# Scaffold Implant for Rotator Cuff Lesions Encountered on the Supraspinatus Tendon

ACTRN12611001082998

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| **Status** | RECRUITING |
| **Sponsor** | Rotation Medical, Inc. |
| **Enrollment** | 36 participants |

## Plain Language Summary

This study is testing whether placing a thin collagen scaffold (a supportive patch made from natural material) during shoulder surgery helps to thicken and repair a damaged rotator cuff tendon better than surgery alone. The rotator cuff is a group of tendons that holds the shoulder together. Partial tears are common and can cause ongoing pain. MRI scans will be used to measure tendon thickness before and after surgery.

You may be eligible if:
- You are between 40 and 65 years old
- You have chronic shoulder pain lasting more than 3 months
- Your pain has not improved with medications or other treatments
- You need surgery for a partial or small full-thickness tear of your shoulder tendon

You may NOT be eligible if:
- You have shoulder instability or significant cartilage damage
- You have previously had rotator cuff surgery on the same shoulder
- You have diabetes requiring insulin, an autoimmune disorder, or an immune deficiency
- You are pregnant or planning to become pregnant
- You are a heavy smoker (more than 20 cigarettes per day)
- You have a known allergy to bovine (cow-derived) materials

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

### Inclusion (5)

- Patients requiring surgical rotator cuff treatment of a partial- or small full-thickness tear of the supraspinatus tendon, as determined jointly by the surgeon and the patient.
- Patients with chronic shoulder pain lasting longer than three months and resistant to pain medication and conservative treatment.
- Patients over 40 years and under 65 years of age at time of surgery.
- Patients who understand the conditions of the study and are willing to participate for the length of the prescribed term of follow-up and rehabilitation.
- Patients who are capable of, and have given informed consent to their participation in the study.

### Exclusion (14)

- Patients with instability of the index shoulder.
- Patients with grade 3 or greater chondromalacia of the index shoulder.
- Patients who require concomitant procedures other than acromioplasty/subacromial decompression, acromioclavicular joint resection, or biceps tenotomy/tenodesis at least 2 cm distal to the site of supraspinatus tendon treatment.
- Patients with evidence of calcification of the rotator cuff of the index shoulder.
- Patients with evidence of grade 2 fatty infiltration or greater of the supraspinatus muscle of the index shoulder on a sagittal view of an MRI scan.

... and 9 more (see full listing online)

## Locations (1 total)

Australia