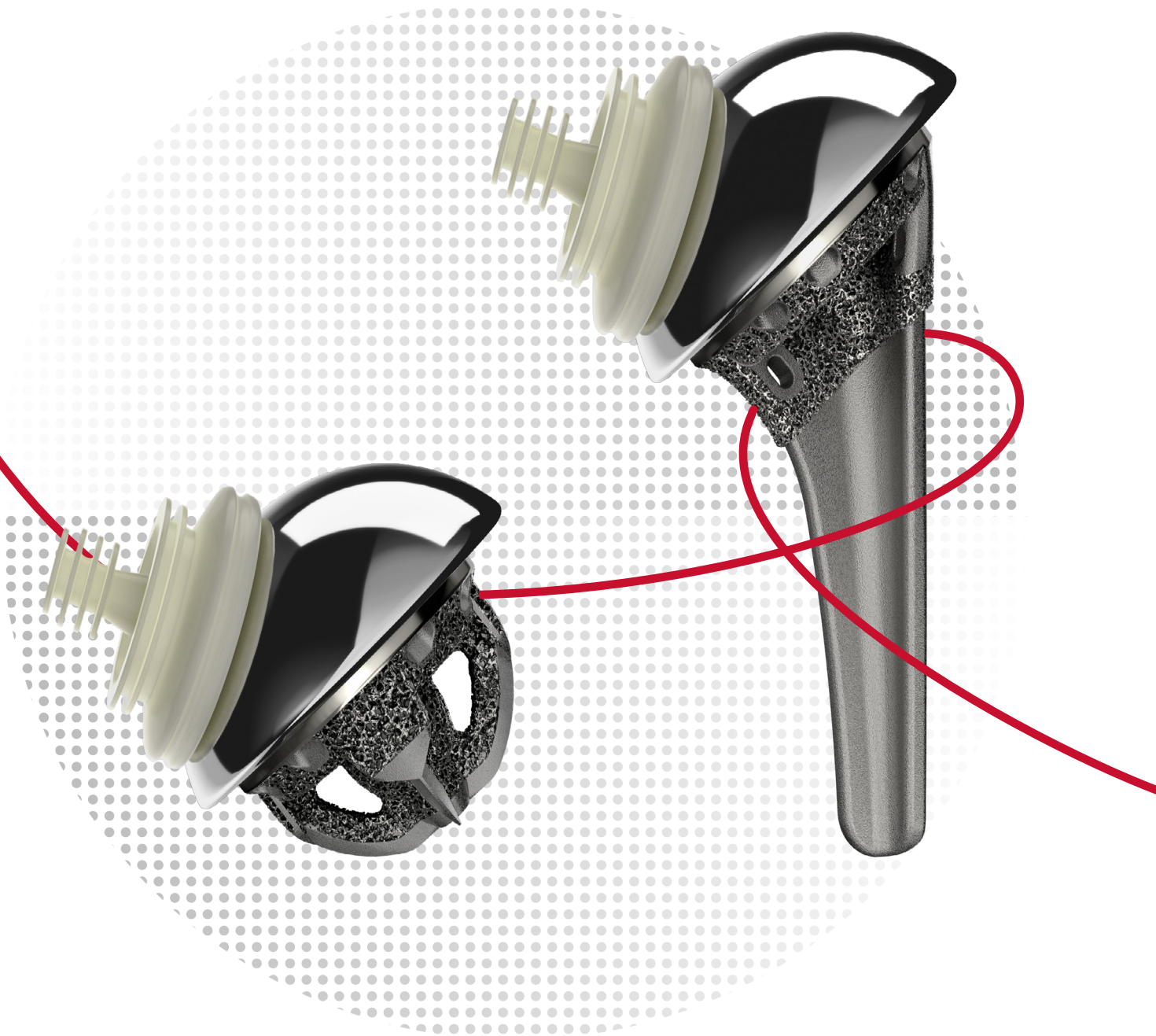


# INHANCE™

SHOULDER SYSTEM

Value Analysis Brief



## Epidemiology

The use of Anatomic Shoulder Arthroplasty has been dramatically increasing in the United States, rising from 9.5 cases per 100,000 (29,685) to 12.5 cases per 100,000 (40,665) between 2012 to 2017.<sup>1</sup> From the years 2017- 2025, there is a projected ~235% increase in the volume of Shoulder Arthroplasties that will be performed. The growth of Shoulder Arthroplasty is expected to outpace the growth in total Hip and Knee Arthroplasty.<sup>2</sup>

## Unmet Needs in Shoulder Arthroplasty

### Intra and Post-Operative Complications and Reoperations

#### Glenoid Component Failure

**Failure of the glenoid component is a common cause for readmission and revision** after anatomic total shoulder arthroplasty. Studies have found glenoid component loosening to comprise 37.7% of all reported failures.<sup>3</sup> Patients with all-cause readmission at 90-days were shown to incur total hospital costs of \$82,348 compared to \$16,621 for patients who were not readmitted ( $p < 0.001$ ).<sup>4</sup>

#### Intraoperative Humeral Fracture

**The rate of intraoperative complications have been demonstrated to be as high as 2.5%, with the majority of these being fractures (1.6%).<sup>5</sup>** Intraoperative humeral fractures may result in the need for intraoperative stem exchange or suture cerclage, adding time and cost to the case.<sup>6,7</sup>

### Operating Room Times and Blood Loss

Shoulder arthroplasty procedures can be associated with **extended surgical durations and blood loss.**<sup>8,9,10,11</sup> Given operating room cost per-minute estimates of \$36-37, this time becomes a valuable resource that should be optimized.<sup>9</sup> Furthermore, **studies have shown that extended surgical duration is associated with a variety of postoperative medical complications and increased use of healthcare resources.**<sup>10,11</sup>

### Inefficiencies in Current System Designs

Current systems offer **no commonality** among instruments and little commonality among implants. Furthermore, new designs are often layered on top of older generation systems which requires **multiple trays with several different tray configurations.** This can lead to:<sup>12-15</sup>

- Pre-, intra-, and post-operative inefficiencies
- High reprocessing costs for surgical equipment (up to \$75/tray)
- Time-drain of maintaining multiple sets which may lead to staff spending up to an hour per shift searching for equipment and leading to added cost to train staff on many surgical sets
- Lifting and transportation of many surgical sets, which may increase the risk of injury

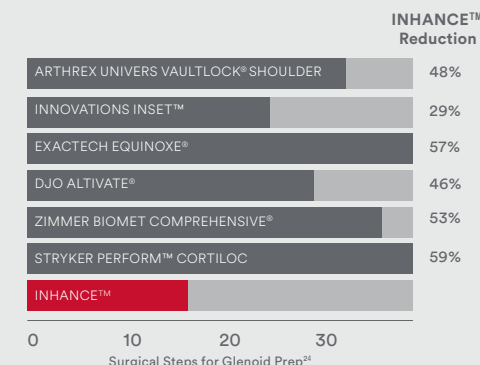
## INHANCE™ Shoulder System Design Features



5 OFFERING A STREAMLINED AND SIMPLIFIED SURGICAL TECHNIQUE & ONE STEP PREP™ FOR GLENOID PREPARATION

6 SHARED FOOTPRINT & COMMON PREPARATION FOR STEM & STEMLESS CONSTRUCTS

7 EFFICIENT INSTRUMENTATION, ONLY REQUIRING TWO TRAYS REGARDLESS OF CONSTRUCT



## Potential Clinical & Economic Benefit

**Cross-linked polyethylene glenoids (XLPE) have demonstrated lower revision rates** relative to other glenoid designs.<sup>3,16,17</sup> Vitamin E Cross-Linking has been shown to reduce wear particles by 780% when compared to unaged polyethylene.<sup>18</sup> Furthermore, glenoid preparation with the INHANCE Shoulder System results in 45% less bone removed compared to a traditional pegged glenoid.<sup>19</sup> Glenoid components designed to reduce the risk of revision and complications may significantly reduce the economic burden to the healthcare system.

**Intraoperative fracture rates have been shown to be lower in stemless compared to stemmed designs,** most likely due to the absence of intramedullary preparation and of the implantation of a stem.<sup>20</sup> A reduction in intraoperative fractures may reduce the risk of added time and cost to the case.

**Stemless constructs have been shown to be associated with lower operating room times compared to standard stems (up to 25 min lower).**<sup>9,21,22,23</sup> Shorter operative time may lower indirect marginal costs due to increased throughput and efficiency.

**Up to 16% lower estimated blood loss** with stemless compared to standard stems, which may reduce the need for costly transfusions.<sup>22,23</sup>

**The INHANCE™ Shoulder System offers a simplified surgical technique and optimized instrumentation, which may result in:**

1. **Efficiency** – Reducing the number of trays necessary to do a case may improve intraoperative efficiency and reduce the number of trays needing to be stored, retrieved, and set up.<sup>13,14,25</sup> Additionally, common preparation and shared footprint allows for conversion between stemless and stemmed constructs intraoperatively without requiring a backup system.
2. **Ease of Use & Consistency** – Allows surgical teams and staff to be trained on and become proficient with a single system vs. multiple different systems, which may improve consistency and repeatability.<sup>14,26</sup>
3. **\$300-375 estimated savings per case** through a reduction in sterilization\*

\*Assumes 6-7 trays (glenoid and humeral) currently used per case and 2 trays used with the INHANCE™ Shoulder System and a cost per tray of \$75.<sup>13</sup>

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**16. Table ST34 Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement by Glenoid Type (Primary Diagnosis OA)**

Glenoid Type	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	13 Yrs
Modular Metal Backed	627	2916	7.2 (6.3, 8.2)	14.9 (13.6, 16.3)	19.3 (17.8, 20.9)	22.5 (20.8, 24.2)	28.5 (26.4, 30.8)	
All Polyethylene	422	9649	1.5 (1.3, 1.7)	3.0 (2.7, 3.4)	3.9 (3.5, 4.3)	4.8 (4.4, 5.4)	6.9 (6.1, 7.7)	
Non Modular Metal Backed	51	848	3.1 (2.1, 4.5)	5.6 (4.1, 7.4)	5.9 (4.4, 7.9)	7.0 (5.2, 9.4)		
<b>TOTAL</b>	<b>1100</b>	<b>13413</b>						

**17. Table ST38 Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement Using All-Polyethylene Glenoids by Polyethylene Type (Primary Diagnosis OA)**

Polyethylene Type	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	13 Yrs
Non XPLE	313	5907	1.6 (1.3, 1.9)	3.4 (2.9, 3.9)	4.5 (3.9, 5.1)	5.7 (5.0, 6.4)	8.0 (7.1, 9.1)	
XLPE	109	3742	1.4 (1.0, 1.8)	2.5 (2.0, 3.1)	2.9 (2.4, 3.6)	3.2 (2.7, 3.9)	4.1 (3.2, 5.1)	
<b>TOTAL</b>	<b>422</b>	<b>9649</b>						

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