

Durable Reinforcement

The *Zimmer* Collagen Repair Patch is a biological implant consisting of an acellular scaffold of collagen and elastin, derived from porcine dermal tissue. The material is purified and cross-linked through a proprietary process that makes it resistant to collagenase degradation. The result is a strong, durable biological implant that is readily and consistently colonized by host tissue cells and blood vessels. The implant is provided in sheet form and is ideal for the reinforcement of large tendon tears at the repair site.

Ordering Information

| Prod No | Description |
|----------------|--|
| 00-4100-001-00 | <i>Zimmer</i> Collagen Repair Patch 1 each, 5cm x 10cm (50 sq. cm) x 1.5mm rectangular sheet |

- 1. Data held on file at Covidien, plc
- 2. Data on file at Zimmer, Inc.

Manufactured by: Covidien, plc
Distributed by: Zimmer, Inc.

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Contact your Zimmer representative or visit us at www.zimmer.com



Zimmer® Collagen
Repair Patch



A History of Strength and Consistency

This revolutionary material has been available since 1998, and over 100,000 implants have been used for hernia repair, urological, and gynecological applications. The *Zimmer*® Collagen Repair Patch is designed to be durable, for results that last. It is resistant to degradation and enzymatic attack. No sensitization, rejection, allergenicity, or no significant inflammatory response has been observed in animal testing.¹

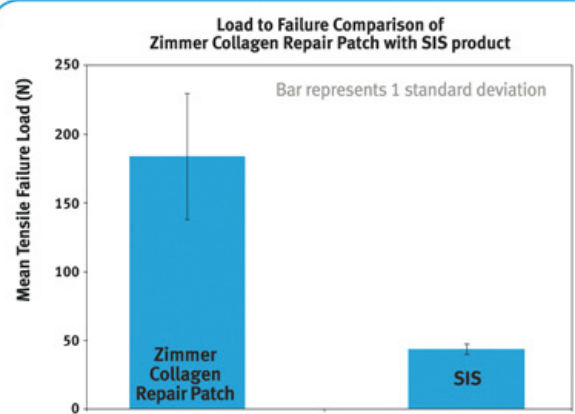
This unique scaffold has proven to be strong with good cell infiltration and rapid revascularization.¹ In tensile tests, the *Zimmer* Collagen Repair Patch can withstand a significantly larger load than small intestinal submucosa (SIS) patches offered by other companies. This is afforded by a 1.5mm thickness and preservation of the original collagen structure of the dermis.

Studies of the *Zimmer* Collagen Repair Patch in an ovine model of rotator cuff repair provided evidence of positive and predictable

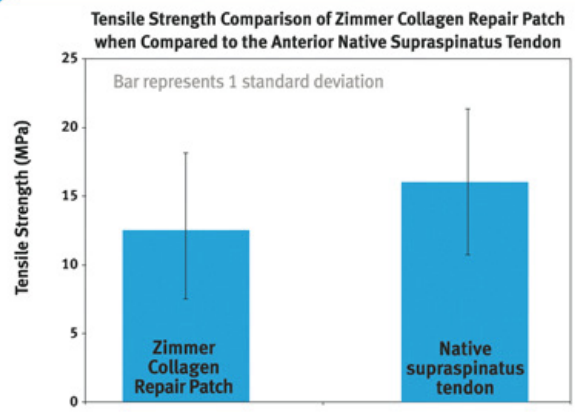
performance characteristics in animals. Good strength of repair and integration with native tendon tissue were invariably shown in all animals at 24 weeks.²

Example of native tendon tissue integration with *Zimmer* Collagen

Repair Patch at 24 weeks. Histology stained with H&E, from ovine animal study.²



Zimmer Collagen Repair Patch can withstand a greater tensile load than an SIS competitor.

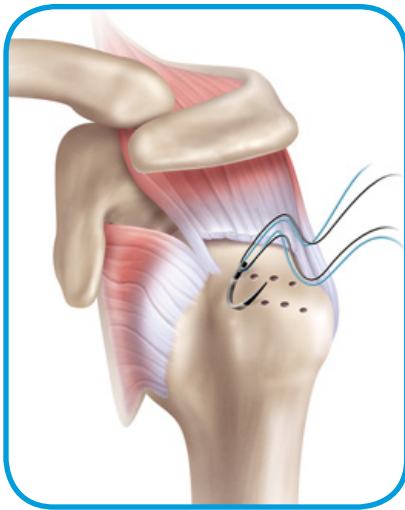


Strength of the *Zimmer* Collagen Repair Patch is comparable to native supraspinatus tendon.¹



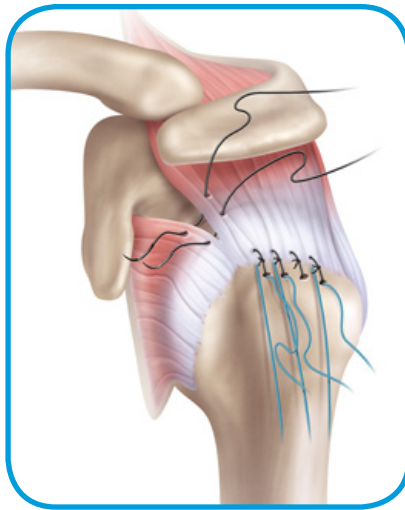
Step 1

After inspection of the rotator cuff tear, place stay sutures to provide traction and assess tendon mobility and quality. Releases of the rotator cuff tendon should be performed on the superior and posterior capsule off the labrum, and the supraspinatus should be released from the coracoid base. Any subacromial space adhesions should be lysed. With the stay sutures in the tendon edge, there should now be a bounce to the tendon and the ability to mobilize it to the anatomic neck. Very minimal if any tendon debridement should be performed.



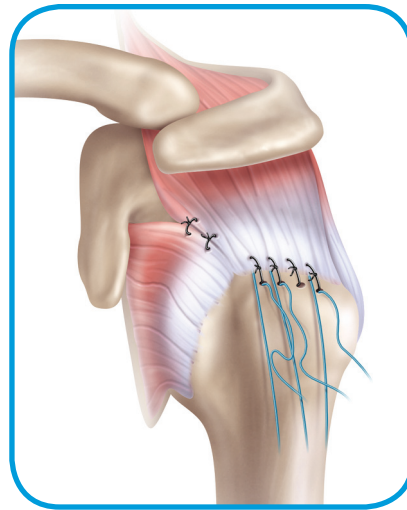
Step 2

The footprint of the rotator cuff should be scarified with a rongeur or curette; a trough is not recommended. Suture holes are established with a curved, penetrating awl. In this way the holes can be staggered along the footprint.



Step 3

Using a trocar needle, permanent #2 braided nylon sutures are placed through the bone tunnels. (A Richard-Allan Mayo trocar needle #217001 is recommended). Load 2 sutures onto 3 of the 4 bone tunnel passes, allowing 3 sutures to remain available for attachment of the *Zimmer* Collagen Repair Patch. More sutures may be necessary for rotator cuff repair, but 3 bone sutures are recommended for *Zimmer* Collagen Repair Patch to allow good fixation for any size tear. Suture anchors may be utilized, but bone tunnels are preferred.

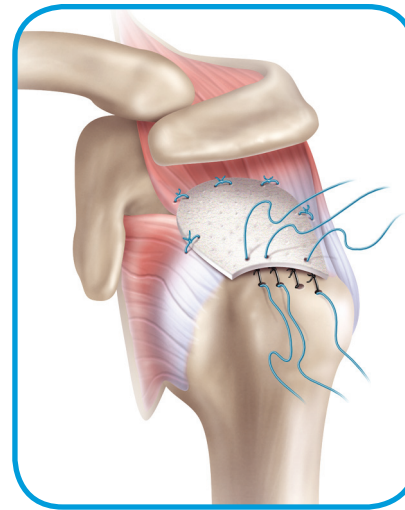


Step 4

Repair the rotator cuff tendon with the bone tunnel sutures, using as many bone sutures as needed. Place sutures in the rotator cuff interval to close the supraspinatus to the upper subscapularis.

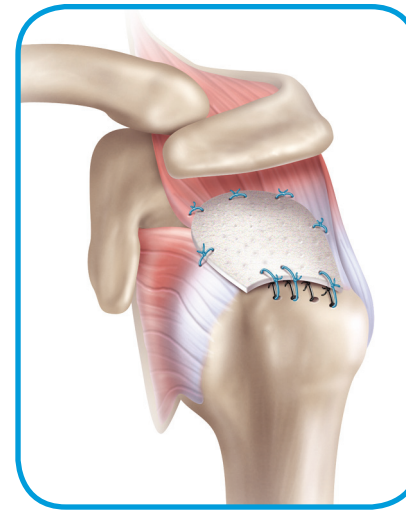
Step 5

Fashion the size and shape of the implant, making sure to cut it slightly larger than necessary, leaving some extra material to be trimmed away after suturing. It is recommended to use a curved apex triangular shape for fit, covering medially but avoiding the coracoid and spine of the scapula. [Approximately 3cm lateral and 3-4cm in length, depending upon the size of the patient and tear.]



Step 6

Apply and suture the *Zimmer* Collagen Repair Patch to the rotator cuff. First affix the graft at the apex with a vertical mattress suture if possible. This is accomplished with a stout small tapered Mayo needle. It can be easiest to attempt to place the sutures through the natural follicles present in the implant. Next place 2 simple sutures anterior to and posterior to the apex suture, and 2 simple sutures on the anterior and posterior edges. These should be placed prior to final repair to the greater tuberosity.



Step 7

Utilizing the 3 previously placed bone sutures, secure the *Zimmer* Collagen Repair Patch to the greater tuberosity with simple sutures. These bone sutures should pull the graft in light tension. Trim any unstable edges or corners after repair.

Step 8

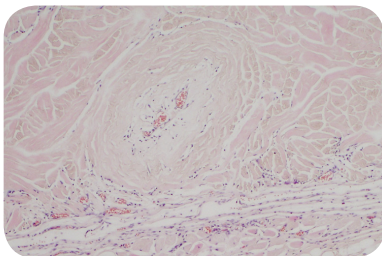
Due to the large, massive, or revision nature of the rotator cuff tear, this is a vulnerable tendon. It is recommended that an abduction type pillow be used for 6 weeks. The goal is a healed rotator cuff repair.

Tissue Healing Response

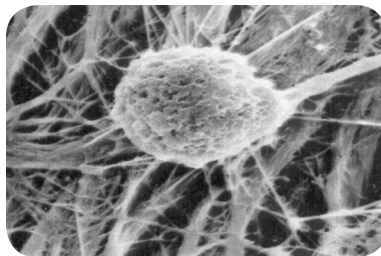
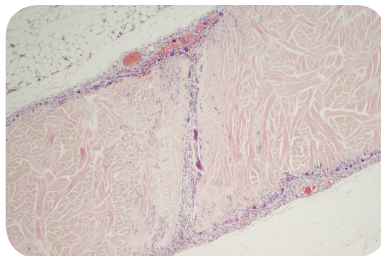
In studies in an ovine model, postoperative inflammatory response, measured by comparison of systemic fibrinogen levels before and after surgery, has not been observed at various time points (3, 6, 9, 12, 24 weeks) postop.¹

There is reduced risk for cross-infection or rejection as lipids, non-collagenous proteins, and cellular material are removed during the manufacturing process. The implant gradually becomes integrated with the surrounding tissue, providing strength and contour support. Animal studies show evidence of early cellular infiltration and new blood vessel formation as early as 2 weeks postop.¹

↓ Cross-section of material through a natural pore shows depth of cellular penetration.

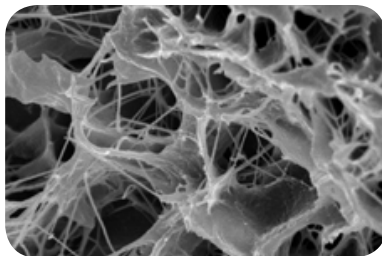


↑ Cross-section of material in subcutaneous rat model shows cellular infiltration and neovascularization.



↑ Fibroblast growing on collagen.

↓ Zimmer Collagen Repair Patch is collagen in its native state.



Indications for Use

Zimmer Collagen Repair patch is intended for the reinforcement of soft tissues repaired by suture or anchor sutures during rotator cuff repair surgery.