

#### QUALITY MANAGEMENT DOCUMENTS

# INFORMED CONSENT FORM FOR UTERINE MYOMECTOMY

Document No: HD-FR-796 Publication Date :04.09.2024

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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.

#### **ANESTHESIA**

In the anaesthesia information sheet you will find information about anaesthesia and possible risks. If you have any concerns, please contact the anaesthetist. If you have not been given an information sheet, please ask for one.

# WHAT TREATMENT/INTERVENTION WILL BE PERFORMED (MUST INCLUDE INFORMATION ABOUT ALTERNATIVE TREATMENTS):

Myoma removal surgery (myomectomy) from the uterus can be performed by closed methods (laparoscopic) with the use of incisions or holes made in the abdomen or in the abdomen and an optical device, depending on the location and size of the fibroids. The procedure takes 1-2 hours on average. During the operation, fibroids are removed from the uterine wall and then the uterus is sutured and healed. Recommended surgical intervention;

With Abdominal Incision (Abdominal)

Vaginal

**Closed Method (Laparoscopic)** 

### **RISKS AND COMPLICATIONS**

Failure to treat my condition may result in adverse consequences and harm. Additionally, there are potential risks associated with the planned surgical, medical, and/or diagnostic procedures. I acknowledge that surgical, medical, and/or diagnostic procedures carry the risk of infection, blood clot formation in the blood vessels and lungs, haemorrhage, allergic reactions, heart attack, lung ventilation deficiency (atelectasis), and even death. I have received comprehensive information regarding the additional risks that are associated with my procedure.

Several of these risks that I have been informed about are exceedingly uncommon. Myomectomy, the



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procedure to remove fibroids from the uterus, poses a higher risk for individuals who have undergone previous surgery such as a caesarean section, or who have pre-existing conditions such as heart disease, diabetes, high blood pressure, kidney disease, or have undergone kidney or liver transplants. Additionally, patients with coagulation disorders, vascular disease, connective tissue disease, endometriosis, intra-abdominal adhesions, or who are smokers are also at increased risk.

In addition to the risks mentioned earlier, there are specific risks associated with uterine fibroid removal surgery (myomectomy), which can be outlined as follows:

- Nausea, vomiting, pain, and fever along with inflammation (possible infection) at the site of the incision, in the abdomen, and in the urinary tract
- Damage to the bladder
- Possibility of injury to the ureter, which is a tube that connects the kidney to the bladder
- Small and large intestine damage that leads to a colostomy (colostomy)
- Damage to large vessels in the abdomen and the appearance of haemorrhage.
- Ligation of the main vessels (arteria interna iliaca) supplying that area due to uncontrollable bleeding or blood collection (haematoma) during and after surgery.
- The emergence of a pre-existing complaint of urinary incontinence or an increase in the existing complaint after the operation.
- Intestinal blockage and pain in the abdomen brought on by surgical adhesions
- Uncontrollably bleeding during myoma removal may require uterine excision.
- After removal, a myoma may return in the same or different areas of the uterus.
- When the endometrium, a layer lining the intrauterine cavity, is damaged, intrauterine adhesions may form. These adhesions can lead to reproductive problems, infertility, and repeated miscarriages.
- Pain, tube obstruction, disturbance of the tubal-ovarian connection, and infertility are all possible outcomes of postoperative intra-abdominal adhesions.
- Because of the above-mentioned complications, the patient might require another operation.
- Long-term consequences of the surgery include the development of an abdominal wall hernia and hardening at the site of the abdominal incision (scar-celoid).

#### **ALTERNATIVE TREATMENT METHODS**

- Taking certain hormones or other medicines (gestagens, GnRH analogues or antagonists)
- Insertion of a hormone-releasing intrauterine device into the uterus
- Complete removal of the uterus
- Angiographic embolisation of fibroids

### CONSEQUENCES OF NOT HAVING THE PROCEDURE

I was told about the following conditions that may occur with my disease if the surgical intervention deemed appropriate for me is not performed:

If surgery is to be performed due to excessive bleeding, anaemia may develop due to the continuation of



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these bleeding and health problems may occur due to anaemia,

• I was told that the fibroids may enlarge and therefore cause compression symptoms, may change into malignancy (sarcomatous degeneration), and may prevent examination or visualisation of the ovaries, resulting in diagnostic delays in terms of ovarian diseases.

I was told that due to my particular situation I could also face the following consequences;

### **BLOOD PRODUCTS**

I agree to the use of blood products if necessary.

### 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.

PERSONALISED INFORMATION				
		Signature:	Date:	
Physician Name Surname	·	Signature:	Date:	
Looppont to the review of a	dinical information from my	modical records for modical	study modical record	

I consent to the review of clinical information from my medical records for medical study, medical research and for the advancement of physician education; provided that the patient confidentiality rules in the patient rights regulation are adhered to. I consent to the publication of research results 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.

**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



Signature

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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.

•	, ,			
appropriate.				
I sign this form without any	additional explanation, without being	under any pressure and consciously.		
Patient Name Surname	:	Date/Time :		
Signature	:			
or				
Patient Guardian / Relative		Date/Time :		
Name Surname	:	Signature :		
(Proximity	)			
Translator's name and surn	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 approve	ed it by signing it.			
Physician Name Surname	:	Date/Time:		