

CLINICAL STUDY PROTOCOL

Title: A prospective, randomized, controlled trial to evaluate the efficacy, tolerability, and feasibility of a single-use disposable hysteroscopic operating system in an outpatient office setting

Public Title: Evaluating a single-use disposable hysteroscopic system in office hysteroscopy: a randomized controlled trial

Protocol Identifier: RedPine-HYST-2025

Ethics Committee Reference: P25/059 (Approved 10/11/2025 by Comitato Etico per la Sperimentazione Clinica - Sezione Azienda U.S.L. Toscana Centro)

Principal Investigator: Prof. Pasquale Florio

Study Site: Department of Maternal and Fetal Medicine, Section of Obstetrics & Gynecology, "S. Jacopo" Hospital, Azienda USL Toscana Centro, Pistoia, Italy

1. ADMINISTRATIVE INFORMATION & SPONSORSHIP

Item	Details
Sponsor Organisation	Azienda USL Toscana Centro, Florence, Italy
Principal Investigator	Prof. Pasquale Florio, Department of Maternal and Fetal Medicine, Section of Obstetrics & Gynecology, "S. Jacopo" Hospital, Pistoia, Italy. ORCID: 0009-0004-8915-9460 Email: pasqualemario.florio@uslcentro.toscana.it
Funding & Support	Non-funded study. Conducted using ordinary resources and standard departmental equipment.
Ethical Approval	Comitato Etico per la Sperimentazione Clinica - Sezione Azienda U.S.L. Toscana Centro (Presidio Ospedaliero di Pistoia, Italy), Ref: P25/059 (Approved 10/11/2025).

2. INTRODUCTION & BACKGROUND RATIONALE

Outpatient office hysteroscopy has become the gold standard diagnostic and operative modality for managing intra-uterine pathologies, such as endometrial polyps, submucosal fibroids, uterine septa, and abnormal uterine bleeding (AUB). Traditional reusable hysteroscopic instruments require stringent sterilization procedures, maintenance, and carry a risk of mechanical wear or cross-contamination over time.

Recent technological advancements have led to the development of single-use disposable hysteroscopic systems designed to streamline outpatient workflow, eliminate sterilization turnover delays, and maintain optimal optical quality and mechanical precision. This trial evaluates the clinical feasibility, efficacy, patient pain perception, and operator satisfaction of the novel RedPine Single-Use Disposable Hysteroscopic Operating System compared to standard reusable hysteroscopic equipment.

3. STUDY OBJECTIVES & ENDPOINTS

3.1 Primary Objective

To evaluate the feasibility and clinical efficacy of the RedPine single-use disposable hysteroscopic operating system compared to standard reusable hysteroscopic equipment in an outpatient office setting, defined as the successful completion of the diagnostic or operative procedure without requiring device switching or procedure abortive measures.

3.2 Secondary Objectives

- To compare total procedural duration and setup times between the two arms.
- To assess patient pain perception immediately post-procedure using the Visual Analog Scale (VAS 0–10).
- To evaluate operator satisfaction regarding image clarity, ergonomics, and instrument maneuverability using a 5-point Likert scale.
- To measure fluid management efficiency (total volume of distension medium used).
- To monitor intraoperative and immediate post-procedural complication rates (e.g., vasovagal syncope, severe bleeding, uterine perforation).

4. STUDY DESIGN & METHODOLOGY

Parameter	Description
Study Type	Interventional Clinical Trial
Study Design	Prospective, Randomized Controlled Trial (RCT), Parallel Group (1:1 Allocation)
Masking	Open Label (Unblinded, due to visible differences in instrument hardware)
Control Type	Active Control (Standard Reusable Hysteroscopic System)
Target Sample Size	144 total participants (72 in Experimental Arm, 72 in Control Arm)
Recruitment Period	15/11/2025 to 30/01/2026
Study Completion Date	31/01/2026

5. ELIGIBILITY CRITERIA

5.1 Inclusion Criteria

1. Female patients aged 18 to 80 years scheduled for outpatient diagnostic or minor operative office hysteroscopy.
2. Indication for hysteroscopy based on suspected intra-uterine pathology (e.g., endometrial polyps, uterine septum, abnormal uterine bleeding [AUB], thickened endometrium).
3. Ability to comprehend the protocol and provision of signed written Informed Consent prior to study initiation.

5.2 Exclusion Criteria

1. Severe pelvic organ prolapse (POP-Q Grade ≥ 3).
2. Active pelvic inflammatory disease (PID) or acute lower genital tract infection.
3. Confirmed or suspected ongoing pregnancy.

4. Inability to understand the study procedures, cognitive impairment, or refusal to grant informed consent.

6. RANDOMISATION & ALLOCATION CONCEALMENT

Patients fulfilling eligibility criteria will be randomly assigned in a 1:1 ratio to either the Experimental Group or the Reference Group. The allocation sequence will be generated prior to study commencement using a validated computer-generated randomisation software program.

Allocation concealment is strictly maintained using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). Envelopes are opened sequentially by the clinical staff only immediately prior to the start of the hysteroscopic procedure after the patient has signed the informed consent.

7. STUDY INTERVENTIONS

7.1 Experimental Group (RedPine Disposable System)

Patients in this arm undergo office hysteroscopy using the RedPine Single-Use Disposable Hysteroscopic Operating System. The procedure encompasses visual inspection of the endocervical canal and uterine cavity, followed by targeted operative interventions (polypectomy, biopsy, septum incision) using integrated disposable micro-instruments as indicated.

7.2 Reference Group (Standard Reusable System)

Patients in this arm undergo office hysteroscopy using the hospital standard reusable hysteroscopic operating sheath and optics currently in clinical routine. Diagnostic and operative steps follow identical clinical protocols regarding distension media, pressure settings, and surgical techniques.

8. OUTCOME MEASURES & EVALUATION TIMELINE

Outcome Category	Specific Measure	Assessment Tool & Method	Timepoint
Primary Outcome	Feasibility & Procedural Success	Binary assessment (Completed vs.	Intraoperative / Immediate Post-

Outcome Category	Specific Measure	Assessment Tool & Method	Timepoint
		Failed/Switched)	procedure
Secondary Outcome	Procedural Time	Chronometer timing (minutes) from sheath insertion to withdrawal	Intraoperative
Secondary Outcome	Patient Pain Perception	Visual Analog Scale (VAS 0 = no pain, 10 = worst imaginable pain)	Immediately post-procedure (prior to discharge)
Secondary Outcome	Operator Satisfaction	5-point Likert Scale (1 = Very Poor, 5 = Excellent)	Immediately post-procedure
Secondary Outcome	Safety & Complications	Recording of vasovagal episodes, bleeding, or trauma	Intraoperative & 1-hour post-procedure

9. STATISTICAL ANALYSIS PLAN

Statistical analysis will be performed on an Intention-to-Treat (ITT) basis. Continuous variables (e.g., procedural duration, VAS pain scores) will be tested for normality using the Shapiro-Wilk test and compared using the Student's t-test or Mann-Whitney U test as appropriate. Categorical variables (e.g., feasibility completion rate, complication rates) will be analyzed using Chi-square test or Fisher's exact test. A p-value < 0.05 will be considered statistically significant.

10. ETHICAL CONSIDERATIONS & DATA PROTECTION

This study is conducted in strict compliance with the Declaration of Helsinki and the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. Ethical

approval was formally granted by the competent Ethics Committee (Comitato Etico per la Sperimentazione Clinica - Sezione Azienda U.S.L. Toscana Centro, Ref: P25/059, Date: 10/11/2025).

All participant data are anonymized and stored securely in compliance with the European General Data Protection Regulation (GDPR). Individual participant data (IPD) will not be publicly shared to protect participant confidentiality.