Myriad™

Soft Tissue Matrix

Coverage and Coding Guide 2019

Unlocking regenerative healing for every*body*

AROA

Myriad™

Disclaimer

This **Coverage and Coding Guide** is intended to provide reference material related to the reimbursement of **Myriad™** when used consistently with the product's labeling.

The information presented in this Coverage and Coding Guide is intended for general informational purposes only, and is not provided as legal advice, advice about how to code, complete, or submit any particular claim for payment for healthcare services or goods, or a recommendation of any kind. This information provides only an overview of **Aroa Biosurgery's** understanding of current coding policies and may not provide all the information necessary for a particular situation. The information provided may not be comprehensive or complete. The coverage and coding information in this guide was obtained from third party sources and can change over time, including as a result of changes in reimbursement laws, regulations, rules, and policies. Coverage and Coding Guide content is informational only, general in nature, and does not cover all situations or all payers' rules or policies and is not intended to apply to any particular situation. This Coverage and Coding Guide is not intended to provide specific guidance on how to utilize, code, bill or charge for any product.

It is the responsibility of the healthcare provider, such as a hospital or a physician, to submit complete, accurate and appropriate bills or claims for payment that comply with applicable laws and regulations, third party payer requirements, and to determine the appropriate codes, charges and modifiers that the provider uses for those purposes.

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For questions regarding reimbursement, please email customerservice@aroabio.com or call 1-877-627-6224.

Myriad™

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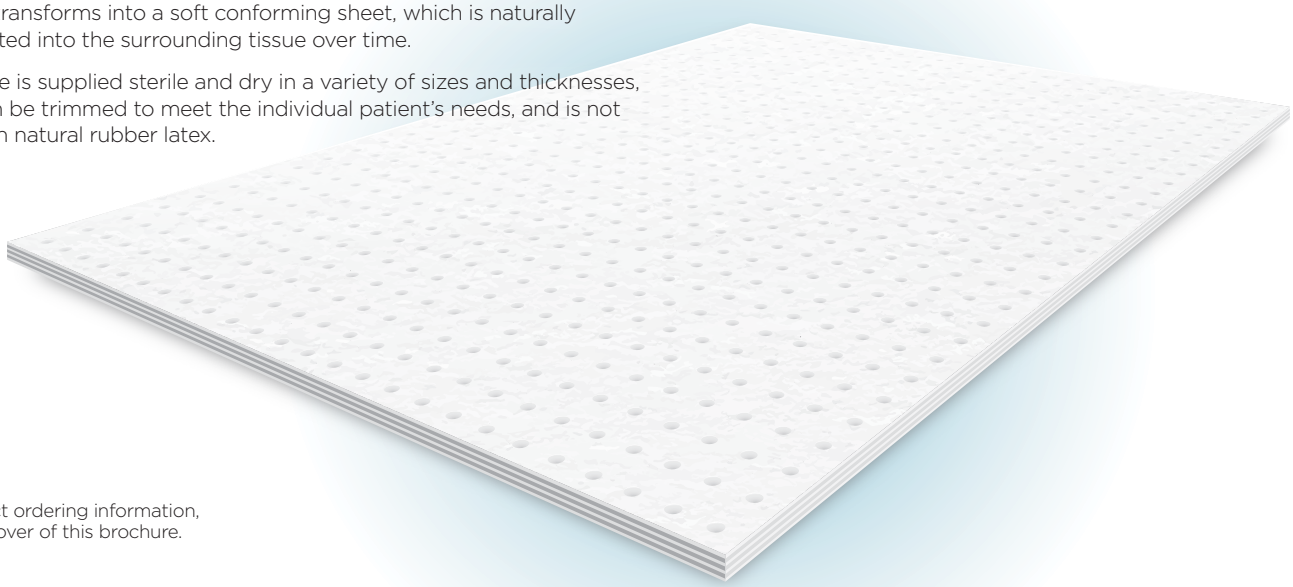
General Information

Product Description

Myriad™ is a collagen matrix with an intact extracellular matrix (ECM). Derived from ovine (sheep) forestomach tissue, this advanced matrix is non-reconstituted collagen, thus it retains the innate biological structure and function of the native ECM-associated macromolecules including elastin, fibronectin, glycosaminoglycans and laminin.

Myriad™ transforms into a soft conforming sheet, which is naturally incorporated into the surrounding tissue over time.

The device is supplied sterile and dry in a variety of sizes and thicknesses, which can be trimmed to meet the individual patient's needs, and is not made with natural rubber latex.



For product ordering information, see back cover of this brochure.

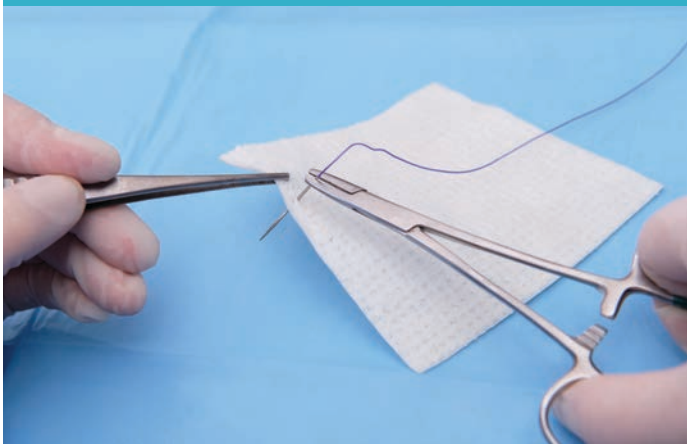
General Information

Intended Use

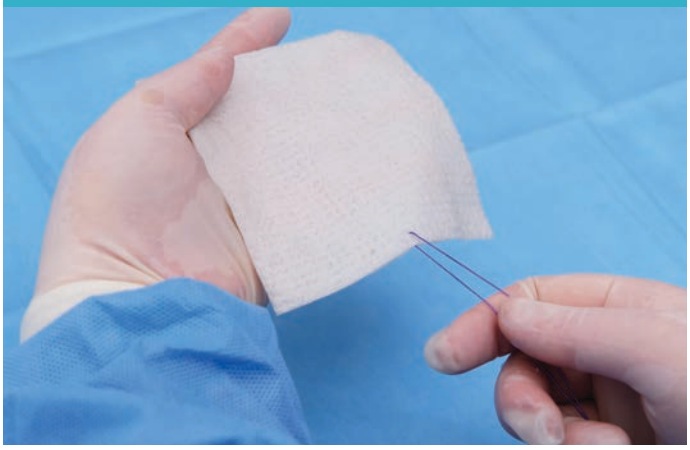
Myriad™ is intended for applications in plastic and reconstructive surgery or to cover, protect, and provide a moist wound environment. The device may be fixed, via sutures, staples, or tacks to the surrounding tissue, if desired.

Handles well

Simple to suture



Resists suture pull-out



Indications for Use

Myriad™ is indicated for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery, or for management of the following wounds:

- partial and full-thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- chronic vascular ulcers
- tunnelled/undermined wounds
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- draining wounds

Myriad™

Coverage

Coverage is the decision of whether or not to include a procedure or technology as a benefit in a health plan. From a reimbursement standpoint, it should be given equal emphasis to coding, because without coverage there is no payment, regardless of having a code.

Private Payer Coverage

While the procedures associated with the above-listed indications are usually covered, third-party payers do not normally cover cosmetic surgery, nor every available dermal repair product. Private payers typically address these issues through prior-authorization, determining whether they will pay for a procedure before it occurs. Prior authorization is also a good time to check for private payer's Cellular and Tissue Products (CTPs) coding requirements. It is highly recommended that hospitals perform a prior-authorization specifying **Myriad™**, before initiating the procedure. Proceeding without a required prior-authorization usually results in non-payment.

Physicians may also wish to perform prior-authorization specifying **Myriad™** because, if the product is non-covered, the procedure is non-covered as well. A template prior-authorization letter is contained in Appendix A, for provider consideration.

FDA Clearance

Myriad™ received FDA 510(K) clearance on June 14, 2017(K171231) and December 20, 2016 (K162461)

Please note: Some third-party payers only reimburse for FDA cleared indications.

Medicare Coverage

Medicare does not prior-authorize, but some local Medicare Administrative Contractors (MACs) have issued bulletins or Local Coverage Determinations on these procedures. **It is the responsibility of the provider to be aware of existing Medicare coverage policies before providing services to Medicare beneficiaries.**

Medicare and other payers determine whether to cover a procedure or technology as a health benefit based on the published literature as well as business considerations. The first requirement is FDA clearance.

> An FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for consideration of Medicare coverage (except in specific circumstances). However, FDA approval or clearance alone does not entitle that technology to Medicare coverage.
>
> 8.7.2013, Federal Register, Vol. 78, No. 152, page 48165

Following FDA clearance, Medicare may develop national or local coverage determinations specific to the procedure or technology. These policies could extend coverage for certain diagnoses or in specific scenarios, or they may identify the procedure or technology as generally non-covered.

When no policy exists, Medicare coverage determinations are based on Medicare's "medically reasonable and necessary" requirement. MACs consider a service medically reasonable and necessary if it is:

- Safe and effective
- Not experimental or investigational

Medicare Advantage plans are managed by private payers and may require prior-authorization for their patients.

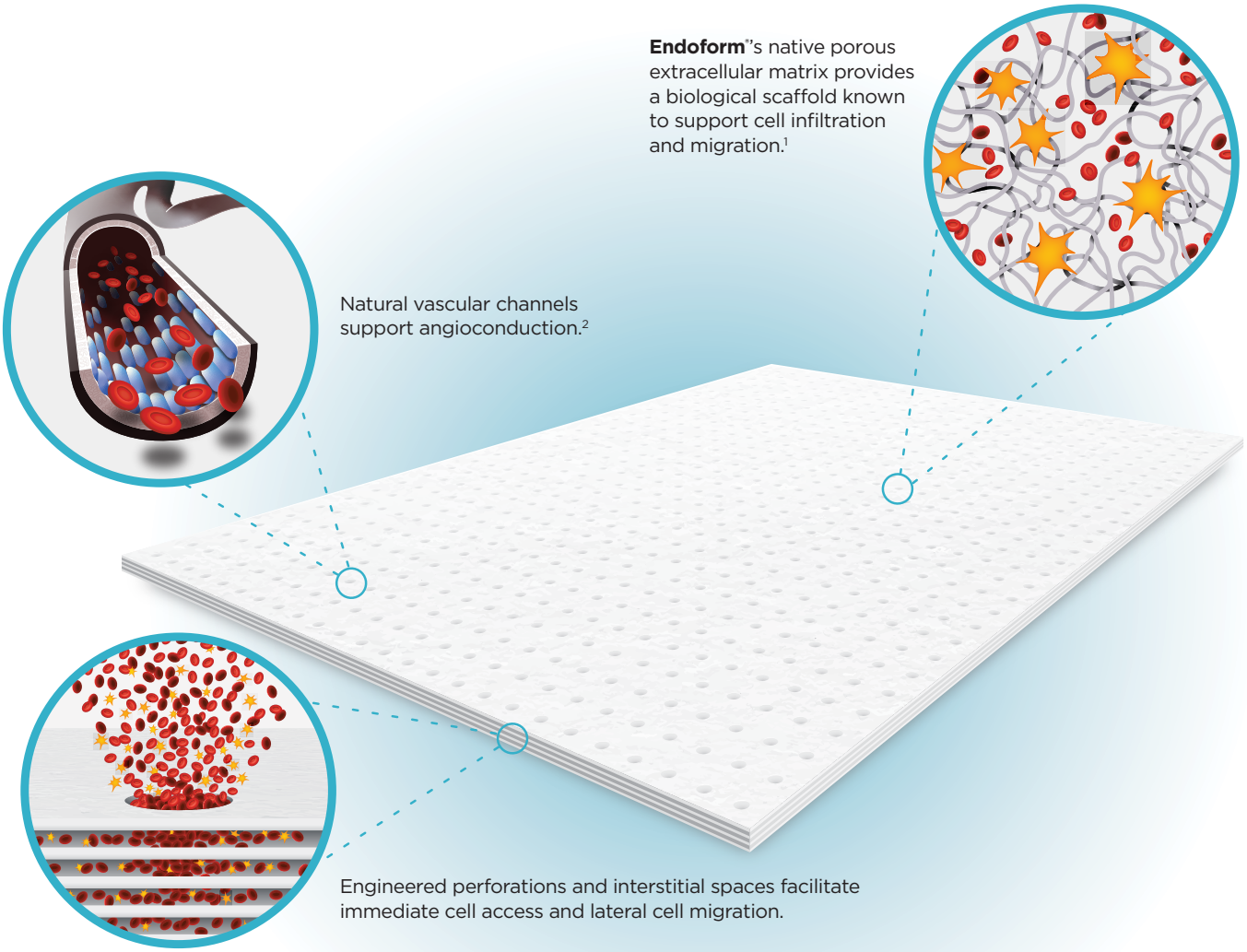
- Appropriate, including the duration and frequency that's considered appropriate for the item or service, in terms of whether it's:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

CMS Publication 100-08, Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.1

Soft Tissue Matrix

Myriad™

Natural structure and engineered architecture enables rapid cell access



1. Lun, S., et al., *A functional extracellular matrix biomaterial derived from ovine forestomach*. Biomaterials, 2010. 31(16): p. 4517-29.
2. Irvine, S.M., et al., *Quantification of in vitro and in vivo angiogenesis stimulated by ovine forestomach matrix biomaterial.* Biomaterials, 2011. 32(27): p. 6351-61. 2011;32(27):6351-61.

Myriad™

Coding

Hospital Inpatient Coding

Procedure Coding – Implant and Dermal Repair

Hospital inpatient services are reported using the International Classification of Diseases, 10th Revision, Procedural Coding System (ICD-10-PCS). Diagnosis codes are used to describe the clinical rationale for physician services. They are reported using the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) coding system. An example ICD-10-PCS code for **Myriad™** when used in dermal repair is provided in Table 1.

Table 1. Example ICD-10-PCS Coding for Inpatient Dermal Repair with Myriad™

ICD-10-PCS Code	ICD-10-PCS Description
0HR<body part>XK4	Replacement of ___ Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach (Note: select the appropriate character for the "Body Part" position)

Coding requirements for Myriad™ are the same for other Non-Autologous Tissue Substitutes, when used in implant or dermal repair procedures.

Hospital Outpatient Department and Ambulatory Surgery Center

General Procedure Coding

Physicians report their procedures and services using Common Procedural Terminology (CPT) codes, developed and owned by the American Medical Association. Physicians are paid the same amount for the procedures they perform in: hospital inpatient, Hospital Outpatient Department (HOPD), or ambulatory surgery center (ASC), facilities.

For HOPD services, not requiring an inpatient admission, hospitals report the same CPT codes as physicians, on their claims. For Medicare payment, the CPT codes are then grouped into Ambulatory Payment Classifications (APCs), based on their clinical and resource similarities. ASCs also utilize CPT codes to report procedures. Facility payments include the cost of the device. **None of these coding requirements are different for Myriad™ than for other implant and dermal repair procedures.**

Product Coding

Where Myriad™ coding differs from some tissue-supplement procedures is the Healthcare Common Procedure Coding System II (HCPCS II) code facilities utilize to describe the product. Products like **Myriad™** when used in dermal repair initially use the code defined in Table 2.

Table 2. HCPCS II Myriad™ Product Code

HCPCS II	HCPCS II Long Description
Q4100	Skin substitute, not otherwise specified

Not-otherwise-specified (NOS) codes require additional work for the facility and the payer. To report them, the facility must describe the product being used (**Myriad™**), on the claim. Also required are the appropriate charges; and the amount of product purchased and the amount used, in cm^2. For initial claims, the peer-reviewed literature is referenced or supplied as well (see Appendix A). The payer then determines the medical necessity of the procedure for that patient and pays the appropriate amount, through a manual review.

Once payers become accustomed to receiving **Myriad™** claims under a NOS code, they typically create work-arounds to allow electronic claims processing, similar to specified codes. Dermal repair procedure claims from facilities, not identifying the product with a HCPCS II code, will not be paid.

Coding

Implantation Procedures

Utilizing **Myriad™** may involve the following procedure codes listed in Table 3.

Table 3. HOPD and ACS CPT Codes for Implantation of Myriad™

CPT	Description
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (list separately in addition to code for primary procedure)
17999	Other Procedures on the Integumentary System

Dermal Repair Procedures

When applying a bioengineered skin substitute, procedures using **Myriad™** are reported under CPT code range C5271-C5278 for topical application to a wound surface (Table 4). **Myriad™** is anchored using the surgeon's choice of fixation.

Table 4. HOPD and ACS CPT Codes for Dermal Repair with Myriad™

CPT	Description
C5271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area
+C5272	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
C5273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children
+C5274	Each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
C5275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area
+C5276	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
C5277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children
+C5278	Each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

Product Billing

1. CTPs represented by Q4100 are classified to the low-cost category. These cost thresholds are set by Medicare annually. Some, but not all, private insurers apply similar criteria.
2. For HOPD payment, the status indicator for Q4100 is N meaning the **Myriad™** is packaged into the payment for other services and not billed separately.
3. For ASC payment, the status indicator for Q4100 is N1 meaning the **Myriad™** is a packaged into the payment for other services and not billed separately.
4. ASCs should report all charges incurred. However, only non-packaged items can be billed as separate line items. Instead, the ASC should bill a single line for the procedure with a single total charge, including not only the charge associated with the operating room but also the charges for the product and all other packaged items. Because Medicare payment is based on the lower of: 80 percent of actual charges for separately payable procedures and services, or the ASC payment rate, breaking packaged charges out onto their own lines can result in reduced payment to the ASC.

   Lhttp://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles on/downloads/SE0742.pdf.

Myriad™

Appendix A: Sample Prior-Authorization Letter

Please modify the items in <brackets> and print on your letterhead before sending.
Note: The bibliography should be included with your letter.

[Date]

[Private Payer]

RE: Pre-authorization for Patient: <Insert name>

Date of Birth: <Insert DOB>

Payer Identification Number: <Insert identifier>

Dear Dr. <Insert Medical Director's name>

I would like to request prior authorization for coverage and payment for reconstructive surgery for the above listed patient. The procedure involves <Use whichever one is appropriate>.

Implantation of a biologic implant, CPT code <Insert CPT code>, OR

My patient is a <Insert age> year old <Male/female> requiring the use of an extracellular matrix for soft tissue reinforcement of the <Insert physical location>. The need for an implant was necessitated by a <insert procedure or trauma> to facilitate proper healing OR determined after the following procedures were tried. <List prior procedures>

Application of skin substitute graft, CPT code <Insert CPT code>

My patient is a <Insert age> year old <Male/female> with <Insert condition> whose x cm^2 by x cm^2 wound will require intervention to build the granulation tissue. Without surgical intervention, via the placement of the product **Myriad™**, the tissue deficit is unlikely to heal by itself and if it were to heal unaided the long term patient outcomes would be poor.

<Use the following in all cases>

The procedure utilizes a soft tissue repair matrix, termed '**Myriad™**' (HCPCS II code Q4100), which is an intact extracellular matrix from Aroa Biosurgery Limited. The FDA clearance Myriad received on June 14, 2017 (K171231) and December 20, 2016 (K162461) includes this indication.

Myriad™ is a collagen matrix with an intact extracellular matrix (ECM). Derived from ovine (sheep) forestomach tissue, this advanced matrix is non-reconstituted collagen, thus it retains the innate biological structure and function of the native ECM associated macromolecules including elastin, fibronectin, glycosaminoglycans and laminin. **Myriad™** transforms into a soft conforming sheet, which is naturally incorporated into the surrounding tissue over time. The device is supplied sterile and dry in a variety of sizes and thicknesses, which can be trimmed to meet the individual patient's needs. The **Myriad™** device is sutured or stapled into the surrounding tissue. Please see the attached bibliography.

Continued on next page.

Appendix A: Sample Prior-Authorization Letter

Please include any specific billing requirements in your reply. Should you require additional information, please contact me at <Insert phone number and/or email address>. Thank you for your consideration.

Sincerely,

<Signature, name, and title>

Bibliography

Chaffin, A. E., A. M. Aballay, G. A. Bohn, P. M. Glat, M. N. Desvigne and B. C. H. May (2019). Multi-Centre Clinical Evaluation of a Cell Conductive Extracellular Matrix Surgical Mesh in Plastics and Reconstructive Surgery – A Case Series. 41st Annual Boswick Burn & Wound Symposium, Wailea Beach, Maui, HI.

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Liden, B. A. and B. C. May (2013). "Clinical outcomes following the use of ovine forestomach matrix (endoform dermal template) to treat chronic wounds." Adv Skin Wound Care 26.

Simcock, J. and B. C. May (2013). "Ovine forestomach matrix as a substrate for single-stage split-thickness graft reconstruction." Eplasty 13: e58.

Simcock, J. W., M. Than, B. R. Ward and B. C. May (2013). "Treatment of ulcerated necrobiosis lipoidica with ovine forestomach matrix." J Wound Care 22(7): 383-384.

Myriad™

Soft Tissue Matrix

Ordering information

Myriad™ – Thin (~1.0 mm)		
Stock no.	**Product Size (L x W)**	**Quantity/Box**
SR03LG0505US	5 x 5 cm	1
SR03LG1010US	10 x 10 cm	1
SR03LG1020US	10 x 20 cm	1
Myriad™ – Thick (~1.5 mm)		
Stock no.	**Product Size (L x W)**	**Quantity/Box**
SR05LG0505US	5 x 5 cm	1
SR05LG1010US	10 x 10 cm	1
SR05LG1020US	10 x 20 cm	1

Company information

Aroa Biosurgery, ("**Aroa**,") is a bioscience company developing and commercializing a portfolio of bioscaffolds for soft tissue repair, including the management of acute and chronic wounds, general surgery, and plastic and reconstructive surgery.

For additional information on **Aroa** or **Myriad™**, please visit **www.aroabio.com.**

RX Only.

For product questions, sampling needs, or detailed clinical questions concerning our products in the US, please email customerservice@aroabio.com or call 1-877-627-6224.

AROA

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