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 pre-procedural MRI or intra-operative assessment. The Cuff tissue is often retracted and degenerated. The muscle tissue can be atrophied and with fat infiltration.

While the average rate of Rotator Cuff re-tear post repair is approximately 20-40%, failure rates of massive tears can approach 100%. Surgeons are looking for a solution which will reduce significantly 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 for smooth and frictionless gliding. The Balloon was initially designed for chronic, massive, non-reparable Rotator-Cuff tears; enabling leverage of other muscles. The Balloon may be inserted arthroscopically, or potentially, even with a mini-open procedure.

The InSpace™ Balloon surgical technique is only five steps of fast and elegant procedure. Still a surgeon who is considering an arthroscopic approach needs to be familiar with several such techniques as well as trained in the InSpace™ Balloon procedure.

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 several other items are required (not part of the implant package):
* Luer-lock 50cc Syringe
* Extension tube + 3 way valve
* Arthroscopic probe
* Saline 0.9%

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™ Balloon comes in 3 sizes:
* Small (40x50mm)
* Medium (50x60mm)
* Large (60x70mm)

Measure the subacromial space by using an arthroscopic probe. Measurements required to select Balloon size are:
* width of the acromion from anterior to posterior
* Distance from greater tuberosity (lateral point) - 2cm medial to superior glenoid rim.

Select InSpace™ Balloon according to your measurement.

Step 3
Prepare the inflating system in advance. Fill syringe with saline heated to 40 degrees Celsius, 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 advanced 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 full volume (check table below). Keep the valve open and let saline flow back into the syringe. Do not over inflate the Balloon to avoid increasing subacromial pressure. When satisfied with Balloon volume seal the Balloon – see recommended inflation volumes according to Balloon size bellow.

<table>
<thead>
<tr>
<th>Size</th>
<th>Width (mm)</th>
<th>Length (mm)</th>
<th>Max. volume (cc)</th>
<th>Recommended Volume (cc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>40</td>
<td>50</td>
<td>15-17</td>
<td>9-11</td>
</tr>
<tr>
<td>Medium</td>
<td>50</td>
<td>60</td>
<td>22-24</td>
<td>15-16</td>
</tr>
<tr>
<td>Large</td>
<td>60</td>
<td>70</td>
<td>40</td>
<td>22-24</td>
</tr>
</tbody>
</table>

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 subluxated or dislocated. If the Balloon can be dislodged, replace the Balloon.

Rehabilitation
The use of a post operative sling is recommended for comfort for one week. Patients may begin full Active Assisted and Passive Range of Motion (ROM) immediately as pain allows and early active ROM at wrist level without restriction. Overhead activity is avoided for 6 weeks. A typical post-operative Physician or Therapist monitored Progressive Resistance Exercise program, including therabands and full closed chain scapular stabilization exercises, is recommended to maximize functional results.

1 Adams, J. E.; Zobitz, M. E.; Reach, J. S., Jr; An, K. N.; and Steenmann, S. P.; Rotator cuff repair using an
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 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.
• Do not re-sterilize or reuse the Balloon or the deployer. These parts are intended for single use only.
• Non-functional instruments should not be used and should be returned to Orthospace™
• 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 temperature.

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 has 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.