



# Aroa Biosurgery INVESTOR DAY

Unlocking regenerative healing for *everybody*



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# AROA at a Glance

Well established high-growth soft tissue regeneration company



**NZ\$23.1m**

product sales FY21 on constant currency basis



**68% Gross Margin**

FY21, impacted by lower sales and FX



**4 million+**

Procedures with AROA's products



**5 patented products**

selling in United States



**Regulatory Approvals**

in 49 countries



**AROA ECM™ platform**

Provides new products and line extensions year on year



**> 20**

Peer Reviewed Publications



**> US\$2.5b<sup>1</sup> TAM**

for existing products



**> 150**

personnel<sup>2</sup>

1. SmartTRAK BiomedGPS data 2020; DRG Millennium Research data; Hernia Repair Devices, 2020, AROA management estimates; DRG Millennium Research, Breast Implants & Reconstructive devices, 2018 Market data was prepared before the onset of COVID-19, the economic effect of which is currently not possible to predict with any certainty. Consequently, while the Company has no reason to believe that the market data does not remain accurate based on the relevant markets operating normally, the impact of COVID-19 on the market data that is referenced is not possible to currently predict with any certainty and investors are cautioned against placing undue reliance on such data.

2. AROA NZ & US employees.

# Catalysts



## Post-COVID

Vaccinations expected to improve throughout CY2021



## AROA Direct Sales

Fully dedicated field sales team. Myriad™ expected to drive growth.



## TELA Bio® Momentum

Clinical outcomes & cost savings driving increasing adoption



## Product Synergies

Complementary products for every phase of healing & continuum of care



## Clinical Data

Endoform™, Myriad™ & Symphony™



## Reimbursement

Potential for changes in the reimbursement of cell and tissue products (Symphony) in outpatient wound centres



## Pipeline Products

From AROA ECM platform & new single-use dead space management platform

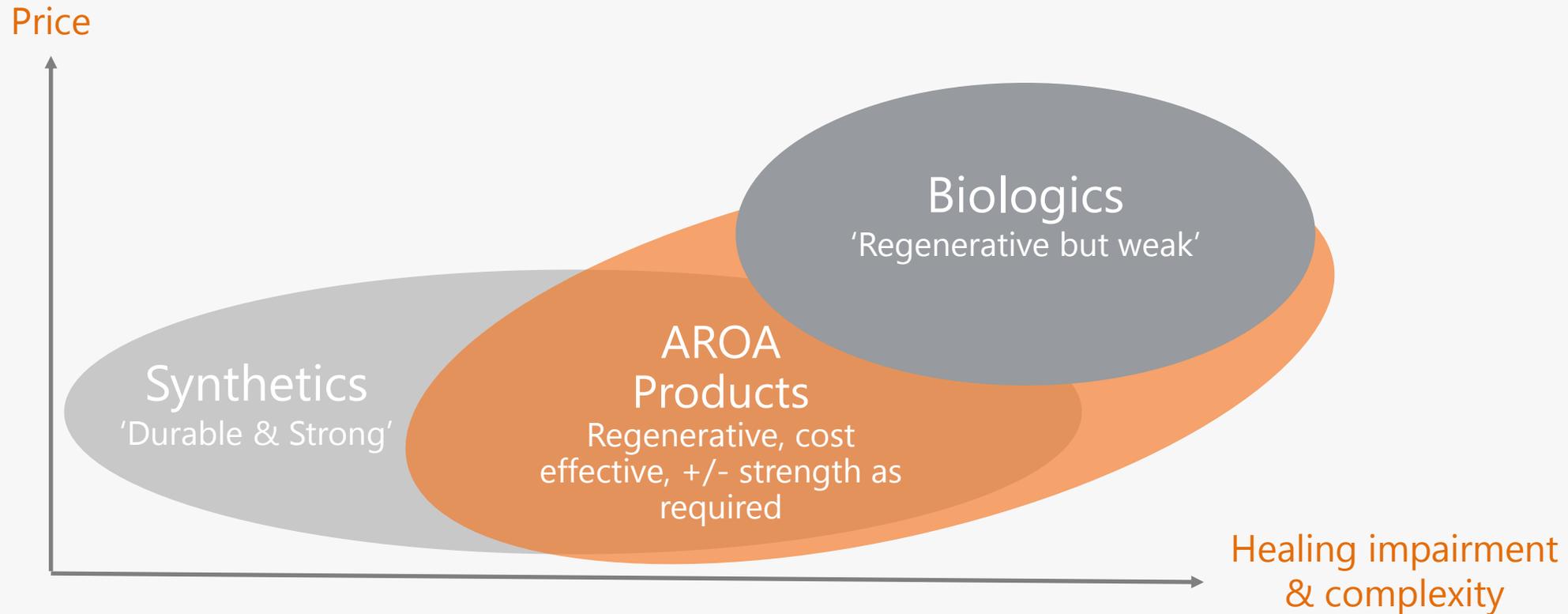


## Global Expansion

Regulatory approval in more than 45 countries

# Unlocking Regenerative Healing for *Everybody*

AROA ECM technology offers leading regenerative performance at a significantly lower cost than other biologics enabling more patients to have access to the benefits of regenerative healing



Note: AROA Management compilation based on peer reviewed publications.



# Q&A

A close-up photograph of a hand holding a square piece of light-colored, textured material, likely an ECM product. To the left, a blue surgical mask is partially visible. The background is a soft, out-of-focus light gray.

# AROA ECM Product Portfolio

Unlocking regenerative healing for *everybody*





**Frazer Murray**  
**Director of Global Marketing & Strategy**

Frazer joined Aroa in September 2020. He has over 8 years in marketing and sales in healthcare across various global markets.

Prior to joining Aroa Biosurgery Frazer was Head of the Project Management Office and Strategic Assistant to the General Manager of Novartis Australia and NZ. Earlier in his career led the standout launch of strategic brand Cosentyx in the UK. Frazer has proven record of accelerating growth through various leadership roles within marketing and sales across a number of brands. Early in his career Frazer worked as a clinical veterinarian in NZ and the UK, and holds a Bachelor's Degree in Veterinary Science, he is a Member of the Royal College of Veterinary Surgeons, and has an MBA from London Business School

# Soft Tissue Reconstruction Technologies

Biologics and Synthetics have different properties and use cases

Product Category	Regeneration	Inflammation	Cost	Strength	Infection Resistance	Infection Resilience	Use Case	Unique selling point
Permanent Synthetics	Low <sup>1</sup>	High <sup>2</sup>	Low <sup>1</sup>	High <sup>3-5</sup>	Low <sup>6</sup>	High <sup>7</sup>	Hernia <sup>8</sup>	Cost & strength <sup>9-11</sup>
Absorbable Synthetics	Low <sup>1,12</sup>	High <sup>2</sup>	Moderate <sup>1</sup>	Moderate – High <sup>3</sup>	Low <sup>13</sup>	High <sup>1</sup>	Hernia <sup>10</sup>	Cost & strength, absorbed <sup>14</sup>
Existing Biologics	Moderate to High <sup>15,16</sup>	Low to Moderate <sup>17,18</sup>	High <sup>3,19</sup>	Low-Moderate <sup>3,19</sup>	Moderate <sup>20,21 22</sup>	Low –Moderate <sup>23</sup>	Soft tissue reconstruction & Hernia <sup>3,13,24,25</sup>	Regenerative healing, less scarring <sup>26-29</sup>

## AROA ECM Competitive advantage

All AROA ECM Products A,B,C,D,E	High <sup>30-32</sup>	Low <sup>33,34</sup>	Moderate <sup>35</sup>	Moderate <sup>36</sup>	Moderate <sup>37</sup>	Moderate <sup>31,38</sup>	Complex wounds & soft tissue reconstructions <sup>30,31,39-42</sup>	Improved rate & quality of regenerative healing <sup>35-43</sup> , & similar costs to absorbable synthetics
Reinforced Bioscaffolds D,E	High <sup>44,45</sup>	Low <sup>45</sup>	Moderate	High <sup>36</sup>	Moderate <sup>45</sup>	Moderate <sup>45</sup>	Hernia <sup>45,46</sup>	Benefits of Endoform with higher strength <sup>45</sup> Similar cost to absorbable synthetics

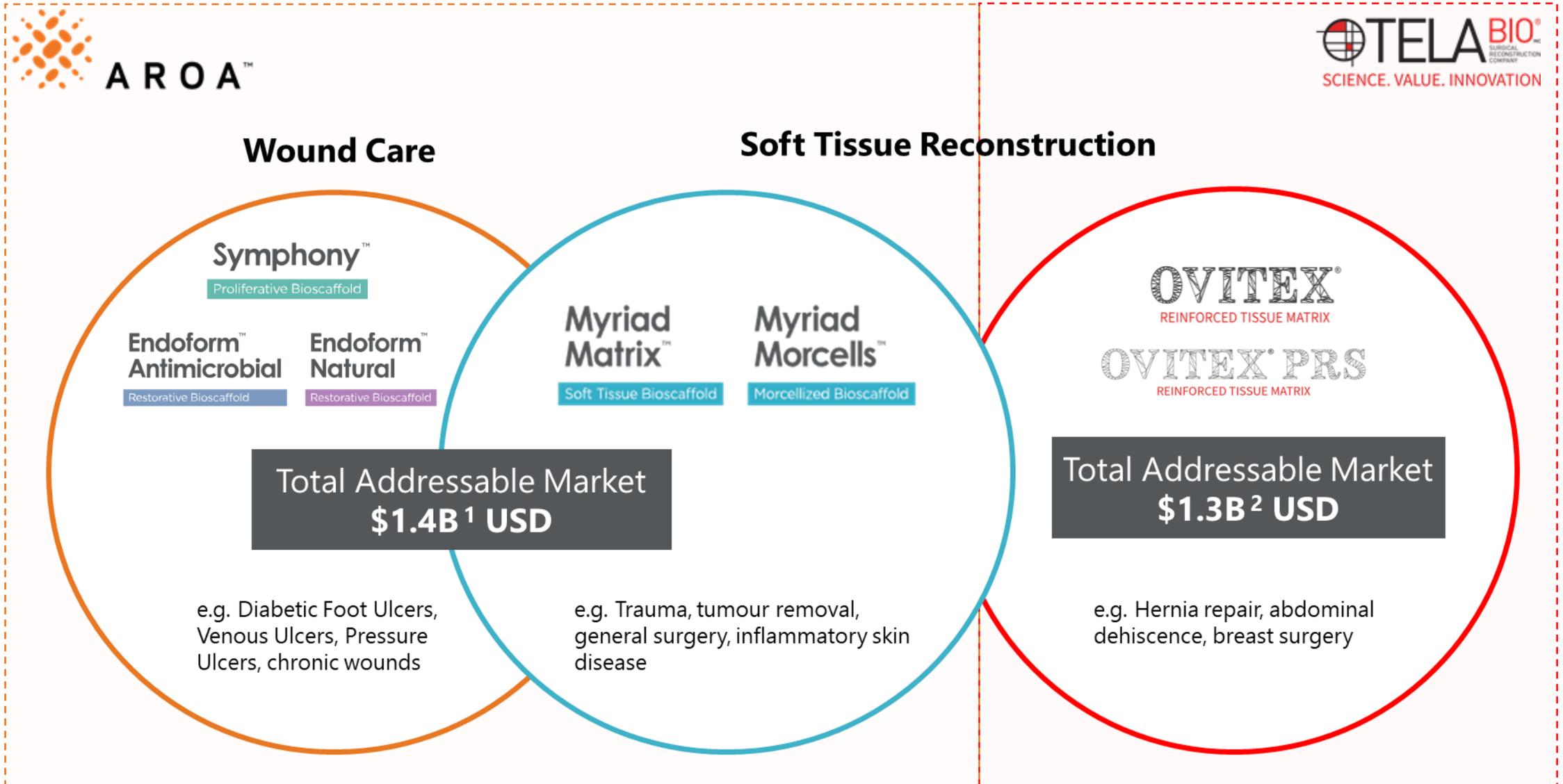
Products: A. Endoform Dermal Template (Natural/Antimicrobial), B. Myriad, C. Symphony, D. OviTex®, E. OviTex PRS.  
Note: Aroa Management compilation based on peer reviewed publications: See Appendix 1 – References 1-46

positive  
attribute\*

neutral  
attribute\*

negative  
attribute\*

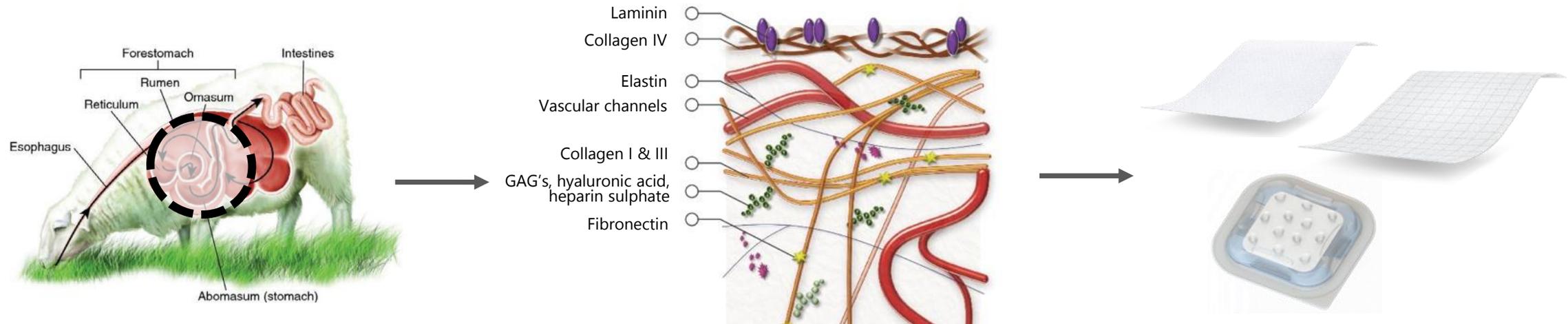
# Substantial Growth Opportunities ~\$2.5B<sup>1</sup> TAM



1. SmartTRAK BiomedGPS data 2020. Aroa management estimates;  
 2. DRG Millennium Research data; Hernia Repair Devices, 2020. DRG Millennium Research, Breast Implants & Reconstructive devices, 2018.

# AROA ECM - An Ideal Foundation for Regenerative Healing

AROA's products utilise the proprietary AROA ECM, which is a unique Extracellular Matrix (ECM) platform technology derived from sheep forestomach



## Source

- Ovine Forestomach has natural characteristics that are desirable in a regenerative soft tissue technology
  - Thick porous ECM with basement membrane
  - Highly vascular
  - Constantly renewing & growing

## AROA ECM Technology (Structural and Biological Building Block)

- AROA ECM (gently processed Ovine Forestomach Matrix) contains:
  - Native porous structure
  - Residual vascular channels
  - 150+ signalling molecules and substrates known to be important in healing
- Clinically this translates to ready to use scaffold and biology which the body uses to direct healing

## Products

- All products that utilise the AROA ECM provide a short-cut to growing new tissue and an associated blood supply
- Each product is engineered for the challenges of a specific use case

# AROA ECM – Unique Regenerative Properties

Graft Origin	Clinical Performance Considerations			
	Structure	Biology	Tissue compatibility	Cost
<b>AROA ECM</b>	+++	+++	+++	\$ - \$\$
Human Dermis	++	+	+++	\$\$
Human Placenta	-	+++	+++	\$\$\$
Intact Mammalian Tissue	+/-	+/-	+/-	\$\$
Mammalian Reconstituted Collagen	+	+	+	\$\$\$
Synthetic	++	-	+/-	\$ - \$\$

Note: AROA Management compilation based on peer reviewed publications:

- The AROA ECM delivers leading clinical performance at a significantly lower cost enabling more patients access to regenerative healing technology
- AROA is well positioned to capitalise on a changing market environment for which value driven healthcare is increasingly important, without compromising clinical performance & patient outcomes

# Endoform Natural and Antimicrobial

A unique "Tissue Matrix" used to "short-cut" healing in complex wounds such as diabetic foot ulcers and venous ulcers



Endoform Natural is a single layer of the Aroa ECM.



Endoform Antimicrobial a single layer of Aroa ECM with 0.3% ionic silver embedded to provide broad spectrum antimicrobial activity

## Endoform Natural in a Diabetic Foot Ulcer

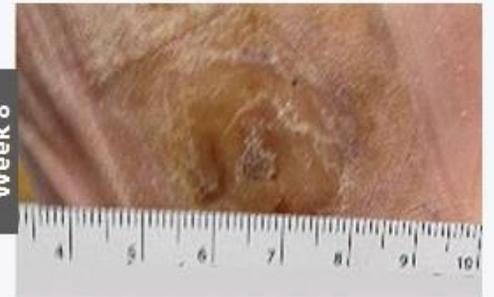
Week 0



Week 5



Week 8



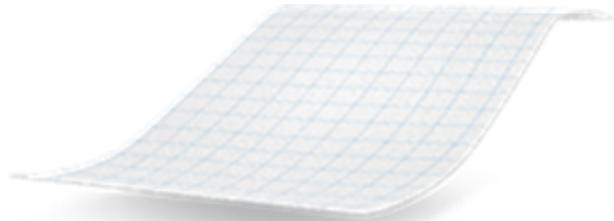
# Ovitex & Ovitex PRS

“Reinforced Bioscaffold” which combines layers of the AROA ECM reinforced with polymers for abdominal wall repair (hernia) & soft tissue reinforcement

## OviTex®

Licensed to Tela Bio for

### Hernia



Ovitex® is an abdominal wall reinforcement product comprised of multiple layers of AROA ECM reinforced with permanent (polypropylene) or resorbable (PGA) polymers.

## OviTex® PRS

Licensed to Tela Bio for

### Breast Surgery



Ovitex® PRS is a soft tissue reinforcement product comprised of multiple layers of AROA ECM reinforced with permanent (polypropylene) or resorbable (PGA) polymers

## OviTex repair of a midline fascial dehiscence and fistula



1 week Post-op



4 weeks Post-op



8 weeks Post-op

# Myriad Matrix

Engineered ECM containing layers of AROA ECM suitable for soft tissue reconstruction, both dermal repair and surgical implantation

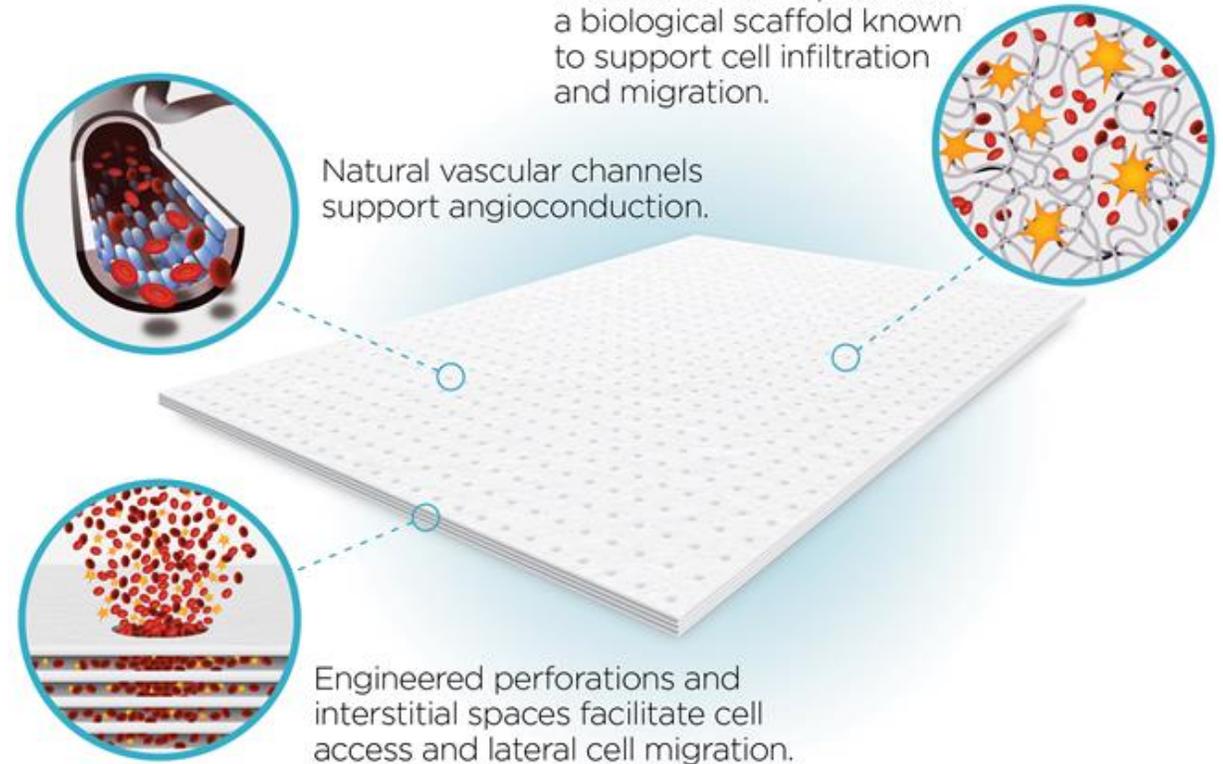
Myriad Matrix placement prior to dermal skin graft



Myriad Matrix surgical implantation in an armpit post significant tissue excision



The **AROA ECM™** provides a biological scaffold known to support cell infiltration and migration.



# Myriad Morcells

A 'Morcellized Bioscaffold' suitable for a wide range of dermal reconstruction and complex wound repair procedures

- Deliver a bolus of the AROA ECM biology to help kick start & sustain healing
- Conforms to optimise contact with irregular wound beds

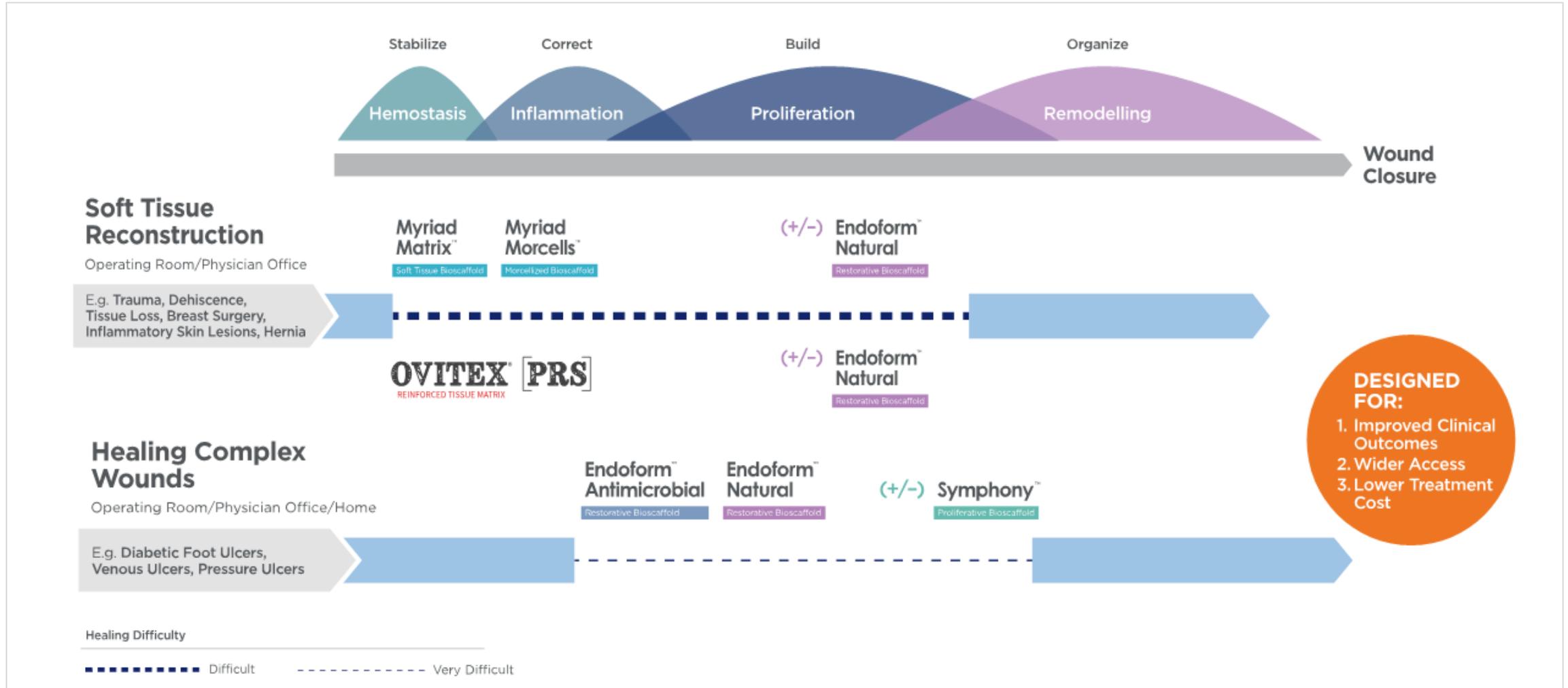


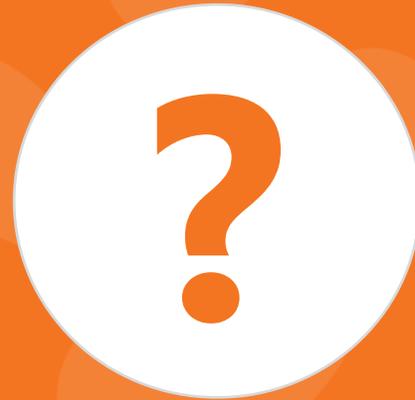
Used in combination Myriad Morcells works synergistically with Myriad Matrix to speed the establishment of new tissue



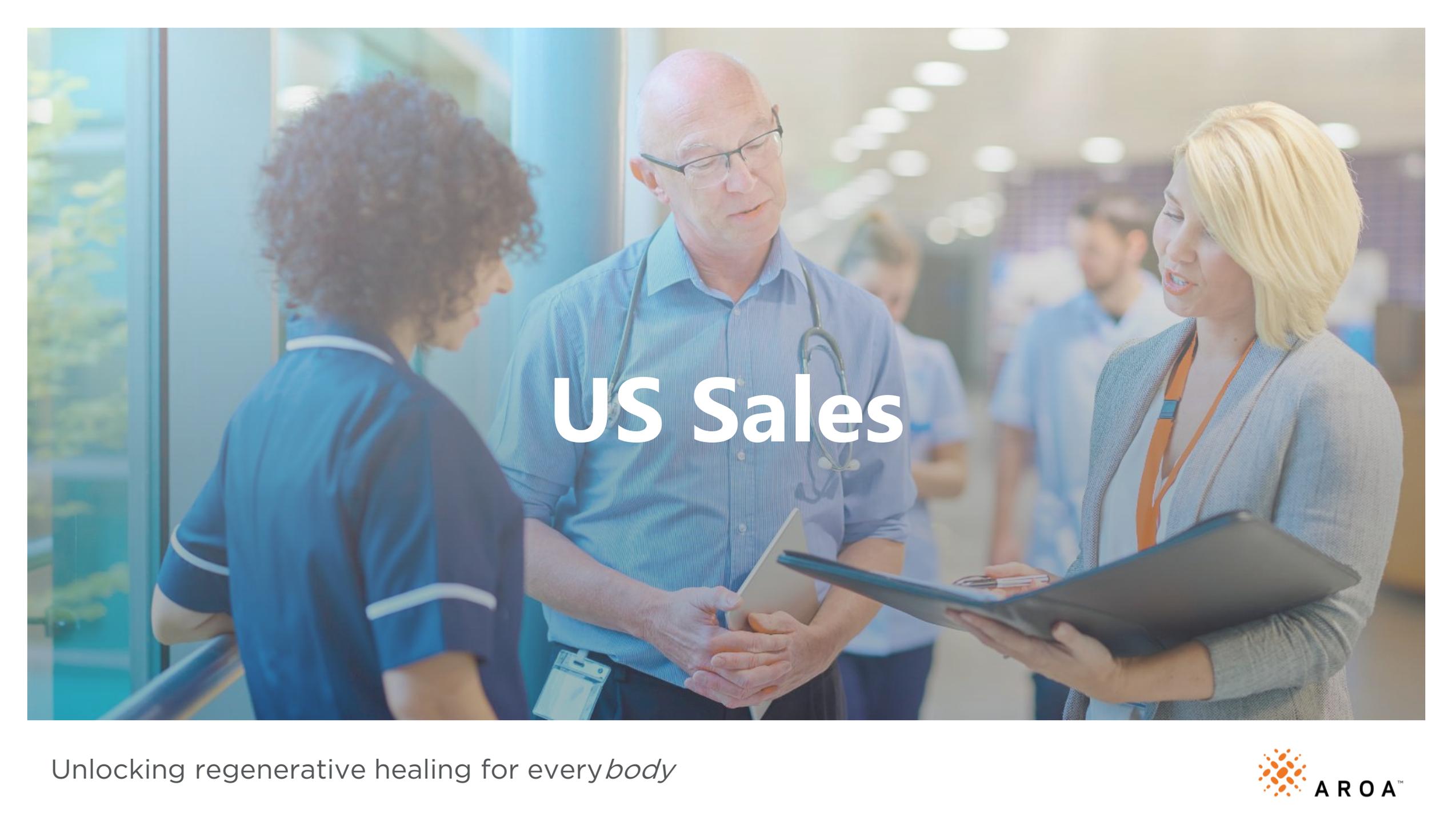
# AROA Product Portfolio

Products to match wound type, stage & site of care





# Q&A



# US Sales

Unlocking regenerative healing for *everybody*



# AROA Sales



**Brad Adams**  
**Vice President of Commercial Operations**

Brad joined Aroa Biosurgery in November 2019. He has over 20 years of experience in the strategic sales and marketing of medical devices within the United States medical system and in other jurisdictions. Prior to Aroa Biosurgery, he served as Vice President, Sales at ACell Inc., a Columbia, Maryland based regenerative medicine company. Brad also has more than 15 years within both the Smith+Nephew and Johnson & Johnson families of companies, much of the time spent in senior global commercial roles. Brad has a proven record of accelerating revenue growth across multiple platforms including medical device, pharmaceutical, biologic, wound/tissue repair and regenerative medicine.

Brad holds a Master of Health Administration (Medical College of Virginia), a Bachelor of Arts in Economics with distinction (Virginia Military Institute) and has undertaken professional courses at Harvard Business School and The Wharton School, University of Pennsylvania. He is a long-standing member of the American College of Healthcare Executives.



**Wes Snodgrass**  
**Director of National Accounts**

Wes brings to Aroa over 30 years of experience in working in the US health care system. He began his career as a Sales Representative with Becton Dickinson in 1990 and has built a proven history of experience, awards, and accomplishments in National Accounts and Sales Leadership. Key areas of focus are national account development/detention, channel relationship management, and contract negotiations as a senior-level contributor with industry leaders KCI, Cardinal Health, B. Braun Medical, and other companies including 3 start-ups.

He lives in Knoxville, Tennessee and has 3 grown children. His interests outside of work of are golf, water sports, and gardening.

# US Sales Operations – Multiple Channels

Unique sales channels based on call point and product indication, collaborating to grow AROA ECM product portfolio in the US

Channel	Products	Target Specialties	Call Point	Sales Force (FTE)	Commercial Strategy
	Endoform	Physicians, WOCN's/RN's, Podiatric	Outpatient Wound Centers	8 Inside	<ul style="list-style-type: none"> <li>• Increase Endoform utilization in current customer base through Antimicrobial &amp; Negative Pressure Wound Therapy campaigns – strong Q1 return</li> <li>• Grow new customer base through expansion of independent distributor network (“IDNs”), and targeting wound care centers with high volumes of debridement</li> </ul>
	Myriad	Physicians, Podiatric, Plastic, Trauma, Orthopedic surgeons	Inpatient Operating Rooms	20 Field & 20 independent	<ul style="list-style-type: none"> <li>• Submit Myriad to value analysis committees of large medical centers</li> <li>• Go deep when Myriad is approved</li> <li>• Use early success of Myriad Matrix to promote Myriad Morcells</li> <li>• Select distributor network supporting specific US geographies for fast approval and use by surgeons</li> </ul>
	OviTex, OviTex PRS (US & Europe rights)	-	-	-	<ul style="list-style-type: none"> <li>• Collaborate with TELA Bio</li> </ul>

# AROA's US Sales Channel

- ★ Direct Sales Representative
- ★ Independent Sales Representative
- ★ VP Commercial
- ★ Inside Sales Team

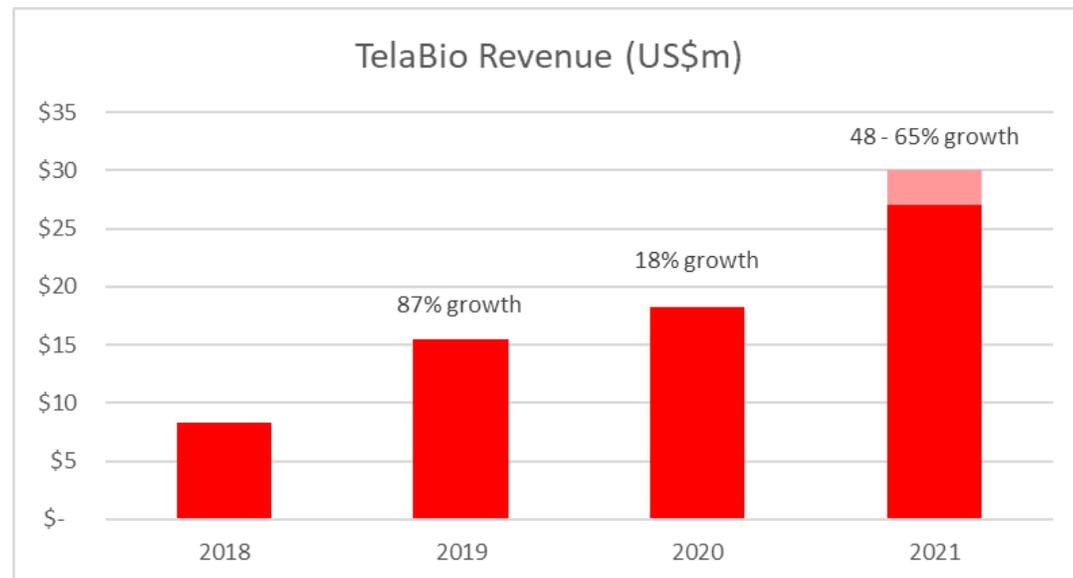


# Tela Bio Sales

# US Sales Operations – Multiple Channels

Unique sales channels based on call point and product indication, collaborating to grow AROA ECM product portfolio in the US

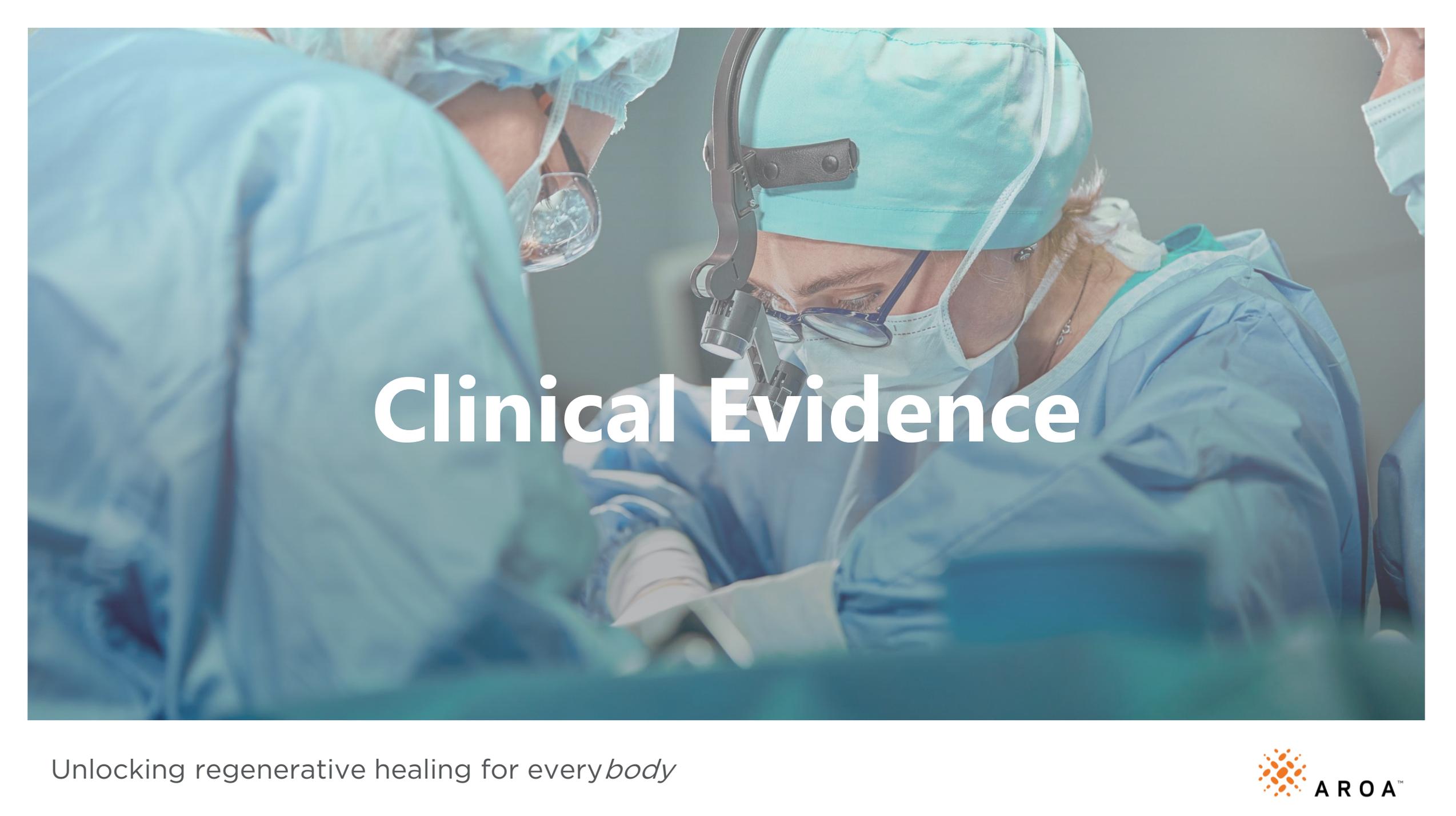
Channel	Products	Target Specialties	Call Point	Sales Force (FTE)	Commercial Strategy
	OviTex, OviTex PRS (US & Europe rights)	General Surgeons, Plastic Surgeons	Operating Room	46 Sales territories as of 30 March 2021	<ul style="list-style-type: none"> <li>• Drive adoption</li> <li>• Increased utilization in accounts</li> <li>• New procedures and products</li> </ul>



- Revenue share - TELA Bio (73%): AROA (27%)
- Consumed early inventory loadings
- AROA and TELA Bio sales now aligned with market demand
- AROA sales lead TELA Bio sales
- Catalysts
  - Clinical Data – Bravo
  - Group purchasing organisations & IDN's
  - Post COVID-19
  - Expanded sales team



# Q&A

A photograph of surgeons in an operating room, wearing blue scrubs and masks, with a large white text overlay in the center. The scene is dimly lit, focusing on the surgeons' faces and hands as they work.

# Clinical Evidence

Unlocking regenerative healing for *everybody*





**Brandon Bosque, DPM, CWSP**  
**Medical Science Liaison**

Dr. Brandon Bosque is board-certified foot & ankle surgeon with extensive training and experience in surgical reconstruction, complex wounds, and limb salvage. His passion for regenerative medicine drove him to join AROA medical affairs to provide first-hand clinical insights, medical education, facilitate clinical trials, and foster relationships with fellow healthcare providers and researchers. Dr. Bosque is based in Philadelphia, Pennsylvania, USA where he lives with his wife and young daughter.

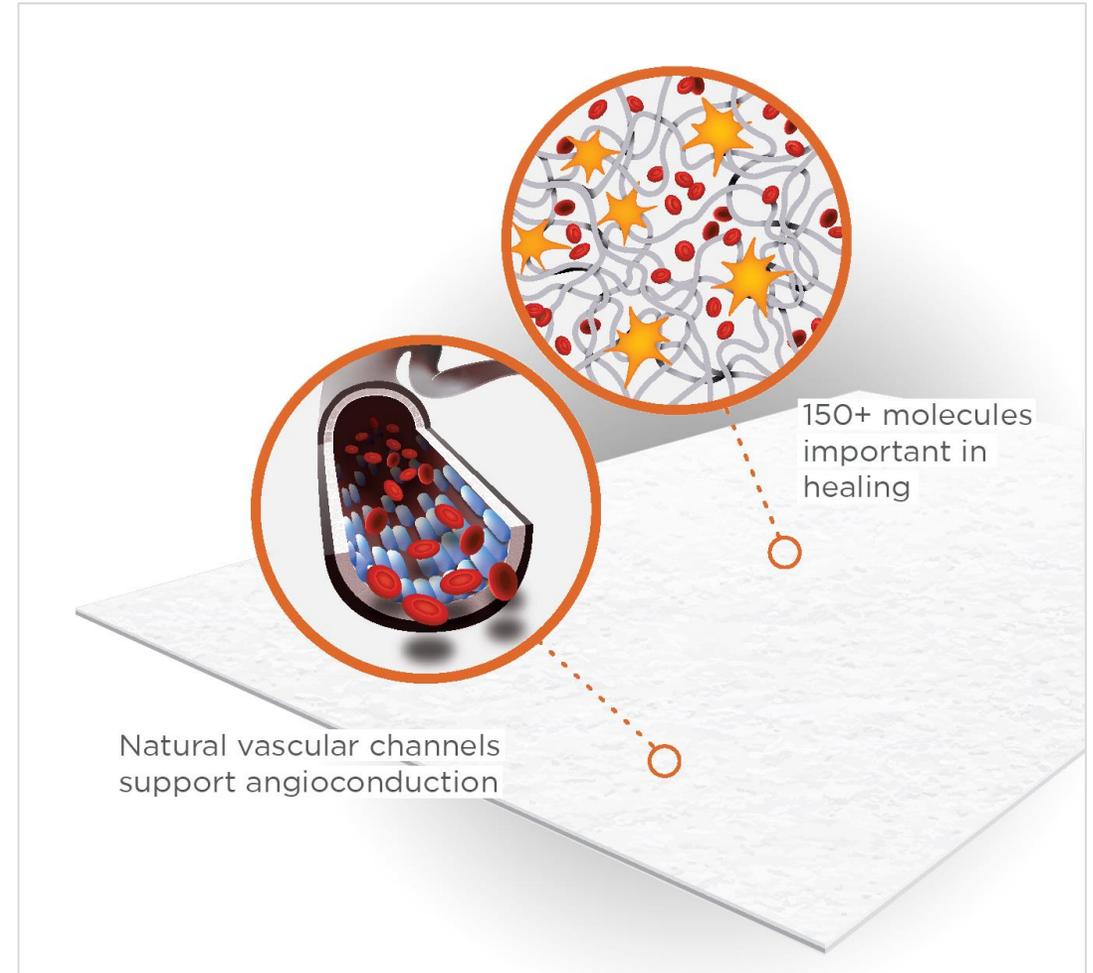


**Barnaby May, PhD**  
**Chief Scientific Officer**

Barnaby joined Aroa Biosurgery's management team over 12 years ago. Barnaby has over 15 years' experience in medical device development and commercialisation. Prior to joining Aroa Biosurgery, Barnaby was Scientific Director for InPro Biotechnology (San Francisco, California) and Adjunct Professor, University of California San Francisco (UCSF). Barnaby has extensive research experience in the fields of regenerative medicine and medicinal chemistry, targeting diseases such as HIV, Alzheimer's, CJD and the neglected tropical diseases. Barnaby is well published with over 35 peer-reviewed publications, numerous international patents and book chapters. During his time at Aroa Biosurgery, Barnaby has lead product and process development and clinical activities. Dr. May has a PhD (Canterbury University, New Zealand) in Medicinal Chemistry and undertook post-doctoral research at the University of California San Francisco.

# Clinical Need

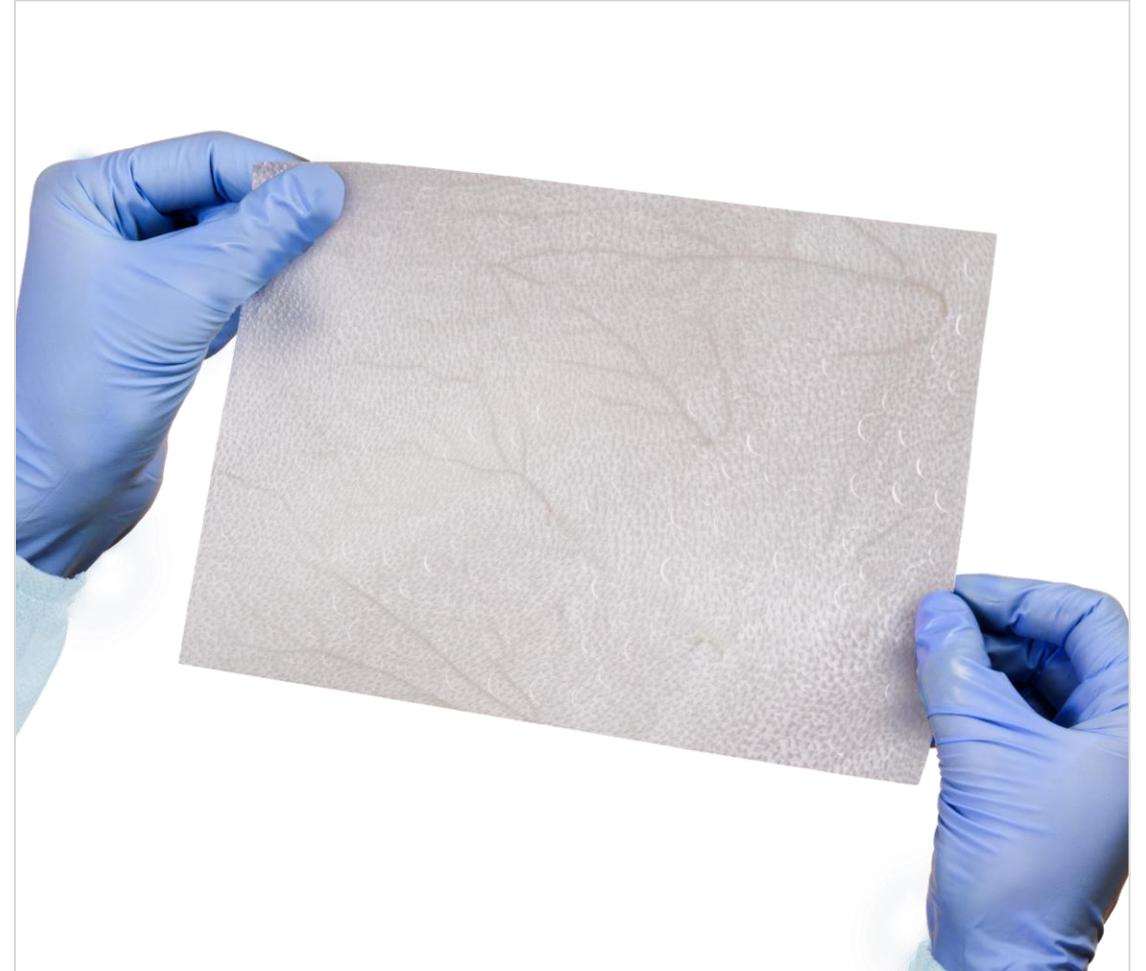
- Increase patient/surgeon access to advanced regenerative scaffolds
- Reduce time to build new tissue
- Reduce time to definitive closure
- Reduce surgical complications (e.g. infection, recurrence, scarring, adhesions)
- Improve patient Quality of Life and outcomes



## Endoform – Key Learnings

- Overcomes wounds inflammation
- Rapid tissue regeneration
- Well vascularized tissue
- Aids wound epithelization
- Use across the spectrum of wound care providers as first-line treatment

4+ million product applications



# Endoform Clinical Evidence

Reference	Sample Size	Wound Types	Complex Non-healing Wounds	Outcomes
Liden, B. A. and B. C. May (2013)	N=24	Various	Yes	50% of wounds closed at 12 weeks
Simcock, J. and B. C. May (2013)	N=4	Tumor excision	Yes	Single stage STSG procedure
Simcock, et al (2013)	N=1	Necrobiosis lipoidica	Yes	Wound closed at 22 weeks
Bohn, G. A. and K. Gass (2014)	N=23	VLU	Yes	96% of wounds closed at 12 weeks
Gonzalez, A. (2016)	N=1	VLU	Yes	Wound closed at 7 weeks
Ferreras, et al (2017)	N=257	Lower extremity	Yes	73% of wounds closed at 12 weeks
Lullove, E. J. (2017)	N=53	Lower extremity	Yes	59% of wounds closed at 12 weeks
Raizman, et al (2020)	N=29	Various	Yes	89% of wounds closed at 12 weeks
Blevins, M. (2021)	N=1	Necrobiosis lipiodica	Yes	Wound closed at 4 months
Boyar, V. (2021)	N=4	Pediatric	Yes	All wounds closed

# Endoform Clinical Evidence



Correct wound inflammation and chronicity



Scaffold the growth of well vascularized granulation tissue



Accelerate wound closure by driving epithelialization

## Myriad Matrix - Key Learnings

- Suitable for a wide range of reconstructive procedures requiring implant or dermal regeneration
- Low rates of surgical complications (e.g. infection, dehiscence, seroma)
- Rapid tissue regeneration
- Well vascularized tissue
- No infections
- Compatible with contaminated surgical fields

~500 procedures completed to date across a range of complex reconstructions and implants



## Myriad Matrix – Procedure Types

Tumor resection, trauma, necrotizing fasciitis, abdominal dehiscence, complex wounds, limb salvage, hidradenitis suppurativa, pilonidal sinus disease, anal fistula...

## Myriad Matrix – Clinical Evidence

Reference	Reconstruction Type	Sample Size	Contaminated Fields	Mode	Rates of Granulation Tissue Formation	Major Complications
Chaffin, A. E. and M. C. Buckley (2020)	Hidradenitis suppurativa	N=8	Yes	Implant and dermal	1-2 weeks	None
Bohn, G. A. and A. E. Chaffin (2020)	Exposed bone and tendon	N=6	Yes	Implant and dermal	1-2 weeks	None
Desvigne, et al (2020)	Complex chronic wounds	N=9	Yes	Implant	NA	None
Bohn, G. A. (2020)	Tumor excision	N=1	No	Dermal	1-2 weeks	None

# Complex Reconstruction of Stage III Hidradenitis Suppurativa

- Complex inflammatory skin condition
- Contaminated surgical sites
- High rates of complications
- Pilot n=8 procedures, 2 minor complications
- No infections, no recurrences

Chaffin A, Buckley M. Extracellular matrix graft for the surgical management of Hurley stage III hidradenitis suppurativa: a pilot case series. *Journal of Wound Care*; Vol 29, No. 11, November 2020. Available online at: <https://www.magonlinelibrary.com/doi/abs/10.12968/jowc.2020.29.11.624>

Innovations in wound care

## Extracellular matrix graft for the surgical management of Hurley stage III hidradenitis suppurativa: a pilot case series

**Objective:** Surgical management of Hurley stage III hidradenitis suppurativa (HS) typically involves the excision of diseased tissue and subsequent reconstruction, potentially leading to complications or recurrence of the disease. This pilot case series sought to evaluate a decellularised ovine forestomach matrix (OFM) extracellular matrix (ECM) graft for soft tissue regeneration as part of surgical reconstruction of stage III HS of the axilla.

**Method:** The prospective pilot case series involved six participants and a total of eight defects. The ECM graft was used either as a dermal substitute for a staged reconstruction (n=3 defects) or as an implant under a fasciocutaneous flap (n=5 defects) following wide excision of the diseased tissue.

**Results:** In all cases complete healing was achieved, with no major surgical complications. When used as a dermal substitute the OFM graft was completely granulated within 2–4 weeks, with defects closing by secondary intention or following placement of a split-thickness skin graft. When used as an implant beneath a fasciocutaneous flap, healing of the surgical sites was observed after 1–3 months. At the long-term follow-up (3–12 months), all participants had excellent range of motion and none had reported disease recurrences.

**Conclusion:** This pilot case series explored the implementation of an ECM graft as part of the surgical management of axilla Hurley stage III HS. Although the study had a limited number of participants, long-term outcomes were promising and suggest further studies are warranted.

**Declaration of interest:** The graft (Myriad Soft Tissue Matrix) was provided by Aroa Biosurgery Limited (Auckland, New Zealand). AEC has received educational travel grants from Aroa Biosurgery Limited. The authors have no conflicts of interest to declare.

dermal substitute • flap reconstruction • hidradenitis suppurativa • ovine forestomach matrix

**H**idradenitis suppurativa (HS) is a debilitating, chronic inflammatory disease of the dermis.<sup>1</sup> The causes of HS may be a combination of genetic, endocrine, environmental and microbial factors.<sup>2</sup> Disease progression involves follicular occlusion caused by inflammation, hyperkeratosis and hyperplasia of sweat glands, and can

be sufficient.<sup>3</sup> In severe cases of HS (for example, Hurley stage III) that include diffuse interconnecting tracts and abscesses across a large area, a significant surgical intervention is required, such as wide excision of the diseased tissue.<sup>4</sup> Following wide excision, several reconstructive approaches are possible, including primary closure, healing via secondary intention, split-

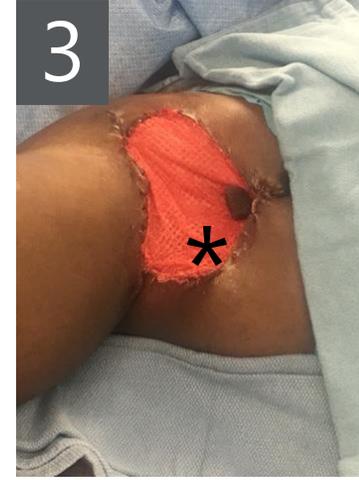
# Example Case – Dermal Reconstruction



1  
29-Year old male with 2-year history of Stage III axillary HS.



2  
Wide excision of the diseased tissue.



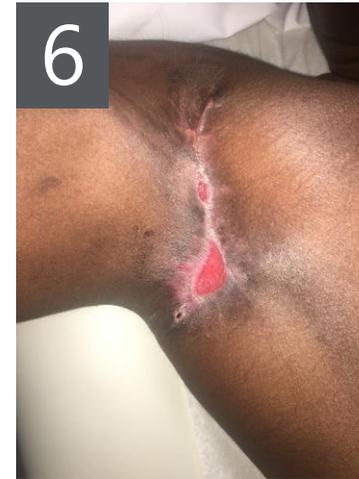
3  
ECM graft (\*) placed into the base of the defect.



4  
4 days  
New tissue begins to 'grow' into the graft to replace the missing tissue.



5  
1.5 weeks  
New healthy tissue has grown in place.



6  
6 weeks  
Wound is nearly closed and patient returns to work with full range of motion.  
Patient at 11+ month long-term follow-up has no surgical complications or recurrences.

# Reconstruction over Exposed Vital Structures

- Complex surgical reconstructions (n=6)
- Rapid Myriad infiltration (1-4 weeks)
- 100% Myriad graft take
- No complications
- No infections

Bohn, G. A. and A. E. Chaffin (2020). "Extracellular matrix graft for reconstruction over exposed structures: a pilot case series." J Wound Care 29(12): 742-749.

practice

## Extracellular matrix graft for reconstruction over exposed structures: a pilot case series

**Objective:** Soft tissue defects, especially those involving exposed vital structures, present a reconstructive challenge because poor vascularity of such defects typically makes immediate skin grafting unviable. Where flap procedures are inappropriate or not possible, dermal matrices represent an alternative reconstructive option for defects with denuded vital structures. With dermal matrices becoming increasingly available and technologically advanced, we evaluated an ovine-derived extracellular matrix graft in the reconstruction of complex soft tissue defects involving exposed vital structures.

**Method:** Six cases of soft tissue defects exhibiting denuded vital structures underwent reconstruction using an ovine forestomach matrix graft as a dermal matrix. Grafts were fixed directly into defects for immediate coverage and subsequently temporised defects via granulation tissue formation for later skin graft or secondary closure. Defect granulation and epithelialisation were monitored until closure and the final aesthetic and functional outcomes were evaluated.

**Results:** Complete healing was achieved in all cases, with defect granulation becoming observable within one to two weeks and complete granulation occurring within one to six weeks. Granulation tissue resulting from the graft was suitable for skin grafting, with 100% take of skin grafts after one week and complete re-epithelialisation in two to three weeks in the four cases that received a skin graft. Good cosmetic, functional and patient satisfaction outcomes were achieved in all cases.

**Conclusion:** The present series demonstrates our initial use of an extracellular matrix-based dermal matrix in reconstructing defects with exposed vital structures. While such dermal matrices do not supersede or replace flap procedures, they represent an alternative option on the reconstructive ladder in cases where flap procedures are not appropriate or possible.

**Declaration of interest:** The graft (Myriad Soft Tissue Matrix) was provided by Aroa Biosurgery Limited (Auckland, New Zealand). AEC and GAB have received educational travel grants from Aroa Biosurgery Limited.

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dermal matrix • diabetes • dressing • exposed bone and tendon • extracellular matrix • ovine forestomach matrix • reconstructive surgery • wound

**R**econstruction of defects presenting denuded vital structures is challenging. Exposed vessels, nerves, tendons, joints and bone must be promptly covered but immediate closure via a split-thickness skin surgery. Flap techniques are recognised as reliable options for reconstruction of complex defects but, depending on the specific defect, flap type and patient factors, flap reconstruction may be complicated by dehiscence, infection, thrombosis, seroma/haematoma,

# Example Case – Complex Forearm Reconstruction



Post debridement



Graft placed



Week 1



Week 4



Week 6



STSG

# Reconstruction of Complex Non-Healing Wounds

- Chronic non-healing wounds (e.g. pressure injuries)
- Contaminated surgical sites
- Surgical reconstructions (n=9)
- All wounds healed
- Two minor complications
- No infections

Desvigne, M. N., K. Bauer, K. Holifield, K. Day, D. Gilmore and A. L. Wardman (2020). "Case Report: Surgical Closure of Chronic Soft Tissue Defects Using Extracellular Matrix Graft Augmented Tissue Flaps." *Frontiers in Surgery* 7(173).



frontiers  
in Surgery

**CASE REPORT**  
published: 26 January 2021  
doi: 10.3389/fsurg.2020.559450



## Case Report: Surgical Closure of Chronic Soft Tissue Defects Using Extracellular Matrix Graft Augmented Tissue Flaps

*Michael N. Desvigne<sup>1,2\*</sup>, Krista Bauer<sup>2</sup>, Kurt Holifield<sup>2</sup>, Kari Day<sup>2</sup>, Denise Gilmore<sup>2</sup> and Ashley L. Wardman<sup>2</sup>*

<sup>1</sup> Desvigne Plastic Surgery, Scottsdale, AZ, United States, <sup>2</sup> Abruzzo Arrowhead Hospital, Glendale, AZ, United States

Chronic soft tissue defects are notoriously difficult to heal. Surgical reconstruction of chronic defects using tissue flaps is a routine approach for closure of challenging chronic defects. Due to the poor tissue quality of chronic defects and associated inflammation, infection and impaired blood supply the success of flap closure is marred by reported complication rates of 25–58%. Extracellular matrix (ECM)-based graft materials are commonly used for resolving chronic wounds and in plastic and reconstructive procedures to create a scaffold for tissue regeneration. We hypothesized combination use of ECM grafts with tissue flaps in a single-stage surgical procedure would reduce complications and improve outcomes in the closure of chronic soft tissue defects. We report a case series ( $n = 9$ ) of chronic soft tissue defect reconstruction using this modified procedure of ECM graft augmented flap closure. Defects included pressure injuries and surgical dehiscence and ranged in wound age from 5 months to 7 years. Successful uncomplicated healing was achieved in six defects. Post-operative complications (dehiscence) occurred in two defects, however, these healed via secondary intention without additional surgical intervention. All healed defects exhibited acceptable cosmetic

**OPEN ACCESS**

**Edited by:**  
Charles M. Malata,  
Anglia Ruskin University,  
United Kingdom

**Reviewed by:**  
Oren Lipid,  
Amsterdam University Medical Center  
(UMC), Netherlands  
Fath Zor,  
Wake Forest School of Medicine,  
United States

# Example Case – Pressure Injury



**Initial tissue defect**



**Graft placement**



**Flap advancement**



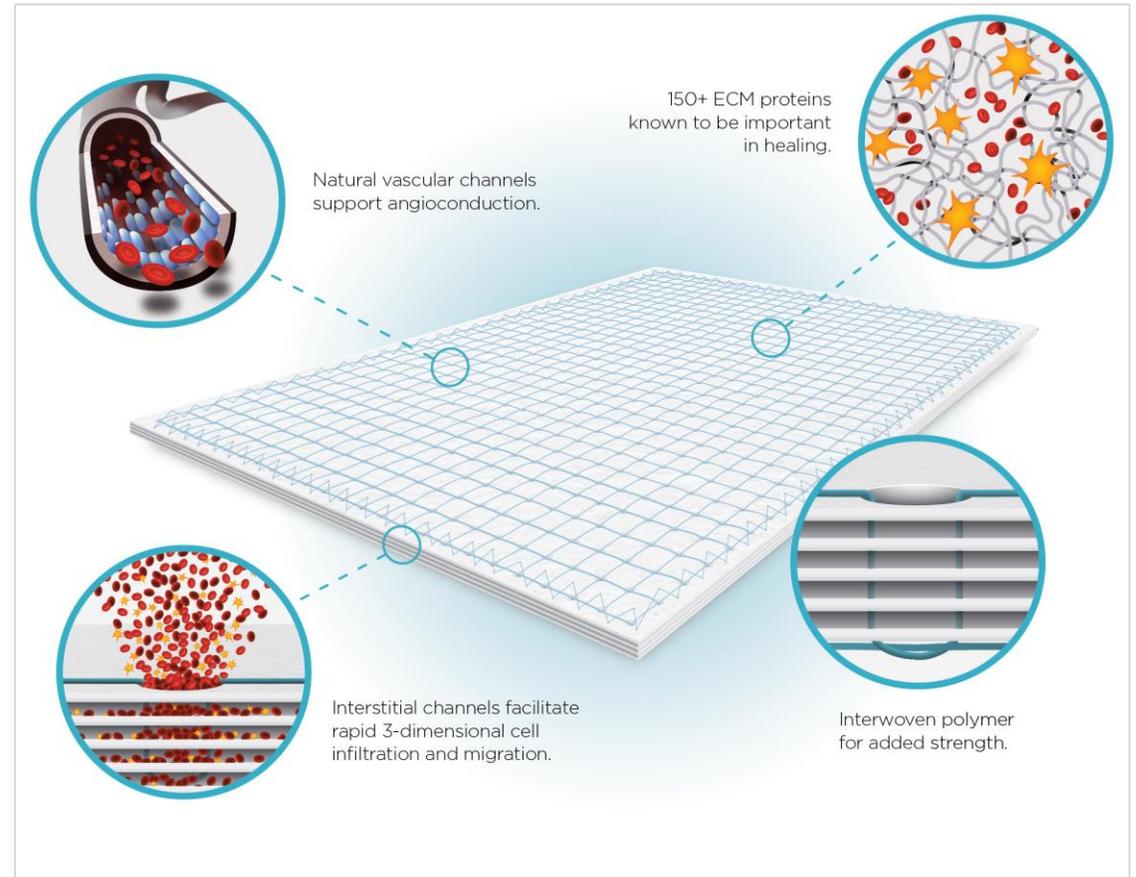
**Negative pressure**

- No complications
- Remained closed at 6 months.

# Reinforced Biologic – OviTex/Myriad Ultra™

- Thoughtfully engineered reinforced biologic for abdominal wall repair
- Low hernia recurrence
- Low rate of complications, infections
- Moderate-to-complex ventral hernia patients
- Compatible with minimal invasive procedures
- Tolerates a contaminated site

~10,000 hernia procedures across multiple hernia types



# OviTex/Myriad Ultra Clinical Evidence

Reference	Type	Sample Size	Contaminated Fields	Recurrence
Ferozoca et al (2018)	Inguinal	N=31	No	N=0 (0%)
Sawyer et al (2018)	Hiatal	N=25	No	N=0 (0%)
Parker, et al (2020)	Ventral	N=100	Yes	N=3 (6%)
BRAVO – 12 month	Ventral	N=76	Yes	N=2 (3%)
BRAVO – 24 month	Ventral	N=51	Yes	N=0 (0%)

# AROA ECM - FY22 Clinical Evidence Pipeline

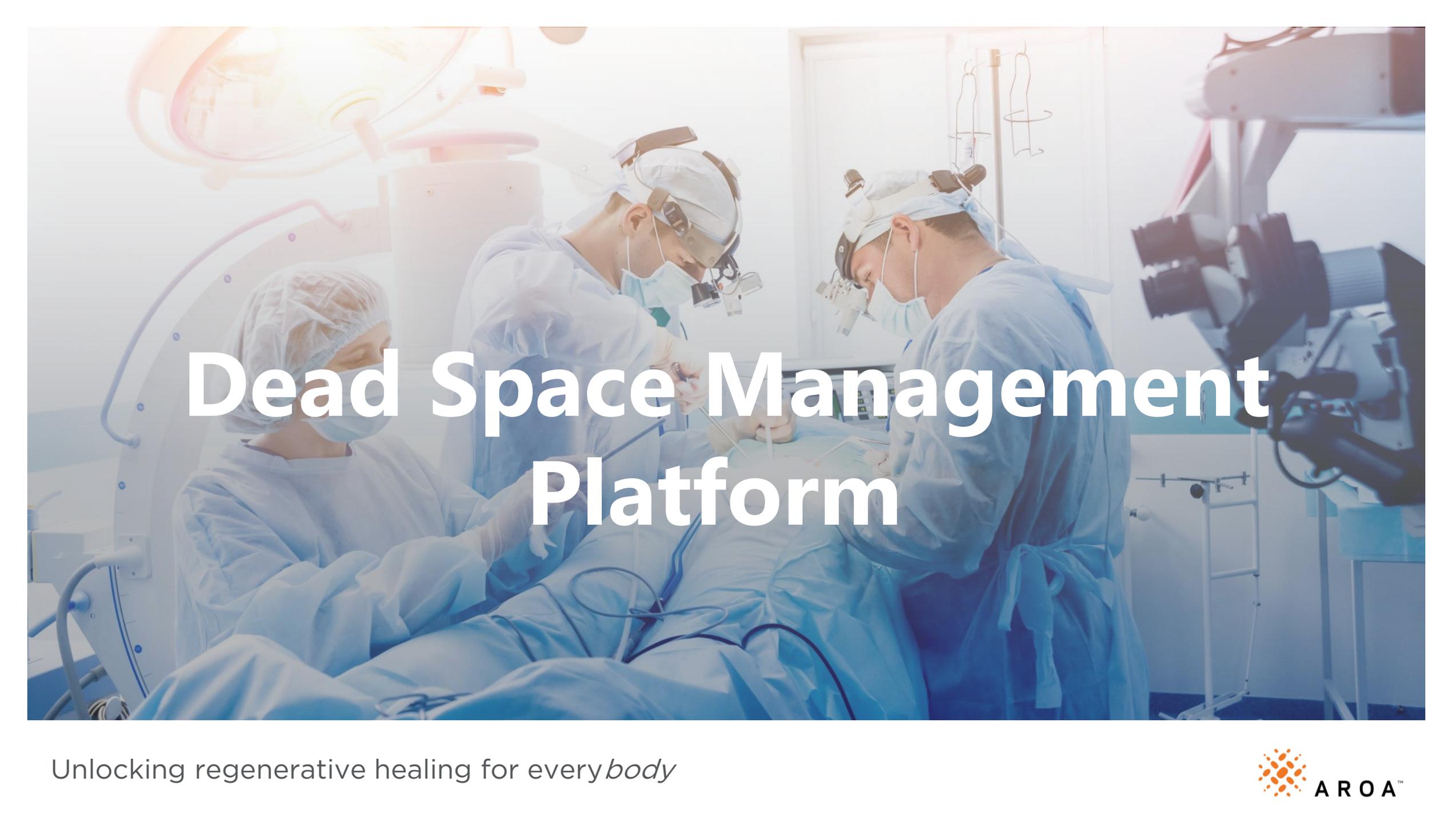
Product	Type	Forecast
Endoform	Real World Data Study – large retrospective comparative analysis in the treatment of DFU (n>2000 wounds)	Q2, FY22
Endoform	Facial burns case series	Q3, FY22
Endoform	Chronic wounds case series	Q3, FY22
Symphony	Pilot (n=10), Endoform + Symphony in treatment of DFU	Q4, FY22
Myriad Matrix	Pilonidal sinus reconstruction case series	Q2, FY22
Myriad Matrix	Limb salvage case series	Q3, FY22
Myriad Matrix and Myriad Morcells	Cases - various	Q4, FY22
OviTex/Myriad Ultra	BRAVO1 - Ventral hernia – study close out	Q3, FY22
OviTex/Myriad Ultra	BRAVO2 – laparoscopic hernia repair	Enrolling



# Q&A

# 10 Minute Session Break

Our next presentation will start at 11:50am

A photograph of three surgeons in an operating room, wearing blue scrubs and masks, focused on a surgical procedure. The room is brightly lit with overhead surgical lamps. The text "Dead Space Management Platform" is overlaid in white on the image.

# Dead Space Management Platform

Unlocking regenerative healing for *everybody*





**Shane Dowling, MSPAS, PA-C, CWS**  
**Medical Science Liaison**

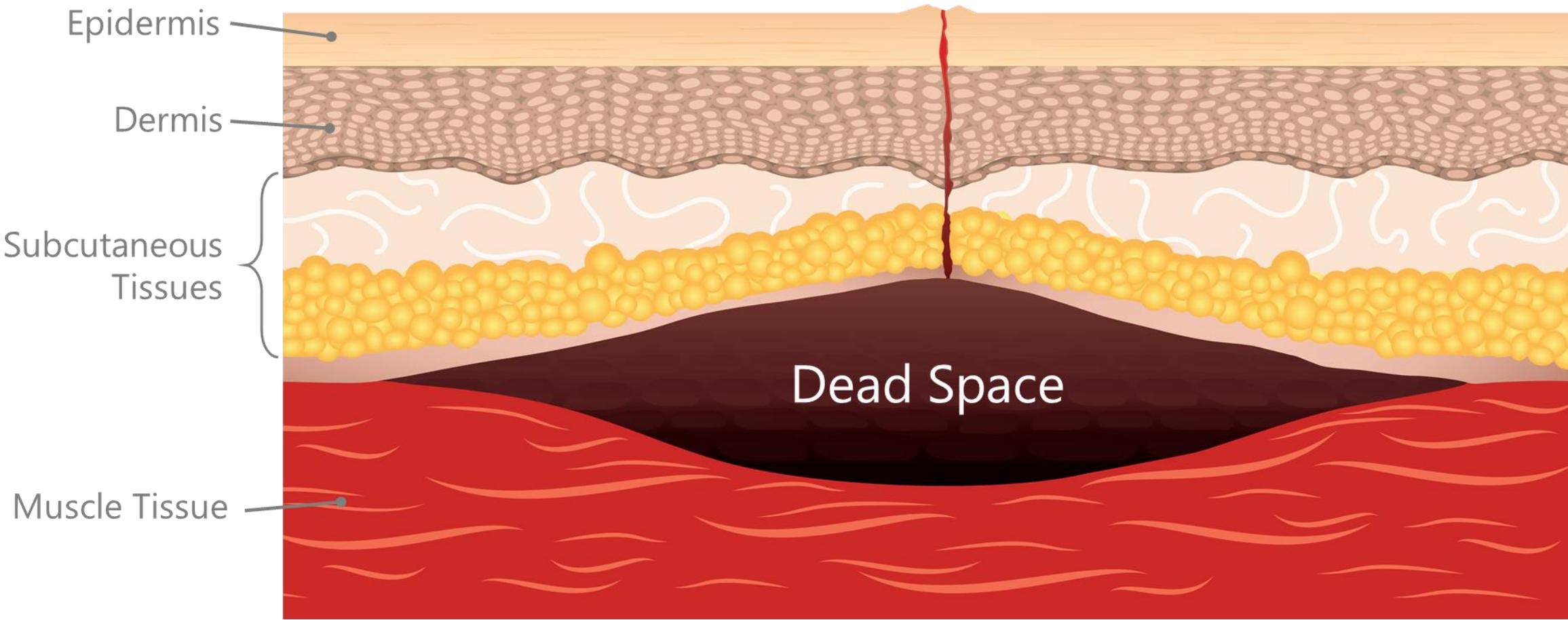
Shane Dowling is a Medical Science Liaison at Aroa, based in Denver, CO. He trained as a Physician Assistant in New York City. His background is centered around trauma and orthopaedics working in both the inpatient and outside setting. He has years of experience with negative pressure wound therapy working as a consultant for 3M+KCI where he gave multiple educational lectures on wound care.



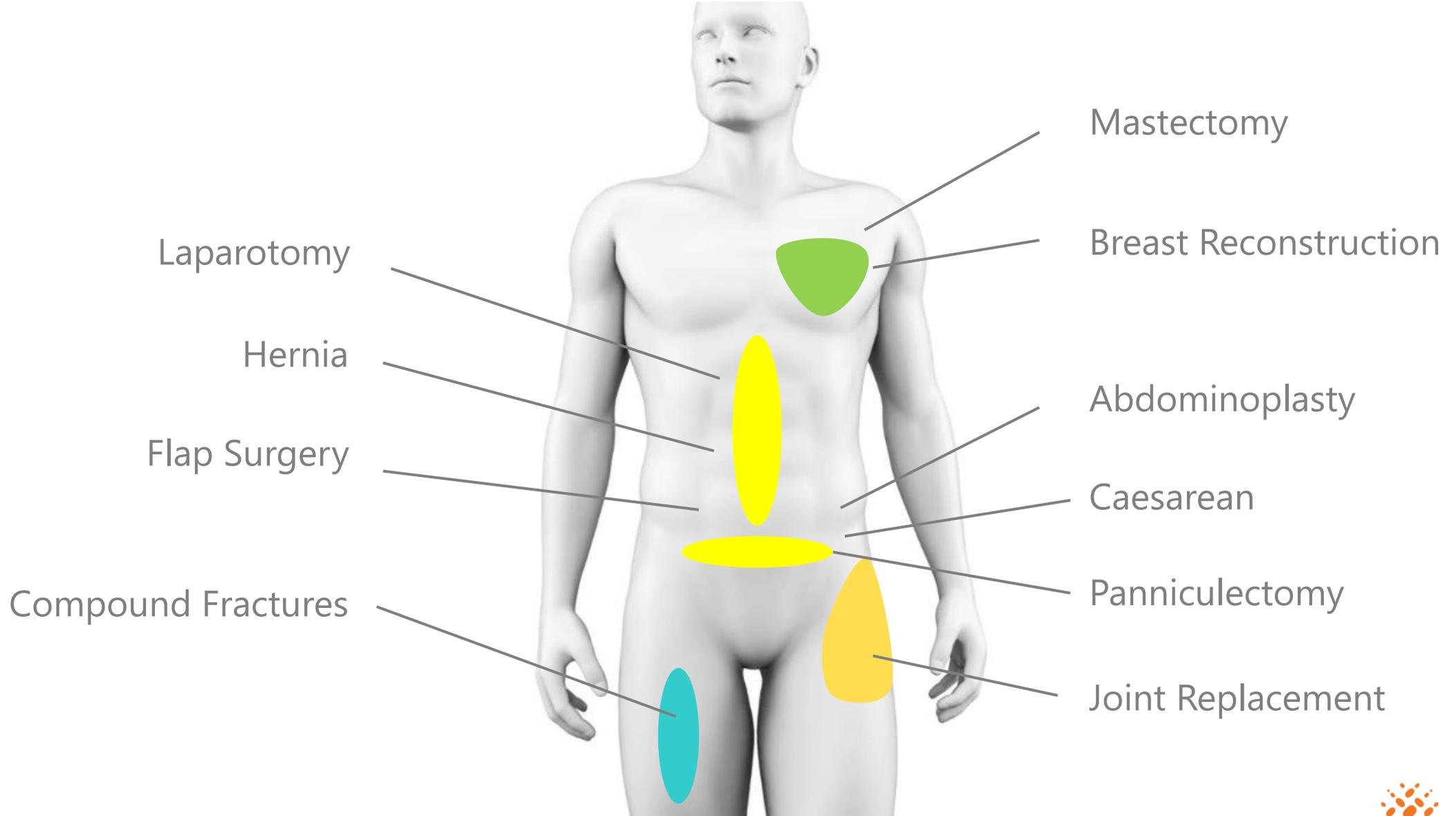
**Isaac Mason**  
**Director of Product Development**

Isaac joined Aroa Biosurgery over 6 years ago and has over 14 years' of experience in medical device design and development. Prior to Aroa Biosurgery, Isaac held various positions as both a process development engineer and product design and development engineer at both Gyrus Medical (a Olympus Surgical Technologies Europe company), a UK based electrosurgical medical device company, and Fisher and Paykel Healthcare, a New Zealand based company specialising in products for acute and chronic respiratory care and the treatment of obstructive sleep apnea. Isaac holds a Bachelor of Mechanical Engineering (with Honours) from the University of Canterbury in New Zealand and has led the development of the Aroa's new active medical device (dead space management) product platform since inception.

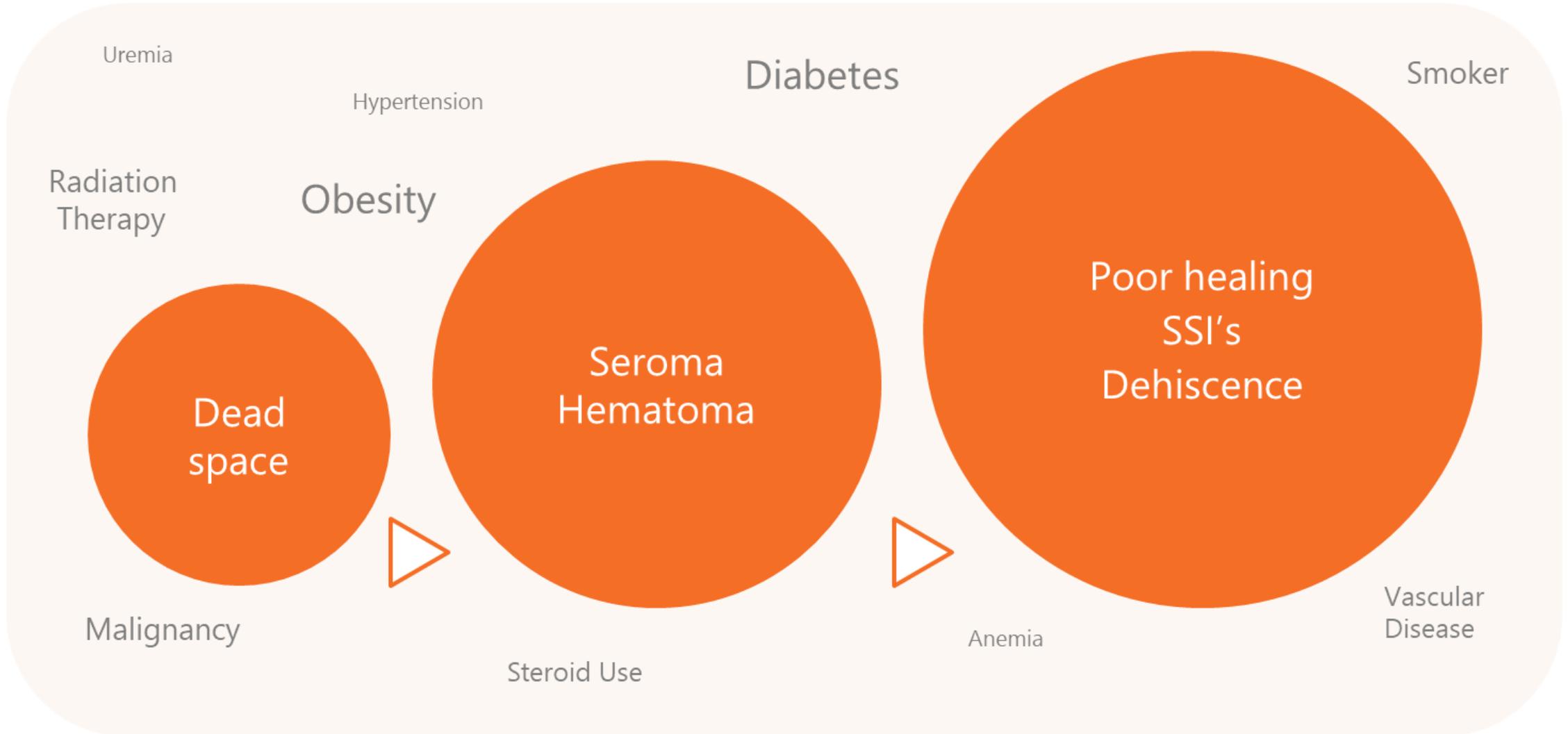
# Clinical Need



# Clinical Need



# Surgical Complications

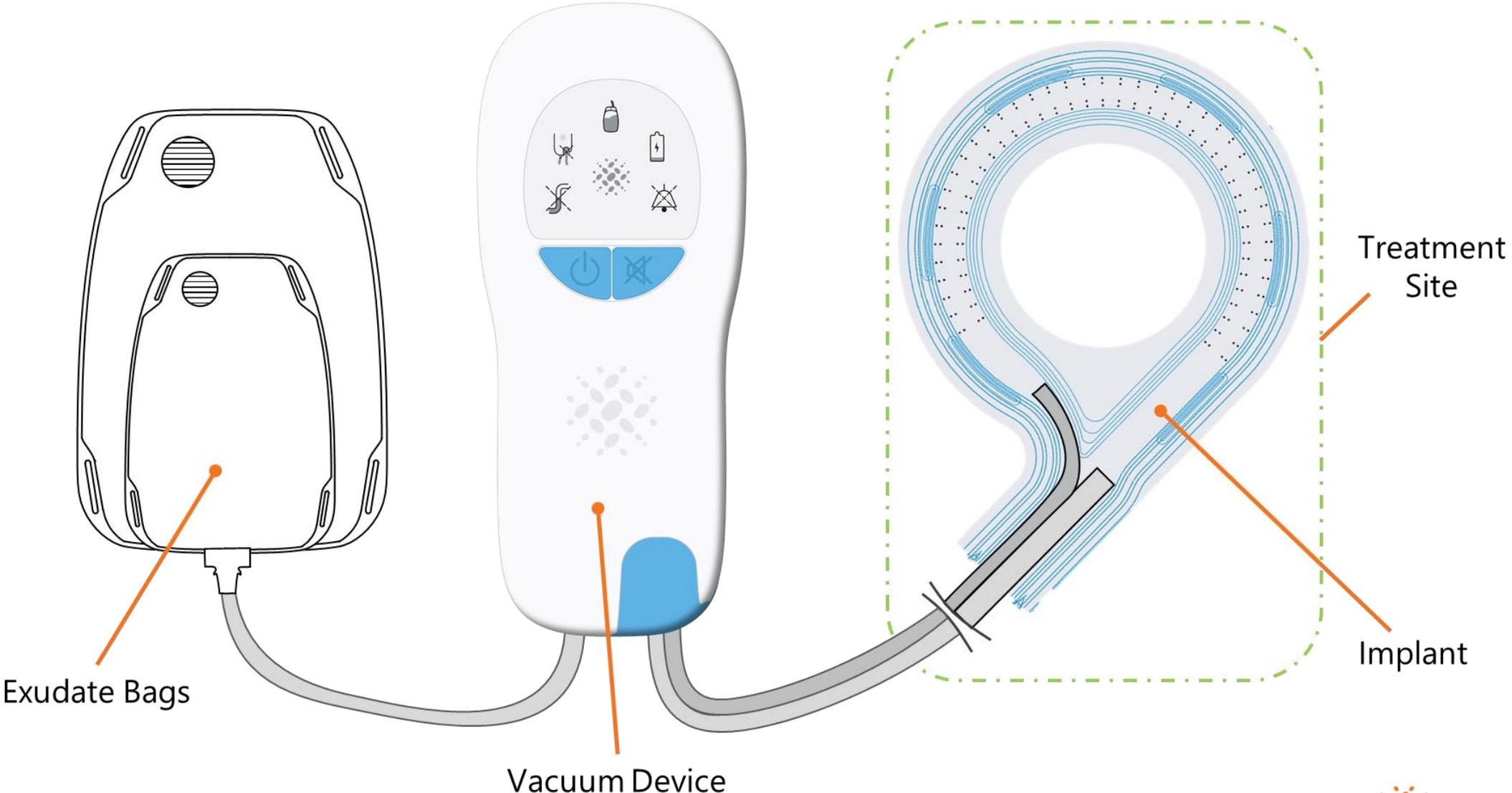


# Surgical Complications

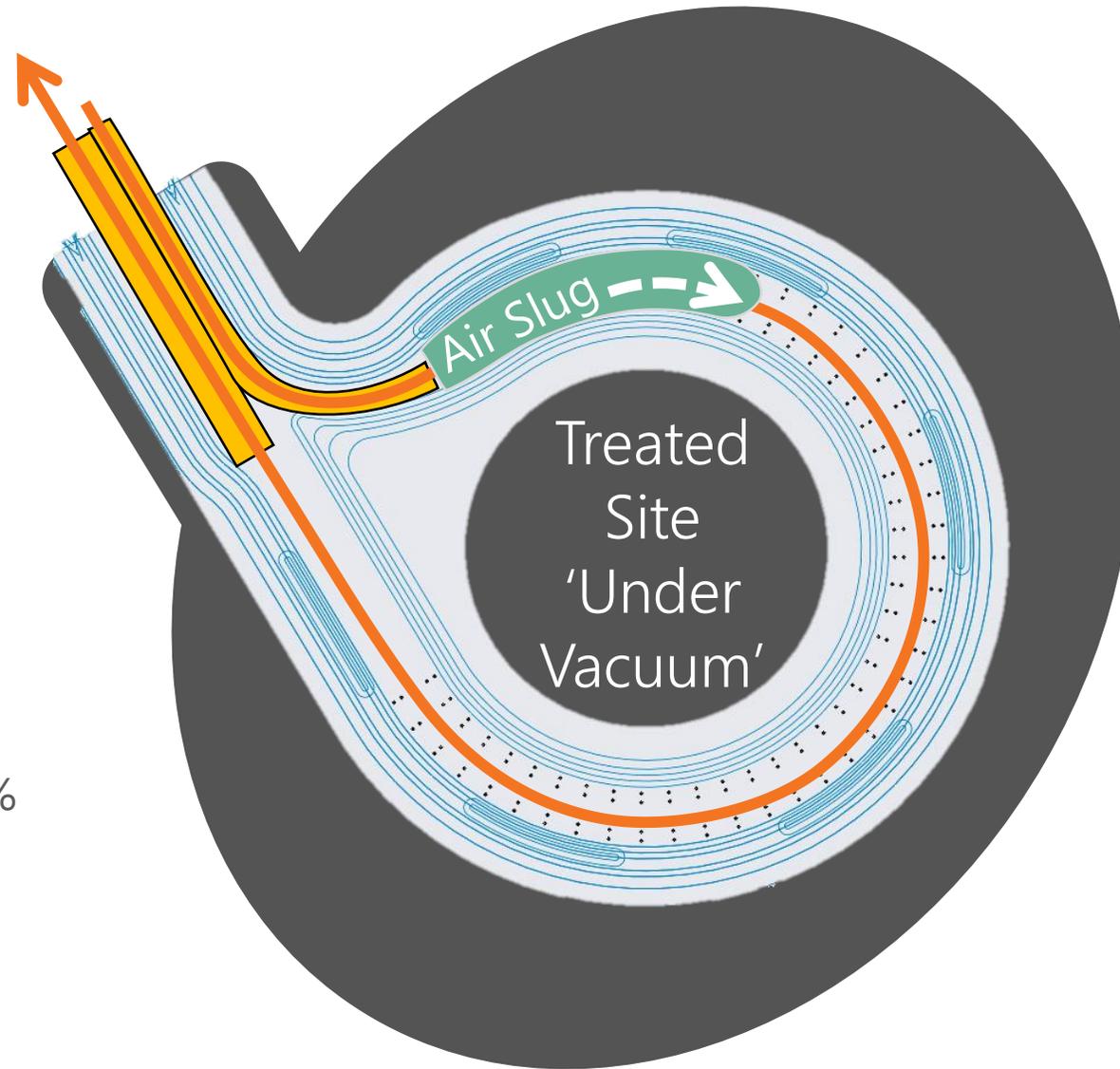
Clinical Speciality	Surgical Sites	Complications
General	Various (Hernia, Laparotomy etc)	9.6% increase in mortality associated with surgical wound dehiscence (SWD) <sup>1</sup>
		SSIs require 7 – 11 days <sup>2</sup> extra hospital care (~US \$38,656) <sup>3</sup>
		Patients with SWD have 61% higher odds of readmission within 30 days <sup>1</sup>
Plastics & Reconstructive	Mastectomy	Dehiscence after abdominopelvic surgery requires ~9.4 days of extra hospital care (US \$40,323) <sup>4</sup>
	Abdominoplasty	
Orthopaedics	Trauma	Additional US \$51,364 <sup>5</sup> cost to treat orthopaedic trauma patients with SSIs
	Hip Revision	
Obstetrics & Gynecology	Caesarean	1.9% to 7.6% incidence <sup>1</sup> of dehiscence following caesarean section

1. Ousey et. al. (2018) – Surgical wound dehiscence: improving prevention and outcomes
2. Anderson et. al. (2014) – Strategies to prevent surgical site infections in acute care hospitals: 2014 update
3. KCI Prevena Active Incision Management Product Brochure
4. Shanmugam et. al. (2015) – Postoperative wound dehiscence: predictors and associations
5. Thakore et. al. (2015) - Surgical site infection in orthopedic trauma: a case-control study evaluating risk factors and cost

# New System



# How Does It Work?

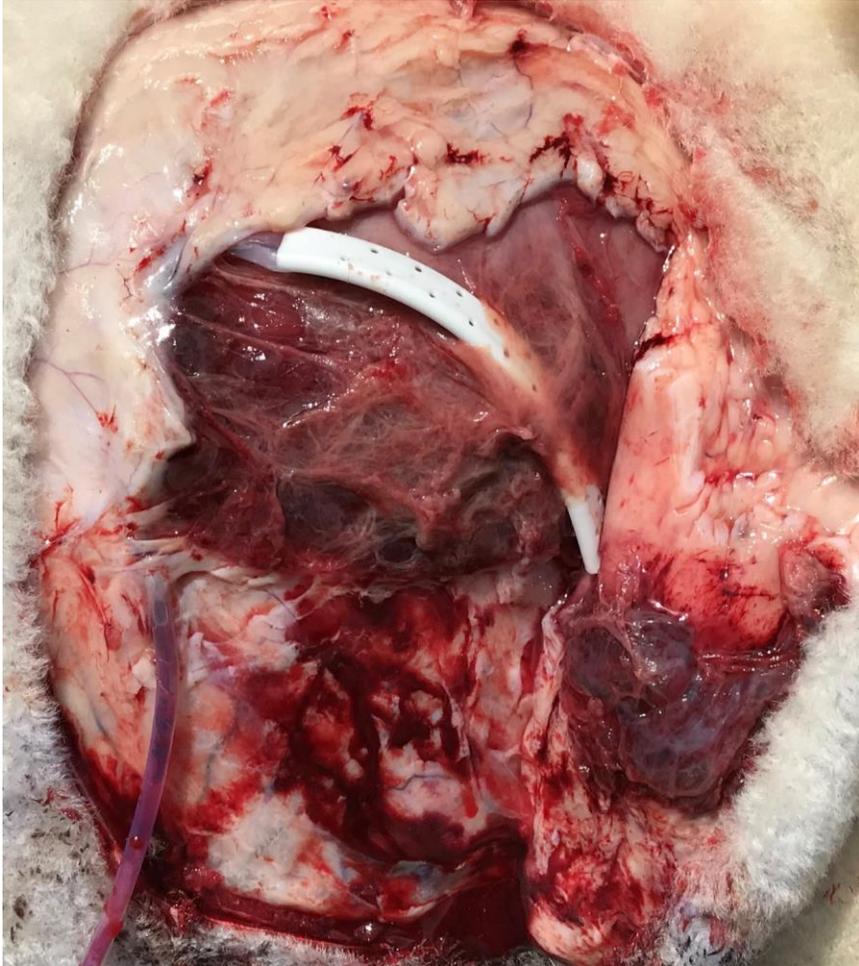


Treatment Area = 100%

Device Area = 75%

Conduit Area = 20%

# Pre-Clinical Validation



Control Device – 'Standard of Care'



Treatment with new system

## Pre-Clinical Snapshot

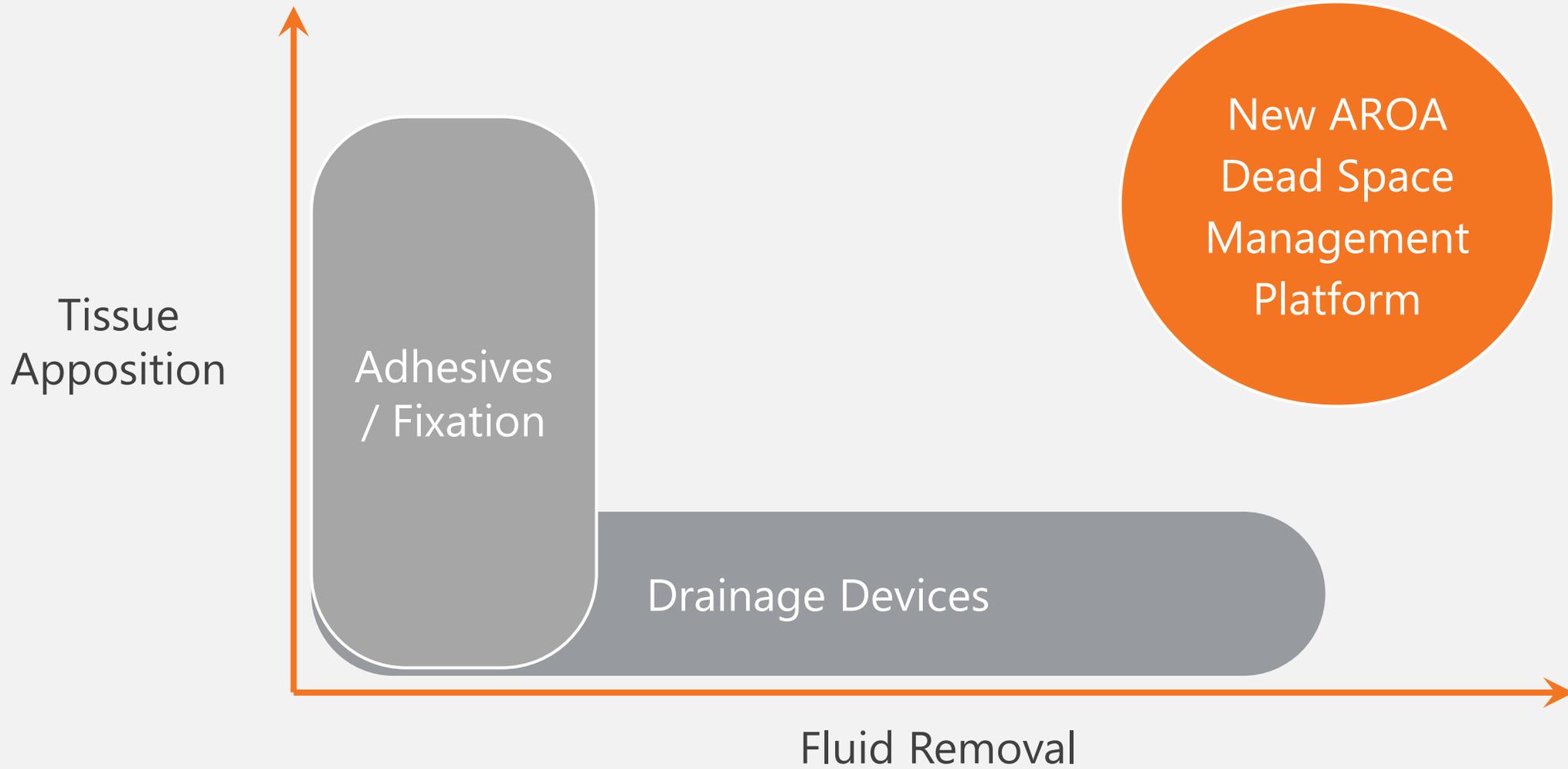
- 48 total test subjects
- +30 versions of treatment system assessed

# Market Opportunity

Clinical Speciality	U.S. TAM (USD) <sup>1</sup>	Primary Use Cases	Addressable Procedures (PA) <sup>1</sup>
General	\$690m	Hernia	~75,000
		Other	~133,000
Plastics & Reconstructive	\$1.09b	Mastectomy	~76,000
		Abdominoplasty	~135,000
Orthopaedics	\$675m	Trauma	~190,000
		Hip Revision	~80,000
Obstetrics & Gynecology	\$260m	Caesarean	~95,000
<u>Total</u>	<u>\$2.715b</u>	<u>Total</u>	<u>~784,000</u>

<sup>1</sup> AROA management estimates

# Competitor Landscape





# Q&A



# Manufacturing Overview

Unlocking regenerative healing for everybody



**Simone Von Fircks**  
**Chief Operations Officer**

Simone joined Aroa Biosurgery's management team over 7 years ago. She brings extensive expertise in biological product manufacture, with more than 30 years of practice in various technical fields. She was previously a senior manager at Baxter Healthcare Austria Biopharmaceuticals. Her proven skills as a leader of international and cross-functional teams and outstanding contribution to successful project completion has been internationally acknowledged. Simone is experienced in quality requirements and systems and has successfully managed inspections from authorities (e.g. FDA, PMDA, ANVISA, European Governments). She holds qualification as an auditor for products manufactured from biological source materials and supported regulatory product licensure for the US, Australian, New Zealand, Japan and EU market. Prior to this role Simone worked for biotech start-up Mologen (Germany), at the University of Amsterdam (The Netherlands) and University of Oldenburg (Germany). She has degrees in Public Health and Laboratory Technology.



**Rod Stanley**  
**Director of Manufacturing**

Rod Stanley joined Aroa over 8 years ago, and has over 12 years' total experience in medical device design and manufacturing. Prior to joining Aroa Rod worked in development of polymer coatings for microfluidic devices at Industrial Research Limited. During his time at Aroa Rod's focus has been on process design and transfer into manufacturing, as well as redevelopment and scale-up activities for the Auckland site. Rod holds Master of Science and Bachelor of Science degrees in Chemistry from the University of Otago.

# Manufacturing and Production

## Well established commercial manufacturing facility

### Unique process produces a high-quality product

- 12 successful Quality inspections since 2014
- 83 staff in Manufacturing and Quality Assurance
- 2 Sites – 5100 m2 total manufacturing floor

### Efficient and low cost

- Purposefully designed gentle & low-cost process & equipment
- Controlled clean room environment built to pharmaceutical standards



In-house manufacturing facility – Auckland, New Zealand



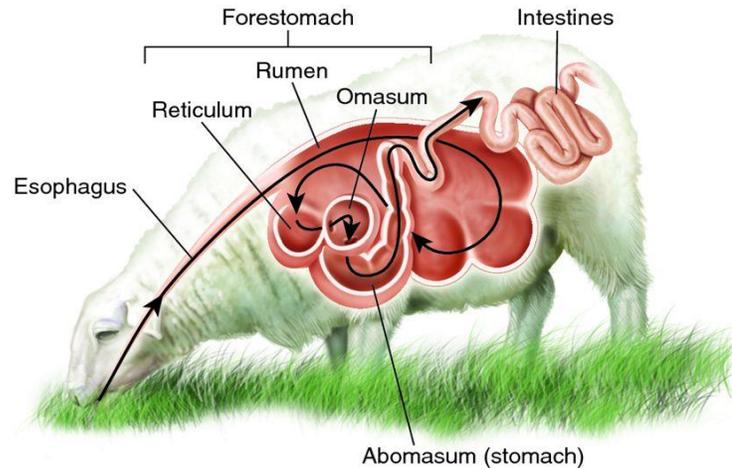
Manufacturing Facility

### Scalable

- Raw materials readily available in New Zealand
- Modular manufacturing design allows production to be easily scaled as sales volumes grow
- Production capacity in place to support revenue of up to NZ\$35m. An investment of ~A\$3 - A\$4 million required to increase facilities capacity by approximately 3x (facilities supporting ~NZ\$100m of revenue). This is expected to be completed end of 2021

# Gentle and Low-Cost Process

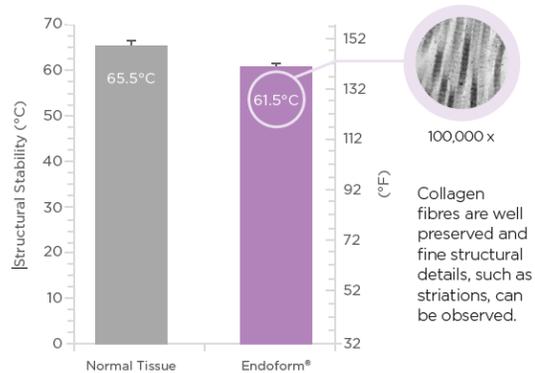
## Subtractive processing



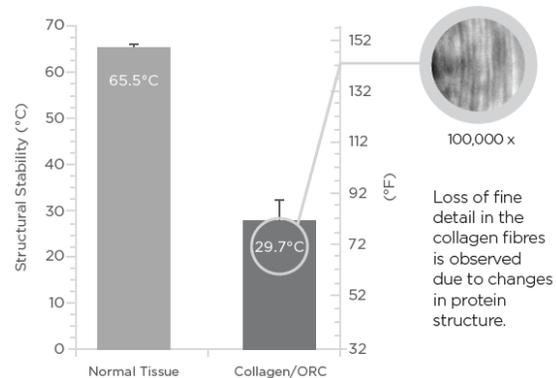
- All products manufactured from the same base AROA ECM material that can be fabricated into different shapes, sizes and designs depending on clinical need.
- Manufacturing process removes everything that 'makes the material a sheep' while retaining the natural structure of the proteins and secondary molecules.
- Manufacturing process does not contain harsh processing conditions or chemicals to avoid damage to tissue.

# Minimally Processed Matrix

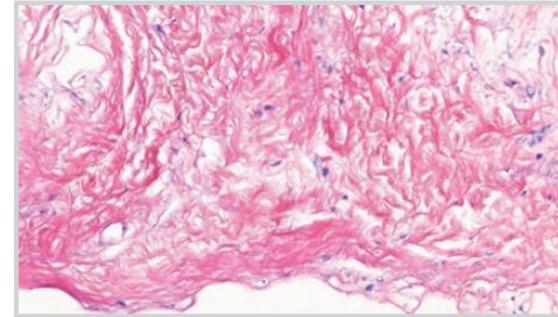
Removal of xenogeneic components while retaining native structure



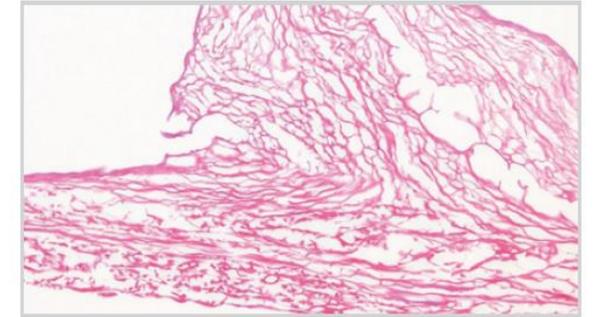
- AROA ECM material has melt onset temperature similar to that of native, unprocessed tissue suggesting minimal damage during processing.



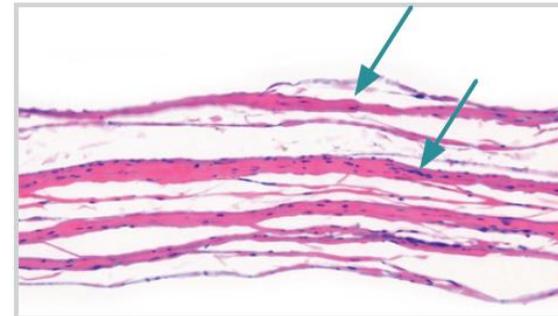
- Histological assessment shows absence of cells (purple haematoxylin staining) and open collagen structure retained from native tissue (pink eosin staining).



Normal Soft Tissue



AROA ECM



Small Intestinal Submucosa ECM



Human Amnion ECM

# VIDEO – Quality Control



**AROA**<sup>TM</sup>

Unlocking regenerative healing for *everybody*

# VIDEO – Manufacturing Tour



**AROA**<sup>TM</sup>

Unlocking regenerative healing for *everybody*



**Q&A**



# FY2022 Outlook & Executive Q&A

Unlocking regenerative healing for *everybody*



# AROA FY22 Outlook



**NZ\$30-\$33m<sup>1</sup>**

product sales FY22  
39-53% higher than FY21



**GM  
improvement**

- **AROA is well placed for FY22** following an improved second half of FY21 and sales transition
- **Focused on building our US commercial operations** over next 24 months to drive revenue growth to take advantage of the opportunities presented by our expanded product portfolio
- **TELA Bio sales expected to deliver strong growth** based on their revenue guidance of 48% to 65% growth in CY21 compared to CY20
- **EBITDA will be negative** (as previously forecasted) as a result of increased investment into its sales force (announced in February 2021)

*<sup>1</sup>Guidance subject to no resurgence of COVID-19 in the US, continued improvement in US medical procedure numbers & TELA Bio sales performance. It assumes an average \$NZD-\$USD exchange rate of US\$0.72*



**Q&A**

# CONTACTS

## **Simon Hinsley**

Investor Relations

m +61 401 809 653

shinsley@aroabio.com

## **Matt Wright**

Media

m +61 451 896 420

matt@nwrcommunications.com.au

Visit our website [www.aroabio.com](http://www.aroabio.com) and find us on LinkedIn at [www.linkedin.com/company/aroa-biosurgery-limited/](http://www.linkedin.com/company/aroa-biosurgery-limited/)

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64 Richard Pearse Drive,  
Auckland 2022, New Zealand

PO Box 107111, Auckland Airport, Auckland 2150,  
New Zealand

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