**Official title :**
Prospective Observational Study for the Evaluation of VEOFIX Varisation Staples

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| **Title of study** | Prospective Observational Study for the Evaluation of VEOFIX Varisation Staples |
| **Methodology** | Monocentric prospective observational study of a continuous exhaustive longitudinal patient series. |
| **Sponsor** | **SERF**<br>85 avenue des Bruyères<br>69150 Décines-Charpieu<br>+33 4.72.05.60.10 |
| **Rational (or justification)** | Based on a clinical evaluation that concluded that the benefit/risk balance was acceptable but using clinical data from equivalent medical devices in the literature, we felt it was necessary to collect our own data in order to confirm the performance and safety of VEOFIX staples. |
| **Implants studied** | Varisation staples (class IIb) from the VEOFIX® range with 4 types of staples according to 2 criteria: angulation and entraxe. |
| **Objectives of the study** | The primary objective of this study is to confirm the efficacy of the varisation staples, in the indications covered by the CE mark (Akin osteotomy) and in current practice.<br>Secondary objectives are to evaluate patient satisfaction and implant safety. |
| **Population concerned Selection criteria and consent** | In order to reflect current practice, all patients requiring varus osteotomy of the first phalanx of the big toe (known as Akin's procedure) may be included in the study.<br>These patients should have been informed about their participation in the study and the personal data collected prior to their surgery. |
| **Primary endpoint** | The primary endpoint is the evaluation of the effectiveness of the implant, the chosen endpoint is the evolution of the AOFAS score between the pre-operative and post-operative state. |
| **Secondary endpoints** | The secondary evaluation criteria are:<br>- Patient satisfaction rate<br>- The safety of the implant through the occurrence of adverse events and adverse effects related to the medical device |
| **Data collected** | The data collected for this study are: demographics, surgery details, clinical scores (AOFAS score, patient satisfaction), possible adverse events related or not to the implant. |
| **Data collection and transmission procedures** | Information will be collected using an Electronic Case Report Form (eCRF) from the source data of each patient included in this study. All relevant data from the clinical follow-up will be recorded, both clinical data and data on possible adverse events.<br>The follow-up modalities correspond to the investigator's current practice, but the investigator is invited to inform the study at each patient follow-up at 3 months and 12 months. The data are recorded directly on an electronic observation book completed by the investigator directly or by any other person authorised by the investigator. |
| **Indirectly nominative nature of the data** | In order to preserve patient anonymity, patients will be identified by their eCRF identification number and matricule.<br>A correspondence list is kept in the investigating centre. |
| **Study duration** | The duration of patient inclusion is 3 months, the maximum expected duration of patient follow-up is 12 months. Thus, the study will last a maximum of 15 months from the first inclusion. |
| **Numbers** | The expected number of patients in the registry is estimated to be 100, reflecting the average number of patients included consecutively over a quarter. |