

Elevating motion



Introducing the

InSpace balloon implant

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

Effectiveness Evidence¹

ded, multi-center, randomized, controlled, pivotal study
he InSpace device, compared to Arthroscopic Partial
ssive rotator cuff tears (MRCT).

ctiveness of the InSpace implant as the primary
ive irreparable rotator tears (MRCT).

as meeting the study
dy group at 24 months
(Table 1)

Subjects ≥ 65 years of age
d ASES improvement ≥ 6.4 at
urgical Interventions (SSSI) and
through month 24

InSpace (n/N)	Partial Repair % (n/N)	Difference (%)
8 (43/49)	88.1 (37/42)	-0.3
4, 93.9)	(73.4, 94.4)	(-21.0, 8.6)
—	—	0.01

del with Firth correction

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.

- Balloon biodeg
- 94% of study
residuals at on
- A subset of InS
6 MRIs. Of thos
deflation (n=4)
findings did not
concerns of saf
- See the package i
of clinical safety

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

● InSpace ● Partial repair

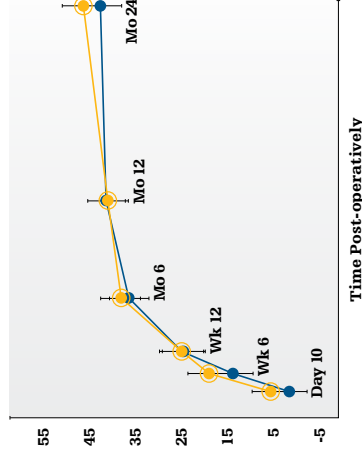


Figure 1. Mean ASES Scores - Change from Baseline
Mean ASES overall scores presented as a change from baseline for the InSpace (N = 93) and Partial Repair (N = 91) Intent to Treat (ITT) Population. ASES = American Shoulder and Elbow Score, possible range: 0-100 (higher score = improvement). No statistically significant differences were found between groups. Error bars indicate 95% confidence intervals.

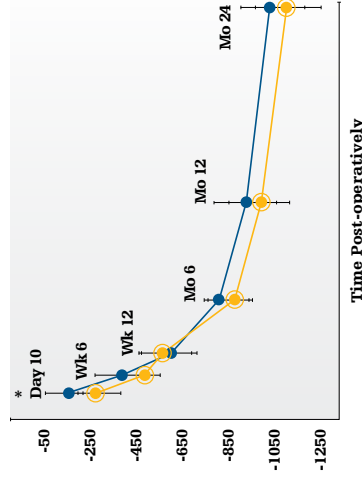


Figure 2. Mean WORC Scores - Change from Baseline
Mean WORC index presented as a change from baseline for the InSpace (N = 93) and Partial Repair (N = 91) Intent to Treat (ITT) Population. Western Ontario Rotator Cuff index, possible range: 0-2100 (lower score = improvement). A statistically significant difference was found between groups at day 10. Error bars indicate 95% confidence intervals.

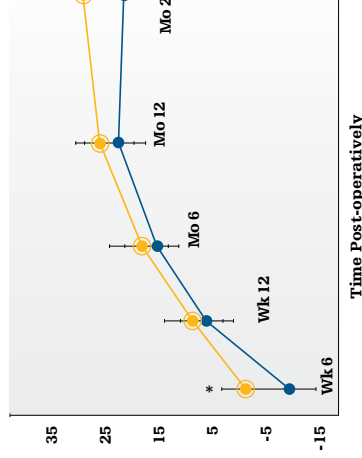


Figure 3. Mean Overall Constant Scores - Change from Baseline
Mean overall constant score presented as a change from baseline for the InSpace (N = 93) and Partial Repair (N = 91) Intent to Treat (ITT) Population. Constant Score possible range: 0-100 (higher score = improvement). No data available for day 10. A statistically significant difference was found between groups at week 6 and month 24. Error bars indicate 95% confidence intervals.

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 indications, contraindications, warnings, precautions, and instructions for use.



Small, medium and large 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

Winner of AANA's 2020

Stephen S. Burkhart, M.D.

Shoulder Innovation Research Award Paper



Nikhil N. Verma, M.D.

Balloon Subacromial Spacer vs. Partial Repair for Massive Rotator Cuff Tears: A Randomized Trial

"Current strategies treating massive irreparable rotator cuff tears often present a challenge to surgeons and may require long and frustration 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.

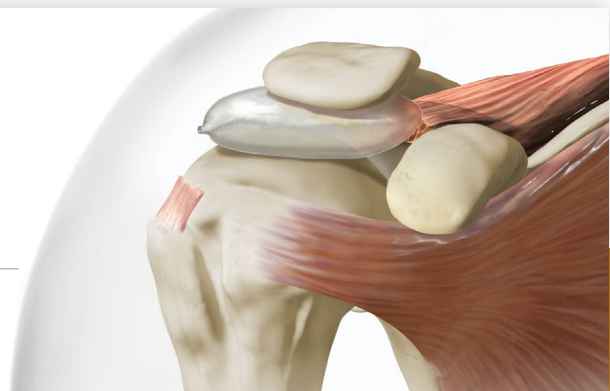
Expanding your options

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 repair¹. 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 rTSA¹⁻⁴

A long history

Changing practice and changing lives across the globe.

In use outside the U.S. since

2010⁵

Cleared for use in the U.S. in

2021¹

OUS procedures

29,000+⁵

Peer reviewed clinical articles

>30⁵

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 years⁷

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.

1. 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 (MRCT). NCT02493660
2. Yamakado, K. "Clinical and Radiographic Outcomes With Assessment of the Learning Curve in Arthroscopically Assisted Latissimus Dorsi Tendon Transfer for Irreparable Posterosuperior Rotator Cuff Tears." *Arthroscopy: The Journal of Arthroscopic and Related Surgery*. (2017)
3. Galvin, J. et. al. "Superior Capsular Reconstruction for Massive Rotator Cuff Tears A Critical Analysis Review." *Journal of Bone and Joint Surgery*. (2019)
4. Crosby, L. et. al. "Conversion to Reverse Total Shoulder Arthroplasty with and without Humeral Stem Retention: The Role of a Convertible-Platform Stem" *THE JOURNAL OF BONE AND JOINT SURGERY*. (2017)
5. Stryker data on file
6. Familiari, F. et al. "Subacromial Balloon Spacer for Massive, Irreparable Rotator Cuff Tears Is Associated With Improved Shoulder Function and High Patient Satisfaction" *Arthroscopy: The Journal of Arthroscopic and Related Surgery*. (2020)
7. Senekovic V, et al. "Prospective clinical study of a novel biodegradable sub-acromial spacer in treatment of massive irreparable rotator cuff tears." *Eur J Orthop Surg Traumatol*. (2012)

Sports Medicine

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