

# Informed Consent Form: HIFU Vaginal Rejuvenation

Name: \_\_\_\_\_ Age: \_\_\_\_\_

Date: \_\_\_ / \_\_\_ / 20\_\_

MRN (if applicable): \_\_\_\_\_

## Procedure Description

You are being offered treatment with High-Intensity Focused Ultrasound (HIFU) for vaginal rejuvenation or functional symptoms such as vaginal laxity, mild stress urinary incontinence, or genitourinary syndrome of menopause (GSM). HIFU delivers focused ultrasound energy to the vaginal tissue to stimulate collagen remodeling, improve tissue tone, and enhance function and comfort.

## Intended Benefits

- Improvement in vaginal laxity
- Reduction of mild urinary leakage (SUI)
- Relief from GSM symptoms such as dryness, irritation, and burning
- Enhanced sexual comfort and function

*Please note that outcomes may vary and full effects may take 4–8 weeks to appear.*

## Treatment Details

- Typical treatment course: 2–3 sessions, spaced 4–6 weeks apart
- Procedure duration: approximately 15–25 minutes
- Noninvasive and typically requires no downtime
- Mild post-treatment discharge or sensitivity may occur

## Risks and Side Effects

While HIFU is generally well tolerated, possible side effects include:

- Mild discomfort, heating, or tingling during the procedure
- Temporary vaginal discharge, swelling, or spotting
- Rarely, infection, burns, or prolonged sensitivity

## Contraindications

You should NOT undergo this treatment if:

- You are currently pregnant or breastfeeding
- You have an active vaginal or pelvic infection
- You have unexplained vaginal bleeding or known genital cancer

## Special Notes and Considerations

- Postmenopausal women may need lower energy settings due to thinner mucosa
- Postpartum laxity may respond well, but only after 6+ months postpartum
- Maintenance sessions may be required every 12–18 months

## Advanced/Optional Add-ons (If applicable)

I understand that the following combination or adjunctive therapies are experimental and not currently standard of care:

- Electromagnetic pelvic stimulation (e.g., EMSELLA)
- PRP (Platelet-Rich Plasma) vaginal injection
- External labial tightening (off-label application)

## Acknowledgment of Off-Label Use

I understand that HIFU for vaginal and vulvar rejuvenation may be an off-label use of this device. I confirm that:

- The nature of the procedure has been fully explained
- I have been informed of alternatives (e.g., pelvic physiotherapy, hormonal treatment, surgery)
- I have had the opportunity to ask questions
- I voluntarily consent to proceed

## Consent Statement

I confirm that:

- I have read and understood the above information
- My questions have been answered to my satisfaction
- I understand the risks, benefits, and limitations
- I understand this is not a guaranteed or permanent solution
- I agree to follow post-treatment instructions and attend follow-ups as advised

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / 20\_\_

Clinician Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / 20\_\_

Clinician Name & Qualification: \_\_\_\_\_