HYSTEROMETER

Class I sterile

Sterile – Single use

1 – DESCRIPTION

 The hysterometer is composed of a white flexible distal part, marked with black ink, in polyethylene fixed on a colored (according models) stiff handle in polystyrene.

2 – REFERENCES AND CHARACTERISTICS

REFERENCE	CH	DIAMETER (mm)	HANDLE COLOR
PS1251000	10	3.3	Blue
PS1251200	12	4	Grey
PS1251400	14	4.6	Green

Packaging: box of 25 units in individual sterile sachet
Sterilization mode: sterilization with ethylene oxide.

3 – CLINICAL INDICATION

The hysterometer allows to assess the uterine cavity depth in the context of a routine gynaecological examination.

DO NOT USE FOR ANY OTHER PURPOSE

The hysterometer is delivered STERILE and for SINGLE USE.

4 – OPERATIONAL PRINCIPLE

After disinfection of the cervix, the marked distal part of the hysterometer is inserted into the uterine cavity via a speculum.

5 – CONTRAINDICATIONS

The hysterometer must not be used in case of (non exhaustive list) :

- Allergy to polyethylene.

6 – POSSIBLE UNDESIRABLE SIDE EFFECTS

The use of the hysterometer can induce the following possible undesirable side effects (not exhaustive list):

- Allergy to a material
- Pain in the uterus
- Slight bleeding

7 – RISKS AND COMPLICATIONS

Complications are mainly due to gynaecological practice. Perforation is the major complication (also related to the patient's anatomy) but remains rare. Since hysterometry is an invasive procedure, serious complications can occur after a perforation such as peritonitis, which is an infection of the peritoneum. If not treated in time, the infection can lead to the patient's death.
In order to prevent the risk of perforation, indications such as a break in the grip of the forceps on the cervix, abutment against an obstacle, pain felt by the patient or syncopal tendency, should lead to the removal of the hysterometer and the stop of the procedure.

8 – RECOMMENDATIONS

- Read the instructions for use in their entirety before use.
- This medical device must only be used by trained and qualified medical staff or authorised person, familiar with gynaecological explorations and acquainted with the pathologies in question as well as their possible complications (under the responsibility of a practitioner).

DO NOT USE the device if its packaging has been opened or damaged or if it shows any defect caused by transport or incorrect storage conditions or incorrect handling, which might adversely affect its use.

9 – STORAGE CONDITIONS

In order to prevent any damage, products should be stored in their original packaging, in a cold and dry place.

10 – PREPARATION OF MATERIALS - USE

- Make sure that the packaging is intact and the shelf-life has not expired as these aspects guarantee the sterility and the quality of the product.
- In order to respect the rules of hygiene and safety, wearing gloves is recommended.
- Open the sachet by peeling off the paper at the point indicated with two arrows.
- Remove the medical device respecting the asepsis rules.
- Make sure that the device is intact.
- Insert a vaginal speculum and visualize the cervix.
- Disinfect carefully the cervix.
- Perform the assessment of the uterine depth by softly pushing the hysterometer.
- Gently remove the hysterometer, respecting the asepsis rules.

HANDLE HYSTEROMETER WITH CAUTION

11 – DISPOSAL OF THE PRODUCT AFTER USE

After use, dispose of the product and its packaging according to the procedures in force in your establishment for the treatment of waste with infectious risk.

We remind you that these products are strictly disposable devices which cannot be reused or resterilized.
In case of reuse or resterilization, their performances could be affected with an important risk of contamination.

SINGLE USE - DO NOT REUSE – DO NOT RESTERILIZE

12 – SIGNIFICATION OF SYMBOLS USED ON LABELS

	Expiry date
	Lot number
	Product reference
	Ethylene oxide sterilization
	Do not use if packaging is damaged
	Do not reuse
	Read the instructions for use
	Avoid heat
	Avoid humidity
	Manufacturing date
	Manufacturer
	Latex free

Any serious incident occurring in connection with the medical device must be notified to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Manufacturer:

PRINCE MEDICAL DEVICES

PRINCE MEDICAL SAS, ZA La Sente du Moulin, 60530 Ercuis - FRANCE
Tél. : + 33 (0)3 44 26 54 76 – prince-medical@omerin.com – www.prince-medical.fr

CE 0459

Year of EC mark : 1999