Introducing the **InSpace** balloon implant

A minimally-invasive biodegradable, subacromial spacer for arthroscopic treatment of massive, irreparable rotator cuff tears
**U.S. Pivotal Study:** Clinical safety and effectiveness evidence¹

**Study design:** A prospective, single-blinded, multi-center, randomized, controlled, pivotal study to assess the safety and effectiveness of the InSpace device, compared to arthroscopic partial repair, for treatment of full thickness massive rotator cuff tears (MRC).  

**Purpose:** To evaluate the safety and effectiveness of the InSpace implant as the primary surgical treatment for full thickness massive irreparable rotator tears (MRCT).

---

**Safety results**

- Similar rates of Subsequent Secondary Surgical Intervention (SSSI) through 24 months (InSpace: 4; Partial repair: 3).
- No InSpace devices required explanation.
- No subject had a Serious Adverse Device Effect (SADE) through the entire 24 months of the study.
- InSpace had a greater number of Adverse Events of the Index Shoulder (AES) compared to Partial Repair (InSpace: 45; Partial Repair: 30). Notably, most were mild/moderate events (93%), and none were device-related.

---

**MRI findings**

- Balloon biodegrades over approximately one year — 94% of study patients demonstrated no balloon residuals at one year.
- A subset of InSpace subjects (n=32) received Week 6 MRIs. Of those subjects with suspected implant deflation (n=4) or displacement (n=6), the radiologic findings did not appear to be correlated with clinical concerns of safety or effectiveness.

See the package insert for complete summary of clinical safety and effectiveness data.

---

**Findings**

High rates of clinical success, defined as meeting the study primary endpoint, in the InSpace study group at 24 months (InSpace: 87.8%, Partial repair 88.1%) (Table 1)

---

**Table 1. Primary composite endpoint — Subjects ≥65 years of age**

<table>
<thead>
<tr>
<th>Analyzed subgroup population</th>
<th>InSpace % (n/N)</th>
<th>Partial repair % (n/N)</th>
<th>Difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects ≥65 years of age</td>
<td>—</td>
<td>87.8 (43/49)</td>
<td>88.1 (37/42)</td>
</tr>
<tr>
<td>95% CI</td>
<td>(74.4, 93.9)</td>
<td>(73.4, 94.4)</td>
<td>(21.0, 8.6)</td>
</tr>
</tbody>
</table>

P-value for non-inferiority (10% margin) — 0.01

Note 1: Results from logistic regression model with Firth correction

---

**Early improvement compared to baseline noted at 6 weeks in Patient Reported Outcomes (PROs) of ASES, WORC, Constant (Figures 1–3)**

- **Figure 1. Mean ASES scores — change from baseline**

  - Mean ASES overall scores presented as a change from baseline for the InSpace (N = 93) and Partial repair (N = 91) Intent to Treat (ITT) Population.
  - A statistically significant difference was found between groups at day 10. Error bars indicate 95% confidence intervals (unpaired t-test, *, p ≤0.05). ITT population.

- **Figure 2. Mean WORC scores — change from baseline**

  - Mean WORC index presented as a change from baseline for the InSpace (N = 93) and Partial repair (N = 91) Intent to Treat (ITT) population.
  - Western Ontario rotator cuff index, possible range: 0–2100 (lower score = improvement). No data available for day 10. A statistically significant difference was found between groups at week 6 and month 24. Error bars indicate 95% confidence intervals (unpaired t-test, *, p ≤0.05). ITT population.

- **Figure 3. Mean overall constant scores — change from baseline**

  - Mean overall constant score presented as a change from baseline for the InSpace (N = 93) and Partial repair (N = 91) Intent to Treat (ITT) population.
  - Constant score possible range: 0–100 (higher score = improvement). No data available for day 10. A statistically significant difference was found between groups at week 6 and month 24. Error bars indicate 95% confidence intervals (unpaired t-test, *, p ≤0.05). ITT population.

---

**Early return to range of motion that is maintained out to 24 months (Figure 4)**

- **Figure 4. Mean ROM forward elevation scores — change from baseline**

  - Mean ROM forward elevation scores presented as a change from baseline for the InSpace (N = 93) and Partial repair (N = 91) Intent to Treat (ITT) population.
  - Statistically significant differences were found between groups at day 10 (p=0.0041), week 6 (p=0.0001), month 12 (p=0.0048) and month 24 (p=0.003). Error bars indicate 95% confidence intervals (unpaired t-test, *, p ≤0.05). ITT population.
Who it’s for
Successful results begin with patient selection

- ≥65 years of age whose clinical condition would benefit from treatment with a shorter surgical time compared to partial repair
- Massive, irreparable, full thickness RCT measuring ≥5 cm in diameter and involving at least two tendons
- Mild to moderate glenohumeral osteoarthritis, with no evidence of significant osteoarthritis or cartilage damage in the shoulder
- Functional deltoid muscle and preserved range of motion on physical examination
- No evidence of significant glenohumeral instability
- No evidence of missing or nonintact coracoacromial ligament
- No known neurovascular compromise
- No known blood coagulation disorders, compromised immune systems, severe chronic diseases such as heart failure, cirrhosis and/or severe liver dysfunction, chronic renal failure or any other conditions that would compromise healing

See the package insert for complete specifications, contraindications, warnings, precautions and instructions for use.

InSpace Implant Compared with Partial Repair for the Treatment of Full-Thickness Massive Rotator Cuff Tears
A Multicenter, Single-Blinded, Randomized Controlled Trial
Nikhil Verma, MD, Uma Srikumaran, MD, MBA, MPH, Colleen M. Roden, MSc, Edwin J. Rogusky, MD, Peter Lapner, MD, FRCSC, Heather Neill, RN, and Joseph A. Abboud, MD, on behalf of the SPACE GROUP

“The results of the study demonstrate the InSpace balloon is a ‘game-changer’ and presents a shorter, less invasive option that may enable sustained, clinically meaningful improvements in shoulder function and symptoms.”
Innovative solution to a complex condition

Your patients rely on you to treat their rotator cuff tears, and now there’s a new minimally-invasive surgical option. It’s the InSpace balloon implant, the only FDA-cleared balloon implant for the treatment of massive, irreparable rotator cuff tears (MIRCTs). This biodegradable, subacromial spacer enables a streamlined, arthroscopic procedure that may offer advantages for your patients.

Expanding your options

The InSpace balloon implant helps fill an unmet clinical need, arming you with a less invasive MIRCT solution that demonstrates results similar to partial rotator cuff repair\(^1\). This approach can be a better match for some patients who are not ideal candidates for more invasive surgery.

Only FDA-cleared MIRCT surgical solution supported by a level 1 randomized controlled trial that preserves musculoskeletal tissues and bone and does not require the use of anchors or permanent implant placement.

The InSpace balloon implant is designed to restore the subacromial space without requiring sutures or fixation devices and has been demonstrated to improve shoulder motion and function.\(^1\)

Illustration of InSpace implant in situ

---

**Procedural efficiency**

- InSpace resulted in significant advantage for operative time compared to Partial Repair (InSpace: 44 min, Partial Repair: 71 min)\(^1\)
- Streamlined procedure. Deployment, from introduction to sealing and retraction, was on average 4 minutes.\(^1\)
- Shorter procedural time than partial rotator cuff repair, tendon transfer, SCR and rTSA\(^1-4\)
The InSpace deployer attached to a 60cc Luer-Lock syringe with extension tube.

References:
5. Stryker data on file

Sports Medicine
This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. We do not dispense medical advice and recommend that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate Stryker’s products. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any of Stryker’s products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your representative if you have questions about the availability of Stryker’s products in your area.

Stryker or its affiliated entities own, use, or have applied for the following trademarks or service marks: InSpace and Stryker. All other trademarks are trademarks of their respective owners or holders. The absence of a product, feature, or service name, or logo from this list does not constitute a waiver of Stryker’s trademark or other intellectual property rights concerning that name or logo.