Amniotic Membrane
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

Anatomy and Physiology

Collagen types: IV, V and VII

Presence of Growth Factors\(^1\)*:

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


*Confirmed by HPLC tests of sterilized AmnioFix
H&E Stain of Amnion after Purion® Process
• Efficacy

• Applications

• Safety
• Efficacy

• Applications

• Safety
Efficacy

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

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

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
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

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).

• Efficacy

• Applications

• Safety
Applications

- Posterior
  - Laminectomy
  - Posterior Decompression

- Anterior
  - ACDF
Posterior Laminectomy Open or MAST Approach
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 placed.
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
Results: Results showed that the average RLU's values from rats with $5 \times 10^6$ Ad-HMScs engineered with 0.03 mg/ml rhBMP-2 on ACS were the highest, followed by the $5 \times 10^6$ Ad-HMScs exposed to rhBMP-2 on ACS, then the $5 \times 10^6$ Ad-HMScs engineered with ACS (no rhBMP-2), and finally the rhBMP-2 on 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 depletion 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 Post laminectomy Rat Model
R.T. Allen, J. Magie, A. Mahar, F. Phillips
*University of California - San Diego, Department of Orthopaedic Surgery, San Diego, CA, USA; Alphatec Spine, Biomechanical and Clinical Research, Carlsbad, CA, USA, Rush University Medical Center, Department of Orthopaedic Surgery, Chicago, IL, USA

Purpose: Epidural fibrosis and adhesions are concerns in lumbar spine revision cases and may in part be responsible for persistent post-operative pain. The purpose of the study was to evaluate the use of an amniotic membrane for prevention of adhesions in a well-established post-laminectomy animal model.

Methods: Thirty two newborn Harlan Sprague-Dawley rats had bilateral laminectomies (L5 and L6) and a right unilateral “joystick” disc injury (L5-L6). Sixteen rats received no treatment (control group) whereas the other sixteen animals received the human amniotic membrane as a barrier (Amnionshield™, 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. Histological analysis involved formalin fixation, ethanol dehydration, poly-methyl-methylacrylate 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 change) 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 ± 154.2 g) demonstrated an approximately 50% greater force required than for the group with a barrier (93.1 ± 98.4 g). The barrier group also demonstrated significantly greater tolerance to pain (14.4 ± 1.2 g) than the no barrier group (11.1 ± 5.4 g) 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 as adhered to the epidural scar as the no barrier group when evaluated via histology, biomechanical evaluation of foraminial adhesions, tissue dissection/exploration and pain tolerance.

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Intradiscal Injections of Autologous Conditioned Serum (ACS) for Lumbar Disc Pain
C. Moser1, D.W. Groenemeyer1, F. Poduch1, J. Becker1, J. Hartmann2, P. Theiling1
*Groenemeyer Institute for Microtherapy, University Witten/Herdecke, Bochum, Germany, Private Group Practice Professor Theiling, Dr. Hartmann, Dusseldorf, Germany, University of North Carolina, Complementary 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, which can be delivered into the intervertebral disc with local injections.

Questions? (666) 473-9440 (11:51), +1(630) 995-9994 (Int'l)
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 epidural fibrosis from dura
  - Adhesion tenacity via a nerve pull-out
  - Pain
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)
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
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
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
Sizes and Potential Applications

- AAS-5440
  - 4cm square

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

• Applications

• Safety
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 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.
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
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.
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
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.
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
Immunoprivileged Characteristics

- Amniotic membrane tissues are immunoprivileged and have negligible antigens on the tissue.

Mothers and Babies can have different blood types but don’t react to each other. Typically the only difficulty could be during the birth where the bloods could mix.
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 Ophthalmics
- 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
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.

Supports the anti-inflammatory and scar reduction properties of AmnioFix.
AmnioFix is terminally sterilized using e-beam radiation.
  - Target radiation level is <2.7 Mrads

AmnioFix has a 5 year shelf-life
Handling Considerations

- Temperature Restrictions
  - 32°F to 100°F

- Distributor Tissue Tracking

- Hospital Tissue Tracking

- Graft Preparation
  - Double Foil Pouch
  - Dry
Competition

• NuTech- NuShield

• AF Cell/Alphatec-AmnioShield

• BioD/ US Spine, Amedica- BioDfence
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)
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
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”\(^2\)


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 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.
# Sizes and Potential Applications

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<tr>
<td>APS-5160</td>
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<tr>
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<tr>
<td>AAS-5440</td>
<td>4x4cm</td>
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<tr>
<td>AAS-5460</td>
<td>4x6cm</td>
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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)
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-β 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.
Q: Are there differences between the tissues being used for different applications?

A: Yes, there are differences 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.
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.
New Customer Account Setup Form

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/dematment 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 bureau?
☐ Yes ☐ No

Completed By: ____________________________ Date: ____________________________
QA Approval: ____________________________ Date: ____________________________
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: ________________________________

[Signature]

I hereby certify that all human allograft tissues received from the MiMedx Group, Inc. will be maintained and stored in our facility under the following conditions:

- AmnioFix, and/or FixAll, will be stored in a monitored location and maintained at temperatures between 08°C and 30°C.

- [Facility Name] understands that it is the responsibility of the facility to notify the MiMedx Group, Inc. in the event of a departure from stated storage requirements (i.e., storage temperatures less than 08°C or greater than 30°C).

- [Facility Name] understands that the MiMedx Group, Inc. reserves 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): ____________________________
Title: ____________________________
Signature: ____________________________
Date: ____________________________

60 Chastain Center, Suite 600, Kennesaw, GA 30144 | 866-477-4219 [p] | 678-815-1508 [f]
www.mimedx.com
# CONSIGNMENT BILLING/FEEDBACK FORM

## Section 1 - General Information

Product Description: ___________________________  Catalog#: ___________________________
Lot/Tissue ID#: ___________________________

## CUSTOMER INFORMATION

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MiMedx Representative Signature: ___________________________  Date: ___________________________
# Conignment Billing/Feedback Form

## Section 1: Feedback Information

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<td>Feedback originated from: ☐ Medical Professional  ☐ Distributor/Sales Rep.  ☐ Other</td>
<td>Explain (if necessary):</td>
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<td>Product meant for instruction for use? (Circonference)</td>
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<td>If yes, in what ways?</td>
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<td>If no, why not?</td>
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<td>Did the feedback indicate serious injury or death or the potential for serious injury or death of patient or user?</td>
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<td>If yes notify head of quality within 2 calendar days of receipt.</td>
<td>Date Head of quality notified:</td>
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<td>Specific suggestions from customer:</td>
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## Section 2: Internal Use Only: To be completed by Quality Assurance

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Completed by: ____________________  Title: ____________________  Date: ____________________
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**BILL TO:**

<table>
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<th>Account</th>
<th>Address</th>
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**SHIPPED TO:**

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<th>Address</th>
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<tr>
<th>City</th>
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<th>Zip</th>
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<thead>
<tr>
<th>Product &amp; Product No.</th>
<th>Qty</th>
<th>Unit Price</th>
<th>Extended Price</th>
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**Total**

**Special Instructions:**

- **International Shipment:** DOL: CIF
- **Shipments Terms:** FOB Kennewick/Marietta

**Terms:**
- Customer acknowledges purchase as detailed in the table above.
- Customer agrees to payment terms as detailed in the Payment Terms section above.
- Customer agrees to standard MiMedx Terms and Conditions of Sale 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:** ___________________________