

PMCF Study on the Safety, Performance and Clinical Benefits Data of the Anatomical Shoulder Bipolar System

NCT05358574

Status RECRUITING
Sponsor Zimmer Biomet
Enrollment 40 participants

Key Eligibility Criteria

Inclusion (5)

- The Anatomical Shoulder Bipolar Adaptor is indicated for hemi shoulder replacement as a salvage solution in situations, where a Zimmer Anatomical Shoulder Inverse/Reverse prosthesis was originally planned, but it is intra-operatively found that the attachment of the Zimmer Anatomical Shoulder Inverse/Reverse glenoid fixation is not possible
- Patient should have received the Anatomical Shoulder Bipolar System
- Patient should have signed the Informed Consent Form
- Patient is 18-100 years of age, inclusive
- Patient is skeletally mature

Exclusion (11)

- Patients who are not willing to return for study required follow-up visits and/or are not willing to comply with the follow-up schedule
- Patients who have any condition which would in the judgement of the Investigator place the patient at undue risk or interfere with the study. Any patient who is institutionalized, or is a known drug abuser, a known alcoholic or anyone who cannot understand what is required of them
- Patient is known to be pregnant or breastfeeding
- Musculoskeletal situation that enables the application of a regular hemi or total shoulder system
- Good quantity or quality of the glenoid bone, where the fixation of a Zimmer Anatomical Shoulder Inverse/Reverse glenoid fixation is possible

... and 6 more (see full listing online)

Locations (1 total)

Helios ENDO-Klinik, Hamburg, Germany