Official title:

Ambispective study to assess the safety of the performance of SAGITTA EVL R stem

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Study Reference	**2022-09**
Title	Ambispective study to assess the safety of the performance of SAGITTA EVL R stem
Sponsor	SERF 85 avenue des Bruyères 69150 Décines-Charpieu +334.72.05.60.10
Principal investigator	Dr POICHOTTE Antoine
Devices under investigation	SAGITTA EVL R revision femoral stems and CLAV.EVL distal locking screws.
Introduction	This clinical study is conducted to collect data on hip arthroplasty with the SAGITTA EVL-R revision femoral stems manufactured by SERF. This study will confirm the performance and safety of the SAGITTA EVL R revision femoral stems within the framework of MDR 2017/745 and in relation to the recommendations of the MEDDEV guide 2.7.1. Rev 4 (Clinical Evaluation Guide), which provides for a systematic procedure to monitor clinical data in order to verify the claimed performance of medical devices.
Purpose	This investigation was led to generate long term clinical data pertaining to devices under evaluation to evaluate performances and safety profile of the devices. This investigation is compliant with required regulatory requirements.
Objectives	The primary objective is to evaluate the long-term survival rate (7 to 10 years post-op +/- 2 years) of SAGITTA EVL R stems. Secondary objectives are to - study long term patient satisfaction with their hip prosthesis, - to confirm the long-term safety of these implants by studying the possible complications observed, - to evaluate the performance of these implants using clinical scores.
Endpoints	Primary endpoint: The survival rate will be determined by the Kaplan-Meier curve with femoral implant replacement for all causes. Secondary endpoints: - The safety of the implants will be assessed by the occurrence of adverse events related to the medical device. These elements will be sought in the context of current practice through the practitioner's clinical examination. - Patient satisfaction with their hip prosthesis will be assessed by means of a satisfaction questionnaire. - The performance of the implant will be evaluated through the modified Harris Hip Score and the Forgotten Hip Score (SHO-12).
Inclusion criteria	- Patient of legal age at the time of surgery, - Patient implanted with a SAGITTA EVL R revision femoral stem within its indications between 01/01/2010 and 31/12/2015, - Affiliated to French social security
Exclusion criteria	- Patient who has objected to the use of his/her personal data, - Patient unable to understand the surgeon's instructions or to carry out the post-operative follow-up.

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Methodology	Monocentric, open-label, ambispective observational study. In order to reflect current practice, the series of patients is exhaustive and consecutive over a period of time between 31/01/2010 and 31/12/2015. The identified patients are contacted by telephone for a questionnaire whose data are therefore collected prospectively, whereas all other data will be collected retrospectively from their medical records.
Schedule	The prospective part of the study will last approximately 3 months depending on the availability of patients. The duration of the study for each patient is limited to the time of the telephone call during which he/she will be offered to participate in the study and to answer 20 questions about his/her complications, quality of life and satisfaction. Retrospective data collection will be carried out in a maximum of 1 month. The total duration of the study is 4 months.
Initiation date	Planned to start in Q1 2023
Completion date	Final report will be available in Q3 2023
Statistical analysis	No statistical tests are planned for this CI. Only a descriptive analysis of the data is planned.