This page is an integral part of the Patient Information Sheet

Dear Madam/Sir,
The information contained in the following Patient Information Sheet is detailed and may appear VERY COMPLEX.

You are kindly requested to agree to participate in this Clinical Investigation ONLY after having carefully read this Patient Information Sheet and after having had a COMPREHENSIVE DISCUSSION with the physician, who will devote the NECESSARY TIME to ensure that you fully understand what is being proposed.

PATIENT INFORMATION SHEET

Version 1, 10th June 2019

Clinical Investigation Title:

"Observational, Prospective, Multicentre Clinical Investigation for the Evaluation of Clinical Parameters in Elderly Patients with Proximal Femoral Fracture Treated with the Chimaera Intramedullary Nail (Orthofix Srl)."

Protocol Code, version and date:	OCI_1901, Version 1, 10th June 2019
Sponsor:	Orthofix Srl
Principal Investigator:	Prof. Roberto Civinini
	Azienda Ospedaliero Universitaria Careggi
	Largo Piero Palagi 1, 50139 - Firenze
Contact Information:	Phone: 055 / 794 111
	Email: roberto.civinini@unifi.it

Dear Madam / Dear Sir,

You are being asked to take part in an observational clinical study. This document is meant to explain what the study is about, why it is being done, what your participation would involve, and what your rights and responsibilities are.

Please read this information carefully before you decide whether to take part. You will have all the time you need to make your choice.
You can ask as many questions as you wish, and you may ask again about anything that is not clear or fully explained.
If, after reading and understanding this information, you decide to take part in the study, you will be asked to sign and date the attached Informed Consent Form.

What is the purpose of the study?

The aim of this study is to evaluate the safety and effectiveness of a medical device called **Chimaera**, which is used to fix fractures of the femur, such as the one you have.

The Chimaera is a nail that is placed inside the bone canal of your femur to keep the bone fragments together and help the fracture heal. Before being placed on the market, this device was tested by the manufacturer (Orthofix Srl) on artificial models and it meets the legal requirements to be considered safe and effective when used correctly.

Now, the manufacturer would like to collect some information from the medical records of patients who agree to participate, in order to confirm with real-life data that the device is indeed safe and effective when used in patients.

The information obtained from this study may also help improve the device if needed, and therefore could benefit patients who may require treatment for a femur fracture like yours in the future.

What does this study involve?

This is an observational study, which means that patients who agree to take part will receive exactly the same care as those who decide not to participate. The only difference is that, if you decide to participate, the doctors treating you will be allowed to collect some of your medical information from your hospital records for the purpose described above.

Your doctor has already decided that the Chimaera nail is the most suitable treatment for your fracture before asking you to take part in this study. You will receive this treatment even if you choose not to participate.

This is an open-label study, meaning that both you and your doctor will know which device is implanted. It is also a single-arm study, meaning that all patients who take part will be treated with the same device, the Chimaera nail.

The study will be conducted in 8 hospitals in Italy where the Chimaera is already in use, and will include about 400 patients, of whom approximately 50 will be enrolled in this hospital.
Your participation in the study will last for about 1 year from the date of surgery with the Chimaera nail. At the end of this period, you will have a final follow-up visit to check on your health status.

What will your participation in the study involve?

If you decide to take part in the study, please note that, after checking whether you can be included in the investigation by reviewing some eligibility criteria through a simple questionnaire (which does not require any additional tests), the study will begin with the surgery needed to implant the Chimaera nail and treat your femur fracture.

As mentioned above, this is an observational study, which means that your participation will not change the medical care you receive compared with patients who do not participate. You will still be treated according to standard practice at this hospital.

The only difference is that, by signing the consent form at the end of this information sheet, you will allow the doctors treating you to collect some information from your medical records. It is important to note that your data will be collected in an anonymous form.

Examinations you will undergo during the study

After the surgery and your discharge from the hospital, which will normally take place a few days later unless complications occur, you will have four follow-up visits planned at about 1, 3, 6, and 12 months after the operation, as is standard practice.

During these visits, the doctors of the department treating you will check the progress of your fracture healing, evaluate how well you are recovering your functions compared to your condition before the fracture, and make sure that you have not experienced any unwanted effects.

If you are able to travel, the follow-up visits at 1 and 3 months will be carried out at the hospital, because the doctor will need to examine you in person to properly assess how your fracture is healing. If you are unable to come to the hospital, the doctor will try to contact you by telephone and will ask you some questions about your health status.

For the 6- and 12-month follow-up visits (the last one being the final visit of the study), you may choose whether to come to the hospital for a personal examination or, if you prefer, you may have these visits carried out by telephone, since the doctor will only need to ask you a few questions.

What are the possible benefits of taking part in the study?

There will be no direct benefit for you from taking part in this study, because, as explained, you will receive the same treatment as patients who do not participate.
However, the results of the study, also thanks to the data you may agree to provide, could help improve the features of the device in the future and therefore improve the treatment of patients with fractures similar to yours.

What are the possible risks of taking part in the study?

Your participation in this study does not involve any additional risks or side effects compared with patients who do not take part, because, as explained several times in this document, you will be treated according to standard practice in this hospital.

The risks or possible inconveniences reasonably expected from the use of the Chimaera device are described in the product information leaflet. If you would like more details, please feel free to ask the doctors who are treating you for your fracture.

Since this is an observational study and Chimaera is a device that is already on the market and in use in this hospital, the law does not require any additional insurance coverage for patients participating in the study. Any possible damage related to the use of Chimaera is already covered by the insurance policies of both the hospital and the manufacturer of the device.

It is important to underline that, to date, more than 3,000 patients in Europe have already been treated with this device, which has also been in use in this hospital for more than two years with very good results and very low complication rates (lower than those observed with other similar devices). For this reason, the Chimaera is not considered an experimental product.

If you experience any unwanted event, even if not necessarily related to your fracture, or if you have any doubts at any time, even between follow-up visits, please contact immediately the study doctor at the following telephone number: 055 / 794 111, asking to speak with one of the doctors responsible for the Chimaera study in the Orthopaedics Department.

Should any medical problem arise during the study, you will in any case receive the most appropriate care.

What are the possible alternatives to taking part in the study?

At present, other types of treatments are also available for femur fractures like yours, each with its own advantages and disadvantages. However, we have already assessed that the device used in this study is the best treatment currently available in this hospital for your type of fracture.

Therefore, the choice of treatment is independent of your participation in the study and would remain the same even if you decide not to take part.

What happens if you decide not to take part in the study?

Taking part in this study is entirely voluntary. You are free not to participate, or, if you decide to take part, you have the right to withdraw at any time, without having to provide any explanation. You only need to inform the study doctor, **Prof. Roberto Civinini (roberto.civinini@unifi.it)**. In this case, no further data about you will be collected, and you may also request the deletion of data already collected.
Your current and future medical care at the Careggi University Hospital will not be affected by your decision, and the doctors will continue to look after you with the necessary attention.
On the other hand, your participation in the study may be interrupted if the doctor considers that the treatment has not provided any benefit for you, or if side effects occur. In such cases, the doctor will promptly inform you, and you will be able to discuss with him other valid treatment options for your fracture.

What will happen at the end of the study?

At the end of the study, that is after the final follow-up visit, you will still be able, as in normal practice, to contact us at any time for any questions regarding your health condition or about the study, by asking to speak with one of the doctors involved in the Chimaera study.

Consent to inform your General Practitioner (GP)

For the best protection of your health, if you decide to participate, you will be asked to inform your General Practitioner (GP) about this study. The involvement of your GP is very important in order to prevent possible harm that could result from the prescription or intake of medicines or other products that might seriously interact with the treatments planned in the study.

How will you be informed about the study results?

If you request it, at the end of the study you may be informed about the overall results of the study and, in particular, about the results that concern you personally.

INFORMATION REGARDING THE PROCESSING OF PERSONAL DATA

Data Controllers and Related Purposes

The Trial Centre, Azienda Ospedaliero-Universitaria Careggi, and the manufacturer of the medical device under investigation (Orthofix Srl), which has commissioned the study described to you, each within their respective areas of competence and in accordance with the responsibilities established by Good Clinical Practice, will process your personal data, in particular health-related data and, only to the extent strictly necessary for the purposes of the study, other data concerning your origin and lifestyle, exclusively for the conduct of the study and for post-market vigilance purposes.

For this purpose, the aforementioned data will be collected by the Trial Centre and transmitted to the manufacturer of the medical device and to the external company acting on their behalf, namely Arithmos Srl (Via Roveggia 122 – 37136 Verona, Italy).

The processing of personal data relating to the assessment of the safety and effectiveness of the treatment is essential for the conduct of the study: refusal to provide such data will prevent your participation. Other data collected in this study, if not already available in the patient's medical records, may instead be provided on a voluntary basis.

Nature of the Data

The physician responsible for your participation in the study will identify you with a unique code: the data concerning you, collected during the course of the study—except for your name—will be transmitted to the manufacturer of the device, recorded, processed, and stored for at least seven (7) years after the conclusion of the study, together with this code, your date of birth, sex, weight, height, origin, and lifestyle information. Only the physician and authorised personnel will be able to link this code to your name.

Methods of Data Processing

The data, processed also by electronic means, will be disclosed only in a strictly anonymous form, for example through scientific publications, statistical analyses, and scientific conferences. Your participation in the study implies that, in accordance with the regulations on clinical investigations of medicinal products, the personnel of the company manufacturing the device or of external companies performing monitoring and study verification on its behalf, the Ethics Committee, and the Italian and foreign health authorities may have access to the data concerning you, including those contained in your original medical records, in ways that ensure the confidentiality of your identity.

Exercise of Your Rights

You may exercise the rights provided for by Article 7 of the Italian Privacy Code (e.g., access to your personal data, integration, updating, rectification, objection to their processing on legitimate grounds, etc.) by contacting directly the trial site through Prof. Roberto Civinini (roberto.civinini@unifi.it) or, through him, the manufacturer of the medical device. You may also withdraw your participation in the study at any time and

without providing any justification. In such case, no further data concerning you will be collected, while the data already collected may still be used, without modification, in order to determine the results of the research.

Further Information

No additional costs will be incurred by you as a result of participation in the study, since Orthofix Srl will provide the necessary financial support. You will not receive any financial compensation for participating in the study.

The study protocol proposed to you was approved by the Ethics Committee of the Central Tuscany Area (COMITATO ETICO AREA VASTA CENTRO) on _____. The Ethics Committee has, among other things, verified the compliance of the study with the European Union Good Clinical Practice guidelines and with the ethical principles expressed in the Declaration of Helsinki.

You may report any matter you deem relevant regarding the research concerning you to the Ethics Committee and/or to the Medical Directorate of this hospital.

Prof.	Civinini Roberto
Phone	055 / 794 111
Email	roberto.civinini@unifi.it

_____ ___/___/_____ _____ _____

Investigator Name and Last name Date Time Signature

INFORMED CONSENT FORM

Version 1, 10th June 2019

Clinical Investigation Title: "Observational, Prospective, Multicentre Clinical Investigation for the Evaluation of Clinical Parameters in Elderly Patients with Proximal Femoral Fracture Treated with the Chimaera Intramedullary Nail (Orthofix Srl)."

Protocol Code, version and date: OCI_1901, version 1, 10th June 2019

Promotore: Orthofix Srl

Principal Investigator: Prof. Roberto Civinini
Azienda Ospedaliero Universitaria Careggi
Largo Piero Palagi 1, 50139 - Firenze

Contact Information: Phone: 055 / 794 111
Email: roberto.civinini@unifi.it

I, the undersigned _____born on _____ and residing in _____, Street/Square _____
Phone_____Domicile (if different from residence) _____

DECLARE

- that I have received from Dr. _____ thorough explanations regarding the request to participate in the observational study in question, as described in the Patient Information Sheet, which forms an integral part of this consent, of which I was given a copy on _____ at _____ (date and time of delivery);
- that the nature, objectives, expected benefits, and the absence of risks due to the observational nature of the clinical study have been clearly explained to me and understood;
- that I have had the opportunity to ask questions and have received satisfactory answers;
- that I have had all the necessary time before deciding whether or not to participate;
- that I have not been subjected to any undue coercion in the request for Consent.
- that it has been clearly explained to me that I am free to decide not to take part in the study or to withdraw from it at any time without providing justification, and that such decisions will in no way affect my relationship with the treating physicians or with the healthcare facility where I am being treated;

- that I am aware of the importance (and of my responsibility) to inform my general practitioner about the study in which I agree to participate; should I decide not to inform him/her, I release both my general practitioner and the physicians conducting the study from any liability for harm that may result from incompatibility between the study device(s) and other medical treatments.

I THEREFORE DECLARE that I

☐ **WISH** ☐ **DO NOT WISH**

to participate in the study

☐ **WISH** ☐ **DO NOT WISH**

to be informed of the results of this research by the study physician

☐ **WISH** ☐ **DO NOT WISH**

to inform my general practitioner of my participation in the study

_____	___/___/_____	_____	_____
Full Name of the Patient	Date	Time	Signature
_____	___/___/_____	_____	_____
Full Name of the Legal Representative	Date	Time	Signature
_____	___/___/_____	_____	_____
Full Name of the Witness	Date	Time	Signature
_____	___/___/_____	_____	_____
Full Name of the Family Member or Cohabitant	Date	Time	Signature

(in accordance with Article 105(3) of Legislative Decree 101/2018)

I, the undersigned Prof./Dr. …… ……

Last name Name

I hereby declare that the Patient (or his/her legal representative, or a witness, or a family member or cohabitant) has voluntarily signed his/her participation (the patient's participation) in the study.

I further declare that I have:

- provided the Patient (and/or his/her legal representative, witness, family member or cohabitant) with comprehensive explanations regarding the purpose of the study, the procedures, the potential risks and benefits, and the possible alternatives;
- verified that the Patient has sufficiently understood the information provided;
- allowed the Patient (and/or his/her legal representative, witness, family member or cohabitant) adequate time and the opportunity to ask questions regarding the study;
- not exercised any coercion or undue influence in requesting Consent.

NOTE

A copy of this form, duly signed and dated, attached to the *Written Information for the Patient*, must be provided to the Patient.