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Information Document

THE USE OF THE MINIFLO EXTERNAL DISTRACTOR FOR THE TREATMENT OF STAGE 3° AND 4° DUPUYTREN'S DISEASE

Code: Miniflo-ITA14

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Dear Madam/Dear Sir,

.....
(surname) (name)

You have been asked to participate in a clinical research study, which is planned at our Operative Unit and which aims to test an external finger fixator called MiniFlo in the treatment of Dupuytren's Disease. Before you make a decision in this regard, it is important that you understand the reason for the study and what you will be asked to do, should you decide to take part. The investigator and his collaborators, in addition to the explanations they will provide during this interview, are fully available for any clarification.

This document aims to provide you with correct and complete information so that you may express a free and informed choice.

The researcher/professional responsible for the information is Dr.

Corain Massimo medical director

(surname) (name) (qualification)

INFORMATION NOTE

What is the purpose of the study?

The purpose of this research study is to proceed with the progressive extension of the digital ray affected by Dupuytren's Disease through the positioning of an articulated external fixator. This would make the severe flexion of the finger significantly less pronounced, to the point of making any further treatment unnecessary. This can be performed under local anesthesia, in a Day Hospital setting, and would avoid the traditional extensive aponeurectomy surgery, that is, the extensive removal of rigid and retracted tissue on the palm or on the finger of the hand responsible for the flexion of the finger itself, which would involve a wound along the entire finger with the need for periodic dressings, removal of stitches and treatment of the scar.

What device is being tested?

The new device has already been tested in previous clinical studies and represents the evolution of devices already extensively used for this pathology. It is already registered for the treatment of Dupuytren's disease, bears the CE mark and is already available on the market.

For what reason have I been selected?

You suffer from Dupuytren's Disease and the doctor believes that you meet the necessary requirements to enter the study. You have been asked to consider the possibility of joining it, in order to evaluate whether the new treatment can help improve the health status of your hand.

Am I obliged to participate?

No. The decision to participate in the study depends solely on you. It is completely voluntary. If you prefer not to participate you do not have to provide explanations. You will in any case receive all the investigations, visits and therapies currently available for your disease.

What will happen if I decide to participate in the study?

If you wish to consider the possibility of participating, you will be given this information sheet to read and keep. You will have the opportunity to ask all the explanations you wish regarding it. You will be asked to sign the consent form attached. Only after you have signed the declaration of consent will the medical evaluation begin to ascertain your suitability for treatment with the new drug/for the collection of your data.

What will my commitment be? What will I have to do?

Upon entry into the study, before starting treatment, the doctor will verify that you meet all the criteria required for participation. You will therefore be asked to undergo a medical examination, during which the following parameters will be recorded: flexion of the joints of the affected finger.

You must provide the investigator with all information regarding your clinical history, the medicines you have taken and those you are currently taking.

During treatment you will undergo the following visits: day of surgery; weekly check-up for a maximum of 5 weeks until removal of the device.

You must carefully follow the instructions that will be provided to you. You must act with a specific key on the device daily in order to proceed with gradual and precise opening of the finger; inform the doctor of any problems/disorders that may arise; keep the device protected, clean and ensure that it does not get wet with water or come into contact with dust that could lead to infection at the screw entry sites.

What benefits can I expect from participation in the study?

It is possible that you may obtain an improvement in your clinical condition by participating in the study. It is expected that finger extension may improve by at least 40 degrees.

What could be the risks, side effects, discomfort?

Risks related to infection of the screw entry sites, progressive tearing of the skin.

Are other therapies available?

Yes, open surgery or percutaneous mini-open techniques. It is also possible treatment with a collagenase-based drug (Xiapex) already available on the market but not covered by the National Health Service at this advanced stage of the pathology.

Will I be able to change my mind after agreeing to participate?

Yes. You may decide to withdraw consent and discontinue treatment at any time, even after the study has started, without having to provide justification unless the decision derives from the appearance of disorders or undesirable or unforeseen effects, in which case you must provide the investigator with all relevant information. Your decision will not affect the care and treatment you will receive in the future.

Will my general practitioner be informed?

Subject to your authorization, your general practitioner will be informed by letter of your participation.

How long does the study last?

Your participation will last approximately 40 days.

Could the experimental treatment be interrupted?

Yes. The investigator may interrupt the study at any time if necessary.

What happens in case of problems or injury?

You must promptly inform the investigator.

Will I have additional costs?

No. No additional costs will be borne by you.

Who reviewed the study?

The protocol complies with EU Good Clinical Practice and the Declaration of Helsinki.

Will my participation remain confidential?

Your data will be handled confidentially.

Who can I contact?

Dr. Massimo Corain 045.8124796 / 045.8124473

DECLARATION OF THE PERSON PROVIDING INFORMATION

I declare that I have informed the patient and discussed the nature and purpose of the study.

Place, Date .../.../...

Signature of the professional _____

INFORMATION SIGNATURE

I declare that I have received and understood all information.

Patient signature _____

CONSENT EXPRESSION – CLINICAL TRIAL

I declare that I accept to undergo the clinical trial THE USE OF THE MINIFLO EXTERNAL
DISTRACTOR FOR THE TREATMENT OF STAGE 3° AND 4° DUPUYTREN'S DISEASE

I have been adequately informed about the purposes, risks and benefits.

I am aware that I can withdraw at any time.

■ I CONSENT

■ I DO NOT CONSENT

I authorize the use and disclosure of my anonymized data.

Place, Date .../.../...

Patient signature _____

Legal Representative _____

Witness _____

Investigator _____