

PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

FOR OFFICE HYSTEROSCOPY

Patient Name:

Date of Birth:

Indication:

Dear Patient,

The information contained in this module is complementary to that provided during your gynecological consultation. It is designed to help you better understand the nature of your clinical condition and the available treatment options. Please read this document carefully and feel free to ask your attending physician for any further clarification before or during your consultation.

1. WHAT IS HYSTEROSCOPY?

Hysteroscopy is an endoscopic technique that allows direct visual examination of the cervical canal and the interior of the uterine cavity (endometrium). Thanks to technological advancements, this procedure can be performed in an outpatient setting in the majority of patients, with minimal discomfort and without anesthesia (**office hysteroscopy**).

In a minor proportion of cases, it may be necessary to perform or complete the procedure in the operating room under conscious sedation or anesthesia (e.g., in cases of severe patient pain, technical inability to navigate the cervical canal, or complex lesions requiring formal surgical intervention).

2. INDICATIONS FOR THE PROCEDURE

Hysteroscopy is an essential diagnostic and therapeutic tool for intra-uterine pathology. Through this procedure, it is possible to make an accurate diagnosis, perform targeted endometrial biopsies, and execute minor operative procedures such as polyp or small fibroid removal.

Main clinical indications include:

- Abnormal intermenstrual bleeding, heavy menstrual bleeding, or irregular bleeding during hormonal therapy.
- Postmenopausal or perimenopausal bleeding.
- Thickened endometrial lining detected on transvaginal ultrasound.
- Removal of retained Intrauterine Devices (IUDs).
- Excision of endometrial or cervical polyps and submucosal fibroids.
- Infertility workup, recurrent pregnancy loss, or uterine malformations (e.g., uterine septum).
- Retained products of conception following delivery or pregnancy loss.

3. CONTRAINDICATIONS

Hysteroscopy can be safely performed in women of any age, **except** in the following circumstances:

- Confirmed or suspected ongoing pregnancy.
- Active pelvic inflammatory disease (PID) or lower genital tract infection.
- Active heavy menstrual flow at the time of examination.
- Known cervical malignancy or severe anatomical malformations preventing scope passage.

4. PRE-PROCEDURE PREPARATION & TIMING

Outpatient Setting: No special pre-procedure fasting or preparation is required. Patients may take an over-the-counter analgesic (e.g., Ibuprofen 400 mg or Paracetamol 1 g) approximately one hour prior to the procedure. It is recommended to be accompanied by a family member or friend.

Timing: For premenopausal women, the exam should be performed within the first 14 days of the menstrual cycle (follicular phase), avoiding active bleeding days. Unprotected sexual intercourse must be avoided from day 1 of the last menstrual period until the examination. Postmenopausal women can undergo the procedure at any time.

5. PROCEDURE DETAILS & POST-PROCEDURAL CARE

The procedure is conducted in the gynecological position by introducing a thin, lighted telescope (hysteroscope) connected to a high-definition camera through the vagina into the uterus. Fluid (saline solution) is used to distend the cavity. The procedure usually lasts between 10 to 20 minutes. Micro-instruments or energy devices may be introduced to harvest tissue samples or resect lesions.

Following outpatient hysteroscopy, an observation period of approximately 20 minutes is recommended. Mild abdominal cramping (similar to menstrual cramps) and light vaginal spotting may occur for a few days. Normal daily activities can usually be resumed on the same day.

6. RISKS AND POSSIBLE COMPLICATIONS

Although office hysteroscopy is a safe procedure conducted according to strict scientific guidelines, potential risks include:

- **Pelvic Pain & Cramping:** Very common, transient, subsides shortly after procedure.
- **Vaginal Spotting:** Frequent, lasting from a few hours to a few days.
- **Vasovagal Reaction:** Uncommon (dizziness, nausea, bradycardia, or transient fainting; rapidly resolves).
- **Procedure Failure / Inability to Pass Scope:** Uncommon (e.g., cervical stenosis or scarring).
- **Uterine Perforation:** Rare (<1 in 1,000 diagnostic; 0.8–1.6% in operative procedures). May require observation or antibiotic coverage.
- **Infection:** Rare (0.06%). Presents with fever, heavy discharge, or pelvic pain requiring medical attention.

Important Notice: Contact the hospital or emergency services immediately if you experience heavy bleeding, high fever, severe unremitting abdominal pain, or malodorous vaginal discharge in the days following the procedure.

7. ALTERNATIVE OPTIONS

Refusing hysteroscopy may delay accurate diagnosis and treatment. Alternatives include classical dilation and curettage (D&C) under anesthesia (an obsolete technique) or performing the hysteroscopy under general/spinal anesthesia in a day-surgery setting if outpatient tolerance is low.

STATEMENT OF INFORMED CONSENT

I, the undersigned patient, confirm that I have been fully informed in a clear and comprehensible language by the physician regarding the necessity, goals, procedures, benefits, and risks of the proposed **Office Hysteroscopy** procedure.

I have had sufficient time and opportunity to ask questions and discuss my clinical condition. I understand that I am free to revoke this consent at any time prior to the execution of the procedure. I also consent to the potential acquisition of anonymized photographic/video recordings for scientific and educational purposes in full compliance with privacy regulations (GDPR / Law 219/2017).

☐ I **CONSENT** to undergo the proposed office hysteroscopy procedure.

☐ I **DO NOT CONSENT** to undergo the proposed procedure.

Date & Location:

Attending Physician:

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Patient's Signature (or Legal Guardian)

Physician's Signature & Stamp

References & Legal Basis: Italian Law 219/2017 (Informed Consent & DAT); Bradley LD et al. UpToDate 2020; Florio P et al. J Minim Invasive Gynecol 2020.