Protocol Synopsis

Title:	*Multicenter Trial of the Sidus Stem-Free Shoulder Arthroplasty System*
Protocol No.:	CIU2012-12E
Sponsor:	Zimmer Inc.
Objectives:	**Primary Objectives** The primary objectives of this study are to evaluate the safety and efficacy of the *Sidus* Stem-Free Shoulder System in unilateral primary total shoulder arthroplasty. **Safety** will be evaluated by monitoring the frequency and incidence of device related adverse events or unanticipated adverse device effects (UADEs) in investigational subjects as well as analyzing survivorship using revision or intended revision as an endpoint. **Efficacy** will be determined by comparing the overall pain and functional performance as well as radiographic success of investigational subjects with those who received the control devices.
Indication/ Target Population:	The *Sidus* Stem-Free Shoulder System is indicated for uncemented use in total shoulder arthroplasty, replacing the shoulder joint of subjects suffering from severe pain or disability resulting from one or more of the following provided there is adequate bone stock to support the fixation of the implants: • Osteoarthritis • Posttraumatic arthrosis • Rheumatoid arthritis without humeral metaphyseal defects • Previous shoulder surgeries that do not compromise fixation
Study Design:	Multi-center, prospective, historical controlled.
Clinical Phase:	Investigational Device Exemption Protocol / Pre-market
Number of Subjects:	95 subjects will be enrolled in this study at up to 15 centers.

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Length of Study:	Initial follow-up will be 2 years from the date of enrollment completion to support product approval. Intervals include pre-op, operative, immediate post-op, 6 weeks, 6 months, 1 year, 2 years, and annually until the last subject completes two years of follow-up.
Investigational Device System:	• *Zimmer Anatomical Shoulder* Glenoid • *Sidus* Humeral Head • *Sidus* Stem-Free Anchor
Scores:	• American Shoulder and Elbow Society Standardized Shoulder Assessment (ASES) • SF-12 • Western Ontario Osteoarthritis Score (WOOS)
Statistical Analysis	Data collected will be summarized and reported to each participating Investigator. Statistical analysis is conducted by Zimmer or its designee. Primary data analysis will be completed after 2 years of follow-up.
Documentation:	Electronic Data Capture.
Anticipated Enrollment Date	Zimmer is currently recruiting investigational sites.

NOTE: The investigation described by this protocol involves a significant risk device as defined by the Investigational Device Exemption (IDE) regulation, Part 812, of the Code of Federal Regulations, Food and Drug Administration (FDA).

***Sidus* Stem-Free Shoulder**