pregnolia®
INFORMED PREGNANCY CARE

PREGNOLIA PROBE

Quick Reference Guide

Short Instructions for Use

P/N 100057-E

2021-09-06

Other languages available at
www.pregnolia.com/instructions
Latest version available at
www.pregnolia.com/instructions

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Important points

- **Do not completely open** the *probe sterile pouch* before connecting the *filters*.
- **Do not touch** the *probe* without gloves.
- **Do not touch** the *probe tip*.
- Start the pump **before** approaching the cervix.
- Measure the anterior lip of the cervix at 12 o'clock position.
- Gently handle the *probe* when the *probe* is in contact with the cervix.
- During the measurement (continuous beeping) **do not push nor pull on the cervix**: the *probe handle* should not be too close to the probe tip nor too close to the *probe end*, but in the centre.

The Pregnolia System is composed of an active *control unit* (REF 100058) and a single-use *sterile probe* (REF 100026).

Intended Use

The intended use of the Pregnolia System is to provide information about the mechanical properties of the uterine cervix by assessing the tissue stiffness through a proxy parameter (the closing pressure, denominated CSI, or Cervical Stiffness Index, in mbar). The Pregnolia System is intended to be used in conjunction with the information obtained from the clinical evaluation of the patient and in addition to other standard examinations. It does not substitute them.

Medical Condition

Any clinical situation where the quantitative determination and monitoring of the uterine cervix stiffness can be beneficial, in order to gather supportive data for diagnostics and characterisation of cervical remodelling. In particular, during pregnancy, when an atypical cervical remodelling condition can be a symptom or a precursor to an abnormal course of pregnancy.

Indications

Assessment of tissue stiffness of the uterine cervix during gynaecological examinations, indicated in any situation where the quantitative determination and monitoring of the uterine cervix stiffness can be beneficial, in order to gather supportive data for diagnostics and characterisation of cervical remodelling. In particular, during pregnancy, where an atypical cervical remodelling condition can be a symptom or a precursor to an abnormal course of pregnancy.

Patient Population

The intended patient population are all pregnant and non-pregnant women for which the assessment of the uterine cervix is indicated.

User Group

The Pregnolia System is intended to be used by healthcare professionals with medical expertise in the fields of gynaecology or obstetrics, such as gynaecologists and midwives. The user must be familiar with speculum-based vaginal examinations. The user must have read these Instructions for Use. The system is not intended to be used by the patient.

Use Environment

The Pregnolia System is designed for use in a gynaecological examination room equipped for speculum-based vaginal examinations. In addition, noise levels should be moderate so as not to obscure the audio signals emitted by the system. The system is to be used with the aid of a speculum and, if necessary, an external illumination source. Furthermore, the use of standard medical accessories is necessary, such as gloves to handle the sterile probe and swabs and saline solution to clear the cervix of excessive mucus or the possible presence of ultrasound gel. The patient shall be seated and positioned in a manner consistent with routine practice for speculum-based vaginal examination.

Contraindications

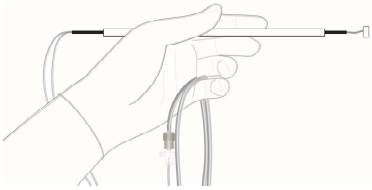
The Pregnolia System has been designed to minimise any foreseeable risks when correctly used. However, the user must assess the appropriateness of using the system on a case by case basis, and evaluate the overall risk posed by its usage to the woman or, if applicable, to the foetus. The use of the Pregnolia System is contraindicated in the following situations: severe vaginal bleeding; light bleeding (if the bleeding can be stopped, it is no longer a contraindication); *placenta praevia totalis* with haemorrhage (irrespective of severity); rupture of membranes before 34 weeks; cervical dilation ≥ 3 cm.

Precautions

While repeated measurements are not harmful, they may temporarily alter the properties of the cervical tissue, yielding different results. It is recommended to note the order in which measurements were taken for future reference and comparison purposes. Special care should be exercised in cases of: female genital mutilation; placenta praevia without bleeding; Müllerian anomalies with two cervices (a direct comparison to the guidance chart may not be possible as the two cervices may have a different stiffness value); psychological reasons; suspected or visible cervical and vaginal bacterial infections and viral infections (to minimize the possibility of damaging the cervical mucus plug and the spread of bacteria leading to ascending infection. Further, in case of suspected or visible cervical and vaginal infection, the stiffness value may not be representative of the native tissue. Special care during the measurement should also be exercised in presence of one the following conditions as the tissue may bleed if manipulated: ectopy and cervical polyps; Nabothian cyst; squamous intraepithelial lesion; conization/LEEP /LLETZ; cervical endometriosis; cervical carcinoma; cervical myomas; cervical condylomas; cervical tears, scar tissue; cervical dysplasia. If any of the above conditions are present at the measurement location, the stiffness value may not be representative of the native tissue as those conditions may influence the tissue stiffness. If possible, measure on a location around 12 o'clock where the tissue is native (for example, at 11 o'clock or 1 o'clock). Data presented in the guidance chart are for pregnant and non-pregnant women aged 18 years or older. Stiffness data for underaged women are not available, so a direct evaluation of the results is not possible.

Important Safety Information

Make sure to use the Pregnolia Probe only in conjunction with the Pregnolia Control Unit - Do not use *probes* from a third-party supplier as this will result in abnormal device functionality and may cause harm to the subject - Prior to each usage, inspect the integrity of the *probe sterile pouch*. Do not use the *probe* if the *probe sterile pouch* looks damaged or open, since sterility may be compromised - Make sure the *probe* expiration date has not passed as the use of expired *probes* might lead to harm to the subject -No reuse or re-sterilization of the *probe* is allowed as this is out of the intended use and may lead to contamination or abnormal device functionality - Use gloves while handling the *sterile probe* to prevent contamination of the *probe* - Do not entirely remove the *probe* from the *pouch* during assembly



prevent the *probe* from contacting non-clean surfaces - Do not dispose of the *probe sterile pouch* before the measurement session is complete as it contains necessary reference information in case of issues with the device.

Probe Connection Instructions

- Open partially the *probe sterile pouch* from the side indicated by the label.
- Pull the *filters* and the *silicone tubes* out of the *pouch* while keeping the *probe* inside the *sterile pouch* to ensure it remains sterile.
- Attach the *filters* to the *connector cable*, while leaving the *probe* inside the sterile *pouch*.

Probe Gripping

- Hold the *probe* as indicated in the figure above.
- Important: support the *filters* by taking the connector cable in your hand.
- Do not squeeze the *filters* and do not bend or kink the tubes.
- Hold the *probe* at the end closest to the *filters*, like a pen.

This guide is intended to supplement and NOT to replace the instructions for comprehensive usage of the Pregnolia System. Please refer to the Instructions for Use (P/N 100041) provided with the Pregnolia Control Unit (REF 100058) or online at www.pregnolia.com/instructions.

MEASUREMENT QUICK START

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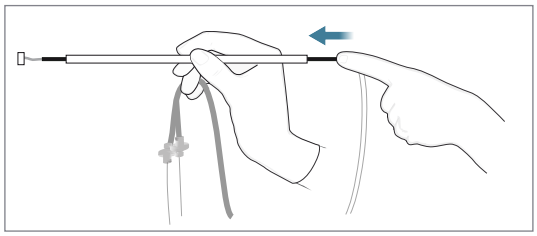
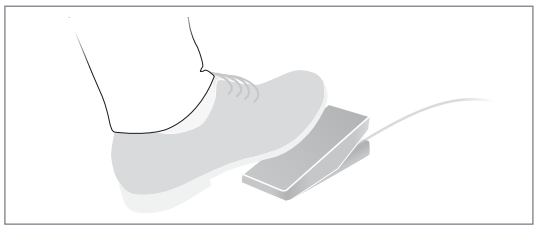
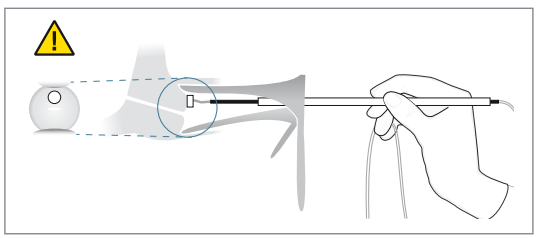


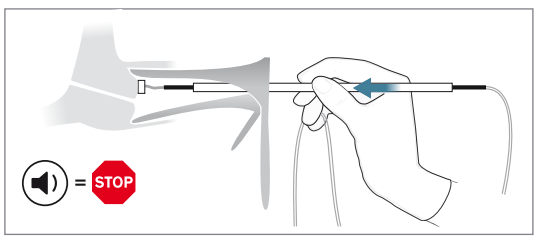
Push the *sliding tubes* completely inward.
Remember to support the *filters* by taking the *connector cable* in the hand.



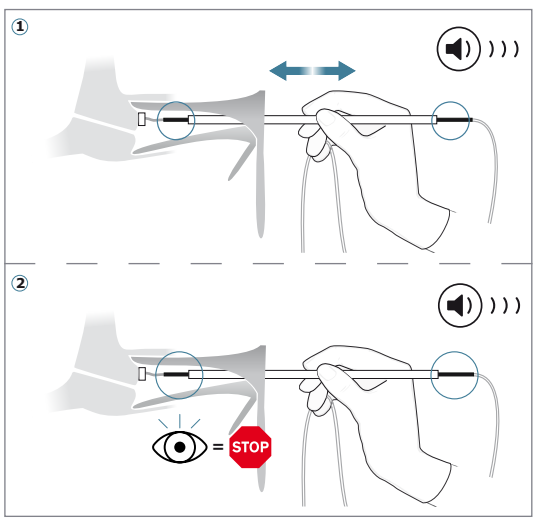
Press and release the *foot switch* to start the pump **before** inserting the *probe* into the vaginal canal.



Gently place the *probe tip* through the speculum on the anterior lip of the cervix at the 12 o'clock position.

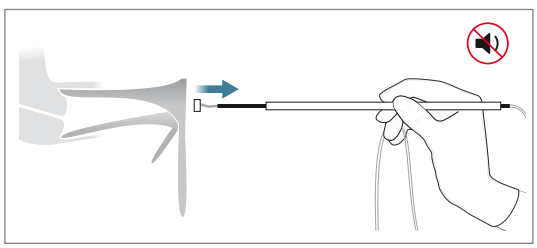


Gently push the *probe handle* inward until the first audio signal is heard (be-beep), then stop pushing the *probe*.
If the *tip* detaches, another sound is made (boop) and you will have to try again.



As soon as the tissue starts to be pulled into the *probe tip*, a continuous beeping is emitted (beep-beep-...).
Position the *handle* approximately in the centre of the *probe* (see below):

The *handle* is centred when you see roughly the same length of free *probe sliding tube* in the front and in the back.
Hold this position until the measurement finishes (be-be-beep).



When the audio signal stops the measurement is completed. Gently remove the *probe* from the vaginal canal.