Space for Medical Institution Name and Logo

ט /OBGYN/6800/6829/0071 מרץ 2000

טופס הסכמה: תסחוף (אמבוליזציה) של שרירני רחם (מיומות)
CONSENT FORM: UTERINE FIBROID EMBOLIZATION

The purpose of the embolization of uterine fibroids is to reduce their size.

The procedure involves the introduction of a catheter(s) through a peripheral artery(ies) up to the area of the uterus, under x-ray guidance, and the injection of contrast medium (iodine) to visualize the blood vessels of the uterus and fibroid. The treatment is performed by injecting a sclerosing agent into the catheters located near the uterine fibroids, causing a reduction in their size.

The procedure is performed under local or regional anesthesia.

Name of Patient: _____ _____ _____ _____
Last Name First Name Father's Name ID No.

I hereby declare and confirm that I have been given a detailed oral explanation by:
Dr. _____ _____
Last Name First Name
regarding the need for **reduction of uterine fibroid by embolization** (henceforth: "the primary treatment").

I hereby declare and confirm that I have been given an explanation concerning alternative therapeutic options for treating uterine fibroids, including hormone therapy and/or resection of the fibroid and/or the uterus through various approaches.

It has been clarified that the purpose of this therapeutic approach is, amongst others, to preserve the uterus, but there is a possibility of failure in which case an alternative treatment will have to be chosen. There is a possibility that after the introduction of the catheter it will not be possible to complete the procedure using this approach, and/or even if the procedure is completed, the desired result will not be achieved and a different therapeutic approach will be necessary. Approximately 15% of the procedures performed have been reported as unsatisfactory.

It has been clarified that this is an innovative treatment conducted successfully throughout the world for several years. However, like any new technique, its long term results can be evaluated only after several more years have passed.

I have been given an explanation concerning the side effects of the primary treatment, including: abdominal pain, and/or pain in other areas, fever, and at times even nausea and vomiting.

In addition, I have been given an explanation concerning the possible complications of the primary treatment, including: complications caused by the introduction of the catheter, allergic reaction to the injected agent, internal or external hemorrhage, formation of an emboli (blood clot), pelvic infection, perforation of the uterus and alterations in sexual function. Damage to the blood supply may cause alterations in the activity of the ovary(ies), in kidney function and in blood clotting. In addition, it has been clarified that the chances of conceiving in the future may be reduced, even though the uterus is preserved using this approach.

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It has been clarified that contrast medium containing iodine is used during the test and I hereby declare that I am not aware of any sensitivity to iodine or any other allergic reaction in the past.

I hereby give my consent to perform the primary treatment.

In addition, I hereby declare and confirm that I have been given an explanation and understand the possibility that during the primary treatment the need to extend or modify the operation or to perform additional or different procedures may arise in order to save my life or prevent physical harm, including additional surgical procedures that cannot be fully or definitely predicted at this time but whose significance has been made clear to me and, therefore, I also give my consent to such an extension, modification or performance of different or additional procedures, including additional surgical procedures, which the institution's physicians deem essential or necessary during the primary treatment.

I hereby also give my consent to the administration of local anesthesia after having been given an explanation concerning the possible complications of local anesthesia, including various degrees of allergic reactions to the anesthetic drug, and possible reactions to the sedatives, which may, in rare cases, cause respiratory disturbances and disturbances in the heart's activity, particularly in patients with respiratory or heart diseases.

If the decision is made to perform the operation under general or regional anesthesia, I will be given an explanation concerning the anesthesia by an anesthesiologist. I know and agree that the primary treatment and any other procedure will be performed by any designated physician, according to the institutional procedures and directives, and that there is no guarantee that it will be performed, fully or in part, by a specific person, as long as it is performed in keeping with the institution's standard degree of responsibility and in accordance with the law, and that the person in charge of the procedure will be *
_____.

_____	_____	_____
Date	Time	Patient Signature

I hereby confirm that I have given the patient a detailed oral explanation of all the above-mentioned facts and considerations as required, and that she has signed the consent form in my presence after I was convinced that she fully understood my explanations.

_____	_____	_____
Name of Physician	Physician Signature	License No.

* Fill in case of private physician.