yes ☐ No

Completed By: _____ Date: _____

QA Approval: _____ Date: _____

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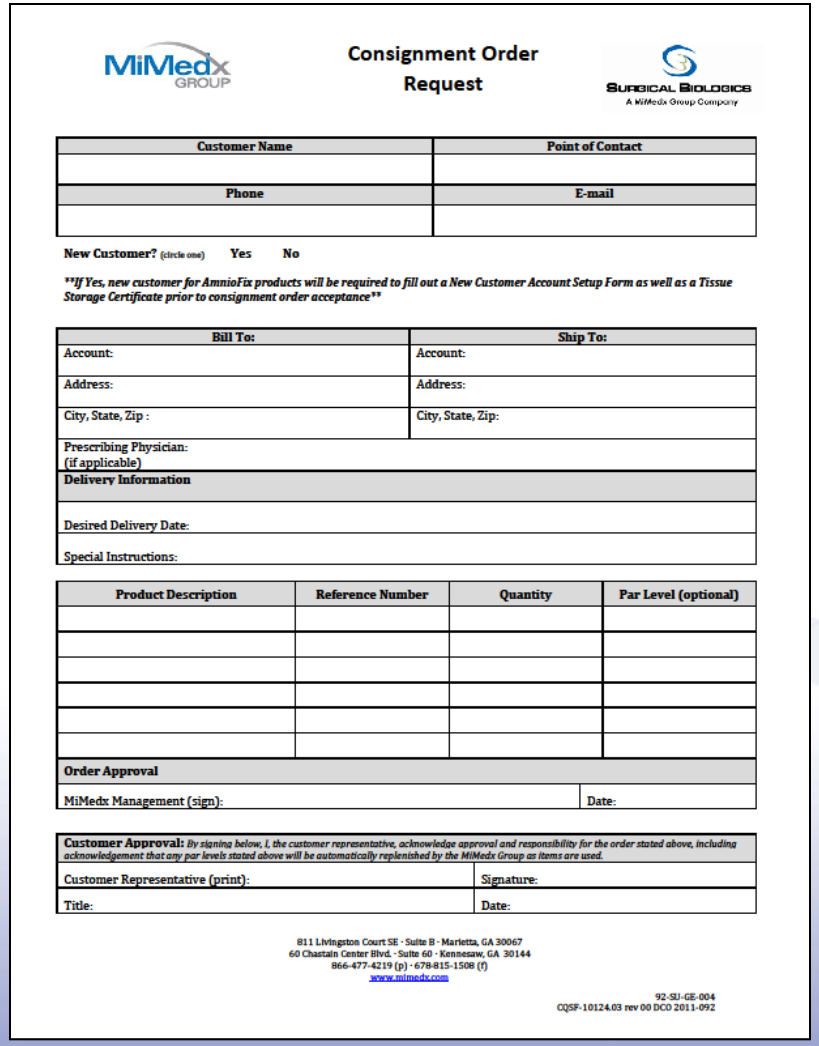
AmnioFix

Forms



MiMedx GROUP

Consignment Order Request

SURGICAL BIOLOGICS
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Customer Name	Point of Contact
Phone	**E-mail**

New Customer? (circle one) **Yes** **No**

If Yes, new customer for AmnioFix products will be required to fill out a New Customer Account Setup Form as well as a Tissue Storage Certificate prior to consignment order acceptance*

Bill To:	Ship To:
Account:	Account:
Address:	Address:
City, State, Zip :	City, State, Zip:
Prescribing Physician: (if applicable)	
Delivery Information	
Desired Delivery Date:	
Special Instructions:	

Product Description	Reference Number	Quantity	Par Level (optional)

Order Approval	
MiMedx Management (sign):	Date:

Customer Approval: *By signing below, I, the customer representative, acknowledge approval and responsibility for the order stated above, including acknowledgement that any par levels stated above will be automatically replenished by the MiMedx Group as items are used.*	
Customer Representative (print):	Signature:
Title:	Date:

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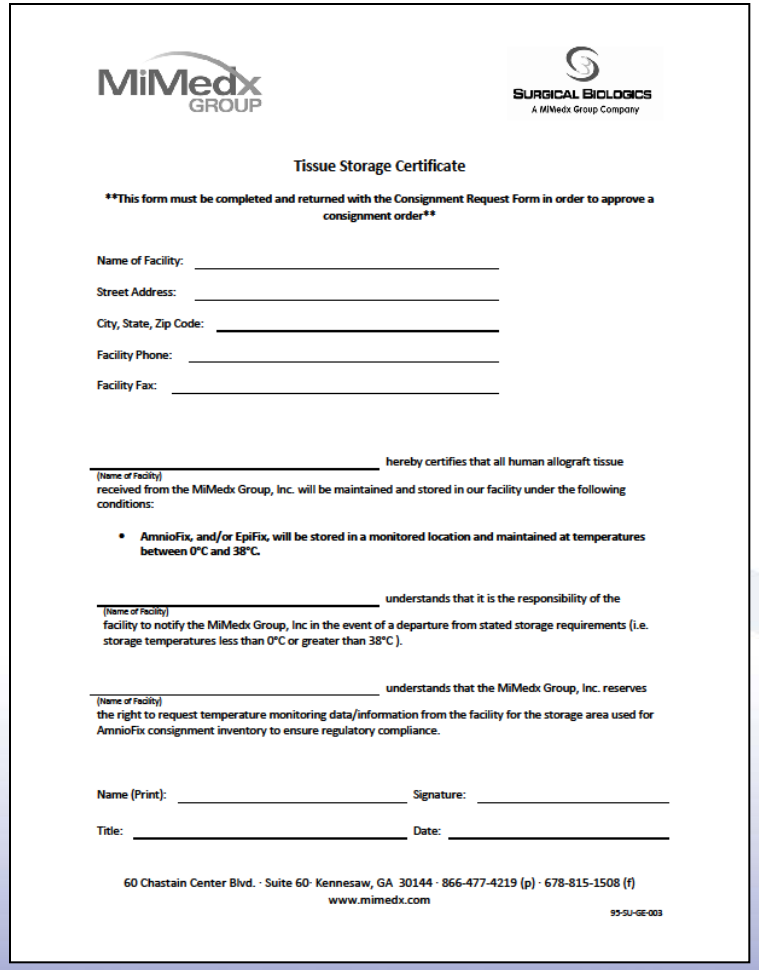

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Tissue Storage Certificate

****This form must be completed and returned with the Consignment Request Form in order to approve a consignment order****

Name of Facility: _____

Street Address: _____

City, State, Zip Code: _____

Facility Phone: _____

Facility Fax: _____

_____ hereby certifies that all human allograft tissue
(Name of Facility)
received from the MiMedx Group, Inc. will be maintained and stored in our facility under the following conditions:

- **AmnioFix, and/or EpiFix, will be stored in a monitored location and maintained at temperatures between 0°C and 38°C.**

_____ understands that it is the responsibility of the
(Name of Facility)
facility to notify the MiMedx Group, Inc in the event of a departure from stated storage requirements (i.e. storage temperatures less than 0°C or greater than 38°C).

_____ understands that the MiMedx Group, Inc. reserves
(Name of Facility)
the right to request temperature monitoring data/information from the facility for the storage area used for AmnioFix consignment inventory to ensure regulatory compliance.

Name (Print): _____ Signature: _____

Title: _____ Date: _____

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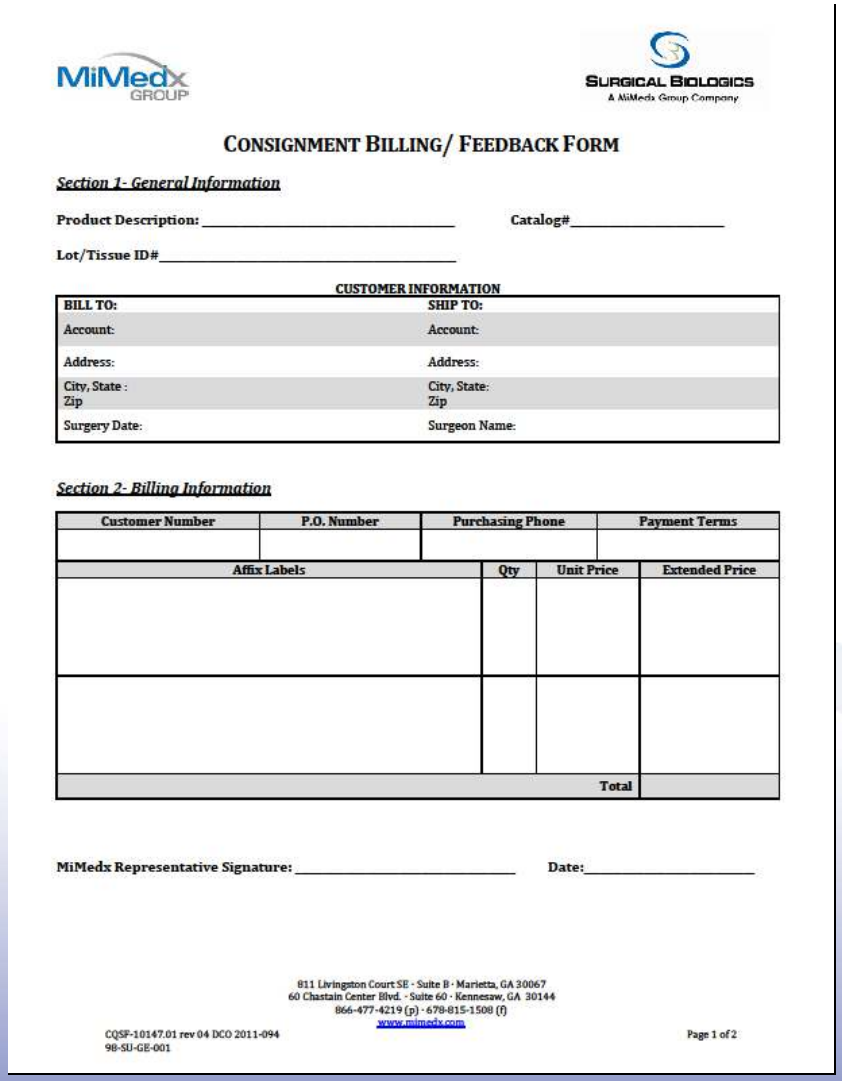
Forms



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CONSIGNMENT BILLING/ FEEDBACK FORM

Section 1- General Information

Product Description: _____ **Catalog#**_____

Lot/Tissue ID#_____

CUSTOMER INFORMATION

BILL TO:	**SHIP TO:**
Account:	Account:
Address:	Address:
City, State : Zip	City, State: Zip
Surgery Date:	Surgeon Name:

Section 2- Billing Information

Customer Number	P.O. Number	Purchasing Phone	Payment Terms

Affix Labels	Qty	Unit Price	Extended Price
		Total	

MiMedx Representative Signature: _____ **Date:**_____

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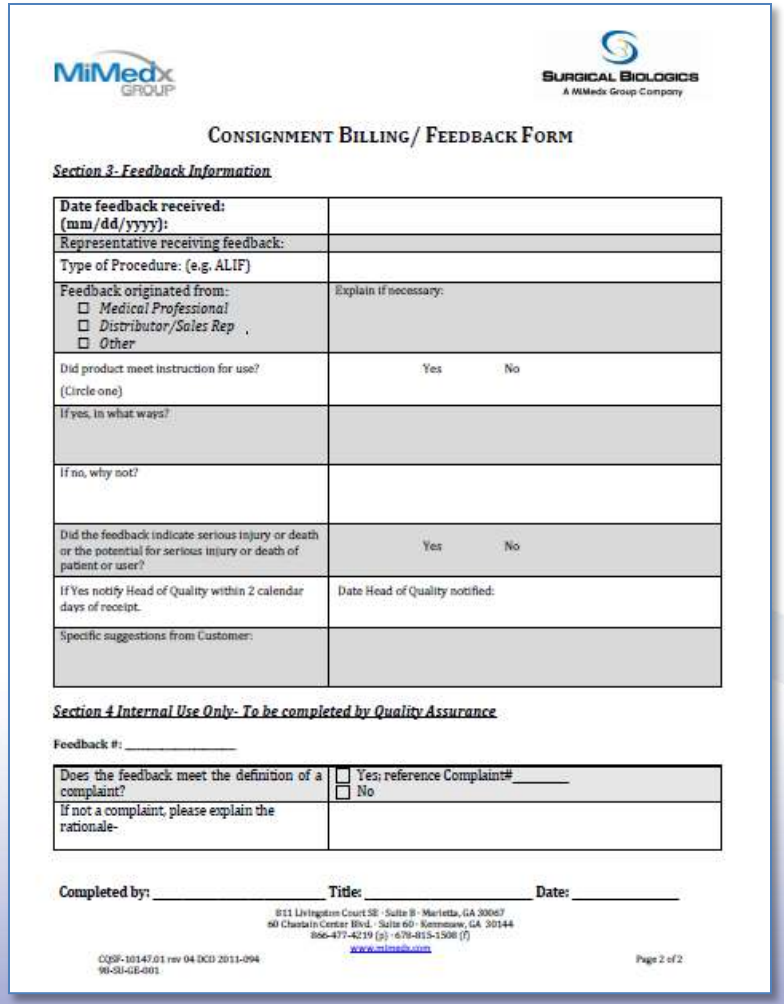

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CONSIGNMENT BILLING/ FEEDBACK FORM

Section 3- Feedback Information

Date feedback received: (mm/dd/yyyy):	
Representative receiving feedback:	
Type of Procedure: (e.g. ALIF)	
Feedback originated from: ☐ *Medical Professional* ☐ *Distributor/Sales Rep* ☐ *Other*	Explain if necessary:
Did product meet instruction for use? (Circle one)	Yes No
If yes, in what ways?	
If no, why not?	
Did the feedback indicate serious injury or death or the potential for serious injury or death of patient or user?	Yes No
If Yes notify Head of Quality within 2 calendar days of receipt.	Date Head of Quality notified:
Specific suggestions from Customer:	

Section 4 Internal Use Only- To be completed by Quality Assurance

Feedback #: _____

Does the feedback meet the definition of a complaint?	☐ Yes; reference Complaint#_____ ☐ No
If not a complaint, please explain the rationale-	

Completed by: _____ **Title:** _____ **Date:** _____

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AmnioFix

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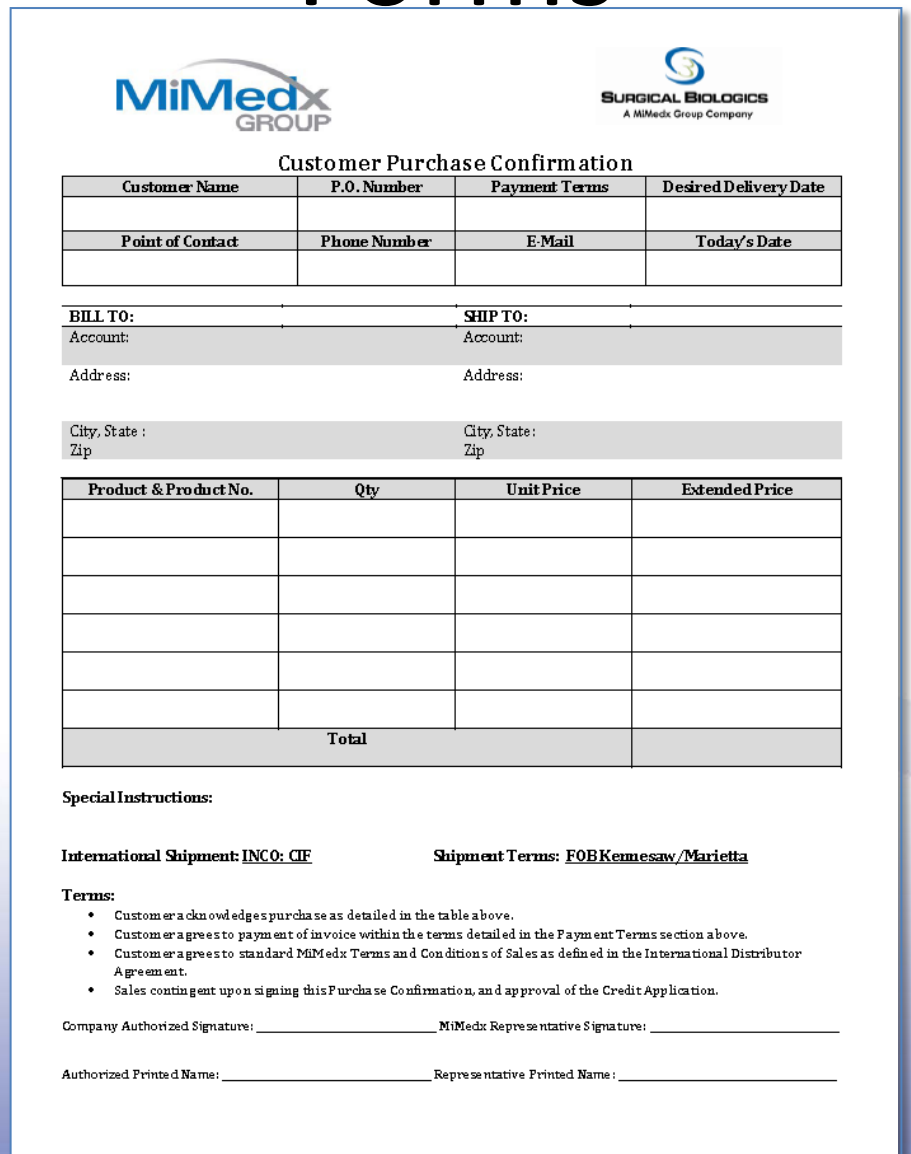

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Customer Purchase Confirmation

Customer Name	P.O. Number	Payment Terms	Desired Delivery Date
Point of Contact	**Phone Number**	**E-Mail**	**Today's Date**

BILL TO:	SHIP TO:
Account:	Account:
Address:	Address:
City, State : Zip	City, State : Zip

Product & Product No.	Qty	Unit Price	Extended Price
Total			

Special Instructions:

International Shipment: INCO: CIF **Shipment Terms:** FOB Kennesaw/Marietta

Terms:

- Customer acknowledges purchase as detailed in the table above.
- Customer agrees to payment of invoice within the terms detailed in the Payment Terms section above.
- Customer agrees to standard MiMedx Terms and Conditions of Sales as defined in the International Distributor Agreement.
- Sales contingent upon signing this Purchase Confirmation, and approval of the Credit Application.

Company Authorized Signature: _____ MiMedx Representative Signature: _____

Authorized Printed Name: _____ Representative Printed Name: _____