Annex II:

PATIENT INFORMATION SHEET MODEL

Version 2.0, September 1st, 2018

PROJECT TITLE: "Feasibility study: clinical validation of 3D personalized orthopedic splints in patients with rhizarthrosis "

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FINANCING ENTITY: Government of the Basque Country (investigation call "Hazitek")

GENERAL DESCRIPTION: Considering that you are suffering osteoarthritis of the trapeziometacarpal joint (rhizarthrosis), we ask for your consent to participate in the study described below. Before deciding whether you want to participate or not, please read this document carefully, which includes the information about this project. You can ask all the questions that may arise and request any clarification on any aspect of it.

PURPOSE OF THE STUDY: We are writing to inform you about a research study in which you are invited to participate. The study has been approved by the Clinical Research Ethics Committee of the OSI Bilbao Basurto, in accordance with current legislation, and is carried out in compliance with the principles set forth in the Declaration of Helsinki and the rules of good clinical practice.

STUDY SUMMARY:

The objective of the study is to assess the possibility of applying a custom orthosis through additive manufacturing and developed by the company Optimus 3D, S.L. compared with a conventional one. We estimate that the clinical results, pain and function of the personalized splint will be at least as good as those of conventional splints, but providing greater comfort and satisfaction for the patient. The company, located in the Araba Technological Park, is specialized in the development of custom sanitary products through additive manufacturing and is authorized to do so by the Directorate of Planning, Management and Sanitary Evaluation of the Basque Government.

The study will be carried out on two groups of patients: experimental group and control group. In the experimental group, the patients will use the custom 3D splint and in the control group they will use a conventional splint. We ask patients to wear the splint for as long as possible, not to disturb their usual activities (work, domestic or any other type). Assignment to study groups will be done through a computer program and centrally, randomly "like tossing a coin" so that neither you nor your doctor can choose one or the other study group. You are invited to participate in this study because you meet the inclusion criteria. If you agree to participate in this study, you must state it by giving your consent in writing.

In this study, you will have three visits: a recruitment visit and two follow-up visits (one at fist month and another final visit at 3 months). At each visit, you will be asked to fill out quality of life questionnaires.

You should know that 40 patients with a problem similar to yours are expected to participate in the study, and all of them will perform the same procedures. You should know that your participation in this study is voluntary and there is no financial consideration of any kind.

BENEFIT AND HEALTH CARE: It is likely that you will not receive any personal benefit from participating in this study. In any case, the data collected in it may lead to a better understanding of the treatment of osteoarthritis of the trapezius-metacarpal joint (TMJ).

Your participation in this study is completely voluntary: If you decide not to participate, you will receive all the medical care you may need and your relationship with the medical team that treats you will not be affected.

In the case that, during the study, any problem or circumstance relevant to your health care is detected, you will be informed about it and you will be advised on the most appropriate measures for its treatment and control.

We do not expect there to be any additional risk from your participation in this study.

DATA PROCESSING AND CONFIDENTIALITY: Your consent is requested for the use of your data for the development of this project. Both personal data (age, sex, race), as well as health data, will be collected using a coding procedure. Only the researcher and / or responsible doctor may relate these data to you, being responsible for keeping the consent document.

The information will be processed during the analysis of the results obtained and will appear in the final reports. It will be never possible to identify you, guaranteeing the confidentiality of the information obtained, in compliance with current legislation.

REVOCATION OF CONSENT: You can decide not to participate or change your decision without giving explanations and withdrawing consent at any time, without thereby altering your relationship with your doctor. If you decide to revoke your consent, no new data will be collected, but this revocation will not affect the investigations carried out so far. The rights of access, rectification, cancellation and opposition can be exercised contacting Iñigo Cearra Guezuraga MD, from Orthopedic Surgery and Traumatology Service, Basurto University Hospital (OSI Bilbao Basurto). Avda. Montevideo, 18. 48013 Bilbao. Spain. Phone: (0034) 94.400.60.00.

ACCESS TO INFORMATION: You have the right to know the clinically relevant data obtained from your participation in the study, whenever you wish and request it.

CONSENT TO CARRY OUT THE RESEARCH PROJECT

Researcher / Clinical Manager: Iñigo Cearra Guezuraga, MD, PhD.

Center/Hospital: Department of Orthopedic Surgery. Basurto University Hospital (OSI Bilbao Basurto). Avda. Montevideo, 18. 48013 Bilbao. Spain. Phone: (0034) 94.400.60.00.

TITLE OF THE PROJECT: BIOFERULA 3D "Proof of concept: clinical study of validation of personalized orthopedic splints with 3D technology in patients with rhizarthrosis".

Me,……, with ID……, declare that I have read the Patient Information Sheet, a copy of which has been provided to me. I have received information about the characteristics of the study, as well as the possible benefits and risks that I can expect, the rights that I can exercise, and the provisions on data processing. I have received enough information about the study.

I know that my identity will be kept secret using an encryption system. I am free to revoke my consent at any time and for any reason, without having to give an explanation and without having a negative impact on any present or future medical treatment.

I consent to the use of my associated clinical data as part of this research project. I consent to participate voluntarily.

I hereby affirm that I have been warned about the possibility of receiving information related to my health derived from my participation in this study:

I want to receive information

I do not want to receive information

after the research on the study results is completed.

Date …… Patient's signature ……..

Date …….. Legal representative signature (if applicable) ……

Name of legal representative:

Relationship with the patient:

I verify that I have explained the characteristics of the research project and the conservation conditions, if applicable, to which the preserved data will be applied.

Name of the Investigator or the person designated to provide the information:

Date …… Signature ……