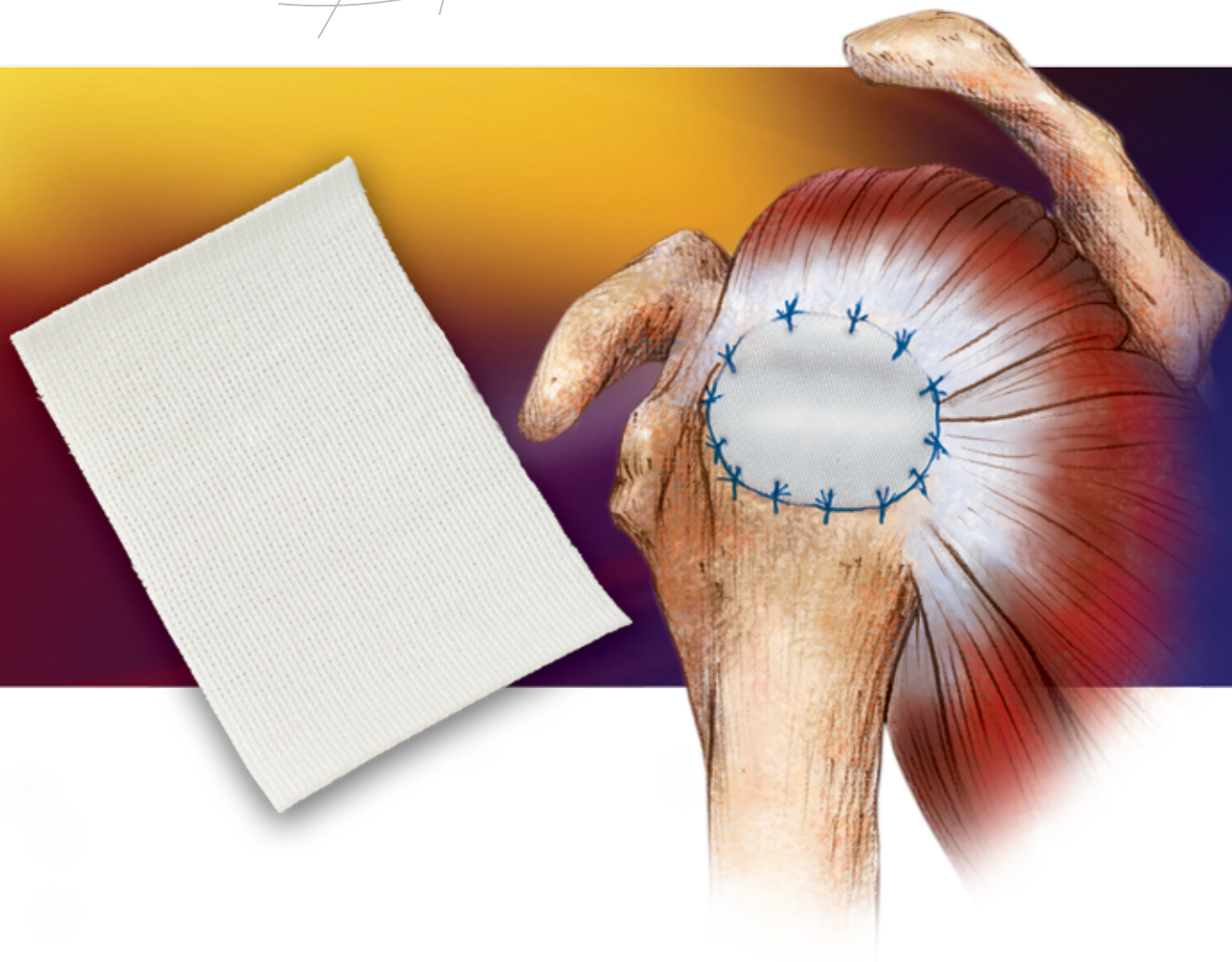


SportMesh™

SOFT TISSUE REINFORCEMENT



ARTHROTEK®
A BIOMET COMPANY





What is SportMesh™ Soft Tissue Reinforcement?

SportMesh™ Soft Tissue Reinforcement is a partially resorbable, synthetic patch that is used for soft tissue reinforcement for the supraspinatus (rotator cuff) tendon in conjunction with sutures and/or anchors. It is designed to act as a scaffold for a torn tendon that is too fragile to maintain a strong connection with the bone on its own.

The pliable, knitted Artelon® material is a biocompatible degradable poly (urethane urea) that provides short and long term reinforcement while acting as a partially degradable scaffold that is incorporated into the patient's own tissue.¹ Excellent biocompatibility has been demonstrated in soft tissue and bone with over eight years clinical experience.¹

Artelon® Fibers—a unique patented biomaterial that acts as a temporary healing tissue scaffold.

What Makes Artelon® Material Unique to the Market?

Biocompatibility

- Unlike traditional treatment methods of collagen or dermis patches that can potentially carry an increased risk of collagen reactions, the SportMesh™ Soft Tissue Reinforcement eliminates this risk.
- Partially resorbable material that demonstrates great biocompatibility.¹
- Short and long term tissue reinforcement while being a degradable scaffold that is incorporated into the patient's own tissue.¹
- This innovative, partially resorbable, synthetic alternative eliminates the risk of donor disease transmission.

Mechanical Properties

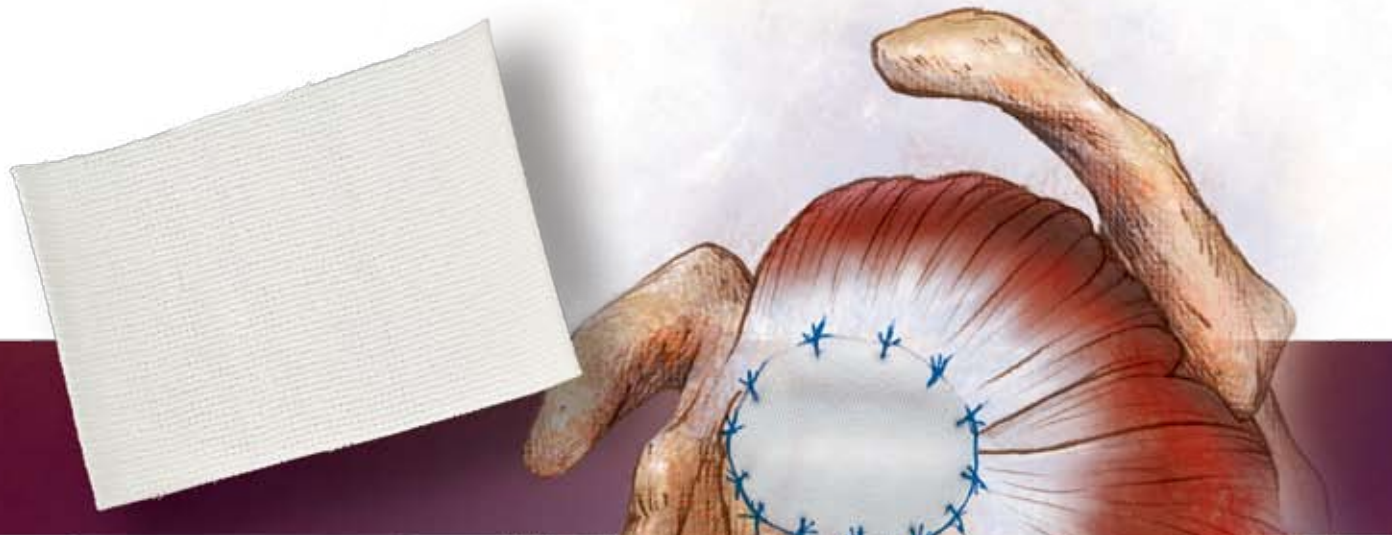
- Provides a secure fixation:
 - *Suture pull out greater than 30N²*
 - *Ball burst strength is 500N²*
- Excellent elasticity and is able to return to its original length after being stretched.

Surface Properties

- Easy to cut and shape to soft tissue.
- Easy to handle.
- Thickness: ~.8mm
- High porosity which acts as a wick to soak and hold e.g. blood or bone marrow and maintain its space keeping the original shape when wet.

Long Term Support

- Artelon® Fibers have 50% resorption in approximately six years, and 50% is integrated into host tissue for more robust tissue giving support and protection to the tendon, muscle and bone.¹
- *In vitro* studies showed approximately 60% of initial tensile strength after 24 months.²
- Controlled, intermediate resorption process.



SportMesh™ Soft Tissue Reinforcement Goals

- Soft tissue reinforcement scaffold
- Facilitates anatomical footprint restoration
- Long-term biocompatible augmentation
- Restoration of joint mechanics
- Assisting to make the first repair the best repair possible

How Does SportMesh™ Work?

The degradable poly (urethaneurea) implant is sutured over torn or degenerative tissue as a reinforcement. The implant has been shown to partially resorb while being a scaffold for host tissue ingrowth. The SportMesh™ Soft Tissue Reinforcement implant shares the load placed on the sutures or suture anchors. Degenerative tissue can be repaired with greater confidence.

References

1. Nilsson A, Liljensten E, Bergstrom C, Sollerman C; "Results From a Degradable TMC Joint Spacer (Artelon) Compared with Tendon Arthroplasty." *The Journal of Hand Surgery*, 380 – 389, 2005.

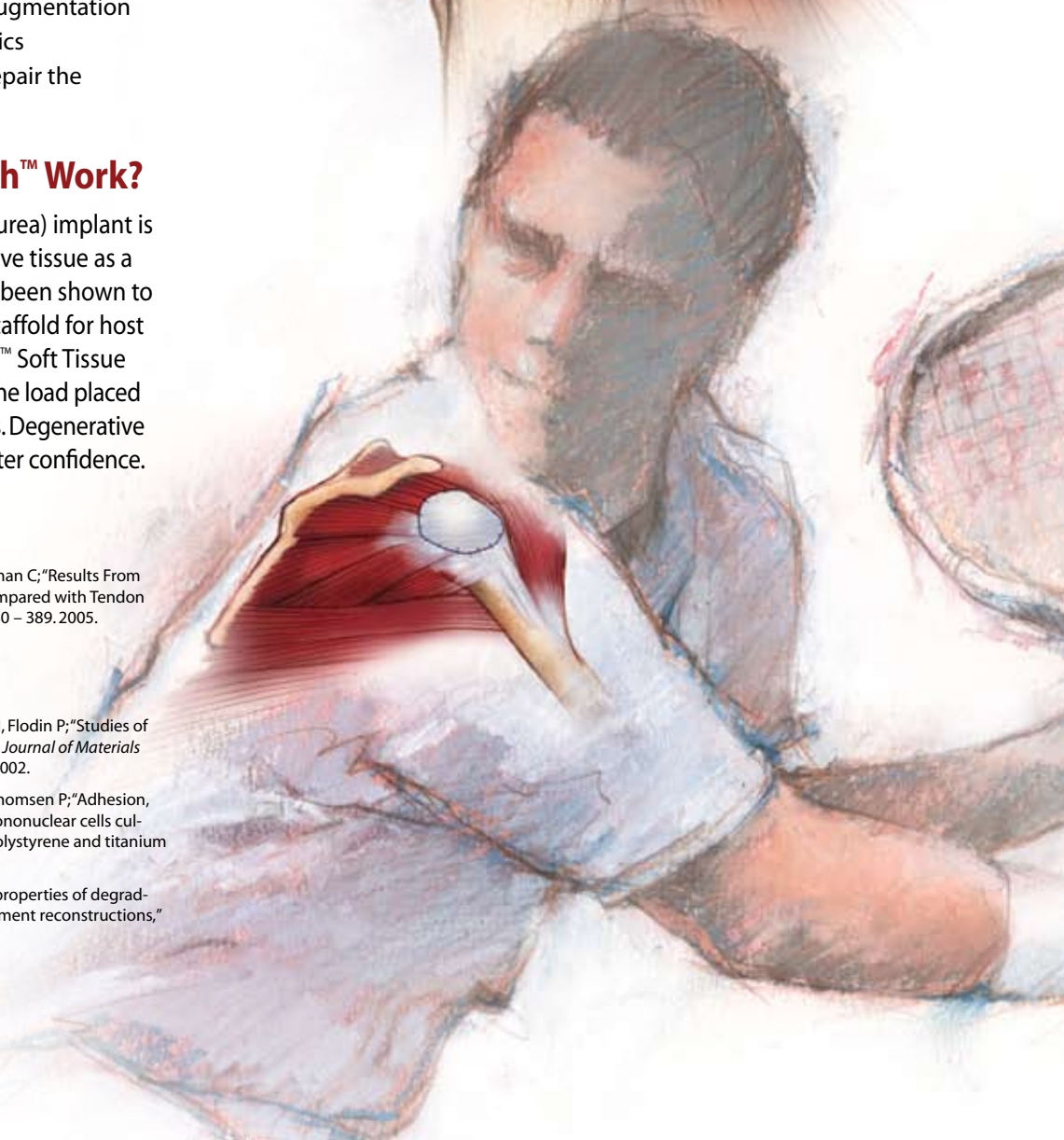
2. SportMesh 510(k) (K052830)

For additional information:

Liljensten E, Gisselbalt K, Edberg B, Bertilsson H, Flodin P; "Studies of polyurethane bands for ACL reconstruction." *Journal of Materials Science: Materials in Medicine*, 13: 351 – 359, 2002.

Gretzer C, Gisselbalt K, Liljensten E, Rydén L, Thomsen P; "Adhesion, apoptosis and cytokine release of human mononuclear cells cultured on a degradable poly(urethane urea), polystyrene and titanium in vitro." *Biomaterials*, 24: 2843 – 2852, 2003.

Gisselbalt K, Edberg B, Flodin P; "Synthesis and properties of degradable poly(urethane urea)s to be used for ligament reconstructions." *Biomacromolecules*, 3: 951 – 958, 2002.



Package Insert

SportMesh™ Tissue Reinforcement ATTENTION Operating Surgeon

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 in sheet form in sterile 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, limited to the supraspinatus, during rotator cuff repair surgery.

SportMesh™ Tissue Reinforcement is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff. 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 possible adverse effects 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 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.

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Artimplant AB
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Sweden

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Ordering Information

SportMesh™ Soft Tissue Reinforcement

920002	4 x 6cm (Domestic)
920003	4 x 6cm (International)
920002S	4 x 6cm (Sample)

MaxBraid™ PE Suture

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

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INVENTING THE FUTURE OF ARTHROSCOPY

