ORTHOSPACE

WARNINGS AND PRECAUTIONS

INTRODUCTION

The InSpace™ balloon system is designed to create a physical barrier (spacer) between tissues in the subacromial space.

- The InSpace™ balloon system is provided sterile.
- The physiological solution that should be used with the InSpace™ balloon system is not supplied with the system.
- The InSpace™ balloon is latex and Phthalate free.

INDICATIONS

The InSpace™ biodegradable balloon implant is used as a spacer to reduce friction between the acromion and humeral head or Rotator Cuff. The indications for the InSpace™ Rotator Cuff Balloon include: scarred or torn tendons due to trauma or degradation; absence of tendon/muscle, or non-functional tendon/muscle; and ruptured tendon. The device is single use and biodegrades within 12 month.

CONTRAINDICATIONS

- The InSpace™ balloon Implant should not be implanted into areas with active or latent infection or signs of tissue necrosis.
- The InSpace™ balloon Implant should not be implanted if the patient has an allergy to the balloon material (PLA and epsilon-caprolactone).

WARNINGS AND PRECAUTIONS

- Prior to using the InSpace™ balloon system for the first time, users must be trained by a company representative in the use and deployment of the balloon system.
- The risks and benefits of implanting the InSpace™ balloon system in patients with blood coagulation disorders, compromised immune systems, severe chronic diseases such as heart failure, cirrhosis, chronic renal failure or any other conditions that would compromise healing should be carefully considered.
- The risks and benefits of implanting the InSpace™ spacer in patients with deltoid palsy should be carefully considered.
- Do not re-sterilize or reuse the balloon or the deployer. All parts of the system are intended for single use only.
- Reuse of the system may cause serious injury to the patient, including but not limited to: local and systemic infection and sepsis that may lead to deterioration of shoulder functions or death.
- Non-functional instruments should not be used and should be returned to OrthoSpace Ltd. Do not use any part of the InSpace™ balloon system beyond the indicated expiration date.
- Do not use the InSpace™ balloon system if the package is opened or damaged, as sterility may be compromised.
- Do not use the InSpace™ balloon system if the Humidity Indicator for the 40% humidity level has turned from a light blue to a purple color.

STORAGE

Until use, the Orthospace™ balloon system should be stored in a clean and dry area at 0-29°C.

USE OF ORIGINAL PRODUCTS

The components of the Orthospace™ balloon system are designed for specific use and to complement each other. No system components may be replaced by a product from another manufacturer even if the other product or part is comparable or identical to the original product in appearance and dimensions. The material used from other manufacturers, any structural alterations resulting from use of products from another source and/or impurities of the material as well as minor differences of adjustment between the implant and instruments introduce unforeseen risks to the subject and user.

DISCLAIMER: The InSpace™ balloon is approved for marketing in EU but not yet in USA. This material should be considered informational only and does not constitute an offer to sell in any jurisdiction in which this product is not yet permitted to be sold.

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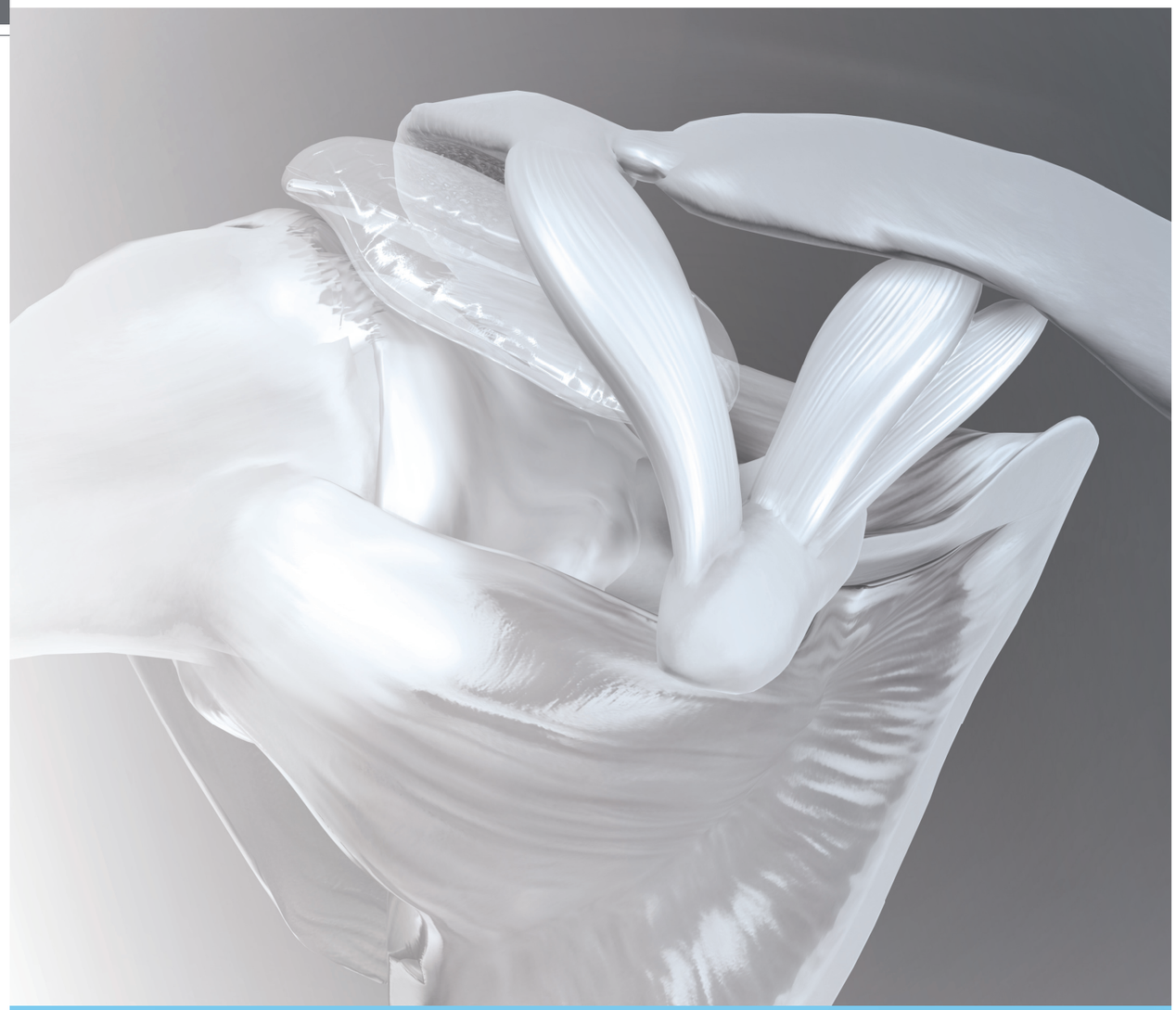
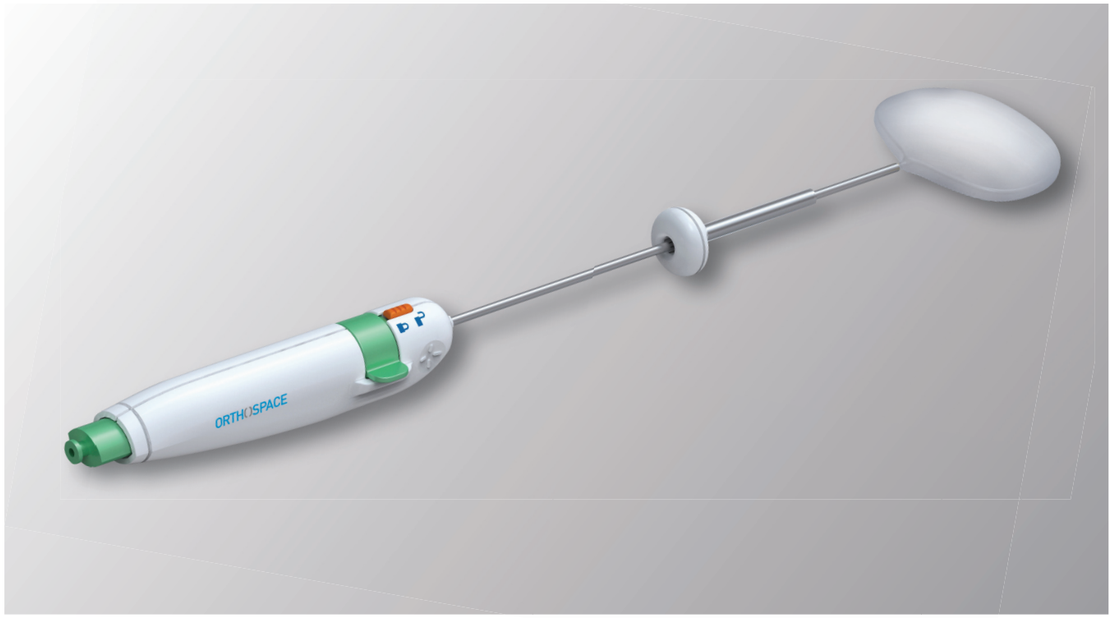
ORTHOSPACE



InSpace™

Surgical Technique

INTRODUCTION



INTRODUCTION

Massive Rotator Cuff tears present both a physical and biological challenge to the surgeon attempting to repair them. The tear is considered irreparable according to preprocedural MRI or intra-operative assessment. The Cuff tissue is often retracted and degenerated. The muscle tissue can be atrophied and with fat.

While the average rate of Rotator Cuff re-tear post repair is approximately 20-40%, failure rates of massive tears can approach 70%[1]. Surgeons are looking for a solution which will significantly reduce their patients' pain.

By having the InSpace™ balloon implanted between the acromion and the humeral head, a space is created between the bone structures, allowing smooth and frictionless gliding. The balloon is initially designed for chronic, massive, non-reparable Rotator-Cuff tears, enabling leverage of other muscles. The balloon may be inserted arthroscopically, or by using mini-open procedure.

The InSpace™ balloon surgical technique is only a five simple steps procedure. Still it is recommended that a surgeon who is considering using the InSpace™ system would be trained by company representative in the insertion technique.

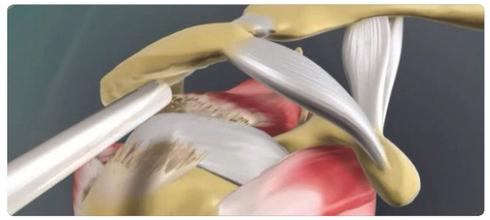
POSITIONING AND SET-UP

A standard arrangement for arthroscopic Rotator Cuff repair is used. Either beach chair or the lateral decubitus position is appropriate. Besides the arthroscopic instrument set, the following items are required (not supplied within the device package):

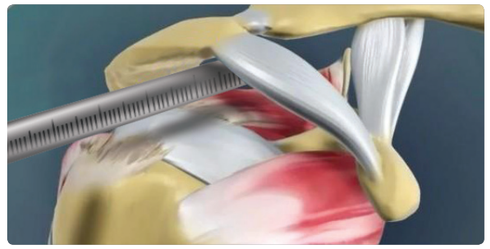
- Luer-lock 50cc Syringe
- Extension tube + 3 way valve
- Arthroscopic probe
- Saline 0.9%

1 Intra-operative Determinants of Rotator Cuff Repair Integrity: s Xiao Wu, BSc MBBS, Sydney, Australia Lisa Briggs, Sonographer, Maroubra, Australia George A C Murrell, MD, Kogarah, Australia
American Academy of Orthopaedic Surgeons (AAOS) 2012 Annual Meeting: Abstract 062. Presented February 7, 2012.

HOW DOES IT WORK

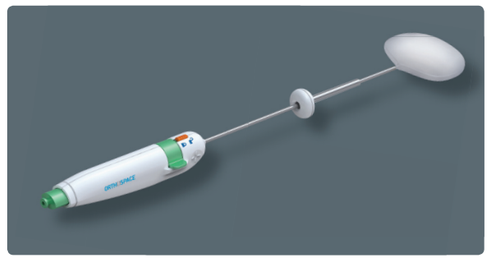


STEP 1 Perform a standard subacromial arthroscopy to estimate the tendon condition and to ensure it is an irreparable Rotator Cuff tear. Mild debridement may be required to clean the synovial tissue and clear the subacromial space.

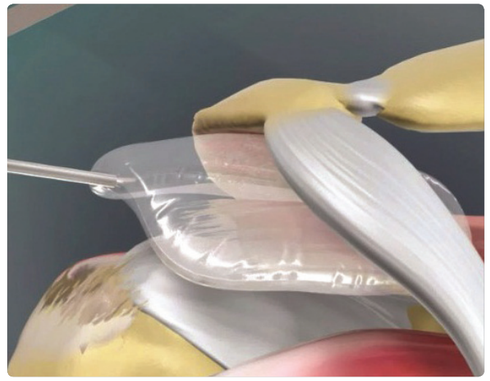


STEP 2 The InSpace™ is available in 3 sizes:
- Small (40x50mm)
- Medium (50x60mm
- Large (60x70mm)

Measure the sub-acromial space using an arthroscopic probe.
Measurements required to select appropriate balloon size are:
- Length of the acromion from anterior to posterior
- Distance from greater tuberosity (lateral point) ~ 1cm medial to superior glenoid rim.

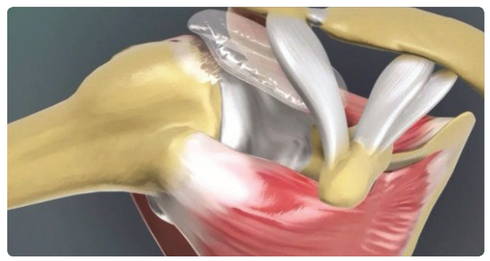


STEP 3 Prepare the inflating system in advance. Fill a syringe with saline heated to ~ 40 ˚C, and remove any air bubbles (in syringe, extension tube and valve).
Introduce the InSpace™ delivery system through a true lateral port. The Balloon should be placed over the glenoid rim and 2cm over the Rotator Cuff tendon stump. After final positioning of the delivery system, pull back the protecting sheath and expose the balloon. Re-verify balloon position in the subacromial space.



STEP 4 Connect the extension tube to the rear side of the delivery system (Luer-lock connector). Inflate the balloon to maximum volume (see table below). Keep the valve open and let saline flow back into the syringe.
To avoid increasing sub-acromial pressure, do not over inflate the Balloon.
When satisfied with balloon volume seal the balloon (see recommended inflation volumes according to balloon size).

Size	Width (mm) LM	Length (mm) AP	Max. vol. (cc)	Recomended vol. (cc)
Small (REF 0127)	40	50	15-17	9-11
Medium (REF 0128)	50	60	22-24	14-16
Large (REF 0129)	60	70	40	23-25



STEP 5 For sealing and detachment of the balloon push the red safety button forward and turn the green knob till full detachment. Remove the delivery system and go through full ROM.
Verify that the balloon is stable in situ and cannot be dislodged, replace it with a new one .

REHABILITATION

For comfort reasons, use of post-operative sling is recommended for approximately one week post implantation. Patients may start with full Active Assisted and Passive Range of Motion (ROM) immediately as pain allows. Early active ROM at waist level is allowed without restriction. Overhead activity should be avoided for 6 weeks. To maximize functional results, a typical monitored post-operative Progressive Resistance Exercise program, including therabands and full closed chain scapular stabilization exercises, is recommended.