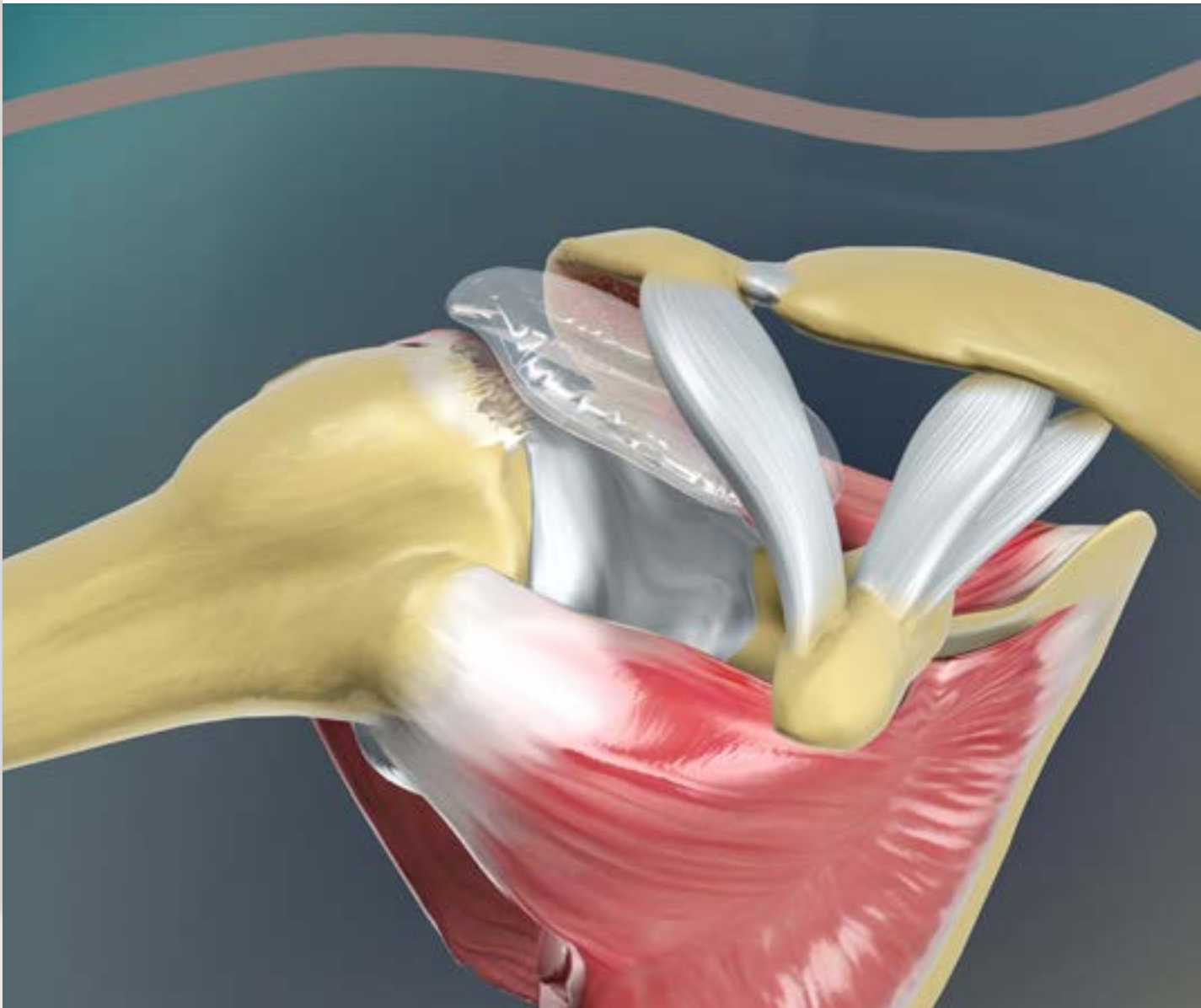
stryker

InSpace

Surgical Technique



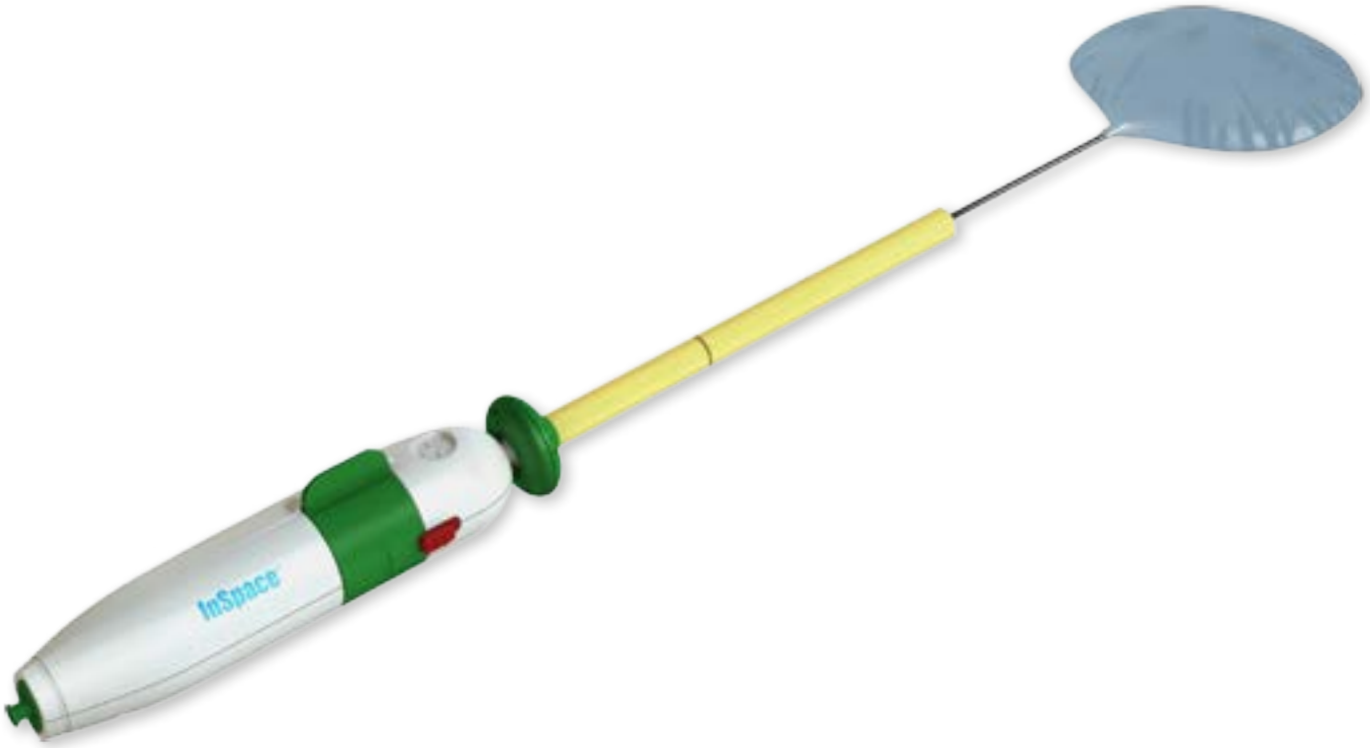
Introduction

Massive rotator cuff tears present both a physical and biological challenge to the surgeon attempting to repair them. The tear may be 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 show evidence of fatty infiltration.
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 an alternative solution which will reduce their patients' pain.
The InSpace biodegradable implantable balloon (spacer) is used as a spacer to reduce friction between the acromion and the humeral head or rotator cuff to allow smooth gliding of the humeral head against the acromion. The balloon may be inserted arthroscopically, or by using mini-open procedure.
The InSpace balloon surgical technique consists of five steps.

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 should be available in the OR setting (not supplied with the device package).

- Luer-lock 50ml Syringe
- Extension tube + 3 way valve (optional)
- 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. Mild debridement may be required to clean the synovial tissue and clear the subacromial space.

Step 2

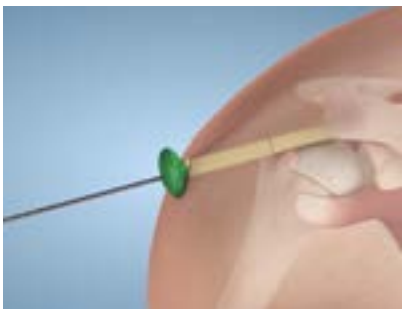
The InSpace balloon comes in 3 sizes:

- Small (40x50mm)
- Medium (50x60mm)
- Large (60x70mm)

Measure the subacromial space using an arthroscopic probe.

To select the appropriate balloon size:

- The surgeon needs to measure the distance from the lateral border of the greater tuberosity to approximately 1cm medial to the glenoid appex.



Step 3

Fill a disposable 50ml luer-lock syringe with predefined amount, as indicated in Table 1 below, of sterile saline. (To ease spacer inflation, it is recommended to pre-warm the saline solution to approximately 40˚C.) 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 proximal end of the delivery system (Luer-lock connector). Inflate the balloon to maximum volume (see Table 1 below). Keep the valve open and let saline flow back into the syringe. To avoid increasing subacromial 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)	Length (mm)	Max. vol. (cc)	Recomended vol. (cc)
Small (REF 0127)	40	50	15-17	9-11
Medium (REF 0128)	50	60	22-24	15-16
Large (REF 0129)	60	70	40	22-24

Table 1: InSpace Size and Inflation Volumes

Step 5

Once the adequate inflation volume is reached; keep the delivery system stable, slide forward the red safety button; and rotate the green knob clockwise. This will seal the spacer and leave it in situ. Once the spacer is sealed, withdraw the deployer and verify again that the spacer is stable, in its proper location and does not interfere with passive maneuvers of the shoulder's range of motion.

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 does not contain latex, Phthalate, or rubber.

Indications

The InSpace biodegradable balloon implant is used as a spacer to reduce friction between the acromion and humeral head or rotator cuff to allow smooth gliding of the humeral head against the acromion. 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-sterilise 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, incuding 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 Stryker. 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 colour.
- Special care must be taken during InSpace insertion to avoid tissue damage. Observe patient for signs of bleeding that may arise from the spacer insertion or deployment.
- Do not inflate the spacer before it is located in its desired final position.
- Do not over inflate the spacer (see recommended inflation volume in Step 4).
- In case any difficulty is encountered with spacer inflation, immediately remove the spacer, or leave it in place deflated.
- If subsequent signs of infection, device displacement or signs/symptoms of pressure on adjacent organs are detected, the patient should be assessed and treated accordingly, using modalities such as: antibiotics, deflation of the spacer by needle aspiration or removal of the spacer.

Storage

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

Use of original products

The components of the InSpace 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.

Sports Medicine

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Ortho-Space LTD
7 Halamish St.
Caesarea 30889, Israel

OrthoSpace Reference Documents:
InSpace IFU P/N 5500
InSpace Brochure P/N 5501 Rev. 04

Stryker European Operations Ltd.
Herikerbergweg 110
1101 CM Amsterdam
The Netherlands
+ 31 20 219 2600