

SportMesh™

SOFT TISSUE REINFORCEMENT

Made from...

Artelon®
optimal tissue repair



BIOMET®
SPORTS MEDICINE





What is SportMesh™ Soft Tissue Reinforcement

SportMesh™ Soft Tissue Reinforcement is a degradable poly(urethaneurea) implant that is sutured over torn or degenerative tissue as a reinforcement. The implant has been shown to partially degrade. The remaining material is incorporated into the patient's surrounding tissue, and intended to strengthen weak or repaired tissue.¹

The implant shares the load placed on the sutures or suture anchor, and acts as a scaffold for a torn tendon that is too fragile to maintain a strong connection to bone.



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Artelon® material is a unique, degradable biomaterial that serves as a scaffold for tissue ingrowth and provides temporary support for healing tissue.

SportMesh™ Soft Tissue Reinforcement is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, and quadriceps tendons.

Rotator Cuff Reinforcement

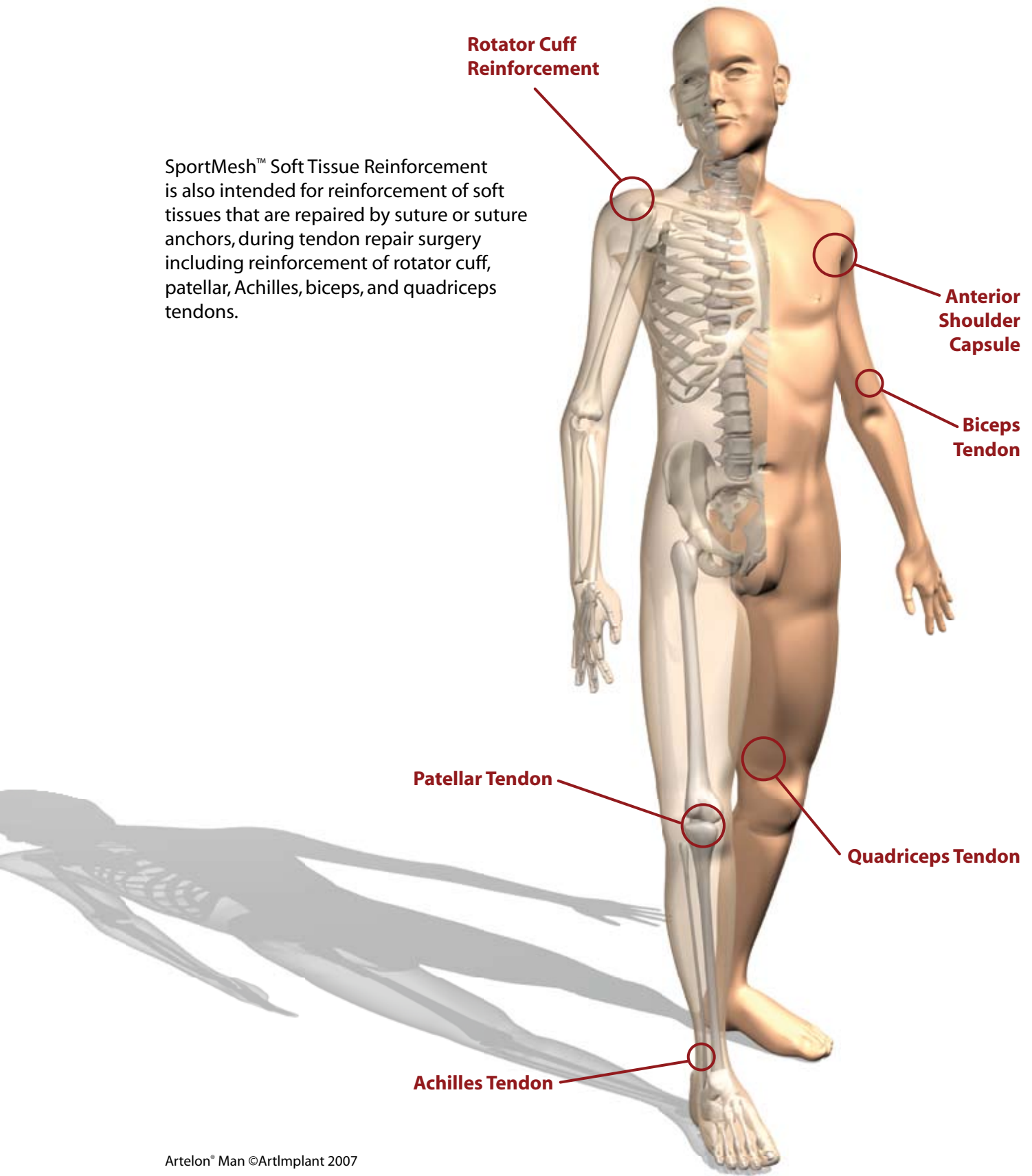
Anterior Shoulder Capsule

Biceps Tendon

Patellar Tendon

Quadriceps Tendon

Achilles Tendon





The SportMesh™ Soft Tissue Reinforcement Edge

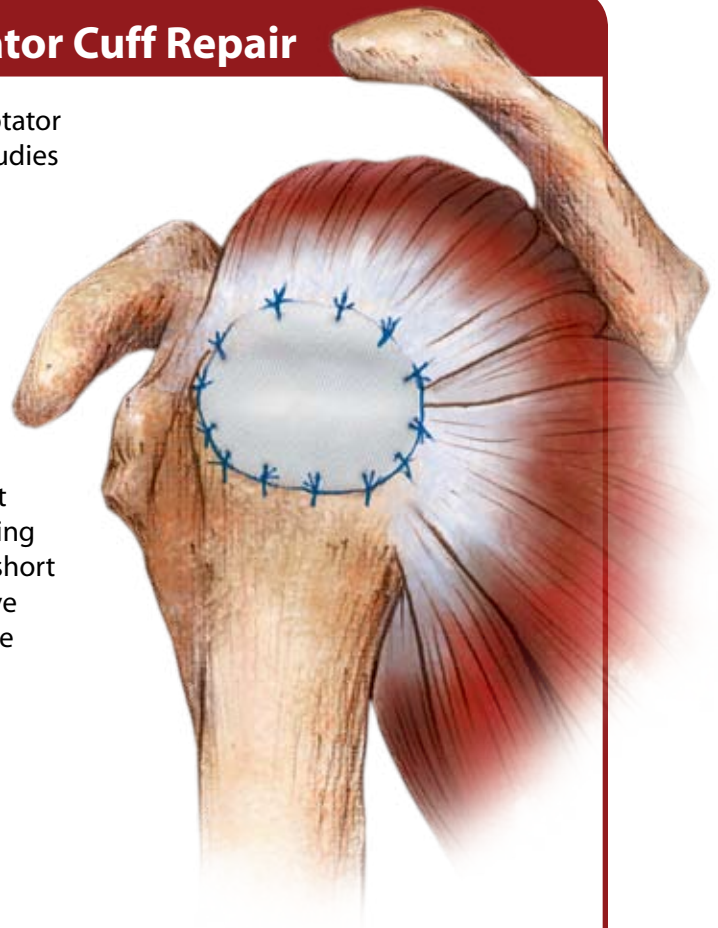
- Strong, consistent, readily available material with a five-year shelf life
- Unlike allograft material, there is no concern with variation of donor tissue
- Cost effective compared to traditional materials
- Extremely easy to handle, cut and shape to soft tissue
- Unlike allograft and xenograft materials, the SportMesh™ implant is a synthetic material and poses no risk of collagen rejection or donor disease transmission
- Porous Artelon® structure permits host tissue in-growth

Encouraging Solutions: Rotator Cuff Repair

It is widely accepted that the weakest link in rotator cuff surgery is the suture-tendon interface.² Studies have shown re-rupture rates as high as 68% depending on the size of the original repair.⁵

The SportMesh™ Soft Tissue Reinforcement was designed with one of the most important issues in soft tissue reinforcement in mind: tissue quality. Due to the tendon's relatively low vascular supply, the tendon's ability to heal is extremely slow.

The important function of the SportMesh™ Soft Tissue Reinforcement is to relieve the load during the sensitive healing period and thus achieve short and long-term stability. The Artelon® Fibers have a unique fiber structure that permits host tissue ingrowth and blood vessels between fibers.





How is SportMesh™ Different from Collagen Patches?

There is no risk of collagen rejection or donor disease transmission issues as the material is synthetic with proven biocompatibility.

Collagen patches have good initial strength. However, several of them degrade within a couple of weeks.³ Since they may degrade quickly, strength may not be retained to support the healing of the RC tears and could lead to re-ruptures.³

With the biocompatible clinical history of Artelon® material, SportMesh™ Soft Tissue Reinforcement features excellent tissue ingrowth, consistent strength and secure fixation with no concern about donor inconsistency of tissue quality. The Artelon® fibers are intended to strengthen weak or repaired soft tissue. The SportMesh™ implant provides consistent reinforcement during the initial healing period, which is a critical step in achieving long-term stability. The controlled degradation rate provides predictable long term support throughout the entire healing process.

"I have been very impressed with your product. I have used it in the wrist and the shoulder. The shoulders were for patients with insufficient capsules and the combined benefits of scaffolding and strength are critical. I think it is clearly better than anything else on the market."

*David Schneider, M.D.
Orthopedic Surgeon*

"For over nine years, I have been using Artelon® products as augmentation in the surgical treatment of ligament tendon and joint capsule injuries and will continue to do so."

*Professor Lars Peterson, MD, PhD
Orthopedic Surgeon
Gothenburg Medical Center,
Sweden*

"I have been using Artelon® material for reinforcement in two types of surgical procedures, rotator cuff repair and the Weaver-Dunn procedure. The Artelon® material gives an augmentation during the entire healing period of 3 – 6 months and the patient can be permitted to start exercises earlier."

*Dr. Carl Zetterberg
Department of Orthopedics
Uddevalla Hospital,
Sweden*

Clinically Proven Biocompatible Material

Artelon® Fibers

- Patented biomaterial with ten years of clinical support¹
- Implant construct allows for fast ingrowth of soft tissue that fills the space between the fibers
- In vitro studies show 50 percent resorption in approximately six years
- 50 percent of initial tensile strength retained after four years⁴

Biocompatibility

- Material demonstrates excellent biocompatibility in both soft tissue and bone.¹
- Artelon® fibers provide short and long term tissue reinforcement while also acting as a partially degradable scaffold that is incorporated into the patient's own tissue.^{1,4}

Consistency

- As a synthetic material, SportMesh™ Soft Tissue Reinforcement eliminates the risk of collagen reactions, which may result from collagen or dermis patches, as well as the potential risk of donor disease transmission.

Mechanical and Surface Properties

- Pull-out strength of 30N using a simple stitch⁴
- Pull-out strength of 82N using a mattress stitch⁴
- Ball burst strength of 500N⁴
- Highly porous material acts as a wick to soak and retain fluid while maintaining space and retaining original shape to allow for cellular infiltration



Highly porous material acts as a wick.

SportMesh™ Tissue Reinforcement

Description

SportMesh™ Tissue Reinforcement is a knitted fabric made from Artelon™ fibers. The construction permits the mesh to be cut into any desired shape or size without unraveling. The device is supplied sterile in sheet form in double layer peelable packaging.

Applications/Intended Use

SportMesh™ Tissue Reinforcement is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists.

SportMesh™ Tissue Reinforcement is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons.

SportMesh™ Tissue Reinforcement is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the tendon repair. SportMesh™ Tissue Reinforcement reinforces soft tissue and provides a degradable scaffold that is incorporated into the patient's own tissue.

Contraindications

The device is contraindicated for use in patients with:

- Active or latent infection,
- Decreased vascularity,
- Pathologic soft tissue conditions that would prevent secure fixation.

The device is contraindicated for use in any patient with mental or neurologic conditions who is unwilling or incapable of following postoperative care instructions.

The device is contraindicated in uses that require rolling, folding, or layering, and which may create a space impermeable to fluid, cells, and blood vessels. Such uses may result in excessive inflammation, drainage, extrusion or infection.

Warning

Use of this product in applications other than those intended for implantation to reinforce soft tissue where weakness exists has the potential for serious complications. The patient is to be made aware of the potential complications as listed.

Precautions

- Do not use this product without reading and understanding the complete instructions enclosed herein.
- Do not resterilize. Discard all open and unused portions of SportMesh™ Tissue Reinforcement.
- The device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
- Discard the device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Ensure that device is hydrated prior to anchoring.
- Aseptic technique must be adhered to throughout the procedure.
- Single patient use only.

Potential Complications

The following complications are possible with the use of surgical graft material. If any of these conditions occur, the device may need to be removed at the surgeon's discretion.

- Infection
- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation.)
- Tissue erosion
- Product extrusion

Instructions for Use

Note: Always handle SportMesh™ Tissue Reinforcement using aseptic technique.

Preparation of SportMesh™ Tissue Reinforcement:

SportMesh™ Tissue Reinforcement shall be soaked in sterile saline (0.9 % NaCl) at room temperature for at least 5 minutes before use.

1. Prepare the graft site using standard surgical techniques.
2. Using aseptic technique, trim the SportMesh™ Tissue Reinforcement to fit the implant site, providing small allowance for overlap.
3. Using aseptic technique, transfer the SportMesh™ Tissue Reinforcement to the graft site and suture or staple into place, avoiding excess tension.
4. Complete the standard surgical procedure.
5. Discard any unused portions of the SportMesh™ Tissue Reinforcement.

Training

SportMesh™ Tissue Reinforcement may be used only by surgeons trained and experienced in soft tissue repair in applications relevant for the device.

Storage

This device should be stored at room temperature and normal relative humidity.

Sterilization

This device has been sterilized using a minimum dose 25 kGy Electron Beam Radiation. Do not resterilize. Do not use after expiration date.

SportMesh™ Tissue Reinforcement is an Artelon® product made by Artimplant AB.

Manufactured By:

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Ordering Information

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|--|---------------------|
| SportMesh Soft Tissue Reinforcement | |
| 920002 | 4 x 6 cm (Domestic) |

MaxBraid™ PE Suture

- 900333** #2 White (Box of 12)
900334 #2 Blue (Box of 12)
900336 2-0 Blue (Box of 12)

References

1. Nilsson, A. *et al.* Results from a Degradable TMC Joint Spacer (Artelon) Compared with Tendon Arthroplasty. *The Journal of Hand Surgery*. 380-89, 2005.
2. MacGillivray JD. An Arthroscopic Stitch for Massive Rotator Cuff Tears. *Arthroscopy*. 669-71, 2004.
3. Valentin J.E., Badylak J.S., McCabe G.P., Badylak S.F., Extracellular Matrix Bioscaffolds for Orthopaedic Applications. A Comparative Histologic Study., *Journal of Bone Joint Surgery Am*. 88:2673-2686, 2006.
4. Data on file at Artimplant
5. Jost B, Pfirrmann C.W.A, Gerber C; "Clinical Outcome After Structural Failure of Rotator Cuff Repairs" *Journal of Bone & Joint Surgery Am*, 304-314, 2000.

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