

### **What is the postoperative rehabilitation after implantation?**

Postoperative therapy and shoulder motion progresses faster than after a typical rotator cuff repair surgery. The protocol may vary by surgeon and therapist preference, but typically involves 2-3 weeks in a sling followed by increasing range of motion exercises over the course of 6-12 weeks. There are no immediate lifting or motion restrictions after the incisions have healed. The expected return to activities is by 4-6 months after surgery. Your specific therapy program may vary depending on your surgeon and procedure(s) performed.

### **Where is the procedure performed?**

The subacromial balloon spacer is implanted in an operating room under sterile conditions with an anesthesia provider as an outpatient day surgery.

### **Why haven't I heard of this before?**

The Food & Drug Administration (FDA) approved the use of the InSpace™ balloon in the United States on July 12, 2021. The InSpace balloon has been in greater use in Europe since 2012 and over 30,000 InSpace™ balloons have been implanted.



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## **Shoulder Subacromial Balloon Spacer**

*The InSpace™ balloon for  
large, non-repairable  
rotator cuff tears*

*Patient Educational Pamphlet*

*updated: Sept 2021*

### **What is a subacromial balloon spacer?**

The InSpace™ (Stryker Corporation) is a co-polymer [Poly-L-lactide-co-ε-caprolactone] biodegradable balloon-shaped spacer that is implanted in the subacromial space between the acromion (shoulder blade) and the humeral head.

### **How is it inserted?**

The balloon spacer is inserted either through arthroscopic minimally invasive surgery or through a small open surgical procedure. It is then inflated with a sterile saline solution.

### **How does it work?**

The balloon spacer attempts to restore painless shoulder motion by decreasing friction in the shoulder and by centering the shoulder joint when moving the arm out to the side or overhead.

### **How long does it take to dissolve?**

The balloon spacer starts to dissolve at 2-3 months after implantation and completely dissolves over the course of 12 months. This period of time allows for shoulder therapy and restoring normal shoulder mechanics for long-term improvement. Scar tissue may form to replace the balloon once it has dissolved.

### **What are the current treatment indications for a subacromial balloon spacer?**

The InSpace™ subacromial balloon spacer is recommended for patients with painful, large, and non-repairable or partially-repairable rotator cuff tendon tears without significant shoulder arthritis and that have run out of other non-surgical options.

The spacer is *not* recommended for patients with severe shoulder arthritis, allergy to the balloon material, any active infection, or a large subscapularis rotator cuff tear.



### **What are the risks?**

In addition to risks related to surgery (pain, bleeding, infection, stiffness), there is a risk of allergic reaction to the balloon material, shoulder inflammation, and balloon dislodgement or migration.

Known complications related to the InSpace™ device are rare (reported between 1-2% of patients) and include temporary nerve symptoms, balloon dislodgement, and infection. Re-operation related to a complication is also rare (about 3%).

### **What are the benefits?**

The surgical time is decreased and the recovery of shoulder motion after surgery occurs more rapidly as compared to a rotator cuff repair. These benefits persist even after the balloon dissolves with appropriate postoperative shoulder therapy.

### **What are the expected outcomes?**

Studies have demonstrated that a majority of patients experience a significant improvement in shoulder pain along with improved shoulder motion and daily function that is maintained at least 5 years after surgery. A majority of patients (on average, more than 8 out of 10) also reported satisfaction with the procedure.

### **What other treatment options are available?**

Large or non-repairable rotator cuff tears can also be treated with physical therapy, anti-inflammatory medications (NSAIDs), injections, shoulder replacement surgery, arthroscopic decompression surgery, partial rotator cuff repair with possible graft augmentation, superior capsular reconstruction (SCR), and/or tendon transfers. Talk to your orthopedic surgeon about the best option for you.