PROTOCOL STUDY

RETRO-PROSPECTIVE AND OBSERVATIONAL STUDY OF 120 PATIENTS FOR THE ASSESSMENT OF THE SAFETY AND THE PERFORMANCE OF THE SAGITTA EVL-R STEMS IN HIP ARTHROPLASTIES

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1 Summary

Title	RETRO-PROSPECTIVE AND OBSERVATIONAL STUDY OF 120 PATIENTS FOR THE ASSESSMENT OF THE SAFETY AND THE PERFORMANCE OF THE SAGITTA EVL-R STEMS IN THE HIP ARTHROPLASTIES
Short Title	Observational retro prospective study for the assessment of the safety and the performance of the Sagitta EVL R stems in first intention or revision of arthroplasties
Identification of the project	2019-06-EVLR-N
Authorities	IDRCB: 2019-A01777-50 Ethical committee approval: ……
Type of study	Observational retro-prospective monocentric study
Study Rational	The pathologies of the hip are a common concern because of their high frequency in the population. These diseases are related either to degenerative pathologies or mechanical traumas. The SAGITTA EVL-R femoral stems are indicated for total hip arthroplasties patients with the following pathologies: • Primary or secondary arthrosis, • Advanced joint destruction resulting from rheumatoid arthritis or traumatic arthritis, • A fracture or an avascular necrosis, • Following a previous surgical operation, on condition that the new device does not interfere with the material in place. • indicated in the case of primary or secondary arthrosis, displaced sub-capital or transcervical fracture as well as stages I and IIB bone loss according to the PAPROWSKI classification. • The SAGITTA EVOLUTION for REVISION implant is recommended for indications according to the bone loss classifications of SOFCOT stages I to VI, PAPROSKY types I to VI and the AAOS types Ia to Ic. All these pathologies induce a pain that had not to be managed with any other previous effective treatments. Apart from fracture cases, the surgery is the ultimate strategy when all others have failed. The total hip arthroplasty is consisting in replacing the femoral head using a femoral stem that is impacted into the femur (Studied sagitta EVL-R stems) or is cemented into. In case of sagitta EVL-R stems, an additional fixation through the positioning of two distal wedges to improve their anchorages. An alloy metal or ceramic head is placed onto the femoral neck stem in case of the use of a Sagitta EVL-R cup. In case of the use of a Novae cup, this alloy metal or ceramic head is impacted into the UHMW polyethylen insert. Considering the acetabular part, a double mobility using the Novae cup range or a simple mobility using the Sagitta EVL-R cup range can be used and impacted into the acetabulum. A UHMW polyethylene insert is placed in the Novae cup range by reduction or; a ceramic or UHMW polyethylene insert is impacted in the Sagitta EVL-R cup range. Depending of the chosen acetabular cup, the reduction maneuver is permitting the assembly of all components (Either couple stem/head/insert into the metal back when using the Novae cup; or the couple stem/head into the couple metal back/insert when using the Sagitta EVL-R cup). Studied Hip pathologies are degenerative or traumatic cases that cannot be managed by other solution than a surgical total hip arthroplasty. Degenerative pathologies are mainly composed of primary or secondary osteoarthritis origins, or osteonecrosis. Traumas are essentially occurred in osteoporotic patients following a fall but may also occurred in a young population following a severe accident. Sagitta EVL-R stems are intended to be used by impaction into the femur with or without

	two additional fixation pins through distal holes using a proven targeting device, thus addressing the needs of most revision cases. There are composed of titanium with a sprayed titanium HAP coating that allow an optimal osteointegration considering the behavior of the body over such materials. A macrostructure is completed this solid anchorage of the stem by increasing the surface of contact between the stem and environmental tissues. The data reviewed from the scientific literature on the equivalent device of the Sagitta EVL-R stems from SERF indicate that they are used for the same clinical condition and the same intended purpose, at the same body site, in a similar population, and not foreseen to deliver significantly different performances; they are in contact with the same body fluids and made of the same materials. This clinical study is designed to confirm the safety and performance of the Sagitta EVL-R stems using a Novae or hype cup (implants and instruments).
Objectives	**First of all, this study is attempting to provide further clinical data on this medical devices for the post market clinical follow up. It will implement the knowledge of this device concerning its performance and its safety. It would consolidate the clinical follow-up dedicated to these devices.** <u>Primary objective :</u> The primary objective is to assess the significant clinical impact on patients treated for a total hip arthroplasty at **their last** follow-up (between 5 to 8 years) after surgery as a performance criteria. <u>Primary endpoint:</u> The functional improvement following a total hip arthroplasty will be evaluated postoperatively at the last follow -up between 5 and 8 years postoperative years through the validated Oxford Hip Score. <u>Secondary objective:</u> Preoperative clinical medical and surgical history will be harvested (Principal medical and surgical history, concomitant treatments if significative for the assessment of the pathology/treatment) to estimate the impact of comorbidity and risks factors on the pathology, and its reparation over time. Postoperative Radiological assessment of the reparation through pictures of the cotyles (face view) and femurs (face and profile views). The goals are to see the evolution of the reparation and moreover the interface behavior between prothesis and surrounding tissues; and if there's no displacement of the stems or more globally to the assembly along time. • The face radiography of the femur and therefore of the stem will be appreciated to estimate a potential subsidence between the immediate postoperative period and middle term / long terms postoperative periods. The radiolucent line will be appreciated to emphasize of radiological level of loosening. • As well as the face femur picture, the profile view of the femur would inform (in another dimension) about a potential subsidence / or a radiolucent line confirming a radiological and/or a clinical loosening of stem, that can lead to a surgical revision. • The face radiography of the cotyle will mainly measured the inclination of the implant and its stability over time through its migration. The radiolucent line will be appreciated (De LEE and Charnley scales) to emphasize of potential radiological level of loosening. The daily physical activity will be harvested postoperatively to see the incidence of the reparation of the patient daily autonomy at their last timepoints. The co-morbidity will be measured preoperatively and postoperatively using the Charnley classification. The goal is to estimate if the co-morbidity may be detrimental to the clinical results and their evolution and potentially to identify the nature of detrimental factors. All complications will be recorded during the study. A global survival rate would therefore be calculated at each timepoints. As the same manner, an aseptic loosening rate and a global

	complication rate will be evaluated. Other specific complication rate would be evaluated if considered representative and pertinent. The global satisfaction of patients will be measured at the last postoperative timepoints. The walking ability will be measured at the last postoperative timepoints. The global functional improvement will be measured at the last postoperative timepoints. The pain release will be estimated at the last postoperative timepoints. The length of the operated limb will be harvested to see of the chosen assembly was adequate and to see its evolution over time. <u>Secondary endpoints:</u> The endpoints are: Postoperative Radiological assessments will be followed at immediate postoperative period and at 6 months, 1, 2, 5, and potentially between 5 to 8 years postoperatively. The inclination of the cup, the localization of the center of rotation, and the presence or not of a periprosthetic radiolucent line will be followed and its location. Moreover, the distance, the height of the stem comparing with an anatomic locator (greater or lesser trochanter) and the presence or not of a periprosthetic radiolucent line all around and its location. The daily physical activity will be appreciated postoperatively at the last follow-up postoperatively. The co-morbidity will be measured preoperatively and postoperatively at 6 months, 1, 2, 5, and potentially between 5 to 8 years postoperatively. The global satisfaction of patients will be measured at the last follow -up between 5 and 8 postoperative years. The walking ability will be measured at the last follow-up between 5 and 8 years postoperative years. The global functional improvement will be measured at the last follow-up between 5 and 8 years postoperatively. The pain release will be estimated at the last follow-up between 5 and 8 years postoperatively. The length of the operated limb will be harvested at 6 months, 1, 2, 5 and/or at 5 to 8 years postoperatively, if available. Adverse events all along the postoperative follow-up and if the information is available in patients files: • Nature and origins of complications. • graded as serious (leading to death, life-threatening condition, requiring hospitalization or lengthening of hospital stay, leading to permanent or significant disability); • or graded as not serious and as implant-related (migration, subsidence) or surgery-related (iatrogenic event) or other relationships (i.e. aseptic loosening…), idiopathic events, possible related pathology events, but not limited to.
Study visits	There's no inclusion period because of the retro-prospective design of the study. Only a phone call will be performed following the start of the data collection. The data collection would be performed during ~~2 to 4~~ 8 to 10 consecutive days, depending of the ease to consult patient files. Duration of the follow-up period for each patient: until a maximum of 8 years postoperatively. In fact, operated patients between 2011 and 2014 in a single center will be potentially eligible. Therefore, the maximum follow-up through a phone call will be between 5 to 8 years. Patients will be followed at 2 stages: through their medical files (pre-operative, per-operative, immediate post-operative and postoperative follow-up), and between 5 to 8 years after implantation through a single phone call.
Study population	Constitution and follow-up of a cohort of patients operated for a primary total hip arthroplasty or a revision of hemiarthroplasty or total hip arthroplasty with implantation of

	the sagitta EVL-R femoral stem at a minimum. Most of time, several implants of the assembly are changed in case of revision. In case of primary surgical intervention, a stem + head and intermediate cup will be implanted for hemiarthroplasty; and a stem + head + insert + cup will be implanted for a total hip arthroplasty. Inclusion criteria: • Patients over 18 years old. • Patients that were treated with the sagitta EVL-R stem for an indication of arthroplasty and according to the Instruction For Use (IFU). ➢ Primary or secondary arthrosis, ➢ Advanced joint destruction resulting from rheumatoid arthritis or traumatic arthritis, ➢ A fracture or an avascular necrosis, ➢ Following a previous surgical operation, on condition that the new device does not interfere with the material in place. ➢ indicated in the case of primary or secondary arthrosis, displaced sub-capital or transcervical fracture as well as stages I and IIB bone loss according to the PAPROWSKI classification. ➢ The SAGITTA EVOLUTION for REVISION implant is recommended for indications according to the bone loss classifications of SOFCOT stages I to VI, PAPROSKY types I to VI and the AAOS types Ia to Ic. ➢ Dysplasia • Patient being informed to the study and non-opposed of its participation and the use its pertaining data. • Patients with a minimum follow up of 24 months. Non-inclusion criteria: • Patient presenting a contraindication indicated in the IFU. Number of needed patients: The number of needed patients was determined arbitrarily and is based on an estimated sufficient number to have a real incidence when means will be calculated. →Number of patients in the cohort: 120
Collected data	Preoperative phase: Sociodemographic data: age, sex, weight, height Medical & surgical history, risk factors and comorbidities Primary diagnosis and operative indication. Daily physical activities Charnley Classification Operative & immediate postoperative phases : Perioperative & immediate postoperative complications; Surgery description (assembly of components and sizes, description of the devices used in combination with Sagitta EVL-R stems); Immediate postoperative radiologic evaluation; Post-operative data (6 months, 1, 2, 5, and potentially between 5 to 8 years): Radiologic evaluation (inclination of the cup, localization of the rotation center, presence of periprosthetic radiolucent line for the cup and the stem, height of the stem comparing with an anatomic locator) Postoperative data through unique individual phone call corresponding to 5 to 8 postoperative years: - Oxford clinical scores - Daily physical activities - Global outcomes: Patient's satisfaction, walking ability, functional improvement,

	release pain - Charnley Classification Postoperative complications all over the follow-up of patients between the preoperative period until the phone call (5 to 8 years)

ABBREVIATIONS

AAOS	**American Academy of Orthopaedic Surgeons**
ADE	Adverse device Effect
AE	Adverse Event
BMI	Body Mass Index
CRF	Case Report Form
HAS	Haute Autorité de Santé
HHS	Harris Hip Score
NICE	National Clinical Guideline Centre
OHS	Oxford Hip Score
SAE	Serious Adverse Event
THA	Total Hip Arthroplasty

2 Rational of the study

The prevalence of total hip U.S. population was 0.83% with an estimated 2.5 million patients treated surgically (1.4 million women and 1.1 million men) in 2010 (Maradit Kremers et al. 2015). In France, there were 111000 procedures in 2012 with an increasing tendency (FOUTEAU 2014). Considering the ageing of the population involving an increasing proportion of pathologies, these surgical procedures are among the most common performed surgical treatments. Moreover, there's tendency of a shift to younger ages, probably due to lifestyles. This public health state must be managed to avoid complications as much as impossible to reduce postoperative costs by applying well codified surgical procedures. So, choices of adequate devices and surgical strategies are essential these hip pathologies.
Total Hip arthroplasties are most preferred to treat coxopathies (Primary or secondary osteoarthritis, osteonecrosis, but not limited to) and fractures of the femoral cervix (FOUTEAU 2014).
To be in accordance with the Medical Devices Directive (93/42 CE) and to the future Medical Devices Regulations (2017/745), SERF must monitor their devices by mounting post-market clinical follow-up (PMCF) investigations. This PMCF study aims to improve the knowledge on the performance, the safety and the benefit/risk ratio of Sagitta EVL-R stems prosthesis and to consolidate the strategy of care for patients through this clinical evaluation. The experience of the investigator is also to be underline considering his historic patient population and results already published (Teyssédou et al. 2013). Thus, good significant clinical results as well as the safety are to be refined with a cohort of patient.

3 Pathology

3.1 Pathological context and medical alternatives

(AAOS 2017) (Brown 2017)
Osteoarthritis is one of the major causes of handicap among adult population in industrial countries until there's 10% of the American population that suffer from hip osteoarthritis. In 2009, the osteoarthritis was the fourth cause of hospitalization.
The osteoarthritis leads to the destruction of joint tissues with functional consequences (major limitation of hip motility) and pains that may be important during the use of the joint or even at rest. Etiologies include genetic factors, traumatic sequalae, the acetabular morphology, toxic factors (drugs and nutritional) and infections. Additionally, overweight and obesity, lifestyle are also risks factors.
Fractures of the neck of the femur occur more often in patient over 65 due to osteoporosis. Risk factors are low bony density and factors linked with the risks of fall (decrease physical capabilities and imbalance; diabetes, decrease of vision, absence of a securized home and lack of help)
Osteonecrosis is due to alteration of the blood flow in the femoral head leading to necrosis of cells. Causes may be traumatic sequalae, drepanocytosis, drugs, corticoids, gas embolism, systemic or infectious diseases, alcoholism. Symptoms are pain and limping that may induce fractures or evolutive arthrosis.
Rhumatoïd arthritis are inflammatory diseases that may attack all articulations. This destruction results in pains and functional incapability that may potentially be treated surgically for the replacement of the articulation.
Previous failed interventions for aseptic loosening, iterative dislocations, infections, wear of a component such as the polyethylene insert or any complications necessitating the change of implant (e.g. implant breakage, metallosis, pseudotumor, Sagitta EVL-Rr sensitivity to one of a component).

Medical alternatives concerning progressive articulation destruction are drug intakes as the first line to decrease pains. Other treatments are mainly oriented to a specific illness such as a rheumatoid polyarthritis, or the origins of an osteonecrosis. The next alternatives may be the physiotherapy. When all these therapeutics strategies become ineffective against the pain functional limitations, the surgical treatment may be considered.
For acute pathologies such as fractures, the treatment is surgical with total hip replacement as mentioned in recommendations (AAOS and NICE) (Brown 2017; « NICE - 2017 - Hip fracture management Guidance and guidelines.pdf » 2017).

Considering principal method of surgical strategies, risk factors appear for revision procedure. Moerman et al. have studied the Dutch arthroplasty registry. They have found a revision rate in hemiarthroplasty (HA) of 1.6% at 1 year and 2.5% at 5 years postoperatively. In total Hip Arthroplasty (THA), the rate was 2.4% at 1 year and

4.3% at 5 years postoperatively (Moerman et al. 2018). They have also analyzed that risk factors for hemiarthroplasty were male sex, age below 80 years, a posterolateral approach and uncemented fixation. Risk factors following THA were exactly the same with smoking in addition. To be noted that the age as a risk factor for revision is not a risk factor for revision in the first year after the fracture but becomes one in the years thereafter (Moerman et al. 2018). Whatever the primary or the revision uses, these stems are used mainly due to the encountered pathologies and the need for the supplemental fixations with distal screws.

4 MEDICAL DEVICE DESCRIPTION

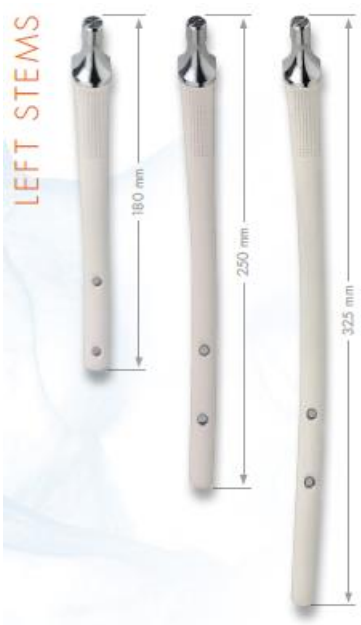
4.1 Ranges

Sagitta EVL-R stem: The Sagitta EVL R range of implants is comprised of revision femoral stems with indications including fracture cases, necrosis, primary and secondary arthrosis, to be implanted with or without femoral flap. They can be used for bone losses classifications as SOFCOT II to IV, AAOS type 1a to 1c and Paprosky types II and III.

Its thinner neck geometry and highly polished surface ensure optimal association with the acetabular cup.

Furthermore, the Sagitta EVL R offers the surgeon the option to insert two pins through distal holes using a proven targeting device, thus addressing the needs of most revision cases.

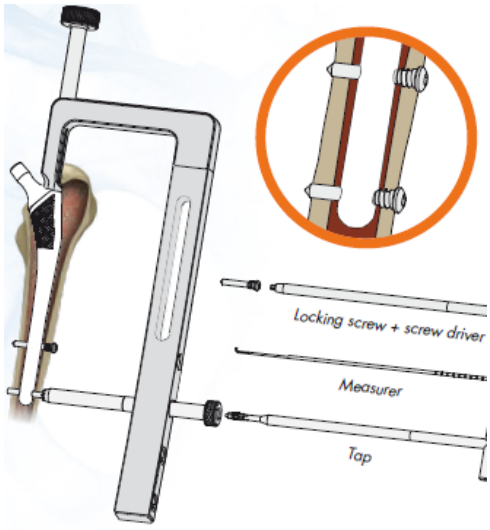
EVL stems



L.	Ø (mm)	Code	Part number
180 mm	Ø 12	SAGIT.EVL R 2-180 G	RM10450520
	Ø 13	SAGIT.EVL R 3-180 G	RM10450521
	Ø 14	SAGIT.EVL R 4-180 G	RM10450522
	Ø 15	SAGIT.EVL R 5-180 G	RM10450523
	Ø 16	SAGIT.EVL R 6-180 G	RM10450524
250 mm	Ø 12	SAGIT.EVL R 2-250 G	RM10450525
	Ø 13	SAGIT.EVL R 3-250 G	RM10450526
	Ø 14	SAGIT.EVL R 4-250 G	RM10450527
	Ø 15	SAGIT.EVL R 5-250 G	RM10450528
	Ø 16	SAGIT.EVL R 6-250 G	RM10450529
325 mm	Ø 13	SAGIT.EVL R 3-325 G	RM10450530
	Ø 14	SAGIT.EVL R 4-325 G	RM10450531
	Ø 15	SAGIT.EVL R 5-325 G	RM10450532
	Ø 16	SAGIT.EVL R 6-325 G	RM10450533

L.	Ø (mm)	Code	Part number
180 mm	Ø 12	SAGIT.EVL R 2-180 D	RM10450500
	Ø 13	SAGIT.EVL R 3-180 D	RM10450501
	Ø 14	SAGIT.EVL R 4-180 D	RM10450502
	Ø 15	SAGIT.EVL R 5-180 D	RM10450503
	Ø 16	SAGIT.EVL R 6-180 D	RM10450504
250 mm	Ø 12	SAGIT.EVL R 2-250 D	RM10450505
	Ø 13	SAGIT.EVL R 3-250 D	RM10450506
	Ø 14	SAGIT.EVL R 4-250 D	RM10450507
	Ø 15	SAGIT.EVL R 5-250 D	RM10450508
	Ø 16	SAGIT.EVL R 6-250 D	RM10450509
325 mm	Ø 13	SAGIT.EVL R 3-325 D	RM10450510
	Ø 14	SAGIT.EVL R 4-325 D	RM10450511
	Ø 15	SAGIT.EVL R 5-325 D	RM10450512
	Ø 16	SAGIT.EVL R 6-325 D	RM10450513

Optional and additional locking screws:



4.2 Technical specifications

The anatomically designed Sagitta EVL R is manufactured from titanium and is entirely coated with hydroxyapatite (HA). It features two distal holes for optional locking.

The hydroxyapatite coating was chosen because of its properties for osteointegration on metallic surfaces by binding rapid link, to assume an initial mechanical stability for the process of implant fixation. The titanium, a porous and rough coating, allows the ingrowth of the osseous tissues by creating solid fixation between the implant and tissues and to minimize pression on implant/bone interface.

4.3 Possible assemblies

Possible assemblies are mentioned in the IFU:

Sagitta EVL-R stems are to be used only with SI, SCC or SD head of SERF, with a 11/13 morse cone.

Materials	Ø (mm)	Code	Part Number
 Stainless steel (ISO 5832-9)	Ø 22,2	SI 22,2/-2,5 (- 2,5 mm)	RM30050009
		SI 22,2/0 (0)	RM30050010
		SI 22,2/+4 (+ 4 mm)	RM30050011
	Ø 28	SI 28/-4 (- 4 mm)	RM30050031
		SI 28/0 (0)	RM30050032
		SI 28/+4 (+ 4 mm)	RM30050033
	Ø 32	SI 32/-4 (- 4 mm)	RM96040020
		SI 32/0 (0)	RM30050050
		SI 32/+4 (+ 4 mm)	RM96040024
 Cobalt-chromium (ISO 5832-12)	Ø 22,2	SCC 22,2/0 (0)	RM30300010
		SCC 22,2/+4 (+ 4 mm)	RM30300015
	Ø 28	SCC 28/-4 (- 4 mm)	RM30300051
		SCC 28/0 (0)	RM30300055
		SCC 28/+4 (+ 4 mm)	RM30300059
 Biolox® delta ceramic (ISO 6474-2)	Ø 28	SD 28/-4 (- 4 mm)	RM30750001
		SD 28/0 (0)	RM30750002
		SD 28/+4 (+ 4 mm)	RM30750003
	Ø 32	SD 32/-4 (- 4 mm)	RM30750004
		SD 32/0 (0)	RM30750005
		SD 32/+4 (+ 4 mm)	RM30750006
	Ø 36	SD 36/-4 (- 4 mm)	RM30750007
		SD 36/0 (0)	RM30750008
		SD 36/+4 (+ 4 mm)	RM30750009

The assemblies of stem+heads are validated with NOVAE, SAGITTA EVL-R, and CHIBF E range cups. (see the following figure)

For this clinical project, all cups will be accepted for the patient inclusion strategy.

5 Indications and target population

5.1 Indications

- Primary or secondary arthrosis,
- Advanced joint destruction resulting from rheumatoid arthritis or traumatic arthritis,
- A fracture or an avascular necrosis,
- Following a previous surgical operation, on condition that the new device does not interfere with the material in place.
- Displaced sub-capital or transcervical fracture as well as stages I and IIB bone loss according to the PAPROSKY classification.
- bone loss classifications of SOFCOT stages I to VI, PAPROSKY types I to VI and the AAOS types Ia to Ic.

5.2 Target population:

Adult patients presenting a pathology necessitating a surgical intervention for joint replacement or a surgical revision of a hemiarthroplasty or a total hip arthroplasty.

5.3 Contraindications

Contra-indications and conditions with higher risk of failure:

- Local or systemic acute or chronic infections (heart disease, uncompensated diabetes, regular hemodialysis, impairment of the immune system, etc.),
- Severe muscular, neurological or vascular deficiencies affecting the extremity concerned,
- Destruction, loss or poor bone quality that could affect the stability of the implant, severe osteoporosis, serious deformation of the joint that needs replacing,
- Any associated disorder that could compromise the function or the implantation of the prosthesis,
- Systemic or metabolic issues,
- A patient's intellectual incapacity to understand the surgeon's instructions,
- Addiction to drugs, alcohol, smoking or medication,
- Local bone tumours,
- Obesity, excess weight, intense activity, intensive sports training, falls,
- Size 1 Sagitta EVL-R® SCC and Sagitta EVL-R® SCS stems must only be used on patients weighing less than 55 kg,
- Size 2 Sagitta EVL-R® SCC, Sagitta EVL-R® SCS and Sagitta EVL-R® SCL stems must only be used on patients weighing less than 70 kg.

6 STUDY OBJECTIVES

The use of femoral stems without cement is known to give long terms satisfying clinical results. In these cases, the sagitta EVL-R stems are especially used for severe traumas of the femur and mainly for revision of arthroplasties for any reason whatsoever, respecting indications of the IFU. The extended and osseointegration of these implants were reported in numerous series, despite the use of stems with many different shapes a, macrostructures, coating repartition materials differences and with or without potentially with additional fixation. This study is attempting to provide further clinical data on this medical device for the post market clinical follow up. It will implement the knowledge of this device concerning its performance and its safety according to the directive 93/42/EEC. The results of this study will be used for marketing supports, conference papers and/or scientific article if possible, and as a basis for claimed current indications for the device.

6.1 Primary objective

The primary objective is to assess the significant clinical impact on patients treated for a total hip arthroplasty at **their last** follow-up (between 5 to 8 years) after surgery as a performance criterion.

6.2 Secondary objectives:

Preoperative clinical medical and surgical history will be harvested (Principal medical and surgical history, concomitant treatments if significative for the assessment of the pathology/treatment) to estimate the impact of comorbidity and risks factors on the pathology, and its reparation over time.

Postoperative Functional improvement periods following a total hip arthroplasty.
Postoperative Radiological assessment of the reparation through pictures of the cotyles (face view) and femurs (face and profile views). The goals are to see the evolution of the reparation and moreover the interface behavior between prothesis and surrounding tissues; and if there's no displacement of the stems or more globally to the assembly along time.

- The face radiography of the femur and therefore of the stem will be appreciated to estimate a potential subsidence between the immediate postoperative period and middle term / long terms postoperative periods. This subsidence can potentially be a primary step to a loosening. The radiolucent line will be appreciated to emphasize of radiological level of loosening. This finding may have no clinical impact on the patient daily life. It will depend of the level of loosening of the cup and its evolution. Generally, a clinical impact is regularly associated with failure and/or pain; thus necessitating a surgical revision. Tangsatapron et al. have analyzed that risks factors inducing femoral stem subsidence were the weight of patients and long sizes of stems and more particularly a medial-lateral stem-bicortical fit less than 2cm (Tangsataporn et al. 2015). Ries et al. have shown that the subsidence was statistically higher in patients collarless stems than with collar (Ries et al. 2019). Girard et al. have emphasized that the bad quality of the osseosintegration of the stem is risk factor for subsidence (Girard et al. 2011).
- As well as the face femur picture, the profile view of the femur would inform (in another dimension) about a potential subsidence / or a radiolucent line confirming a radiological and/or a clinical loosening of stem, that can lead to a surgical revision.
- The face radiography of the cotyle will mainly measured the inclination of the implant and its stability over time through its migration. The radiolucent line will be appreciated (De LEE and Charnley scales) to emphasize of potential radiological level of loosening. This finding may have no clinical impact on the patient daily life. It will depend of the level of loosening of the cup and its evolution.

The daily physical activity will be harvested postoperatively to see the incidence of the reparation of the patient daily autonomy at their last timepoints.
The co-morbidity will be measured preoperatively and postoperatively using the Charnley classification. The goal is to estimate if the co-morbidity may be detrimental to the clinical results and their evolution and potentially to identify the nature of detrimental factors.
All complications will be recorded during the study. A global survival rate would therefore be calculated at each timepoints. As the same manner, an aseptic loosening rate and a global complication rate will be evaluated. Other specific complication rate would be evaluated is considered representative and pertinent.
The global satisfaction of patients will be measured at the last postoperative timepoints.
The walking ability will be measured at the last postoperative timepoints.
The global functional improvement will be measured at the last postoperative timepoints.
The pain release will be estimated at the last postoperative timepoints.
The length of the operated limb will be harvested to see if the chosen assembly was adequate and to see its evolution over time.

6.3 Primary endpoint

The clinical improvement at the postoperative periods will be evaluated postoperatively at the last follow-up using through the validated Oxford Hip Score and with its primary interpretation. The Oxford Hip Score (OHS) is a short 12-item patient-reported PRO specifically designed and developed to assess function and pain with patients undergoing hip replacement surgery. It is short, reproducible, valid and sensitive to clinically important changes. The overall time needed to fill for the patient is about 5 to 7 minutes. There are a dozen of items. The score has a maximum of 60 points (worst possible outcome) and a minimum of 12 points (best possible score). he OHS is a patient self-completion PRO containing 12 questions on activities of daily living. The OHS has been developed and validated specifically to assess function and pain for patients undergoing total hip replacement (THR) surgery. The OHS is the most evaluated hip specific measure available.

6.4 Secondary endpoints

The endpoints are:

- The functional improvement following a total hip arthroplasty will be evaluated postoperatively at the

last follow -up between 5 and 8 years postoperative years through the validated Oxford Hip Score
- The daily physical activity will be appreciated postoperatively at the last follow-up postoperatively.
- The co-morbidity will be measured preoperatively and postoperatively at 6 months, 1, 2, 5, and potentially between 5 to 8 years postoperatively.
- The global satisfaction of patients will be measured at the last follow -up between 5 and 8 years postoperative years.
- The walking ability will be measured at the last follow-up between 5 and 8 years postoperative years.
- The global functional improvement will be measured at the last follow-up between 5 and 8 years postoperatively.
- The pain release will be estimated at the last follow-up between 5 and 8 years postoperatively.
- The length of the operated limb will be harvested at 6 months, 1, 2, 5 and/or at 5 to 8 years postoperatively, if available.
- Adverse events all along the postoperative follow-up and if the information is available in patients' files:
  - Nature and origins of complications.
  - graded as serious (leading to death, life-threatening condition, requiring hospitalization or lengthening of hospital stay, leading to permanent or significant disability);
  - or graded as not serious and as implant-related (migration, subsidence) or surgery-related (iatrogenic event) or other relationships (i.e. aseptic loosening…), idiopathic events, possible related pathology events, but not limited to.

6.5 Secondary radiographic outcomes:

Postoperative Radiological assessments will be followed at immediate postoperative period and at 6 months, 1, 2, 5, and potentially between 5 to 8 years postoperatively. The inclination of the cup, the localization of the center of rotation, and the presence or not of a periprosthetic radiolucent line will be followed and its location. Moreover, the distance, the height of the stem comparing with an anatomic locator (greater or lesser trochanter) and the presence or not of a periprosthetic radiolucent line all around and its location.

7 Study design

7.1 Type of study

This is a monocentric retro-prospective observational study. Patients were already treated since many years before the beginning of the study.

7.2 Study placement

The study will take place in the following centers:
CHU de Poitiers: 2 rue de la Milétrie, 86000 Poitiers.

7.3 Study timelines

Total duration: 13 days
Duration of the inclusion period: considering that all patients have already been treated, therefore, there's no inclusion period. Potential
Duration of the follow-up period for each patient: 10 years
Study start (estimated): November 2019
Recruitment end: Not applicable
End of the patient follow-up period (estimated): September November 2019
Data analysis period (estimated): Q1 2020
End of the study (estimated): Q1 2020

8 Study population

8.1 Sample size

The sample size was arbitrarily chosen to have a cohort of consecutive patients to have the strongest power in

such type of study and by limiting exclusion criteria. Only contraindications of the IFU were taken as exclusion criteria. In that way, a cohort of 120 consecutive patients was defined to have a basis of calculation.

8.2 Inclusion criteria

The inclusion and exclusion criteria are controlling legal aspects of a clinical study in general; and the respect of indications cited in the instruction for use of the medical device. There's no other imposed restrictions.
The inclusion criteria are:

- Patients over 18 years old.
- Patients that were treated for an indication of arthroplasty and according to the Instruction For Use (IFU).
  - Primary or secondary arthrosis,
  - Advanced joint destruction resulting from rheumatoid arthritis or traumatic arthritis,
  - A fracture or an avascular necrosis,
  - Following a previous surgical operation, on condition that the new device does not interfere with the material in place.
  - indicated in the case of primary or secondary arthrosis, displaced sub-capital or transcervical fracture as well as stages I and IIB bone loss according to the PAPROWSKI classification.
  - The SAGITTA EVOLUTION for REVISION implant is recommended for indications according to the bone loss classifications of SOFCOT stages I to VI, PAPROSKY types I to VI and the AAOS types Ia to Ic.
  - Dysplasia
- Patient being informed to the study and non-opposed of its participation and the use its pertaining data.
- Patients with a minimum follow up of 24 months.

8.3 Non-inclusion criteria

The Non-inclusion criteria are:

- Patient presenting a contraindication indicated in the IFU.

8.4 Definitive inclusion

A patient is definitely included in the study if declared eligible during the electronic file assessment.

8.5 Exclusion criteria

After inclusion, patients can be excluded from the study if the final follow up is 24 months and if available data at the 24 months postoperative visit is too poor.

9 Study procedures

Patient information:
This observational study does not require any additional eligibility criteria, any additional exam. According to French regulation, each patient is appropriately informed of his/her freedom to decline or agree to participate to the study (thanks to the information note) and of his rights regarding medical data collection.
Study withdrawal:
Patients may withdraw from the study at any time at their own request, or they may be withdrawn at any time at the discretion of the investigator or sponsor for safety, behavioral, or administrative reasons. In any circumstance, every effort should be made to document patient outcome, if possible.

10 Collected data

Patients will be followed at 2 stages: in their medical history files and through a phone call after the surgery.

Endpoints		Preoperative	Per-operative	Immediate post-operative	Visit 6 months	Visit 1 year	Visit 2 years	Last visit over 2 years	Phone call to patients
Patient information (gender, age, weight, height)		X							
Eligibility criteria		X							
Medical & surgical history		X							
Oxford questionnaires									X
Daily physical activity									X
Charnley Classification		X			X	X	X	X	X
Surgery - Assembly components description			X						
Peroperative Incidents			X						
Global results: Patient satisfaction Walking ability Functional improvement Pain release									X
Length of the operated limb									X
Radiologic assessment	Inclinaison of the Cup and localization of the center of rotation			X	X	X	X	X	X
	Periprosthetic radiolucent line - Cup			X	X	X	X	X	X
	Stem height/ anatomic locator			X	X	X	X	X	X
	Periprosthetic radiolucent line - stem			X	X	X	X	X	X
Complications (including implant migration, iterative disclocation, aseptic loosening, device breakage…)			X	X	X	X	X	X	X

Table 1: Collected data and study timelines

10.1 Preoperative phase

During the ~~first visit~~ selection phase, the principal investigator records patient data and checks eligibility criteria (inclusion and non-inclusion criteria).

Then, the data collected are:

Sociodemographic data:

- Age, sex, weight, height,

Medical history:

- Primary diagnosis and operative indication.
- Co-morbidities and risk factors: alcoholism, Overweight, anticoagulant intake, cardiovascular, Sagitta EVL-R tension, diabetes, thromboembolic history, Rheumatoid arthritis, Osteoporosis, Musculoskeletal comorbidity, other (to be defined)

Daily physical activity: these parameters is graded as:

- Bedridden
- Sedentary
- Semi sedentary
- Light activity
- Moderate activity
- Heavy activity

Classification of Charnley – Adversely impacting outcomes factors: this classification is graded as 3 levels (A: none factor, B: damage of the contralateral hip, C).

10.2 Operative phase

The investigator noted in the CRF all of the following items:

- Type of anesthesia
- Surgical approach
- Sagitta EVL-R device description and the overall assembly for the THA
- Perioperative complications such as surgical complications: all data will be recorded if concerning the treatment of the pathology.

10.3 Immediate postoperative phase

Radiological evaluation:

The inclination of the cup, the localization of the center of rotation, and the presence or not of a periprosthetic radiolucent lines will be followed and their potential locations. Moreover, the distance, the height of the stem comparing with an anatomic locator (greater or lesser trochanter) and the presence or not of a periprosthetic radiolucent line all around and its location.

10.4 Postoperative phases at 6 months, 1, 2, 5 to 8 years

Daily physical activity: this parameter is graded as:

- Bedridden
- Sedentary
- Semi sedentary
- Light activity
- Moderate activity
- Heavy activity

Classification of Charnley – Adversely impacting outcomes factors: this classification is graded as 3 levels (A: none factor, B: damage of the contralateral hip, C: Other associated morbidities interfering on the walking ability).

The global results of the surgery - through the global satisfaction of patients, the potential improvement of the walking ability, the functional improvement and the pain release; using closed-questions.

Radiological evaluation:
The inclination of the cup, the localization of the center of rotation, and the presence or not of a periprosthetic radiolucent lines will be followed and their potential locations. Moreover, the distance, the height of the stem comparing with an anatomic locator (greater or lesser trochanter) and the presence or not of a periprosthetic radiolucent line all around and its location. Qualitative migration and subsidence of the implant are also deduced indirectly.

Postoperative Complications
Complications will be recorded as soon as there will be encountered in patients' files. All data will be recorded if available? Analysis of these events will be analyzed jointly with the investigator. In retrospective manner, No relevant events in nature or incidences will be declared following the procedure in the following section, if applicable. The investigator should investigate the occurrence of adverse events.

10.5 Postoperative phases at 5 to 8 years – Patient' phone call

Functional improvement: The assessment of the results of the hip surgery at the last follow-up will be evaluated postoperatively through the validated Oxford Hip Score. It will be monitored by a dedicated clinical research associate and the questionnaire will be fill in directly by phone with the patient.

11 Safety assessment

11.1 Adverse Device Effect (ADE)

Adverse event related to the use of an investigational medical device (Guidelines on medical devices ; Clinical investigations: serious adverse event reporting under Directives 90/385/EEC and 93/42/EEC , December 2010).
This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device.
This includes any event that is a result of a use error or intentional misuse.

11.2 Adverse events

During the study data harvest, safety assessments will consist of collecting retrospectively all adverse events and serious adverse events. The available Information about all adverse events in patients' files will be collected and recorded and followed as appropriate; principally during the phone call with simple questions.
An adverse event is the appearance or worsening of any undesirable sign, symptom, or clinical condition occurring during or after the surgery even if the event is not considered to be related to study device. Medical conditions/diseases present before starting study are only considered adverse events if they worsen after medical device implantation. Once an adverse event is detected in the patient file, it should be followed historically through the file until its resolution and assessment should be made through any change in severity, the suspected relationship to the medical device, the interventions required to treat it, and the outcome.
Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons whether or not related to the investigational medical device (Guidelines on medical devices ; Clinical investigations: serious adverse event reporting under Directives 90/385/EEC and 93/42/EEC , December 2010).
This includes events related to the investigational device.
This includes events related to the procedures involved. For users or other persons this is restricted to events related to the investigational medical device.

11.3 Serious Adverse Events

A serious adverse event is an undesirable sign, symptom or medical condition which:

- is fatal or life-threatening
- results in persistent or significant disability/incapacity
- constitutes a congenital anomaly/birth defect

- requires inpatient hospitalization or prolongation of existing hospitalization
- is medically significant, i.e., defined as an event that jeopardizes the patient or may require medical or surgical intervention to prevent one of the outcomes listed above
    - This includes device deficiencies that might have led to a serious adverse event if a) suitable action had not been taken or b) intervention had not been made or c) if circumstances had been less fortunate.
    - A planned hospitalization for pre-existing condition without a serious deterioration in health, is not considered to be a serious adverse event.

The investigator must assess and record the relationship of each SAE with sagitta EVL-R stems, complete the information in the CRF, and inform by the usual way of reporting the sponsor (SERF).

12 Data flow

12.1 Case Report Forms - database

All protocol-required data should be recorded in an excel database (Microsoft office) while they are collected. The access to this database will concerned only the investigator and the sent clinical research associate of SERF. This recorded raw data will be transferred in SERF facilities and a copy of these raw data will be kept in the archives of the hospital. The duration of archiving is 15 years since the end of the study.

12.2 Source documents

Source documents include all recorded observations or notes of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study. They include, but are not limited to subject file notes, imagery pictures and any other medical reports performed in the current practice.
The investigator will allow study-related monitoring, audits and regulatory inspection, providing direct access to source data.

12.3 Personal data

Personal data will be harvested on site to have a working document between the name, the patient file and the internal code of the patient for the sponsor document. The codification for the sponsor will be the two first letter of the investigation site (e.g. CHP for “Centre Hospitalier Poitiers”) and the order number of the included patient in the study (e.g. for the first included patient, CHP001). No direct personal data will be recorded by the sponsor such as the name and surname, the birth date. All is made to reduce the risk as much as possible.
All personal data that the sponsor need are specific.
Other personal data that will be recorded, analyzed and that the sponsor need:

- the intervention date,
- the type of intervention,
- the sex and
- the medical history.

No personal data that the sponsor needs will be transferred into another country or another organization. Processing of personal data is necessary for scientific research purposes.
All other requirements suggested by the General Data Protection Regulation (GDPR) are respected. No data protection officer was designated in SERF due to the low number of employees.

13 Data MANAGEMENT and Statistical data analysis

13.1 Data management

If missing, illegible or inconsistent data is detected, requests for additional information will be sent to the concerned investigator.
The consistency and validity of the database will be ensured by the clinical affairs project manager of SERF. Upon detection of errors or inconsistencies, additional information requests are sent to the investigator concerned; modifications will be incorporated into the database by the responsible person.
The database is then locked and statistical analysis can begin.

13.2 Statistical analysis

The data will be analyzed using an excel Microsoft office 2016. All data will be expressed qualitatively and/or quantitatively (frequency and/or percentage). All data will finally be compared to those found in the bibliography.
The previous section includes the main elements of the statistical analysis plan. This plan may be revised to reflect any modifications to the protocol. Any such revisions will be made before freezing the database.
Statistical analysis will be performed in SERF's facilities.

14 Quality assurance

14.1 Data quality control

The clinical research associate of the sponsor is responsible for monitoring the harvested database, using a sampling manner to verify only specific and the most important data, according to the study control procedure and the monitoring plan of the study. He will check the accuracy and completeness of CRF. The CRA mandated by the sponsor will have a direct access to the source documents (hospital record and other document related to the study for each patient of the study).
The presence, likelihood and coherence of the data will be controlled in the database. Queries will be edited when corrections are detected and needed.

14.2 Monitoring – On site visits

One or two visits will be performed considering that the harvest will be made only once during ~~2 to~~ 4 8 to 10 days. These visits will be performed either by a person suitably qualified and appointed by the Sponsor, either at distance.
The monitoring visit will be made by mandated Clinical Research Associates under the Sponsor responsibility.
The Investigator and staff members agree to be available during the quality control visit. This visit will be programmed once. Following items will be checked:
- Compliance to the protocol and its procedures;
- Quality of data recorded in the CRF: accuracy, missing data, consistency with source data;
- Reporting of serious adverse events.

The investigator must maintain a comprehensive and centralized filing system (investigator site folder) of all study-related documentation that is suitable for inspection by sponsor's monitor or representatives of other regulatory agencies.

15 Ethics and regulatory aspects

15.1 Information to patients

The patient is contacted by a phone call. The study will be explained, and all the points of the information note will be raised. The patient will have a judged adequate and sufficient time in order to take its own decision for its participation in the study. The patient gives orally its agreement to be included in the study, or to refuse it. If he accepts and does not object to the collection of the data, the questionnaire can then begin. The information notice can be sent after the phone call.
All other requirements suggested by the General Data Protection Regulation (GDPR) are presented the information sheet.

This study has received a favorable opinion from the ethical committee.

15.2 Participants compensations

Adult participants will receive no compensations for their participation to the study.

15.3 Data confidentiality

All persons involved in the study agree that the protocol and all information related to the patients enrolled in this study are and must be kept confidential. The investigator must ensure data confidentiality.
The information sheet will notify that every subject can have a direct or indirect access to nominative data concerning his participation to the study.
All data will be collected with regards to the patient's confidentiality. Patients' identification code (composed like that: center code- patient initial letter- inclusion number) only will be used on CRF and all study documents to be provided to the study sponsor SERF.
Documents that are not submitted to the sponsor should be treated with regards to data confidentiality.
The investigator agrees that a sponsor representative or any regulatory agency may consult the patients' medical files in order to verify study procedures and data. The patient must be informed that his medical data related to the study may be consulted as mentioned above, provided that the subject's identity remains anonymous.

16 REPORT AND PUBLICATION

16.1 Data property

SERF retains exclusive property rights over the results of the study. Accordingly, SERF may use freely those data (raw data reports with or without comments, with or without analysis). An article will be submitted for possible publication to a scientific journal. Outcomes will serve for the marketing department and also for communications in conferences (e.g. conference paper), but mainly as proves for the performance and the safety in the claimed indications in the IFU.

16.2 Final study report

A final study report will be written analyzing all outcomes. This report will serve for authorities and regulatory instances.

17 Investigators approbation and signatures

17.1 Investigators approbation

Investigators signatures are collected below in the section 17.2 of this clinical investigation plan; it also established a collaboration agreement with each of them.
These two documents form part of this clinical investigation plan.
By signing these documents, the investigator certifies having read the entire content and agrees to comply with all of their elements.

17.2 Signatures

This protocol must be dated and signed by all the investigators.

Investigators:

Professeur Louis-Etienne GAYET

Date: 19 JUIN 2019

___/_____

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Signature: _____

Sponsor :

M. Jean-Luc AURELLE (SERF) Date: ___/___/_____

Signature: _____

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Patient information note

Study title : Retroprospective and observationnal study of 120 for the assessment of the safety and the performance of the SAGITTA EVL-R Stems in hip arthroplasty

Principal Investigator: Pr Louis-Etienne GAYET, Professor of University-pratictitioner, Head of orthopaedic and traumatology Department, CHU of Poitiers

Study's sponsor : SERF (Société d'étude, de recherche et de fabrication), 85 avenue des Bruyères 69150 Décines-Charpieu
Mail : clinical@serf.fr

Data Protection organization: SERF, 85 avenue des Bruyères 69150 Décines-Charpieu
Mail : clinical@serf.fr

Lady, Sir,

You have had surgery on your hip by your surgeon. The surgeon replaced your joint with a SAGITTA EVL-R type hip prosthesis. The manufacturer of the SAGITTA EVL R implant is the company SERF.

Study purpose :
You have been asked by telephone to participate in a clinical study. This study collects data obtained as part of the standard care of any patient who has received a hip prosthesis..

Expected benefits :
As this study is carried out as part of the standard care of any patient who has received a hip prosthesis, there is no direct personal benefit from participating in this study. Nevertheless, the study will make it possible to collect data concerning the performance and safety of SAGITTA EVL-R type hip prostheses.

Constraints and possible risks :
No additional examinations to your surgeon's routine practice will be required of you. There is no risk in participating in the study. Only a telephone call is made to collect data concerning your state of health and your quality of life.

You have the choice to object to the processing of your data. You can also withdraw from the study at any time, by indicating this to your Surgeon, without having to justify it and without consequences on your care or your relations with the healthcare team.

Study's informations sur l'étude :
This study is offered to patients who have undergone hip surgery by Professor GAYET with the SAGITTA EVL R stem. The number of people participating in the study is set at 120 people. Your surgeon or a delegated person will complete an observation notebook using the data present in your medical file and also including the reports of your visits as part of the usual monitoring after the operation. The main elements collected from your medical file concern the physical examination, data from x-rays, the type of equipment implanted during the operation, possible complications during and after the operation as well as data concerning your quality of life.

Then, a telephone call is made by a person designated by your surgeon, subject to medical confidentiality. This call aims to collect data on your quality of life using a questionnaire. At the start of the call, the principle and objectives of the study are presented to you. You are then asked whether you wish to object to the collection of your data or not. Finally, the questionnaire is carried out. The estimated time to complete is approximately 15 minutes.

Study cost :
Your participation in this study does not generate any additional costs for you since the examinations carried out are part of your usual follow-up after hip surgery. This research is not compensated, according to article L1121-11 of the French Public Health Code. However, to be able to participate in this study you must still be affiliated to or benefit from a social security system.

Data collection's onfidentiality :
As part of the study in which you are asked to participate, processing of your personal data will be implemented to enable the results of the research to be analyzed with regard to the objective of the latter. The data processing manager is the company SERF. Your data will be anonymous and identified by a code. These data (x-rays, medical data) may be used in the context of scientific publications on the medical device used, unless you object, while respecting confidentiality.
This data processing has been declared to the National Commission for Information Technology and Liberties (declaration number: 2146708 v 0, MR003 in force) and the Committee for the Protection of People South-East VI has given a favorable opinion to this research on 09/25/2018.
ATo this end, the medical data concerning you and the data relating to your lifestyle habits as well as your quality of life will be transmitted to the promoter of the study or to the people or companies acting on its behalf, in France.
This data may also be transmitted to French or foreign health authorities. In accordance with the provisions of the CNIL and Law 2018-493 of June 20, 2018 relating to the protection of personal data and more specifically section 3 "rights of the person concerned by the processing of personal data", you have different rights with regard to the collection of your medical data:

- **Right to consent** : In the event of opposition on your part before the start of the study or at any time during the study and without having to justify yourself, your anonymized medical data will not be collected or used, and this will not will have no impact on your relationship with your surgeon or the surgical treatment he offers you. However, during the study, you have the right to object at any time, but it is your right that the use of your personal data already collected before this withdrawal remains possible.
- **Right to rectification** : Updating your data can be requested at any time directly from your surgeon.
- **Right to be forgotten and to deleted** : at any time you can request the withdrawal or erasure of your personal data by simple request to your surgeon without this impacting your relationship with him or your medical treatment.
- **Right to be informed in case of hacking**. The SERF company undertakes to take all necessary security measures to avoid this situation.
- **Right to limit the data collected** : The company SERF undertakes to only collect the data necessary to carry out the study (monitoring the performance and constant improvement of its product and possibly scientific publications on the demonstrated performance).
- **Right to object to profiling and prospecting** : SERF undertakes not to use your medical data for commercial purposes.

- **Right to portability** : According to article L.1122-1 of the public health code, at the end of the research in which you participate, if you request it, SERF undertakes to give you the possibility of recovering information on the overall results of the study. You will thus be able to store them or transmit them easily from one information system to another, with a view to their reuse for personal purposes.

If you have any questions, you are advised to ask your surgeon. You can also exercise your rights mentioned above by writing to the following email address: clinical@serf.fr.
When you have read this information note and obtained the answers to the questions you ask yourself by asking your surgeon or the medical team, you must give your non-opposition to the use of your data by telephone.
Your decision to authorize or not the use of your data for this research is entirely free and voluntary.
If you do not object to the processing of your data, your surgeon will provide access to your medical data relating to this study to the person responsible for collecting the data, as permitted by law. All nominative and personal information about you used by this person during the study will be kept in the center for 15 years after the end of the study and will be destroyed at this time.