7.01.180	Balloon Spacers for Treatment of Irreparable Rotator Cuffs of the Shoulder		
Original Policy Date:	July 1, 2025	Effective Date:	July 1, 2025
Section:	7.0 Surgery	Page:	Page 1 of 24

Policy Statement

I. Subacromial balloon spacer implantation is considered **investigational** as a treatment for massive, irreparable, full-thickness rotator cuff tears.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

Description

Subacromial balloon spacer implantation represents a minimally invasive treatment modality for massive irreparable rotator cuff tears. The biodegradable spacer is introduced arthroscopically into the subacromial region where it functions to depress the humeral head, successfully reestablishing normal shoulder mechanics by blocking upward displacement of the humeral head toward the acromion. This technique addresses pain and functional limitations by creating a temporary articulating interface between the humeral head and acromion by reducing subacromial impingement. The biodegradable spacer gradually deflates over several months, potentially allowing time for adaptation of surrounding tissues and pain reduction without the complexity of tendon transfers or reverse shoulder arthroplasty.

Summary of Evidence

For individuals with massive irreparable rotator cuff tears (MIRCTs) who receive subacromial balloon spacer implantation (SBSI) as an adjunct to routine care, including surgery, the evidence includes meta-analyses, RCTs, non-randomized comparative studies, and uncontrolled studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Two RCTs provided conflicting evidence regarding the efficacy of SBSI. The non-inferiority trial comparing SBSI to partial repair found comparable improvements in American Shoulder and Elbow Surgeons (ASES) scores at 24 months, with SBSI demonstrating better forward elevation and shorter operative times. However, an FDA analysis recommended using a composite primary efficacy endpoint instead of ASES alone and found non-inferiority only in the subset of patients aged 65 years or older. Another RCT that compared arthroscopic debridement with and without SBSI was terminated early due to futility, with results favoring debridement alone over SBSI. This was supported by a 2024 meta-analysis comparing SBSI to arthroscopic debridement, which found that debridement alone demonstrated superior outcomes in pain reduction and Constant-Murley scores. A second review showed significant improvements in pooled patient-reported outcomes following SBSI from baseline through 2 years follow-up on Constant-Murley, ASES scores, and pain reduction, but a meta-analysis of comparative trials revealed no benefits over alternative therapies. Nonrandomized comparative studies typically reported improvements in functional outcomes and pain scores following SBSI compared to baseline; however, none showed it to be superior to other surgical reconstruction techniques. Case series have

reported long-term follow-up of up to 8 years, with most showing a sustained benefit in functional and pain outcomes. Device-related complications were uncommon, with one review reporting that most studies (52%) did not observe any complications related to SBSI. Complications reported included implant migration, implant removal due to pain, early deflation of the implant resulting in temporary functional impairment, worsening of glenohumeral osteoarthritis, revision to other surgical procedures, and infection. Multiple studies emphasized the importance of proper patient selection and noted that while SBSI may provide short-term benefits, its long-term effectiveness compared to alternative treatments remains uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
Not applicable.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

Regulatory Status

In July 2021, the InSpace™ Subacromial Tissue Spacer System (Stryker; previously Ortho-Space Ltd.) was granted De Novo classification by the FDA (DEN200039; Product Code: QPQ). The device is a biodegradable subacromial balloon spacer indicated for the treatment of MIRCTs in patients at least 65 years of age with mild to moderate glenohumeral osteoarthritis who may benefit from a shorter surgical time compared to partial rotator cuff repair. The InSpace system consists of a resorbable polymer implant pre-loaded on a deployer, which is inflated with sterile saline after being positioned within the subacromial space. The inflated balloon aims to reduce acromiohumeral contact pressure and restore shoulder biomechanics while it remains inflated for 3 to 4 months and the device is designed to biodegrade over approximately 1 year. The device purports to result in shorter operative times as well as earlier functional and pain relief when compared to partial repair.[5,]

Rationale

Background
Massive, Irreparable Full-Thickness Rotator Cuff Tears
Rotator cuff tears represent a common shoulder injury affecting a significant portion of the population, with overall incidence rates ranging from 5% to 40%, and approximately 54% of individuals over the age of 60 experiencing partial or complete tears.[1,] Massive tears, commonly defined as full-thickness tears involving at least 2 tendons or measuring greater than 5 cm in the coronal plane, constitute about 20% of all rotator cuff tears and 80% of recurrent tears. However, multiple definitions exist for what constitutes a massive tear, and a recent Delphi consensus of expert

orthopedic shoulder specialists suggested that the most agreed upon definition would be tears with retraction of tendons to the glenoid rim in either the coronal or axial plane and/or a tear with at least 67% of the greater tuberosity exposed in the sagittal plane.[2,3,] Rotator cuff tears are considered irreparable when they cannot be restored to their original insertion on the tuberosities using standard surgical release and mobilization techniques due to excessive size, tendon retraction, and muscle degeneration, including atrophy and fatty infiltration.[3,] Without intervention, the natural progression of untreated massive tears can lead to muscle atrophy, fatty infiltration, and further tendon retraction, rendering potentially reparable tears irreparable over time.

Treatment

Management of massive, irreparable full-thickness rotator cuff tears (MIRCTs) encompasses both nonoperative and surgical approaches. Nonoperative treatments primarily focus on alleviating pain and enhancing shoulder function. These include physical therapy, activity modification to reduce strain on the shoulder, and pharmacological interventions such as nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroid injections to manage inflammation and discomfort.[4,] Surgical interventions are considered when nonoperative treatments fail to provide adequate relief or in patients with higher functional requirements. Options include partial rotator cuff repair, which may restore some function depending on the tear's extent and tissue quality.[3,] For patients with significant deficits, tendon transfer procedures, such as latissimus dorsi or lower trapezius transfers, can compensate for lost rotator cuff function. Additionally, reverse total shoulder arthroplasty is a treatment option, particularly in individuals with pseudoparalytic shoulder, irreparable rotator cuff tears, and glenohumeral osteoarthritis who are not candidates for tendon transfers.[3,]. Arthroscopic debridement with subacromial balloon spacer implantation (SBSI) is being investigated as a potential alternative treatment for managing MIRCTs.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Balloon Spacers for Treatment of Irreparable Rotator Cuffs of the Shoulder

Clinical Context and Therapy Purpose

The purpose of sub-acromial balloon spacer implantation (SBSI) in patients who have massive, irreparable, full-thickness torn rotator cuff tendons (MIRCTs) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population(s) of interest are individuals with MIRCTs due to trauma or degradation with mild to moderate gleno-humeral osteoarthritis in patients greater than or equal to 65 years of age.

Interventions
The therapy being considered is the InSpace SBSI (Stryker; formerly OrthoSpace Ltd.). The implant is designed to restore the subacromial space and is placed arthroscopically without requiring sutures or fixation devices. The procedure involves arthroscopic debridement along with implantation of the balloon spacer in the subacromial space. Once positioned, the device is filled with saline to a pre-specified volume. The device provides immediate restoration of the subacromial space and gradually biodegrades over time, being fully absorbed by the body after approximately one year.

Comparators
The following conservative treatments are being used to manage individuals with rotator cuff tears: physical therapy, activity modification, nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, and platelet-rich plasma (PRP) injections. Surgical treatment options for individuals with MIRCTs include debridement, partial rotator cuff repair, superior capsular reconstruction, tendon transfer, and reverse total shoulder arthroplasty.

Outcomes
The general outcomes of interest are functional outcomes (American Shoulder and Elbow Surgeons [ASES] score, Constant-Murley Shoulder [CMS] Score, Oxford Shoulder Score [OSS], QuickDASH, Simple Shoulder Test, Subjective Shoulder Value), symptoms (Western Ontario Rotator Cuff [WORC] Index, Visual Analog Scale [VAS] for pain), quality of life, range of motion (ROM), and treatment-related morbidity and mortality. A summary of outcomes of interest included in the evidence base for balloon spacers for the treatment of irreparable rotator cuffs is shown in Table 1.

The sustained clinical benefits of the balloon spacer after 1 year remain unexplained despite its degradation over time. Some authors suggest the procedure may induce a fibrotic capsule or barrier providing temporary relief of pain that allows for rehabilitation and restoration, and another hypothesis attributes improvements to concurrent procedures like debridement, bursectomy, acromioplasty, partial rotator cuff repair, or biceps tenotomy.[6,]

Follow-up at 2 years is important for monitoring outcomes, providing additional observation time after the device has fully reabsorbed.

Table 1. Outcomes of Interest for Individuals with Torn Rotator Cuff

Outcome	Measure (Units)	Description and Administration	Thresholds for Improvement/Decline or Clinically Meaningful Difference (if known)
American Shoulder and Elbow Surgeons (ASES) Score	Continuous scale (0-100); higher scores indicate better shoulder function.	Assesses shoulder function and pain via a 16-item self-reported questionnaire consisting of 2 dimensions, pain and difficulties with activities in daily living.	A change of approximately 11.1 to 21 points is considered clinically meaningful.[7,8,]
Constant-Murley Shoulder Score	Continuous scale (0-100); higher scores indicate better shoulder function.	Measures pain, daily activities, range of motion, and strength through both patient-reported and clinician-measured components. Subjective findings on pain and daily activity account for 35 points and objective measurements from range of motion and strength account for the remaining 65 points.	A change of about 10.4 points is considered clinically significant.[9,]

Outcome	Measure (Units)	Description and Administration	Thresholds for Improvement/Decline or Clinically Meaningful Difference (if known)
EuroQol-5 Dimensions-5 Level (EQ-5D-5L)	Higher scores indicate better health; analyzed as a continuous variable.	Assesses health across 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each rated on a 5-level Likert scale. It also includes a visual analog scale (VAS) to measure self-rated health.	A change of 0.03 to 0.07 in the utility index is considered meaningful.[10,]
Oxford Shoulder Score (OSS)	Continuous scale (0-48); higher scores indicate better shoulder function.	Evaluates shoulder pain and function using a 12-item self-reported questionnaire with each item scored 0-4 with higher values indicating worse or more severe symptoms.	A change of approximately 6 points is considered clinically significant.[11,]
Patient Global Impression of Change (PGIC)	Ordinal scale (1-7); lower scores indicate greater improvement.	Captures the patient's overall perception of change in their condition using a single-item self-reported.	A change of 1 point is considered a clinically meaningful change.[12,]
QuickDASH Score	Continous scale (0-100); higher scores indicate greater disability. It is a shortened version of the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire.	This tool assesses upper limb disability and function. It is a self-reported questionnaire with 11 items scored on a Likert scale, covering symptoms and physical function.	A change of 12 to 15 points is considered clinically meaningful.[13,]
Simple Shoulder Test (SST)	Ordinal scale (0-12); higher scores indicate better function.	This measure evaluates shoulder function through a self-administered questionnaire with 12 yes-or-no questions.	A change of at least 2.3 points is considered clinically meaningful.[14,]
Visual Analog Scale (VAS) for Pain	Continuous scale (0-10 cm or 0-100 mm); higher scores indicate greater pain.	Pain intensity is measured by having the patient mark a point on a line representing their pain level.	A change of about 1.4 cm (14 mm) is considered clinically meaningful.[15,]
Western Ontario Rotator Cuff (WORC) Index	Continuous scale (0-2100); higher scores indicate worse symptoms.	Evaluates quality of life in rotator cuff disorders using a 21-item self-administered questionnaire across 5 domains. Each item is scored by having the patient mark a point on a line with, one end indicating no symptoms or difficulty and the other end indicating extreme symptoms or difficulties.	A reduction of between 283 to 589 points is considered clinically significant.[16,]

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Sandler et al (2023) conducted a meta-analysis comparing outcomes of SBSI versus arthroscopic debridement alone for the treatment of MIRCTs.[17,] A total of 28 studies met the inclusion criteria, with 14 studies (n=528 patients) in the SBSI group and 14 studies (n=479 patients) in the debridement group (see Tables 2 and 3). Baseline characteristics showed comparable ages across the groups; however, the debridement-only group had a significantly higher proportion of male patients, shorter operative times, and reported data for a significantly longer follow-up period. Patient-reported outcomes favored debridement over SBSI (see Table 4). The pooled analysis demonstrated a significantly larger reduction in VAS pain scores for debridement compared with SBSI (mean difference [MD], -0.7; p<.001). Similarly, debridement resulted in greater improvement in the CMS compared with SBSI (MD, 5.5; p<.001). Both procedures significantly improved ROM in forward flexion, internal rotation, external rotation, and abduction (p<.001). However, final abduction was greater following SBSI placement, while forward flexion and internal rotation improvements were superior in the debridement group. Operative time was significantly longer for the SBSI group compared to debridement alone (64.8 vs. 35.5 minutes; p<.001). General complication rates were higher in the debridement group compared with SBSI (5.2% vs. 3.5%; p<.001). However, no significant differences were found between SBSI and debridement in terms of persistent symptoms requiring reintervention (3.3% vs. 3.8%; p=.252) or reoperation rates (5.1% vs. 4.8%; p=.552). The mean time to conversion to reverse total shoulder arthroplasty was worse in the SBSI group (11.0 months) compared to the debridement group (25.4 months), but this was reported only by a single study. The findings suggest debridement may be preferable to SBSI given its superior pain relief, greater improvement in patient-reported outcomes, and longer time to conversion to reverse total shoulder arthroplasty; however, the study is limited by having only a single study which compared SBSI and debridement directly and an absence of estimates of heterogeneity for the reported outcomes.

Sirignano et al (2024) performed a meta-analysis evaluating the effectiveness of SBSI in treating MIRCTs. A total of 27 studies encompassing 894 SBSI patients (mean age, 67.8 ± 5 years) with a mean follow-up of 29.4 ± 17 months were included.[18,] Significant improvements from baseline levels were observed when pooling outcome data across SBSI studies in patient-reported outcomes. CMS increased from 34.8 at baseline to 64.2 at 12 months and 67.9 at 24 months (p<.001) (see Table 4). Similarly, the ASES scores improved from 35.1 at baseline to 83.3 at 12 months and 81.8 at 24 months (p<.001). VAS pain scores also showed significant reductions, from 6.6 at baseline to 2.6 at 12 months and 2.0 at 24 months (p<.001). ROM outcomes also improved. Forward flexion increased from 108.5° at baseline to 128.5° at 12 months and 151.2° at 24 months (p=.01). Abduction increased from 97.7° at baseline to 116.3° at 12 months and 142.3° at 24 months (p=.02). Regarding adverse events, 51.9% of studies reported no device-related complications, and the overall rate of complications was low. However, reoperation due to device failure or conversion to reverse total shoulder arthroplasty occurred in 33 patients, and a small number of patients experienced device migration, early deflation, or required removal of the implant due to pain (see Table 4). Despite these positive findings, comparative studies revealed small effect sizes and statistically insignificant differences when SBSI was compared with partial rotator cuff repair or debridement alone in a meta-analysis. Additionally, high heterogeneity among included studies limited the ability to draw definitive conclusions. While SBSI implantation demonstrated improvements in pain and function at 24 months relative to baseline measures, its effectiveness compared to other treatment modalities remains uncertain.

Table 2. Comparison of Trials/Studies Included in SR & M-A

	Sandler et al (2023)[17,]	Sirignano et al (2024)[18,]
Atoun et al (2024)[19,]		●
Davey et al (2022)[20,]		●

Deranlot et al (2017)[21],	●	●
Dhir et al (2022)[22],		●
Familiari et al (2021)[23],	●	●
Garafalo et al (2022)[24],		●
Garcia Moreno et al (2022)[25],	●	
Garriguez-Perez et al (2022)[26],		●
Gervasi et al (2016)[27],		●
Gervasi et al (2021)[28],		●
Holschen et al (2017)[29],		●*
Kaisidis et al (2022)[30],	●	●
Malahias et al (2019)[31],		●*
Malahias et al (2021)[32],		●
Maman et al (2017)[33],	●	●
Metcalfe et al (2022)[34],	●	●*
Minarro et al (2024)[35],		●*

	Sandler et al (2023)[17]	Sirignano et al (2024)[18]
Piekaar et al (2018)[36]		●
Piekaar et al (2020)[37]	●	●
Prat et al (2018)[38]	●	●
Ricci et al (2017)[39]	●	●
Ruiz Iban et al (2018)[40]	●	●
Senekovic et al (2013)[41]		●
Senekovic et al (2017)[42]		●
Vecchini et al (2022)[43]		●
Verma et al (2022)[8]		●*
Yallapragada et al (2018)[44]	●	●
Yamak et al (2019)[45]	●	●

* Study included in meta-analysis

Table 3. SR & M-A Characteristics

Study	Dates	Studies	Participants	N (Range)	Design	Duration
Sandler et al (2023)[17]	1997-2022	27 (includes studies of debridement only; n=14 SBSI)	Patients with MIRCTs who underwent either SBSI or arthroscopic debridement (mean age 66 years); studies with partial rotator cuff repair were excluded.	1007 (15-93) SBSI: 503 Other treatment: 504	RCTs, non-randomized comparative studies, case series	Mean follow-up, mos: SBSI: 30.7 ± 16.5 Other treatment: 57.7 ± 27 *Significantly shorter in SBSI arm (p<.001)*
Sirignano et al (2024)[18]	2010-2024	27 (5 comparative studies were included in the meta-analysis)	Patients with MIRCTs who underwent SBSI (mean age 67.8 years) or partial rotator cuff repair, attempted rotator cuff repair, or debridement alone	SBSI: 894 Other treatment: NR	RCTs, non-randomized comparative studies, case series	Mean follow-up, mos: SBSI: 29.4 (range, 6 to 72.5)

MIRCTs: massive irreparable rotator cuff tears; Mos: months; NR: not reported; RCT: randomized controlled trial; SBSI: subacromial balloon spacer implantation.

Table 4. SR & M-A Results

Study	ASES	CMS	VAS Pain	Complications
Sandler et al (2023)[17]				General complications; reintervention; reoperation
Total N		1007	1007	1007
SBSI, MD from BL		29.4 (p<.001)	-3.8 (p<.001)	
Debridement, MD from BL		34 (p<.001)	-5 (p<.001)	
MD between groups		5.5 (p<.001), favoring debridement	-.7 (p<.001), favoring debridement	-1.7 (p<.001), favoring SBSI;.5 (p=.25); -.3 (p=.552)
Sirignano et al (2024)[18]				
Total number of comparative studies	3	4	3	
Cohen's d (95% CI)	.81 (-.02 to 1.65; p=.06)	.11 (-.93 to 1.14; p=.84)	-.11 (-.44 to.22; p=.06)	
I^2	.81 (p<.001)	. 92 (p<.001)	.36 (p=.2)	
Total number of SBSI studies	10	20	14	27
MD from BL at 12 mos; 24 mos (p)	48.2 (p<.001); 46.7 (p<.001)	29.4 (p<.001); 33.1 (p<.0001)	-4 (p<.001); -4.6 (p<.001)	No device-related complications: 51.9% (14/27 studies) Adverse events, n: Revision to RTSA: 33 Infection with synovitis or cyst formation: 9 SBSI migration or early deflation: 11 Implant removal due to pain: 4

ASES: American Shoulder and Elbow Surgeons Score; BL: baseline; CI: confidence interval; CMS: Constant-Murley Shoulder Score; MD: mean difference; mos, months; RTSA: reverse total shoulder arthroplasty; SBSI: subacromial balloon spacer implantation; VAS: Visual Analogue Scale.

Randomized Controlled Trials

Verma et al (2022) published findings from a multicenter, single-blinded, non-inferiority RCT comparing SBSI (n=93) to partial repair (n=91) in patients aged at least 40 years with symptomatic, irreparable, posterosuperior massive rotator cuff tears and an intact subscapularis who had failed nonoperative management (NCT02493660).[8] The primary outcome was improvement in ASES scores through 24 months, with secondary outcomes including WORC score, VAS pain score, CMS, EQ-5D-5L score, and ROM. At 24 months, 89% of SBSI and 87% of partial repair patients completed follow-up. Both groups showed significant improvements in ASES scores (SBSI, 46.22; partial repair, 42.53 both p<.0001 vs. baseline), with no significant between-group differences in patients achieving the minimally clinically important difference ([MCID] change of 11.1; 83% vs. 81%), substantial clinical benefit (change of 17.5, 82% vs. 79%), or patient acceptable symptom state (PASS) thresholds. The SBSI group demonstrated better forward elevation at 24 months (p=.003) and significantly shorter operative time (44.6 vs. 71.2 minutes; p<.0001).

Originally, the study's primary endpoint was set at 12 months to evaluate short-term efficacy. However, as part of the Investigational Device Exemption (IDE) study, the U.S. FDA requested an extension to month 24 to assess the durability of treatment effects over time. A modified primary

endpoint was requested to measure both early improvements and their long-term sustainability using a composite measure of patient success, which required a WORC score improvement of at least 275 points and an ASES score improvement of at least 6.4 points from baseline, the absence of device-related serious adverse events, and the avoidance of a secondary surgical procedure. Each of these criteria had to be met by week 6 and maintained through month 24 to be considered a successful outcome. In the per-protocol analysis, the trial failed to demonstrate non-inferiority for the overall population (SBSI 86.6% vs. partial repair 91.1%; p=.06). However, in a stratified analysis, non-inferiority was achieved in the subgroup of patients aged 65 years or older (SBSI 87.8% vs. partial repair 88.1%; p=.01).[46,]No device-related surgical complications were reported, and 7 patients required reoperation at 24 months follow-up (4 SBSI, 3 partial repair). Key limitations included lack of standardization of concomitant procedures and repair techniques, unblinded physical examination evaluators, and challenges in estimating the relative contribution of SBSI due to differences in concomitant procedures and other interventions (e.g., physiotherapy and medications).

Metcalfe et al (2023) conducted a multicenter, double-blinded RCT comparing arthroscopic debridement with and without SBSI in patients with symptomatic irreparable rotator cuff tears (START:REACTS).[34,] The trial enrolled 117 individuals with a mean age of 67 years who had failed conservative management and were randomized 1:1 to arthroscopic debridement with SBSI (n=56) or arthroscopic debridement alone (n=61). The study used an adaptive design with 2 planned interim analyses and more than 80% power to detect improvement in OSS substantial clinical benefit achievement (6 point change) from 80% for partial repair to 95% for SBSI at 24 months with a sample of 221. The study met predefined futility stopping boundaries at the first interim analysis, allowing early termination after randomizing approximately half the planned sample size with outcomes assessed through 12 months only. Follow-up at the interim stopping point was high, with primary outcome data obtained from 114 (97%) participants. The primary outcome analysis showed the mean OSS at 12 months was 34.3 in the debridement-only group compared to 30.3 in the debridement with SBSI (MD, -4.2, favoring control; 95% CI -8.2 to -0.26; p=.037). A prespecified secondary adjusted model accounting for baseline OSS, sex, tear size and age showed similar results (MD, -4.2; 95% CI, -7.8 to -0.6; p=.026). Secondary outcomes, including CMS score, ROM measures, and WORC index, were not significantly different between groups but generally showed poorer outcomes in the SBSI group compared to debridement alone; however, many physical measures had substantial missing data due to COVID-19 restrictions. No significant differences in the rate of adverse events were observed. However, two serious adverse events in the SBSI group were attributed to the intervention: one required a reverse shoulder replacement, and the other necessitated ongoing secondary care at the study's conclusion.

Haque et al (2025) reported the 24-month outcomes of the START:REACTS RCT for 99 (85%) participants at 24 months.[47,] No statistically significant difference was observed in the primary outcome, the OSS, between groups (adjusted MD, -3.8; 95% CI, -7.9 to 0.4; p=.075), though the trend continued to favor the control group. Secondary outcomes showed a significant difference in the WORC index, again favoring debridement alone (adjusted MD, -10.1; 95% CI, -19.5 to -0.8; p=.041). Patient-reported global improvement was also significantly worse in the SBSI group (odds ratio, 0.4; 95% CI, 0.2 to 0.8; p=.015). EQ-5D-5L quality-of-life scores and satisfaction ratings did not significantly differ between groups. Key limitations included missing objective physical measurements for many participants, a sample size smaller than the pre-specified power calculation, and challenges in estimating the relative contribution of SBSI due to differences in concomitant procedures and other interventions (e.g., number of physiotherapy sessions and medications). Tables 5 and 6 summarize key RCT characteristics and results, respectively. Limitations are summarized in Tables 7 and 8.

Table 5. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants[2]	Interventions[1]	
					Active	Comparator
Verma et al (2022)[8,]	US and Canada	20	2015-2018	Individuals ≥40 years of age with MIRCTs diagnosed by MRI with functional deltoid muscle and preserved passive ROM, VAS pain > 30 mm, failed nonoperative treatment of at least 4 mos duration and were eligible for partial repair. Individuals with severe glenohumeral arthritis (International Cartilage Repair Society Grade 3 or higher) and subscapularis tears were excluded.	SBSI with no tendon repair (n=93)	Partial repair (n=91)
Metcalfe et al (2023)[34,]; Haque et al (2025)[47,]	UK	24	2018-2021	Individuals with MIRCTs diagnosed with pain and loss of function who had failed nonoperative treatment. Individuals with advanced glenohumeral arthritis (Kellgren-Lawrence grade 3 or 4) were excluded.	Standard debridement plus SBSI (n=56)	Debridement alone and biceps tenotomy (n=61)

MIRCTs: massive, irreparable rotator cuff tears; MRI: magnetic resonance imaging; RCT: randomized controlled trial; ROM: range of motion; SBSI: Subacromial baloon spacer implantation; VAS: visual analogue scale.

Table 6. Summary of Key RCT Results

Study	Primary Endpoint	ASES	CMS	WORC	EQ-5D-5L	VAS
Verma et al (2022)[8,]	(WORC improvement ≥ 275; ASES improvement ≥6.4; no device related					

Study	Primary Endpoint	ASES	CMS	WORC	EQ-5D-5L	VAS
	AE or secondary surgical interventions) 24 Mo Per-protocol; <65 Yrs; ≥65 Yrs					
SBSI (n=93), Median change, Mo 3; 6; 12; 24	86.6%; 84.8%; 87.8%	~22; 42; 42; 48	~-10; 22; 26; 30	~-525; -800; -1100; -1150	~-2.0; -4.0; -4.0; -4.0	~-44; -60; -60; -60
Partial repair (n=91), Median change, Mo 3; 6; 12; 24	91.1%; 94.6%; 88.1%	~20; 35; 42; 45	~4; 22; 25; 25	~-650; -825; -975; -1050	~-2.0; -3.4; -2.8; -4.0	~-35; -50; -52; -55
p-value	p=.06; p=.93; p=.01, non-inferiority met in subgroup ≥65 Yrs	NS difference between groups at any time point	SS difference at week 6 and 24 Mo (p=.05), favoring SBSI	SS difference at day 10 (p=.035), favoring SBSI, NS difference at other time points	NS difference between groups at any time point	NS difference between groups at any time point
Metcalfe et al (2023)[34]; Haque et al (2025)[47]	OSS	PGIC (% with substantially better or moderately better function) at 12 Mo		*WORC items summed and presented as % of the total score (0-100)*		
N at 3, 6, 12, 24 mos	113, 112, 114, 98	114, 117	86, 55, 22	108, 105, 107, 94	114, 112, 113, 98	
SBSI (n=56), Mean at Mo 3; 6; 12; 24	25; 28.5; 30.3; 31.4	63%; 51%	36.7; 45.2; 47.5	40.2; 49.1; 51.7; 51.7	.556;.592;.590;.620	
Debridement alone (n=61), Mean at Mo 3; 6; 12; 24	30.4; 33.3; 34.3; 34.3	67%; 68%	46; 49; 63.6	54.8; 60.2; 61.6; 62.7	.632;.666;.667;.638	
Mean difference (95 %CI; p-value), adjusted model	12 mos: -4.2 (-8.2 to -.26; p=.037), favoring debridement alone 24: -3.8 (-7.9 to.4; p=.075)	NS difference between groups	NR due to high loss of follow-up at 12 mos	12 Mos: -8.4 (-16.7 to -.01; p=.055) 24 Mos: -10.1 (-19.5 to -.8; p=.041)	12 Mos: -.056 (-.150 to.035; p=.239) 24 Mos: -.009 (-.0107 to.088; p=.852)	

AE: adverse event; ASES: American Shoulder and Elbow Surgeons; BL: baseline; CI: confidence interval; CMS: Constant-Murley Shoulder score; Diff: difference; EQ-5D-5L: European Quality of Life 5 Dimensions 5 Level; Mo: month; NR: not reported; OSS: Oxford Shoulder Score; PGIC: Patient Global Impression of Change; RCT: randomized controlled trial; SBSI: subacromial balloon spacer implant; SS: statistically significant; VAS: visual analogue scale; Wk: week; WORC: Western Ontario Rotator Cuff Index; Yr: year.
~ values approximated from figure

The purpose of the study limitations tables (see Tables 6 and 7) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence

following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Verma et al (2022)[8,]		5. Concomitant procedures were not standardized			
Metcalfe et al (2023)[34,]; Haque et al (2025)[47,]	3. Study population not representative of intended use; inclusion of patients with unrepaired subscapularis tears and poor preoperative range of motion	5. Concomitant procedures were not standardized			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 8. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Verma et al (2022)[8,]		2. Outcome assessors not blinded				3. Multiple outcomes required extraction from figures
Metcalfe et al (2023)[34,]; Haque et al (2025)[47,]				1. High loss to follow-up for objective outcome measures such as Constant-Murley Shoulder score; impacted by Covid-19 pandemic	4. Accrual stopped before achieving the originally planned number of participants	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3.

High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Holschen et al (2017) conducted a retrospective case-control study investigating the clinical outcomes of InSpace SBSI compared to conventional arthroscopic treatment for MIRCTs.[29,] The study included 23 patients (mean age 64.6 years in conventional arthroscopy [n=11] and 62.4 years in SBSI [n=12]) with painful loss of shoulder function but no osteoarthritis or cuff tear arthropathy (see Table 9). Outcomes were assessed at 30.6 months for conventional arthroscopy and at 11.4 and 22.3 months for the SBSI group (Table 10). At final follow-up, both groups showed significant improvement in ASES shoulder score (conventional arthroscopy: 29.5, p<.001; SBSI: 54.2, p<.001) and CMS (conventional arthroscopy: +16.9, p<.001; SBSI: +32.7, p<.001) compared to baseline pre-operative levels. Despite greater absolute improvement in the SBSI group, due primarily to lower baseline ASES scores in the SBSI group, final ASES scores and CMS were similar (ASES: 88.6 vs. 85.7; CMS: 77.6 vs. 69.5). Two patients in SBSI with pseudoparalytic shoulders showed little improvement postoperatively. One patient experienced persistent pain and MRI-confirmed balloon remnants, which evolved into scar tissue. Limitations included retrospective design, single-center study, small sample size, lack of randomization, and shorter follow-up for the SBSI group. Additionally, the study was not powered for subgroup analyses, and long-term durability of SBSI effects was uncertain.

Oh et al (2019) performed a case-control study comparing arthroscopic SBSI versus other reconstruction methods for MIRCTs, including 53 patients with a minimum 2-year follow-up. Seventeen patients received SBSI with/without partial repair, while 36 patients underwent other techniques (partial repairs or bridging grafts).[48,] Two patients were excluded after conversion to reverse shoulder arthroplasty before follow-up. The only significant difference between groups was operative time (80.3 vs. 134.6 minutes, p<.001). At final follow-up (mean 24-60 months), there were no significant differences between groups in functional scores or range of motion (see Table 10). Study limitations included a retrospective design, small sample size, and lack of long-term follow-up.
Malahias et al (2021) conducted a matched-pair case-control study comparing arthroscopic partial repair alone versus arthroscopic partial repair plus SBSI for MIRCTs.[32,] A total of 32 patients were included (16 in each group), matched for age, sex, dominant arm, and baseline tear characteristics (see Table 9). Clinical outcomes were assessed using VAS, CMS, ASES shoulder score, ROM, and patient satisfaction at 12 months. Both groups experienced significant improvement from baseline in ASES shoulder score, CMS, pain, and ROM (p<.05). However, there was no significant difference between the 2 groups in success rates for achieving MCID in ASES (>17), CMS (>10.4), pain relief, or ROM at 12 months (Table 10). Limitations included a small sample size, single-center study, short 12-month follow-up, and absence of MRI confirmation of healing.

Table 9. Summary of Key Nonrandomized Trials OR Observational Comparative Study Characteristics

Study	Study Type	Country	Dates	Participants	SBSI	Comparator	Follow-Up
Holschen et al (2017)[29,]	Retrospective case-control study	Germany	Not specified	Individuals with MIRCTs who had painful loss of shoulder function with no osteoarthritis and cuff tear arthropathy (mean age 64 years)	Conventional arthroscopic treatment (debridement of the rotator cuff, synovectomy, bursectomy, biceps	Conventional arthroscopic treatment (debridement of the rotator cuff, synovectomy, bursectomy, biceps tenotomy/tenodesis, and partial	11-22 months

Study	Study Type	Country	Dates	Participants	SBSI	Comparator	Follow-Up
					tenotomy/ tenodesis, and partial reconstruction of the rotator cuff) with InSpace SBSI (n=11)	reconstruction of the rotator cuff) without SBSI (n=11)	
Oh et al (2019)[48]	Retrospective cohort study	South Korea	2010-2017	Individuals with symptomatic MIRCTs. Patients where biceps augmentation could not be performed had SBSI. Patients with MIRCTs and intact bicep tendons had arthroscopic rotator cuff repair with long head of the bicep tendon as the bridging graft.	Individuals with MIRCTs who had InSpace SBSI (n=17; mean age 61.7 years)	Arthroscopic partial repair with bridging grafts (n=36; mean age 65.4 years)	24-60 months
Malahias et al (2021)[32]	Retrospective matched case-control study	Greece	2016-2017	Individuals with MIRCTs, age >50, confirmed by MRI and intra-operative diagnosis	Arthroscopic partial repair with Inspace SBSI (n=16; mean age 65.7 years)	Arthroscopic partial repair alone (n=16; mean age 69.7 years)	12 months

MIRCT: massive, irreparable rotator cuff tears; SBSI: subacromial balloon spacer implantation.

Table 10. Summary of Key Nonrandomized Trials OR Observational Comparative Study Results

Study	ASES	CMS	VAS	QuickDash	SST
Holschen et al. (2017)[29]					
SBSI, Median change from BL to 12 mo	54.2 (p<.001)	32.7 (p<.001)			
Partial Repair, Median change from BL to 12 mo	29.5 (p<.001)	16.9 (p<.001)			
Between group comparison at final f/u, p-value	p<.001, greater absolute change in SBSI group but no SS difference in 12 mo ASES scores	p<.001, greater absolute change in SBSI group but no SS difference in final CMS scores			
Oh et al (2019)[48]					
SBSI, Mean change from BL to 12 mo	35.5 (p=.001)	7.7 (p=.011)	-4.7 (p<.001)	29.7 (p=.019)	5.4 (p=.002)
Other reconstruction methods, Mean change	15.2 (p=.047)	11.4 (p=.021)	-4 (p<.001)	28.7 (p=.003)	2.9 (p=.115)

Study	ASES	CMS	VAS	QuickDash	SST
from BL to 12 mo					
Between group comparison at final f/u, p-value	p=.672	p=.281	p=.479	p=.548	p=.342
Malahias et al. (2021)[32]					
Partial repair + SBSI, Mean change from BL to 12 mo	28.8	27.9	-3.3		
Partial repair, Mean change from BL to 12 mo	42.1	37	-3.7		
p-value	NS	NS	NS		

ASES: American Shoulder and Elbow Surgeons Score; BL: baseline; CI: confidence interval; CMS: Constant-Murley score Diff: difference; f/u, follow-up; mos: months; NS: not significant; RCT: randomized controlled trial; SBSI: subacromial balloon spacer implantation; SST: simple shoulder test; VAS: visual analogue scale;

A summary of case series not discussed in the systematic reviews and meta-analyses included in this assessment is presented below.

Several case series examining the long-term efficacy of SBSI for MIRCTs demonstrate significant functional improvements and pain reduction that generally persist over follow-up periods ranging from 3 to 8 years (see Tables 11 and 12).[49,50,51,] Patients typically experience significant gains in shoulder ROM, reduced pain scores, and improved functional metrics as measured by ASES shoulder scores and CMS relative to baseline levels. However, 1 author reported a "balloon dip" phenomenon occurring between 12-26 weeks post-implantation, when the biodegradable balloon begins to resorb, causing temporary functional impairments, particularly with overhead activities and lifting.[52,]

Progressive glenohumeral osteoarthritis was observed in a significant percentage of patients (43.9% in 1 study), and the osteoarthritis grade increased significantly in another study (1.36 points on the Hamada classification).[50,51,] At the last follow-up, 1 study reported moderately high patient dissatisfaction (42.9%).[50,]

Table 11. Summary of Key Case Series Characteristics

Study	Country	Participants	Treatment Delivery	Follow-Up
Fares et al (2024)[49,]	USA	10	SBSI for MIRCTs	Range 5-7 years
Kishan et al (2024)[50,]	USA	42	SBSI for MIRCTs	Range 5-8 years
Savarese et al (2024)[51,]	Italy, UK	61	SBSI for MIRCTs with or without partial repair	3 years
Sirignano et al (2024)[52,]	USA	65	SBSI for MIRCTs	Mean 40 weeks (range: 24.1 - 89.7 weeks)

MIRCT: massive, irreparable rotator cuff tears; SBSI: subacromial balloon spacer implant.

Table 12. Summary of Key Case Series Results

Study	Treatment	Outcomes (Mean Difference from BL)	Adverse Events
Fares et al (2024)[49,]	SBSI for MIRCTs	ASES Score: 50.3; p=.001 VAS Pain: -5.3; p=.004 Forward Elevation: 53°;	One patient converted to arthroplasty (20%)

Study	Treatment	Outcomes (Mean Difference from BL)	Adverse Events
		p=.007 Revision-free survival: 80%	
Kishan et al (2024)[50]	SBSI for MIRCTs	CMS: 42.2; p=.001 SF-12 Physical: 10.3; p=.001 OA Grade: 1.36; p=.001 Patient dissatisfaction with procedure: 42.9% Revision-free survival: 83.3%	7 patients required revisions within 2 years (16.7%)
Savarese et al (2024)[51]	Arthroscopic rotator cuff repair with SBSI	ASES Score: 48.7; p<.05 CMS: 39.5; p<.05 Revision-free survival: 96.7%	1 patient required shoulder replacement (1.6%); 1 patient required implant removal (1.6%); Glenohumeral OA Progression in 24 patients (43.9%)
Sirignano et al (2024)[52]	SBSI for MIRCTs	ASES Score: 15; p<.05 VAS Pain: -3; p<.05 Flexion ROM: 50°; p<.05	No major adverse events reported

ASES: American Shoulder and Elbow Surgeons Score; BL: baseline; CI: confidence interval; CMS: Constant-Murley score Diff: difference; f/u, follow-up; MIRCT: massive, irreparable rotator cuff tears; NS: not significant; OA: osteoarthritis; RCT: randomized controlled trial; ROM: range of motion; SBSI: subacromial balloon spacer implantation; SST: simple shoulder test; VAS: visual analogue scale.

Section Summary: Balloon Spacers for Treatment of Irreparable Rotator Cuffs of the Shoulder

Evidence for the use of SBSI in treating MIRCTs includes 2 meta-analyses, 2 randomized controlled trials (RCTs), and multiple nonrandomized studies. Two RCTs provided conflicting evidence regarding the efficacy of SBSI. The non-inferiority trial comparing SBSI to partial repair found comparable improvements in ASES scores at 24 months, with SBSI demonstrating better forward elevation and shorter operative times. However, an FDA analysis recommended using a composite primary efficacy endpoint instead of ASES alone and found non-inferiority only in the subset of patients aged 65 years or older. Another RCT that compared arthroscopic debridement with and without SBSI was terminated early due to futility, with results favoring debridement alone over SBSI. This was supported by a 2024 meta-analysis comparing SBSI to arthroscopic debridement, which found that debridement alone demonstrated superior outcomes in pain reduction and CMS. A second review showed significant improvements in pooled patient-reported outcomes following SBSI from baseline through 2 years follow-up on CMS, ASES, and pain reduction, but a meta-analysis of comparative trials revealed no benefits over alternative therapies. Nonrandomized comparative studies typically reported improvements in functional outcomes and pain scores following SBSI compared to baseline; however, none showed it to be superior to other surgical reconstruction techniques. Case series have reported long-term follow-up of up to 8 years, with most showing a sustained benefit in functional and pain outcomes. Device-related complications were uncommon, with one review reporting that most studies (52%) did not observe any complications related to SBSI. Complications reported included implant migration, implant removal due to pain, early deflation of the implant resulting in temporary functional impairment, worsening of glenohumeral osteoarthritis, revision to other surgical procedures, and infection. Multiple studies emphasized the importance of proper patient selection and noted that while SBSI may provide short-term benefits, its long-term effectiveness compared to alternative treatments remains uncertain.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Orthopedic Surgeons

The most recent American Society of Orthopedic Surgeons (AAOS) guidelines for the management of rotator cuff injuries do not provide guidance regarding the use of subacromial balloon spacer implantation for the treatment of rotator cuff tears or shoulder conditions.[53,]

National Institute for Health and Care Excellence

In 2023, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on the use of biodegradable subacromial spacer insertion for rotator cuff tears.[54,] For individuals where debridement is suitable, NICE recommends that subacromial spacers should not be used. When debridement is not a suitable option, NICE recommends that the procedure be only used in a research setting with patient selection done by a multidisciplinary team, including clinicians with specific training in the procedure due to limited evidence.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 13.

Table 13. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05329584[a]	An Assessment of Two Accelerated Rehabilitation Programs for Use With the InSpace™ Subacromial Tissue Spacer System in the Treatment of Full-thickness Massive, Irreparable Rotator Cuff Tears	160	Apr 2026
NCT04704700	Evaluate the Rotator Cuff Repair With "InSpace" VS Without "InSpace"	48	Jul 2025

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Kovacevic D, Suriani RJ, Grawe BM, et al. Management of irreparable massive rotator cuff tears: a systematic review and meta-analysis of patient-reported outcomes, reoperation rates, and treatment response. J Shoulder Elbow Surg. Dec 2020; 29(12): 2459-2475. PMID 32763381
2. Schumaier A, Kovacevic D, Schmidt C, et al. Defining massive rotator cuff tears: a Delphi consensus study. J Shoulder Elbow Surg. Apr 2020; 29(4): 674-680. PMID 32197762
3. Novi M, Kumar A, Paladini P, et al. Irreparable rotator cuff tears: challenges and solutions. Orthop Res Rev. 2018; 10: 93-103. PMID 30774464
4. Juhan T, Stone M, Jalali O, et al. Irreparable rotator cuff tears: Current treatment options. Orthop Rev (Pavia). Sep 24 2019; 11(3): 8146. PMID 31616552

5. Stryker. InSpace Baloon Implant. 2024; https://www.stryker.com/content/dam/stryker/sports-medicine/products/inspace/images/InSpace_Brochure_1000903813RevB.pdf. Accessed February 13, 2025.
6. Sewpaul Y, Sheean AJ, Rashid MS, et al. Subacromial Balloon Spacer for the Massive Irreparable Cuff Tear. Curr Rev Musculoskelet Med. Feb 2024; 17(2): 47-57. PMID 38194186
7. Tashjian RZ, Hung M, Keener JD, et al. Determining the minimal clinically important difference for the American Shoulder and Elbow Surgeons score, Simple Shoulder Test, and visual analog scale (VAS) measuring pain after shoulder arthroplasty. J Shoulder Elbow Surg. Jan 2017; 26(1): 144-148. PMID 27545048
8. Verma N, Srikumaran U, Roden CM, et al. InSpace Implant Compared with Partial Repair for the Treatment of Full-Thickness Massive Rotator Cuff Tears: A Multicenter, Single-Blinded, Randomized Controlled Trial. J Bone Joint Surg Am. Jul 20 2022; 104(14): 1250-1262. PMID 35777921
9. Kukkonen J, Kauko T, Vahlberg T, et al. Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. J Shoulder Elbow Surg. Dec 2013; 22(12): 1650-5. PMID 23850308
10. McClure NS, Sayah FA, Xie F, et al. Instrument-Defined Estimates of the Minimally Important Difference for EQ-5D-5L Index Scores. Value Health. Apr 2017; 20(4): 644-650. PMID 28408007
11. van Kampen DA, Willems WJ, van Beers LW, et al. Determination and comparison of the smallest detectable change (SDC) and the minimal important change (MIC) of four-shoulder patient-reported outcome measures (PROMs). J Orthop Surg Res. Nov 14 2013; 8: 40. PMID 24225254
12. Hui D, Bruera E. Reply to minimal clinically important difference and Edmonton Symptom Assessment Scale. Cancer. Jan 01 2016; 122(1): 159-60. PMID 26383968
13. Galardini L, Coppari A, Pellicciari L, et al. Minimal Clinically Important Difference of the Disabilities of the Arm, Shoulder and Hand (DASH) and the Shortened Version of the DASH (QuickDASH) in People With Musculoskeletal Disorders: A Systematic Review and Meta-Analysis. Phys Ther. May 01 2024; 104(5). PMID 38438144
14. McLaughlin RJ, Whitson AJ, Panebianco A, et al. The minimal clinically important differences of the Simple Shoulder Test are different for different arthroplasty types. J Shoulder Elbow Surg. Aug 2022; 31(8): 1640-1646. PMID 35318157
15. Tashjian RZ, Deloach J, Porucznik CA, et al. Minimal clinically important differences (MCID) and patient acceptable symptomatic state (PASS) for visual analog scales (VAS) measuring pain in patients treated for rotator cuff disease. J Shoulder Elbow Surg. 2009; 18(6): 927-32. PMID 19535272
16. Dabija DI, Jain NB. Minimal Clinically Important Difference of Shoulder Outcome Measures and Diagnoses: A Systematic Review. Am J Phys Med Rehabil. Aug 2019; 98(8): 671-676. PMID 31318747
17. Sandler AB, Gil LG, Scanaliato JP, et al. Subacromial Balloon Placement Demonstrates No Advantage Over Debridement in the Treatment of Massive Irreparable Rotator Cuff Tears: A Dual-Armed Systematic Review and Meta-analysis of Over 1000 Patients. Am J Sports Med. Mar 2024; 52(4): 1088-1097. PMID 37369101
18. Sirignano M, Nyland J, Krupp R. Subacromial balloon spacer massive rotator cuff tear treatment systematic review and meta-analysis: Patient selection and physical therapy may be keys to outcome success. Knee Surg Sports Traumatol Arthrosc. Sep 2025; 32(9): 2346-2357. PMID 38922784
19. Atoun E, Oulianski M, Bachar-Avnieli I, et al. Subacromial Balloon Spacer for Irreparable Rotator Cuff Tear Treatment Shows Improved Pain and Strength at 5-Year Follow-Up. Arthroscopy. Feb 2024; 40(2): 543-550. PMID 37586666
20. Davey MS, Kaar K. Clinical outcomes at medium-term follow-up of sub-acromial balloon spacer insertion in the operative management of massive rotator cuff tears. Ir J Med Sci. Aug 2022; 191(4): 1687-1691. PMID 34480320

21. Deranlot J, Herisson O, Nourissat G, et al. Arthroscopic Subacromial Spacer Implantation in Patients With Massive Irreparable Rotator Cuff Tears: Clinical and Radiographic Results of 39 Retrospectives Cases. Arthroscopy. Sep 2017; 33(9): 1639-1644. PMID 28602388
22. Dhir R, Prinja A, Singh J, et al. The role of biodegradable spacer implantation under local anesthesia for patients with massive rotator cuff tears and significant medical comorbidities. JSES Rev Rep Tech. Aug 2022; 2(3): 310-314. PMID 37588874
23. Familiari F, Nayar SK, Russo R, et al. Subacromial Balloon Spacer for Massive, Irreparable Rotator Cuff Tears Is Associated With Improved Shoulder Function and High Patient Satisfaction. Arthroscopy. Feb 2021; 37(2): 480-486. PMID 33068742
24. Garofalo R, De Crescenzo A, Fontanarosa A, et al. Rotator cuff repair protected with subacromial balloon spacer shows a low rate of non-healing. Knee Surg Sports Traumatol Arthrosc. Jun 2022; 30(6): 2123-2129. PMID 35022825
25. García Moreno J, Correa Bellido P, Salazar Aguilar JR, et al. Results after the application of biodegradable spacer balloons as a therapeutic option in non-repairable massive ruptures of the shoulder rotator cuff. Rev Esp Cir Ortop Traumatol. 2022; 66(1): 68-73. PMID 33663991
26. Garríguez-Pérez D, Lópiz Y, García-Fernández C, et al. Poor Results After Arthroscopic Treatment of Irreparable Rotator Cuff Tears Using a Subacromial Balloon Spacer. J Am Acad Orthop Surg. Oct 01 2022; 30(19): e1260-e1268. PMID 35834816
27. Gervasi E, Maman E, Dekel A, et al. Fluoroscopy-guided biodegradable spacer implantation using local anesthesia: safety and efficacy study in patients with massive rotator cuff tears. Musculoskelet Surg. Dec 2016; 100(Suppl 1): 19-24. PMID 27900707
28. Gervasi E, Maman E, Dekel A, et al. Fluoroscopically Guided Subacromial Spacer Implantation for Massive Rotator Cuff Tears: Two Years of Prospective Follow-up. Orthop J Sports Med. Apr 2021; 9(4): 2325967121993469. PMID 33889641
29. Holschen M, Brand F, Agneskirchner JD. Subacromial spacer implantation for massive rotator cuff tears: Clinical outcome of arthroscopically treated patients. Obere Extrem. 2017; 12(1): 38-45. PMID 28868086
30. Kaisidis A, Pantos P, Bochlos D. The subacromial spacer system for irreparable posterosuperior rotator cuff tears: A retrospective study of 47 patients with a two-year follow-up. Shoulder Elbow. Jul 2022; 14(1 Suppl): 76-82. PMID 35845623
31. Malahias MA, Brilakis E, Avramidis G, et al. Satisfactory mid-term outcome of subacromial balloon spacer for the treatment of irreparable rotator cuff tears. Knee Surg Sports Traumatol Arthrosc. Dec 2019; 27(12): 3890-3896. PMID 30888449
32. Malahias MA, Brilakis E, Avramidis G, et al. Arthroscopic partial repair with versus without biodegradable subacromial spacer for patients with massive rotator cuff tears: a case-control study. Musculoskelet Surg. Dec 2021; 105(3): 247-255. PMID 32124328
33. Maman E, Kazum E, Abboud JA, et al. Biodegradable balloon spacer for massive irreparable rotator cuff tears is associated with improved functional outcomes, low revisions, and complications rate at minimum one year follow-up. Int Orthop. Mar 2022; 46(3): 573-579. PMID 35112145
34. Metcalfe A, Arnold S, Parsons H, Parsons N, Bhabra G, Brown J, Bush H, Diokno M, Elliott M, Fox J, Gates S, Gemperl Mannion E, Haque A, Hutchinson C, Kearney R, Khan I, Lawrence T, Mason J, Rahman U, Stallard N, Ul-Rahman S, Viswanath A, Wayte S, Drew S, Underwood M. Subacromial spacers for adults with symptomatic, irreparable rotator cuff tears: the START:REACTS novel group sequential adaptive RCT. Southampton (UK): National Institute for Health and Care Research; 2023 Aug. PMID 37871150.
35. Minarro JC, Bassi C, Boltuch A, et al. Subacromial Balloon Spacer Does Not Reduce the Retear Rate for Massive Rotator Cuff Tears: A Comparative Study. Arthroscopy. Feb 2024; 40(2): 242-248. PMID 37394148
36. Piekaar RSM, Bouman ICE, van Kampen PM, et al. Early promising outcome following arthroscopic implantation of the subacromial balloon spacer for treating massive rotator cuff tear. Musculoskelet Surg. Dec 2018; 102(3): 247-255. PMID 29151232

37. Piekaar RSM, Bouman ICE, van Kampen PM, et al. The subacromial balloon spacer for massive irreparable rotator cuff tears: approximately 3 years of prospective follow-up. Musculoskelet Surg. Aug 2020; 104(2): 207-214. PMID 31250379
38. Prat D, Tenenbaum S, Pritsch M, et al. Sub-acromial balloon spacer for irreparable rotator cuff tears: Is it an appropriate salvage procedure?. J Orthop Surg (Hong Kong). 2018; 26(2): 2309499018770887. PMID 29665765
39. Ricci M, Vecchini E, Bonfante E, et al. A clinical and radiological study of biodegradable subacromial spacer in the treatment of massive irreparable rotator cuff tears. Acta Biomed. Oct 18 2017; 88(4S): 75-80. PMID 29083357
40. Ruiz Ibán MA, Lorente Moreno R, Ruiz Díaz R, et al. The absorbable subacromial spacer for irreparable posterosuperior cuff tears has inconsistent results. Knee Surg Sports Traumatol Arthrosc. Dec 2018; 26(12): 3848-3854. PMID 30097688
41. Senekovic V, Poberaj B, Kovacic L, 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. Apr 2013; 23(3): 311-6. PMID 23412287
42. Senekovic V, Poberaj B, Kovacic L, et al. The biodegradable spacer as a novel treatment modality for massive rotator cuff tears: a prospective study with 5-year follow-up. Arch Orthop Trauma Surg. Jan 2017; 137(1): 95-103. PMID 27957596
43. Vecchini E, Gulmini M, Peluso A, et al. The treatment of irreparable massive rotator cuff tears with inspace balloon: rational and medium-term results. Acta Biomed. Mar 10 2022; 92(S3): e2021584. PMID 35604261
44. Yallapragada RK, Apostolopoulos A, Katsougrakis I, et al. The use of a subacromial spacer-inspace balloon in managing patients with irreparable rotator cuff tears. J Orthop. Sep 2018; 15(3): 862-868. PMID 30166800
45. Yamak K, Karahan HG, Altay T, et al. Is Subacromial Balloon Spacer Appropriate for Treatment of Irreparable Rotator Cuff Tears in Elderly Patients?. Ortop Traumatol Rehabil. Dec 31 2019; 21(6): 417-426. PMID 32100716
46. Food and Drug Administration (FDA). De Novo Classification Request For Inspace Subacromial Tissue Spacer System. 2020; https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN200039.pdf. Accessed February 12, 2025.
47. Haque A, Parsons H, Parsons N, et al. Two-Year Follow-up of a Group-Sequential, Multicenter Randomized Controlled Trial of a Subacromial Balloon Spacer for Irreparable Rotator Cuff Tears of the Shoulder (START:REACTS). Am J Sports Med. Mar 28 2025: 3635465251326891. PMID 40156172
48. Oh JH, Park JH, Jeong HJ, et al. Comparing Clinical Outcomes After Subacromial Spacer Insertion Versus Other Reconstruction Methods in the Treatment of Irreparable Massive Rotator Cuff Tears. Orthop J Sports Med. Sep 2019; 7(9): 2325967119869600. PMID 31598526
49. Fares MY, Koa J, Singh J, et al. The Insertion of a Subacromial Balloon Spacer Can Provide Symptom Relief and Functional Improvement at a Minimum 5-Year Follow-Up in Patients With Massive Irreparable Rotator Cuff Tears. Arthrosc Sports Med Rehabil. Apr 2024; 6(2): 100907. PMID 38495636
50. Kishan A, Russo R, Goldfarb SI, et al. Arthroscopic Subacromial Balloon Spacer for Massive Rotator Cuff Tears Demonstrates Improved Shoulder Functionality and High Revision-Free Survival Rates at a Minimum 5-Year Follow-Up. Arthroscopy. Jun 22 2024. PMID 38914297
51. Savarese E, Aicale R, Romeo R, et al. Shoulder balloon spacer for massive irreparable rotator cuff tears results in significant improvements. Knee Surg Sports Traumatol Arthrosc. Aug 27 2024. PMID 39189116
52. Sirignano M, Nyland J, Krupp R. "Surviving the dip" after subacromial balloon spacer implantation for massive rotator cuff tear treatment: a retrospective case series. Eur J Orthop Surg Traumatol. Nov 14 2024; 35(1): 1. PMID 39540990
53. American Academy of Orthopaedic Surgeons (AAOS). Evidence-based clinical practice guideline on the management of rotator cuff injuries. 2019.

https://www.aaos.org/globalassets/quality-and-practice-resources/rotator-cuff/rotator-cuff-cpg-final-12-20-19.pdf. Accessed Feb 9, 2025.
54. National Institute For Health And Care Excellence (NICE). Biodegradable subacromial spacer insertion for rotator cuff tears (Interventional procedures guidance [IPG775]). Nov 2023. https://www.nice.org.uk/guidance/ipg775. Accessed February 3, 2025.

Documentation for Clinical Review

- No records required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	29999	Unlisted procedure, arthroscopy
HCPCS	C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/01/2025	New policy.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary: Healthcare Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield of California, are: (a) consistent with Blue Shield of California medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the member; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the member's illness, injury, or disease.

Investigational or Experimental: Healthcare Services which do not meet ALL of the following five (5) elements are considered investigational or experimental:

A. The technology must have final approval from the appropriate government regulatory bodies.

- This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
- Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
- The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.

B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

C. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

D. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as, or more than, established alternatives.

E. The improvement must be attainable outside the investigational setting.
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	AFTER Blue font: Verbiage Changes/Additions
New Policy Policy Statement: N/A	Balloon Spacers for Treatment of Irreparable Rotator Cuffs of the Shoulder 7.01.180 Policy Statement: I. Subacromial balloon spacer implantation is considered **investigational** as a treatment for massive, irreparable, full-thickness rotator cuff tears.