

#### QUALITY MANAGEMENT DOCUMENTS

# INFORMED CONSENT FORM FOR DIAGNOSTIC/OPERATIVE HYSTEROSCOPY

Document No: HD-FR-800 Publication Date: 03.10.2024

Revision No:00 Revision Date.: Page No :1/3

Patient Name-Surname : Date of Birth

Date : Protocol No :

### **GENERAL INFORMATION**

You have the inherent right to be informed about your medical condition, as well as all medical/surgical treatment and diagnostic procedures that are recommended for the treatment of your disease. You are responsible for determining whether or not to consent to the procedure after understanding the potential risks and benefits of medical treatment and surgical interventions. The objective of this elucidation is not to induce anxiety or fear in you, but rather to enable you to participate more actively in the decision-making process regarding your health. If desired, all health-related information and documents may be provided to you or a relative who you deem appropriate. We have developed this form to assist the attending physician in informing you of the risks associated with the proposed treatment/intervention and alternative treatment methods. It is imperative that you thoroughly review this consent form and sign it only after the physician has addressed any questions you may have regarding the relevant procedure.

## WHAT YOU NEED TO KNOW ABOUT YOUR CONDITION

Diagnostic and/or interventional hysteroscopy is a procedure in which a special optical device with a cold light source is used to observe the lining of the uterus after the uterus is filled with fluid and intrauterine interventions are performed using small hand instruments. Under general anesthesia or regional (epidural/peridural) anesthesia, the cervix is dilated, the uterus is filled with fluid and the optical device is advanced into the uterus. Hysteroscopy is used to evaluate the lining of the uterus. If necessary, intrauterine adhesions, fibroids and abnormal structures (such as polyps) can be intervened hysteroscopically.

## **ANESTHESIA**

In the anesthesia information sheet you will find information about anesthesia and possible risks. If you have any concerns, talk to the anesthesiologist. If you were not given the information sheet, please ask for it.

#### **RISKS AND COMPLICATIONS**

There are risks and harms if my condition continues without treatment, as well as risks associated with the surgical, medical and/or diagnostic procedures planned for me. I am aware that infection, formation of blood clots in the blood vessels and lungs, bleeding, allergic reactions, heart attack, lack of ventilation in the lungs (atelectasis) and even death are all possible risks associated with surgical, medical and/or diagnostic procedures. I have been told in detail that the following risks are also associated with the procedure. Some or all of the risks mentioned here are extremely rare. In addition, the risks of surgical intervention are particularly high in people who are obese, have had previous abdominal surgery or have an existing disease (e.g. heart disease, diabetes, high blood pressure) and smokers.

# The risks of surgical intervention specific to hysteroscopy are listed below:

- Risk of injury or rupture of the cervix and, if necessary, removal of the uterus
- Perforation of the uterus, damage to surrounding organs (such as intestines, bladder, large vessels), necessity of surgical correction
- Removal of the uterus due to bleeding or rupture of the uterus
- Air enters through the opened vascular openings and this affects the circulation and the heart in a way that



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can lead to death.

- Failure to observe the intrauterine cavity
- Damage to the cervix due to dilation of the cervix and the risk of early miscarriage in subsequent pregnancies
- Fluid accumulation in the lungs during intervention (pulmonary edema)

In one or more of the above cases, there is a risk that the procedure will turn into an open surgery (laparotomy) and that damaged organs will be repaired or removed. It is possible that adhesions may form in the uterus or that pre-existing adhesions may persist. Unexpected reactions to the drugs used for sedation or anesthesia or to the drugs to be used in the operation. Injuries or injuries of the type mentioned above may require surgery, either at the time or later. In conclusion, I understand that it is not possible to list all the possible unwanted effects of this operation, which is recommended for diagnostic purposes. My condition may not be improved and in some rare cases may even be worsened by undergoing the surgery. Some concomitant surgical interventions may increase the risk.

## **ALTERNATIVE TREATMENT METHODS**

- -Open surgical intervention to the uterus
- -Imaging techniques (ultrasonography, computed tomography, magnetic resonance imaging) without intervention Consequences if treatment is not accepted: If this procedure, which is recommended to clarify what my current problem is, is not performed, the nature of my condition may not be understood and my future treatment may be incomplete or incorrectly planned. Procedures for my treatment may be incomplete with some interventions that can be performed simultaneously. Thus, my condition may worsen.

# APPROVAL FOR TREATMENT OF PREVIOUSLY UNPREDICTABLE CONDITIONS

I understand that my physician may reveal different conditions that may require additional or different procedures other than the planned procedure required by my condition during the intervention. In this case, I agree that my physician will perform the appropriate additional intervention required by my condition and health.

nealth.						
Patient or legally responsible person	on					
Name-surname :	Signature :					
Witness Name-surname :	Signature :					
Kinship to the patient :						
PERSONAL INFORMATION						
Patient Name Surname :	Signature:	Date:				
Physician Name Surname :	Signature:	Date:				
I consent to the review of clinical in	nformation from my medical records for m	nedical study, medical research				
and for the advancement of physic	ian education; provided that the patient co	onfidentiality rules in the patient				
rights regulation are adhered to. I	consent to the publication of research res	sults in the medical literature as				

long as patient confidentiality is maintained. I am aware that I can refuse to participate in such a study and

that this refusal will not adversely affect my treatment in any way.



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**Photography/ Viewers:** I consent to the photographing or videotaping of the procedure, including appropriate parts of my body, for scientific, medical or educational purposes, provided that the pictures do not reveal my identity. I also consent to the presence of qualified observers in the operating room during surgery for the purpose of enhancing medical education. I have read and understood the contents of the informed consent form. All blanks on this form were filled in before my signature and I have received a copy.

#### **Patient Consent:**

I understand that medical practices are not an exact science and that no guarantee can be given about the outcome or treatment. I was given detailed information about my condition, the procedure to be performed and its risks, and treatment options in the consent document and in my interview with the physicians. We declare that we are aware that the responsibilities in this regard belong to us and that we accept and consent to the surgery without any violence, suggestion, material or moral pressure.

I am aware that the use of medical devices such as X-ray, scopy, ultrasonography, scintigraphy, computed tomography, magnetic resonance, etc. may be required during interventions; I am aware that I may be exposed to rays that may cause adverse effects on my health in some of these devices / applications, and I approve the use of these medical devices if deemed necessary

I am aware that in very rare cases, an unprecedented situation may develop during the procedure and in this case, I authorise and consent to the team that will carry out the procedure to take such action as they deem appropriate.

I sign this form without any	additional explanation, without being	under any pre	ssure a	nd consciously.
Patient Name Surname	:	Date/Time	:	
Signature	:			
or				
Patient Guardian / Relative		Date/Time	:	
Name Surname	:	Signature		:
(Kinship	)			
Translator's name and surna	ame:			
Signature	:			

Sufficient and satisfactory explanations have been made by me to the patient / patient's relative whose name is written above about his/her disease, the intervention to be performed, the reason and benefits of this intervention, the care required after the intervention, the expected risks, the type of anaesthesia to be applied if necessary for the intervention, and the risks and complications of anaesthesia. The patient/caretaker of the patient has read this form with his/her own consent that he/she has been sufficiently informed about his/her admission and has approved it by signing it.

Physician Name Surname	:	Date/Time:

Signature :