stryker

Elevate motion

Introducing the

InSpace balloon implant

A minimally-invasive biodegradable, subacromial spacer for arthroscopic treatment of massive, irreparable rotator cuff tears

Clinically **proven**

U.S. Pivotal Study:
Clinical safety and effectiveness evidence[1]

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

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=5), 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
WORC improvement ≥275 at month 24 and ASES improvement ≥6.4 at month 24 with no Subsequent Secondary Surgical Interventions (SSSI) and no Serious Adverse Device Effects (SADEs) through month 24

Analyzed subgroup population		InSpace % (n/N)	Partial repair % (n/N)	Difference (%)
Subjects ≥65 years of age	—	87.8 (43/49)	88.1 (37/42)	-0.3
	95% CI	(74.4, 93.9)	(73.4, 94.4)	(-21.0, 8.6)
	P-value for non-inferiority (10% margin)	—	—	0.01

Note 1: Results from logistic regression model with Firth correction
Note 2. Per protocol population

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

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

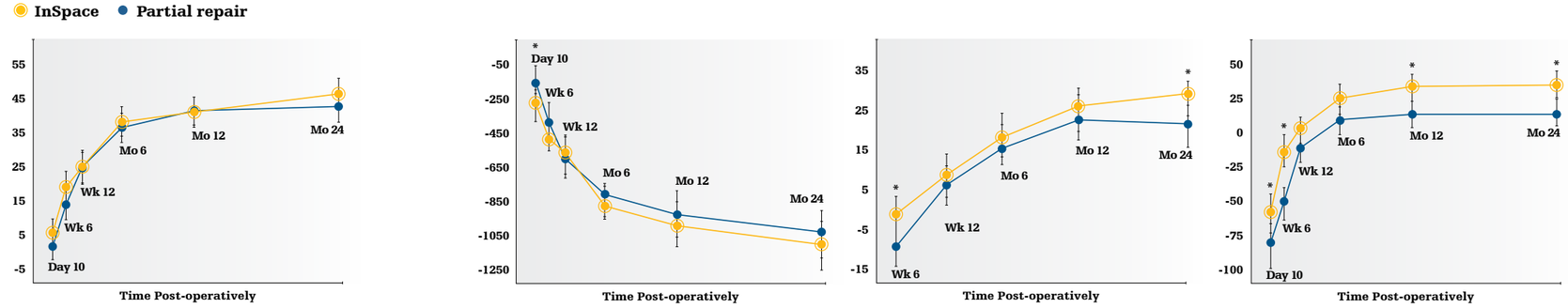


Figure 1. Mean ASES scores — change from baseline
Mean ASES overall scores presented as a change from baseline for the InSpace (N = 93) and Partial repair (N = 91) Intent to Treat (ITT) Population. ASES = American Shoulder and Elbow Score, possible range: 0–100 (higher score = improvement). No statistically significant differences were found between groups. 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). 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 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.

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 pepair (N = 91) Intent to Treat (ITT) population. Statistically significant differences were found between groups at day 10 (p=0.041), 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 ≥5cm 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

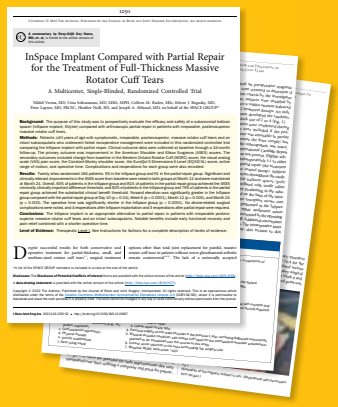
See the package insert for complete indications, contraindications, warnings, precautions and instructions for use.

Small (0130)**, medium** (0131) **and large** (0132) **sizes** to suit patient anatomy

Made of poly (L-lactide-co-ε-caprolactone) a biodegradable polymer

Not made with natural rubber latex or phthalates

InSpace balloon implant is supplied sterile (sterilized by EtO) and intended for single 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[**]

"Current strategies treating massive irreparable rotator cuff tears often present a challenge to surgeons and may require long and frustrating rehabilitation processes for patients," said the lead investigator in the clinical study.
Dr. Nikhil Verma, M.D.[†]

"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]

A long history

Changing practice and changing lives across the globe.

In use outside the U.S. since
2010[5]

OUS procedures
41,000+[5]

Cleared for use in the U.S. in
2021[1]

Peer reviewed clinical articles
>30[5]

Has been used clinically in
40 countries

Studies showing
sustained benefits
at 2, 3 and 5 years[1,6,7]

Over 80% of patients
achieved clinically significant improvement in TCS at 5 years[7]

Making healthcare better, one solution at a time

By innovating new treatment options and instruments, we aim to improve your procedural experiences and — combined with your skill — procedural outcomes. To trial the InSpace balloon implant or to learn more about our broader rotator cuff portfolio, contact your Sports Medicine sales representative, **call 866 596 2022 or visit stryker.com/inspace.**

The InSpace deployer attached to a 60cc Luer-Lock syringe with extension tube.

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Sports Medicine

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