Informed Consent Form (ICF)

Official Title: Minimal Invasive Urology Society Benign Prostatic Obstruction (BPO) Study Group Data Collection Project

NCT Number: Not yet assigned

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Participating Centers:
Academic and community urology centers (International, multicenter registry)

Version: 1.0

Reviewed / Approved by: Local Institutional Ethical Board

Local Ethics Committee Approval Number:

B.30.2.ODM.0.20.08/386-422

Patient Information and Informed Consent Form

Study Title

Multicenter International Urological Surgery Registry for Benign Prostatic Obstruction (MIUS-BPO)

Introduction

You are being invited to participate in a medical research registry. Before you decide, it is important for you to understand why the study is being conducted and what your participation will involve. Please take the time to read the following information carefully and ask questions if anything is unclear.

Purpose of the Study

This study is a prospective, multi-center registry designed to collect information about surgical treatments for benign prostatic obstruction (BPO). The registry will record details of patient demographics, clinical characteristics, surgical procedures, and outcomes. The purpose is to better understand surgical practices and results across different centers.

Why Have I Been Invited?

You have been invited because you are undergoing surgery for benign prostatic obstruction. Your participation will help provide valuable information that may improve care for future patients.

Do I Have to Take Part?

Participation in this registry is voluntary. If you decide not to participate, this will not affect the quality of medical care you receive. If you do agree to participate, you are free to withdraw at any time without providing a reason.

What Will Happen if I Take Part?

If you agree to take part:

- Information about your medical history and current condition will be collected.
- Details about your surgery and hospital stay will be recorded.
- Information about your recovery, complications, and follow-up will be noted.

No additional procedures, visits, or interventions are required beyond your routine medical care.

Possible Risks and Benefits

There are no direct medical risks to you from participating, since only routine clinical information will be recorded. You will not receive direct benefits, but your participation will contribute to improving knowledge about BPO surgeries and may help improve treatment for future patients.

Confidentiality

All information collected about you will remain strictly confidential. Data will be anonymized (your personal identifiers will be removed) before being analyzed. Results will only be reported in aggregate form, without identifying individual participants.

Use of Data

Your anonymized data may be used for future scientific analyses related to BPO surgeries. Any such analyses will be approved by an ethics committee if required. Future studies using this registry data will be registered separately on ClinicalTrials.gov with their own protocols.

Voluntary Participation and Withdrawal

Participation is entirely voluntary. You may withdraw at any time. If you withdraw, no further information will be collected. Data already collected will remain in the study database in anonymized form.

Contact Information

If you have any questions about this study or your rights as a participant, please contact your study doctor or the local ethics committee.

Consent Statement

I have read and understood the information provided above. I have had the opportunity to ask questions, and my questions have been answered to my satisfaction. I understand that my participation is voluntary and that I may withdraw at any time without consequences for my medical care.

Participant's Name: .....

Signature: .....

Date: .....

Investigator's Name: .....

Signature: .....

Date: .....