INFORMED CONSENT FORM

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form.

PART I: INFORMATION SHEET

INTRODUCTION

The General Surgery Department of Virgen del Rocío University Hospital, collaborating with the European Hernia Society, is doing research on inguinal hernia in women. The researcher has invited you to be part of that research, which aims to evaluate the two actual laparoscopic techniques to repair inguinal hernia

In this document, we are going to give you information about the research, so that you can decide whether or not you would like to participate in it.

You do not have to decide today if you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask the investigator to stop as we go through the information and he/she will take time to explain. If you have questions later, you can ask them anytime to the researchers or the staff.

PURPOSE OF THE RESEARCH

Inguinal hernia is a prevalent condition in society, traditionally treated with open surgery. Laparoscopic techniques are also used to repair inguinal hernia, both in men and women, but in the case of women research does not agree about which particular laparoscopic technique is better, regarding post-operative pain and recover.

That is why our group is doing research to compare TAPP (Trans Abdominal PrePeritoneal) technique and TEP (Totally ExtraPeritoneal) technique.

TAPP technique consists of a laparoscopic approach, by insufflating air (Carbon dioxide) in the abdominal cavity, and from there repairing the hernia with a mesh, placed between the peritoneum (the inner layer in the abdomen) and the muscles in the groin.

TEP technique consists in accessing an intermediate space between the peritoneum and the muscles, without entering the abdominal cavity. The mesh will be placed in that intermediate space.

TYPE OF RESEARCH INTERVENTION

This research will involve a surgery to repair your inguinal hernia, under general anaesthesia. The surgery will depend on the group you will be assigned to.

PARTICIPANT SELECTION

We are inviting all women suffering from an inguinal hernia to participate in the research.

VOLUNTARY PARTICIPATION

Your participation in this research is entire voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital. You may change your mind later and stop participating even if you agreed earlier.

INFORMATION ON THE TRIAL TECHNIQUES

The surgical techniques we are testing have been tested before and are routinely performed in this hospital. We now want to investigate if one of the techniques is better than the other, regarding postoperative pain and evolution.

PROCEDURES AND PROTOCOL

Once you consent on participating in the research, and we check that you match the inclusion criteria, you will be part of the research.

As we need to compare the two techniques, we will put people taking part in this research into two groups, which are selected by chance. Participants in one group will undergo TAPP technique, while the other group will undergo TEP technique. We will then compare which of the two has the best results.

Your participation will last for one year, during this period and after the discharge you will be evaluated five times on an outpatient basis. All the visits will be in the Diagnose and Treatment Centre in the Virgen del Rocío University Hospital (Sevilla)

The healthcare workers will be looking after you and the other participants very carefully during the study. If there is anything you are concerned about, please talk to me or one of the other researchers.

DURATION

The research takes place over twelve months in total. During that time, it will be necessary for you to come to the hospital 5 days, for one hour each day. We would like to meet with you one year after your surgery for a final check-up, and perform an image test (CT or ultrasound)

In total, you will be asked to come 5 times to the hospital in 12 months. At the end of twelve months, the research will be finished.

BENEFITS

You may benefit from the research about the surgery. It's expected that the TEP approach to the inguinal hernia might have better results regarding postoperative pain than TAPP approach.

Moreover, with your participation, you will contribute to have a better knowledge of your condition.

SIDE EFFECTS

The risk of complications is low. However, you will not be exempt of the inherent risks of any surgical intervention, and the associated complications of this procedure. Those complications will depend on the personal background of the participant.

Up to now, toxic reaction to the material we use has not been described, and it ir commonly used in worldwide centres, with optimal performance. The adverse events that may take place are the same as the ones that are described in relation to the surgical procedure you will undergo.

If you are allergic to any medical or surgical component, asthmatic or other medical condition, you must communicate it to the researchers.

VOLUNTARY PARTICIPATION AND RIGHT TO REFUSE OR WITHDRAW

Your participation in this research is entire voluntary. You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier, only by signing the consent revocation form.

In the case you want to voluntarily stop participating, or any doctor asks you to do it, you have to notice the research team. Neither your medical assistance nor the relationship with the research team will be disrupted. In this case, it is advisable that you follow the

instructions given by the researcher, so as we can proceed to finalize your participation in a proper way, by performing the activities scheduled for the final visit.

We also inform you that the research or your participation could end any moment, and your consent will not be necessary, whether or not for medical reasons; as the sponsor, the researchers or the health authorities consider it.

The researcher in charge can stop you from participating in the research if he considers it is for your good, or in case you do not follow the indications. He will also update you about any significant findings related to your participation.

CONFIDENTIALITY

The processing, sharing and cession of the personal data of the participants in the research will adjust to European Union's data legislation, specifically Law 2016/679 from European Parliament and General Data Protection Regulation entered into application in May 2018.

You will be able to exercise your rights of access, rectification, opposition and cancellation of your personal data, according to the stablished limits by Organic Law. You will have to ask the researcher to do so. Likewise, your medical history will be kept for at least five years after the last medical visit, as required by Law 41/2002, from 14th November, which regulates patient's autonomy and rights and obligations concerning documentation and clinical information.

As signing the Informed Consent Certificate you authorise an agent from sponsor or Ethical Committee to access your medical history with the aim to confirm the medical information generated along the research. You also authorise the research team to access your personal and clinical data. You authorise data cession solely and exclusively for the purpose data was collected.

Only the authorised staff will access your personal and medical data. Authorised staff includes: principal researcher and research team, health authorities, Clinical Research Ethical Committees, and the personnel designed by the sponsor; and always maintaining confidentiality according to applicable law. Your medical data can be transferred to other companies representing the sponsor, including external European Economic Area companies.

Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone but the research team. Your identity will only be revealed in case of medical emergency or legal requirement.

However, only personal data needed to achieve the research's aim will be shared with the sponsor, with no access to irrelevant-for-the-research data. Strict confidentiality is granted.

Your identity will not be revealed during the research, and if your data are examined and written down, we will lock your identity when the results become public.

WHO TO CONTACT

If you have any questions you may ask them now or later, even after the study has started. Any new information concerning your treatment which is found during your participation will be shared with you, and you will have the opportunity to withdraw your consent for the participation in the research.

If you wish to ask questions later, or you want to communicate any adverse event, you may contact the following:

Dr: _____ Phone number: 955012295

You have to decide if you participate or not. If you want to participate we will provide you with this Information Sheet, where you will have to sign in the Informed Consent Form. You will keep a copy of this Information Sheet and the researcher will keep the original one.

If you choose to participate you can revoke your consent anytime with no explanations required. Neither your medical assistance nor the relationship with the research team will be disrupted. In this case, it is advisable that you follow the instructions given by the researcher, so as we can proceed to finalize your participation

PARTICIPANT'S DUTY

As a participant in this research, you will have to attend all the scheduled medical visits. You will have to inform the researcher of all medication you take, medical processes you undergo, or adverse events you suffer.

COSTS FOR YOUR PARTICIPATION

Your participation in the study, the treatment you receive, or the procedures performed will not entail any expense to you.

Likewise, you will not perceive any financial reward for your participation.

ETHICAL ASPECTS

The research will be performed according to the Good Clinical Practice (ICH-GCP) rules, the Declaration of Helsinki, the Oviedo Convention, and the Spanish legislation concerning clinical trials (Real Decreto 223/2004)

PART II: CERTIFICATE OF CONSENT

"Randomized clinical trial to compare TAPP vs TEP approach for women's inguinal hernia on an outpatient basis"

Principal investigator: **Dr. José Tinoco González**
Abdominal Wall Surgery Unit. General and Gastrointestinal Surgery Department.
Virgen del Rocío University Hospital. Sevilla (Spain)

I, …… have been informed by Dr ……,
collaborator of the investigation project WOLAP, and I declare:

- I have read the foregoing information, or it has been read to me.
- I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this research.

Name of Participant ……

Signature of Participant ……

Date …./…./…..

INFORMED CONSENT WITH WITNESS

I have witnessed the accurate reading of the Informed Consent Form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Witness …….

Signature of Witness ……

Date …./…./…..

STATEMENT BY THE RESEARCHER

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1. She will undergo minimally invasive surgery for inguinal hernia, either TAPP or TEP depending on the randomization.
2. She will be discharged within the first post-operative hours, after meeting outpatient discharge criteria, unless medical indication.
3. She will have a one-year follow-up, and her post-operative development will be evaluated

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher …….

Signature of Researcher ……

Date …./…./…..