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InSpace balloon implant

Post-operative and rehabilitation guidelines

The following recommendations have been collected and presented based on InSpace's pre- and post-market experience, as well as specific patient and healthcare professional feedback since 2010. These recommendations are applicable to implantation of the InSpace device without any rotator cuff tendon repairs.

Progression is at the discretion of the Surgeon and Physical Therapy team as the patient's pain and tolerance allows.*

General post-op instructions

During the first 3 months post-operation, the patient is recommended to avoid quick sudden movements, repetitive movements, lifting any weight and any activity that requires force or power. Driving is not recommended until the patient can safely hold the steering wheel with both hands and operate the vehicle safely.

Patient sling use recommended for 4 weeks. Sling use can be used for comfort thereafter.**

**Based on physical therapy protocol in clinical trial!

Phase I: Early Motion Phase (1–4 weeks)

Phase I Overview

- **Sling immobilization during the day and night for approximately 4 weeks.** Afterwards, sling may be removed unless needed for comfort reasons (however, recommended while sleeping or during activities of daily living [ADLs]).
- Depending on patient progress, exercises may include passive shoulder (only) ROM and active elbow, wrist, and hand ROM therapy exercises. Recommended to begin immediately post-operatively, during which the sling may be removed.
- Forward flexion and abduction are recommended to be limited to no more than 60° (less if painful).

Phase I Exercises

- Passive shoulder ROM:
 - Pendulum exercises
 - Supine elevation in the scapular plane, up to 140°
 - External rotation to tolerance with arm at side:
 - Emphasize external rotation with a minimum goal of 40°
 - Side-lying scapular stabilization exercises
- Active ROM (AROM):
 - Elbow, wrist, and hand exercises
 - Deltoid isometrics in a neutral (submaximal) position, as ROM improves, and as tolerated
 - Do not use pulley or canes until 6 weeks post-op

Phase II: ROM Progression Phase (4–6 weeks)

Phase II Overview

- **Sling use may be discontinued.**
- Passive and active exercises are recommended to achieve functional ROM with slow steady stretching (without pain), beginning lightly and increasing over time.

Phase II Exercises

- Begin Active Assisted ROM (AAROM) exercises and advance to AROM, as tolerated
 - Elevation in scapular plane and external rotation, as tolerated
 - No internal rotation or movement of the arm recommended behind the back until 6 weeks post-op

Phase III: Dynamic Strengthening Phase (6–12 weeks)

Phase III Overview

- By the end of this phase, the patient is expected to regain their preoperative ROM or at least continue to make steady gains weekly (including ROM and strengthening exercises) until return to normal activity.
- Please note with some of your patients in this stage it is expected to experience temporary discomfort or transient increase in shoulder pain.

Phase III Exercises

- Shoulder AAROM to AROM, as tolerated
 - Maintain elevation in scapular plane and external rotation to tolerance
 - Begin internal rotation, as tolerated
 - Light stretching at end ranges
- Rotator cuff isometrics with the arm at the side
- Leverage an Upper Body Ergometer, as available, to support strengthening

Phase IV: Return to Activity Phase (> 12 weeks)

Phase IV Exercises

- Advance to full ROM (as tolerated) with passive stretching at end ranges
- Advance strengthening, as tolerated: Isometrics > Bands > Light weights (1–5 lbs)
 - 8–12 reps/2–3 sets per rotator cuff, deltoid, and scapular stabilizers
 - Strengthening exercises only 3x/week to avoid rotator cuff over use and tendonitis
- Begin sports related/more strenuous ADLs rehab at 4 ½ months, including advanced conditioning
- MRI is usually at 12 months post-op

References:

1. Verma N, Srikumaran U, Roden CM, Rogusky EJ, Lapner P, Neill H, Abboud JA. (2022). InSpace implant compared with partial repair for treatment of full-thickness massive rotator cuff tears. *J Bone JT Surg Am*. Advance online publication. doi. 10.2106/JBJS.21.00667.

*Please note that the treating health care professional (HCP) has the full and final authority to assess a patient's rehabilitation program and any other post-surgery therapy based upon the HCP's assessment of the patient's clinical condition, an assessment that may be affected by factors such as age, pain, and general health condition, individual postoperative progression, etc. Consequently, any recommendations herein should be evaluated and implemented only at the discretion and under the authority of the HCP.

Sports Medicine

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