T.E.S.S® VERSION 2

Retrospective and Prospective, Multi centre Study on
T.E.S.S® V2 Shoulder System

PROTOCOL NO. ORTHO.CR.E13

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PROTOCOL VERSION:
2012-05-30 - REV. 2.0

STUDY SPONSOR

ZIMMER GMBH
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Title:	Retrospective and Prospective, Multi centre Study on T.E.S.S® V2 Shoulder System
Sponsor:	Zimmer GmbH
Objectives:	The objective of this study is to evaluate mid-term (5-year) clinical performance of the T.E.S.S® Version 2 Anatomic and Reverse prostheses in shoulder arthroplasty. Patient and Shoulder function will be collected along with Constant Score, radiographic and survivorship data.

Outcome Measures	• Primary outcome:
	  ○ Clinical efficacy using Constant Score
	• Other outcome measures
	  ○ Passive and active mobility
	  ○ Radiographic Evaluation
	  ○ Complications (including dislocation and revisions/removals)
	  ○ Survivorship.

Indication/ Target Population:	200 subjects suitable for T.E.S.S® Shoulder Replacement can be included into this study: 100 subjects in each subgroup

Inclusion/Exclusion criteria	**Inclusion criteria**
	The inclusion criteria are the same as the indications stated in the G-Med cleared labeling for
	the device.
	The range of T.E.S.S.® shoulder prostheses are indicated in the following cases:
	• Except in special cases, the "anatomic" type is indicated for:
	  ○ Centered osteoarthritis of the shoulder
	  ○ Humeral head fractures
	  ○ Rheumatoid arthritis (with intact rotator cuff)
	  ○ Avascular necrosis of the humeral head
	• Except in special cases, the "reversed" type is indicated for:
	  ○ Offset osteoarthritis of the shoulder
	  ○ Massive and non-repairable rotator cuff tears
	  ○ Rheumatoid arthritis (with degenerative rotator cuff)
	• Revision in cases of:
	  ○ Replacement of an "anatomic" prosthesis with a "reversed" prosthesis
	  ○ Conversion of a hemi-arthroplasty into a total arthroplasty
	  ○ Increasing the size of the stem (length and/or diameter)
	  ○ Replacing a glenoid prosthesis
	  ○ Replacing a competitor's prosthesis
	  ○ In rare cases, removing a "reversed" prosthesis and replacing it with an "anatomic" prosthesis
	<u>Additional inclusion criteria include</u>
	  ○ Patient who read, understood study information and gave informed consent (oral or written depending on specific local regulatory requirements)
	Exclusion criteria
	The Exclusion criteria are the same as the indications stated in the G-Med cleared labeling for the device

	Contraindications: Subjects displaying any of the following contra-indications shall be excluded from this evaluation: • Local or systemic infections. • Severe muscular, neurological, or vascular deficiency of the affected joint. • Bone destruction or poor bone quality liable to affect the stability of the implant (Paget's disease, osteoporosis, etc.) • Cases where the corolla cannot be two-thirds covered with bone stock and including the stem/corolla junction. • Any concomitant complaint likely to affect the functioning of the implant. • Allergy to any of the implant components. • Local bone tumors. Additional exclusion criteria include • Patient over 18 under law supervision
Length of Study:	The study assessment period will be 6,5 years: 18 months of recruitment and 5 years followup. The follow-up clinical reviews for all patients will be at discharge, 6 weeks, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years.