

Zimmer Biomet: Sequencing ROSA Shoulder

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Decision date and information cutoff: March 1, 2024

Decision scope: How to sequence the initial U.S. commercial rollout of ROSA Shoulder and the evidence gates for expansion

Case convention: The decision assignment is hypothetical. Company disclosures are historical; no private deliberations are represented.

The decision

On March 1, 2024, Zimmer Biomet's strategy team is preparing for the expected U.S. availability of ROSA Shoulder in the second half of 2024. FDA has granted 510(k) clearance. The team must propose how to sequence the initial commercial rollout and what evidence should govern expansion: offer the system broadly as it becomes available, begin with selected surgeons and sites and expand against readiness and use evidence, or adopt another staged approach.

The question is about execution after clearance. It is not whether to pursue clearance or whether the system has already demonstrated clinical superiority. No public disclosure specifies a launch budget, a binding resource constraint, site capacity, or a management conflict. Treat rollout alternatives and any proposed gates as a hypothetical strategy assignment.

A broad orthopedic portfolio

Zimmer Biomet sells orthopedic products across several categories. In 2023, company net sales were \$7.394 billion, up 6.5% from 2022. Knees were \$3.038 billion, Hips \$1.967 billion, S.E.T. \$1.753 billion, and Other \$636 million. S.E.T. means Sports Medicine, Extremities and Trauma; the category includes Craniomaxillofacial and Thoracic (CMFT) products. The company reported that "Other" sales increased 11.6%, primarily due to higher ROSA robot sales. The category also includes Technology, Surgical and Bone Cement products, so its growth is not a ROSA-only measure. [P1]

Management attributed Knees and Hips growth to a recovery in elective procedures, improved supply chain and new product launches. It attributed S.E.T. growth to CMFT, sports medicine and upper extremities, partly offset by trauma and reimbursement factors. These are company explanations; the public information does not isolate each factor's contribution. [P1]

ROSA Shoulder clears a regulatory milestone

On February 22, 2024, Zimmer Biomet announced FDA 510(k) clearance for ROSA Shoulder, which it described as the fourth ROSA application in five years. The company said the system was designed for anatomic and reverse shoulder replacement, integrates with its Identity Shoulder portfolio and Signature ONE Surgical Planning 2.0, and provides intraoperative data. These product descriptions and intended functions are company statements. [P3]

The announcement said U.S. commercial availability was expected in the second half of 2024. That was a forecast, not a reported launch. Zimmer Biomet described a cadaveric study of the system but cautioned that cadaveric studies are not indicative of clinical performance. The release disclosed that Mayo Clinic has a financial interest in the referenced technology. Neither the clearance nor the cadaveric work establishes comparative patient outcomes, clinical superiority, adoption, or hospital economics. [P3]

Zimmer Biomet's February 8 results release reported 2023 sales growth of 6.5% on a reported basis and 7.5% at constant currency. For 2024, management guided to reported sales growth of 4.5%-5.5%, including a stated 0.5 percentage-point foreign-exchange headwind, and constant-currency growth of 5.0%-6.0%. This company-wide guidance does not identify a ROSA Shoulder target. [P2]

What robotic-assistance studies can-and cannot-say

Published research offers context on two questions: whether robotic assistance changes technical accuracy or patient outcomes, and how users adapt to a robotic workflow. The available studies below concern knee arthroplasty, not ROSA Shoulder. They do not establish shoulder outcomes or Zimmer Biomet's commercial returns.

Evidence available by the cutoff	What it reports	Boundary for this decision
A 2023 meta-analysis of seven randomized trials of robotic versus conventional total knee arthroplasty	The authors found better pooled alignment measures with robotic assistance, but no statistically significant pooled difference in knee scores, WOMAC, range of motion, or complications. The included systems were ROBODOC and NAVIO. [A1]	It does not study ROSA or shoulder procedures, and alignment is not the same as improved patient function.
A retrospective study of one surgeon's first 100 ROSA knee procedures compared with 100 manual procedures	Mean operative time was 80.2 minutes for ROSA and 68.2 minutes manually. The authors summarized learning as roughly 70 cases, with different mastering-phase markers in the abstract and main text. [A2]	One surgeon and team, knee procedures, and a particular implant do not establish the shoulder learning curve or rollout burden across multiple sites.

Questions for a rollout plan

The company's disclosures establish a regulatory milestone and an expected availability window, while leaving important operating questions open. The team's proposal should address which surgeons and sites, if any, should be included first; what training and service support would be required; what outcomes should be tracked; and what evidence should trigger broader availability, a pause, or a change in support.

Potential measures could include surgeon and staff readiness, setup and procedure workflow, system use, technical performance, patient outcomes, and hospital experience. The team must

specify how each measure would be collected and interpreted. No particular site population, threshold, or clinical benefit is given in the public record.

Known at the cutoff	Not established by the cited public evidence
510(k) clearance; issuer forecast of U.S. availability in H2 2024; integration with the Identity Shoulder portfolio and Signature ONE planning; company-reported ROSA contribution to “Other” category growth. [P1] [P3]	ROSA Shoulder units or installed base; surgeon/site readiness; procedure volume; utilization; clinical outcomes; comparative effectiveness; implementation cost; reimbursement; pricing, margin or customer economics; launch budget or binding internal constraint.

The choice

Should Zimmer Biomet prepare a broad offer for the stated availability window, start with a selected group of surgeons and sites and expand as evidence accumulates, or use another sequence? What evidence gates would make the chosen sequence workable? Address the strongest argument against your proposal and distinguish regulatory clearance, product capability claims, clinical evidence and commercial performance.

Sources and conventions

All information is limited to material public by March 1, 2024. Company statements and forecasts are attributed. Reported “Other” category revenue is not presented as ROSA revenue. Academic findings are limited to knee arthroplasty and are not treated as shoulder or company-specific estimates. No post-cutoff launch outcome is included.

- **P1:** Zimmer Biomet FY2023 Form 10-K, filed Feb. 23, 2024, Item 7 product-category table and discussion, printed pp. 29-30.
- **P2:** Zimmer Biomet Q4/FY2023 results release, Feb. 8, 2024, FY/Q4 results, 2024 guidance and constant-currency explanation.
- **P3:** Zimmer Biomet ROSA Shoulder 510(k)-clearance announcement, Feb. 22, 2024, paragraphs 1-6, 8 and 10.
- **A1:** Alrajeb et al. (2023), randomized-trial systematic review/meta-analysis of robotic versus conventional TKA, *Eur J Orthop Surg Traumatol* 34(3), 1333-1343.
- **A2:** Kenanidis et al. (2023), ROSA TKA operative-time learning-curve study, *Eur J Orthop Surg Traumatol* 33, 3357-3363.