

# Sidus<sup>®</sup> Stem-Free Shoulder

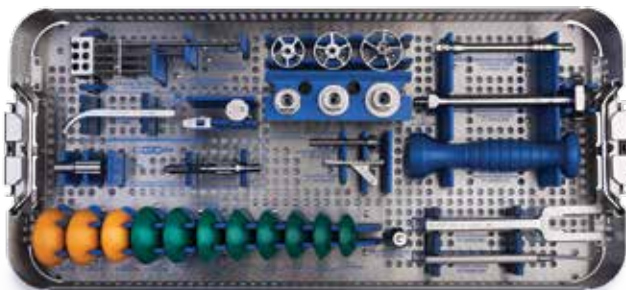
Secure fixation through a bone-sparing design





### **An efficient, bone-sparing solution, should revision become necessary**

- Humeral shaft is untouched, minimal bone is removed from the humerus.
- Anchor contains four large windows for an enhanced view of the humerus, in case of revision.
- Anchor contains osteotome slots that minimize the impact on bone in case of revision surgery.

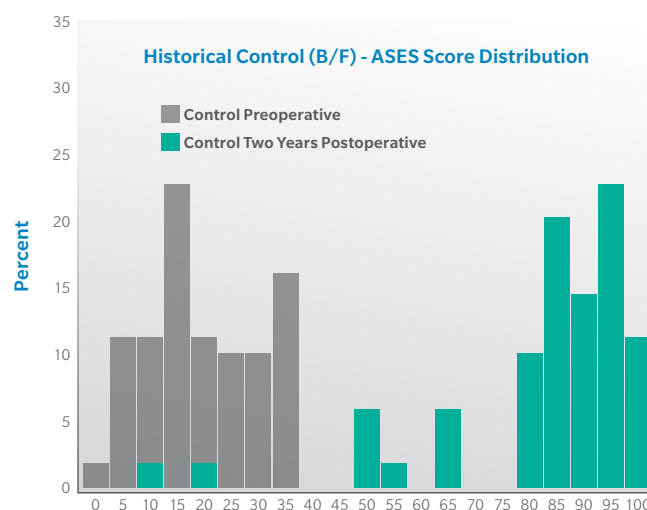
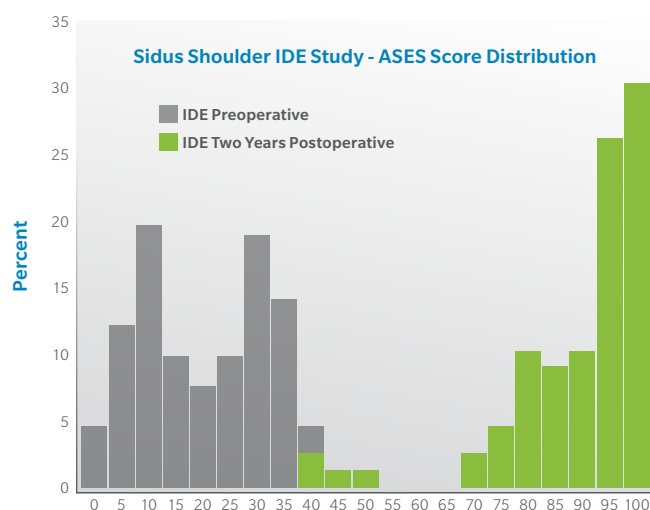


### **Procedural efficiency with easy-to-use instrumentation**

- Single-layer tray weighing less than 10 lbs.
- Streamlined flow of the instruments to mimic the surgical technique.
- Revision instruments included in the single tray.

# Anatomic reconstruction while preserving bone stock

Zimmer Biomet continues to lead the way in bone-preserving arthroplasty solutions with the Sidus Stem-Free Shoulder System. The Sidus System has demonstrated continued success with clinical data from a two year IDE study in the US and Canada<sup>1</sup>. The studies targeted patients with good bone stock and osteoarthritis.



## Clinically-proven, bone-sparing alternative for Total Shoulder Arthroplasty<sup>1</sup>

In a two-year analysis of 71 patients from the Sidus IDE Study:

- **98.5%** of patients have over a **30** point improvement on the ASES score from preoperative.
- Excellent survivorship of **95.8%**; three patients underwent revision due to integrity of the subscapularis.
- **98.5%** of patients completing two year visits successfully passed the radiographic success criteria with no progressive radiolucencies of the humeral component >2 mm and no migration or subsidence of the humeral component.

In a two-year analysis of 48 patients from the Bigliani/Flatow<sup>®</sup> Shoulder Historical Control Study.<sup>5</sup>

- 91.7% of patients have over a 30 point improvement on the ASES from preoperative.
- 97.9% survivorship; one revision due to anterior shoulder pain.
- 100% of patients completing two year follow-up successfully passed the radiographic success criteria with no progressive radiolucencies of the humeral component >2 mm and no migration or subsidence of the humeral component.

## Clinical IDE study demonstrated increased mobility and reduced pain compared to preoperative state<sup>1</sup>

In a two-year analysis of 71 patients from the Sidus IDE Study:

- Statistically significant improvement in range of motion.
- Significant improvement in the functions of daily life.
- **92.6%** of the patients were either very satisfied or satisfied at two years post-op.

In a two-year analysis of 48 patients from the Bigliani/Flatow Shoulder Historical Control Study:<sup>5</sup>

- Significant improvement in range of motion when compared to preoperative state.
- Significant improvement in functions of daily life.
- Satisfaction data was not recorded for Bigliani/Flatow Shoulder.

Sidus Shoulder IDE	Range of motion	
	Pre-op	2-yr post-op
Forward Elevation Active	93.7 ± 25.3	141.5 ± 25.6
Forward Elevation Passive	93.7 ± 25.3	141.5 ± 25.6
External Rotation Arm at Side Active	20.4 ± 15.7	50.9 ± 17.1
External Rotation Arm at Side Passive	23.8 ± 18	55.2 ± 16.7
External Rotation Arm at 90° Active	24.9 ± 26.6	66.8 ± 25.6
External Rotation Arm at 90° Passive	26.9 ± 26.9	72 ± 24.9
Cross-body Adduction Active	35.6 ± 12.6	28.9 ± 8.1
Cross-body Adduction Passive	33.7 ± 12.4	27 ± 7.2

Sidus Shoulder IDE	Not Difficult	
	Pre-op	Post-op
Put on a coat	1/71 (1.4%)	54/68 (79.4%)
Sleep on affected side	1/71 (1.4%)	41/68 (60.3%)
Wash back/Do up bra in back	1/71 (1.4%)	34/68 (50.0%)
Manage toileting	7/71 (9.9%)	61/68 (89.7%)
Comb hair	9/71 (12.7%)	63/68 (92.6%)
Reach a high shelf	1/71 (1.4%)	45/68 (66.2%)
Lift 10 pounds over head	0/71 (0%)	41/68 (60.3%)
Throw ball	0/71 (0%)	38/68 (55.9%)
Do usual work	0/71 (0%)	58/68 (85.3%)
Do usual sport	2/71 (2.8%)	46/68 (67.6%)

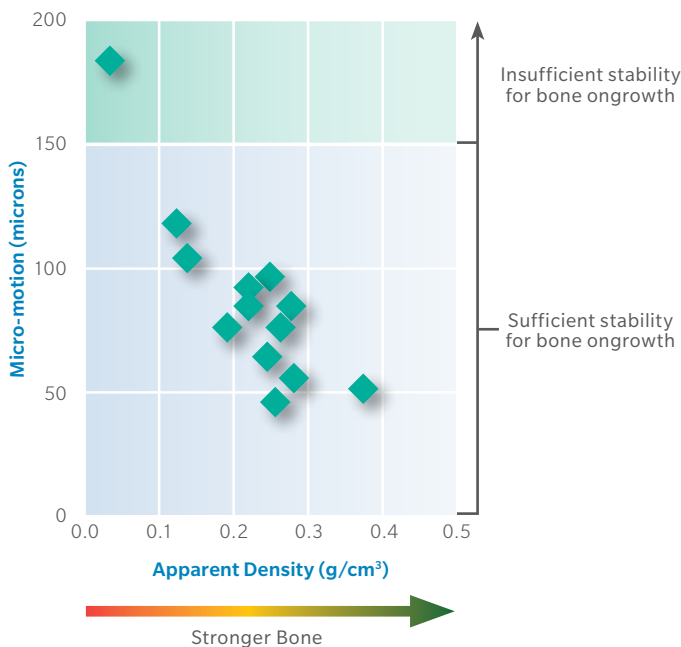
B/F Historical Control	Range of motion	
	Pre-op	2-yr post-op
Forward Elevation Active	86.4 +/- 6.9	126.80 +/- 7.3
Forward Elevation Passive	100.61 +/- 7.7	139.51 +/- 6.9
External Rotation Arm at Side Active	17.03 +/- 4.0	47.14 +/- 4.7
External Rotation Arm at Side Passive	23.32 +/- 5.3	51.27 +/- 5.0

B/F Historical Control	Not Difficult	
	Pre-op	Post-op
Put on a coat	2/48 (4.2%)	30/48 (62.5%)
Sleep on affected side	0/48 (0%)	28/48 (58.3%)
Wash back/Do up bra in back	1/48 (2.1%)	13/48 (27.1%)
Manage toileting	8/48 (16.7%)	38/48 (79.2%)
Comb hair	1/48 (2.1%)	33/48 (68.8%)
Reach a high shelf	1/48 (2.1%)	20/48 (41.7%)
Lift 10 pounds over head	1/48 (2.1%)	18/48 (37.5%)
Throw ball	2/48 (4.2%)	23/48 (47.9%)
Do usual work	0/48 (0%)	27/48 (56.3%)
Do usual sport	4/48 (8.3%)	26/48 (54.2%)

## Designed for anatomic flexibility and secure fixation<sup>1-3</sup>

- Position of Anchor is independent of humeral canal, enabling optimal coverage and tensioning.
- Flexibility to mate with a variety of Zimmer Biomet Glenoids.<sup>4</sup>
- Anchor geometry and surface finishes designed to resist rotational and lever-out forces.
- Four open-fin press-fit anchors designed to provide rotational stability and allow for bone through-growth.

### High Stability Demonstrated in specimens with average to excellent bone density\*



Note: Data obtained from biomechanics testing of the Sidus Stem-Free shoulder under simulated conditions of high joint loading in patient rehabilitation phase. Please note that clinical outcomes will depend on appropriate patient bone quality and activity levels, and it is anticipated that up to 33% of total shoulder candidates lack sufficient bone stock to support a stemless device [Churchill et al, JBJS 2012]. Refer to the Surgical Technique for further details about appropriate patient selection.

\* Bench testing is not necessarily indicative of clinical results.



## Sidus Stem-Free Shoulder demonstrates:

1. an effective **clinically-proven**, bone-sparing option for Total Shoulder Arthroplasty.<sup>1</sup>
2. **restored** mobility and **alleviated** pain through clinical studies.<sup>1</sup>
3. anatomic **flexibility** and **secure fixation**.<sup>1-3</sup>
4. an efficient, **bone-sparing solution**, should revision become necessary.
5. procedural efficiency with **easy-to-use** instrumentation.



Data on file with Zimmer Biomet

1. Multicenter Trial of the Sidus Stem-Free Shoulder Arthroplasty System (Protocol CIU2012-12E/G130026, "IDE")
2. Favre, Philippe, Henderson, Adam D.: Prediction of stemless humeral implant micromotion during upper limb activities. *Clinical Biomechanics* 36 (2016) 46-51.
3. Favre, Philippe, Seebeck, Jorn, Thistlethwaite, Paul A E, Obrist, Marc, Steffens, Jason G, Hopkins, Andrew R, Hulme, Paul A. In vitro initial stability of a stemless humeral implant. *Clinical Biomechanics* 32 (2016) 113-117.
4. Zimmer Biomet Compatibility Website: <http://www.zimmerbiomet.com/medical-professionals/support/product-compatibility.html#shoulder>.
5. Litchfield RB, McKee MD, Balyk R, Mandel S, Holtby R, Hollinshead R, Drosdowech D, Wambolt SE, Griffin SH, McCormack R.: Cemented versus uncemented fixation of humeral components in total shoulder arthroplasty for osteoarthritis of the shoulder: a prospective, randomized, double-blind clinical trial-A JOINTs Canada Project. *J Shoulder Elbow Surg.* 2011 Jun;20(4):529-36.

This document is intended for healthcare professionals and is not intended for laypersons. The Sidus Stem-Free Shoulder System is designed for total shoulder arthroplasty in combination with Zimmer Biomet's glenoid components for arthritic or bone deformities in patients with adequate humeral bone and an intact rotator cuff.

Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects, and patient counseling information.

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