Balloon Spacer Devices for Management of Massive Rotator Cuff Tears

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Policy contains: subacromial balloon spacer, biodegradable balloon spacer, shoulder spacer, rotator cuff tear, massive irreparable rotator cuff tear, rotator cuff injuries.

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Coverage policy

Subacromial balloon spacer implantation for the treatment of massive, irreparable rotator cuff tears is considered investigational/not clinically proven and therefore not medically necessary.

Background

Rotator cuff tears affect adults across their lifespan and become more common with age (Varacallo, 2024). Population studies that include people without symptoms estimate full-thickness tears in roughly 20% of adults (Yamamoto, 2010). Prevalence rises further with aging, with more than 50% of people in their 80s showing rotator cuff changes on imaging (Tempelhof, 1999). Many tears remain silent at first, which delays diagnosis and allows deterioration of tendon and muscle (Keener, 2015).

What defines a massive, irreparable rotator cuff tear? Clinicians use size and anatomy to define massive tears, which account for about 10% to 40% of diagnosed full-thickness tears (Agout, 2018). A tear larger than five centimeters or involving two or more cuff tendons qualifies as massive (Sánchez-Losilla, 2022). Tears that are considered irreparable show a 50% or more fatty change on magnetic resonance imaging, tendon retraction to the socket edge, or a space between the acromion and the ball of the upper arm bone of less than seven millimeters on radiographs (Sánchez-Losilla, 2022). These markers signal tissue that surgeons cannot mobilize back to bone with acceptable tension and that will not regain function after a standard repair (Virk, 2016).

Reverse total shoulder arthroplasty is the most common operation when shoulder function is lost and the cuff cannot be restored (Virk, 2016). Surgeons place the ball on the shoulder blade and the socket on the upper arm so the deltoid muscle can lift the arm in place of the torn cuff (Berliner, 2024). They select this option most often for older adults or for any individual with arthritis or pseudoparalysis who needs reliable pain relief and overhead use of the arm (Berliner, 2024). The tradeoff in reverse total should arthroplasty is the use of a prosthesis with long-term risks, so surgeons reserve it for individuals whose goals cannot be achieved with repair, partial repair, or tendon transfer (Virk, 2016).

For adults who prefer to preserve the native joint when repair is not feasible and arthroplasty is undesirable, surgeons may use a subacromial balloon spacer to restore spacing and improve mechanics (Sheean, 2024). This biodegradable implant sits between the acromion and the upper arm bone, helps recenter the ball, and reduces painful contact when the rotator cuff cannot stabilize the joint (Sheean, 2024). It dissolves over about one year and may be combined with other limited procedures to control pain and maintain motion (Sheean, 2024). In the United States, the Food and Drug Administration issued a De Novo classification in 2021 for a resorbable shoulder spacer for adults 65 years or older with massive, irreparable tears and mild to moderate arthritis, which guides labeling, testing, and use (Food and Drug Administration, 2021).

Findings

Evidence for biodegradable subacromial balloon spacers is mixed. Observational studies show that individuals who received these spacers experienced substantial improvements from baseline at 24 months: Constant-Murley scores increased from 34.8 to 67.9, visual analog pain scores decreased from 6.6 to 2.0, flexion improved from 108.5° to 151.2°, and approximately 83% achieved the minimal clinically important difference. However, comparative meta-analyses do not demonstrate superiority of the spacers over partial repair or arthroscopic debridement, with negligible effects on pain (mean difference −0.11) and motion. Randomized data are comparator dependent: adding a spacer to debridement yields worse function at 12 months and inferior 24-month quality of life, whereas outcomes are comparable to partial repair with shorter operative time and modest early advantages in elevation. Methodological limitations, heterogeneity, and sparse long-term threshold outcomes temper certainty. Guideline discordance mirrors these patterns, with the National Institute for Health and Care Excellence advising against routine use outside trials when debridement is suitable, and the American Academy of Orthopaedic Surgeons offering a consensus option for selected individuals without glenohumeral osteoarthritis.

Guidelines

Clinical practice guidelines present divergent recommendations regarding the use of biodegradable subacromial balloon spacers for the treatment of irreparable rotator cuff tears, reflecting the conflicting nature of the available evidence. The National Institute for Health and Care Excellence recommended against biodegradable

subacromial spacer use when arthroscopic debridement is suitable, and restricted use to research when debridement is not suitable. The committee based this chiefly on a U.K. multicenter randomized clinical trial in which debridement plus spacer was inferior to debridement alone at 12 months on Oxford Shoulder Score and Constant score, and the trial was stopped for futility. Evidence syntheses and a randomized clinical trial against partial repair show short- to mid-term improvements in pain and function within the group after spacer implantation, but long-term benefits remain uncertain (National Institute for Health and Care Excellence, 2023). Conversely, the American Academy of Orthopedic Surgeons states that balloon spacers may be considered for massive, irreparable rotator cuff tears without arthritis, but only as a consensus-based option — the lowest evidence grade — given inconsistent evidence and the need for individualized decision-making (American Academy of Orthopedic Surgeons, 2025). This consensus rating acknowledges the absence of reliable evidence due to significant heterogeneity and conflicting results among existing studies, including randomized trials that show both favorable and unfavorable outcomes for the device, depending on the comparator (American Academy of Orthopedic Surgeons, 2025).

Systematic reviews

Symptom and function improvement versus comparative advantage

Across the literature, balloon spacers have been shown to reliably produce within-group gains but not superiority over established options. Kunze synthesized contemporary reports and found high proportions of individuals achieving minimal clinically important difference on the Constant-Murley score (83%), American Shoulder and Elbow Surgeons score (83% – 87.5%), Oxford Shoulder Score (78% – 87%), and numeric pain rating scale (69% – 74%) from a pooled cohort (n = 748; spacer subset n = 379). However, achievement of a patient-acceptable symptom state and substantial clinical benefit was inconsistent and methodologically heterogeneous, limiting the ability to infer absolute outcome levels and durability of balloon spacers (Kunze, 2023).

In a head-to-head pooled comparison, Sandler reported greater visual analog scale pain reduction with debridement (adjusted mean difference −0.7, $P < 0.001$) and larger Constant-Murley gains (+5.5, $P < 0.001$), with neither study arm meeting the patient-acceptable symptom state threshold for pain (Sandler, 2024). The randomized evidence aligns with other researchers' findings. Metcalfe found Oxford Shoulder Scores favored debridement at 12 months (mean 34.3 versus 30.3; adjusted difference −4.2, 95% confidence interval −7.8 to −0.6, $P = 0.026$) in a trial that was stopped early for futility (Metcalfe, 2022).

Movement domains and what they mean clinically

Improvements in movement occurred with both approaches, but advantages differed by plane and did not change the overall comparative picture. Sandler observed relatively larger gains in abduction and external rotation with spacers, whereas forward flexion gains were larger with debridement. These directional differences did not translate into superior overall function for spacers (Sandler, 2024). Metcalfe reported no clinically meaningful advantage for spacers across secondary outcomes despite standardized rehabilitation and blinding, reinforcing that plane-specific gains do not overcome the absence of comparative benefit (Metcalfe, 2022).

Safety and durability

Device-specific risks and uncertain durability weigh against routine adoption. In Sandler, nearly one-half of spacer complications were migration or rupture, one-quarter of spacer reoperations were device revision or removal, and mean time to reverse shoulder arthroplasty was shorter after spacers than after debridement

(Sandler, 2024). Kunze's review emphasizes heterogeneity in thresholds and designs that can inflate apparent success in single-arm reports, underscoring the need for consistent definitions and comparative designs before concluding durable benefit (Kunze, 2023). Metcalfe's masked, intraoperative randomization and standardized rehabilitation minimize bias and provide the highest-quality signal to date that spacers do not confer comparative benefit (Metcalfe, 2022).

Meta-analyses

Comparative evidence does not show an advantage of the subacromial balloon spacer over alternative surgery (Daher, 2023; Sirignano, 2024). Daher's meta-analysis pooled three comparative studies (n = 311) and found no significant differences across pain, quality of life, function, or range of motion; for example, the pooled mean difference for visual analog scale pain was −0.11 (95% confidence interval −0.48 to 0.27), and range of motion contrasts were negligible for abduction (−2.6°) and forward elevation (−0.4°) (Daher, 2023). Sirignano's systematic review included twenty-seven studies spanning both comparative and noncomparative designs, with only six being comparative, which explains the difference between the total sample (n = 894) and the smaller pooled comparative analyses; its meta-analysis likewise reported a pooled visual analog scale effect of −0.11 (95% confidence interval −0.44 to 0.22) and no overall difference in active shoulder flexion (overall effect size 0.11, p=0.87) (Sirignano, 2024).

This pattern contrasts with noncomparative cohorts, which consistently showed within-group gains after balloon spacer implantation at 12 and 24 months in pain, function, and motion, even as pooled head-to-head comparisons remained null (Sirignano, 2024; Daher, 2023). Methodological quality was fair as measured by the Modified Coleman Methodology Score (mean 61.4 ± 11), and heterogeneity and small samples with clinically diverse patients limited precision (Sirignano, 2024; Daher, 2023). Outcomes may be better in carefully selected patients who can re-establish the glenohumeral force couple and who adhere to prescribed physical therapy; closer alignment between surgical and rehabilitation teams, with clearer reporting of postoperative rehabilitation, may further improve results (Sirignano, 2024).

Other evidence

Across studies, individuals improved meaningfully from baseline. In a level-one randomized controlled trial, use of a subacromial balloon spacer was compared with arthroscopic partial repair. The use of the spacer produced similar improvements to partial repair in the American Shoulder and Elbow Surgeons score and the Western Ontario Rotator Cuff Index without between-group pain differences, but the Constant–Murley score favored the balloon spacer at week six and month 24 ($P = 0.021$ and $P = 0.05$), and forward elevation favored the balloon spacer at every measured time point through 24 months ($P \leq 0.0048$ after week six) (n = 184) (Verma, 2022). In a retrospective series, the adjusted Constant–Murley score rose to 76.0 at approximately 33 months with gains in elevation, abduction, and external rotation (n = 39 shoulders) (Deranlot, 2017).

In a multicenter randomized controlled trial with debridement as the comparator, debridement alone outperformed debridement plus balloon on the Western Ontario Rotator Cuff Index and the Patient Global Impression of Change at 24 months, with the Oxford Shoulder Score trending the same way; range of motion data was not collected (n = 117) (Haque, 2025). In a separate report, adverse events and reoperations were infrequent and balanced in the randomized controlled trials, and no device-related serious events were reported (Verma, 2022). Operative time was shorter with the balloon spacer than partial repair, 44.6 minutes versus 71.2 minutes ($P < 0.0001$) (Verma, 2022). Operative time was shorter with InSpace than partial repair, 44.6 versus 71.2 minutes ($P < 0.0001$) (Verma, 2022). Deranlot reported one revision for spacer migration and limited

radiographic progression, with Hamada advancing one stage in four shoulders and three stages in one (Deranlot, 2017).

References

On 9/4/2025, 2025 we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were subacromial balloon spacer, biodegradable balloon spacer, shoulder spacer, rotator cuff tear, massive irreparable rotator cuff tear, reverse shoulder arthroplasty, tendon transfer, arthroscopic debridement. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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