

8200 • Pipelle® Endometrial Suction Curette

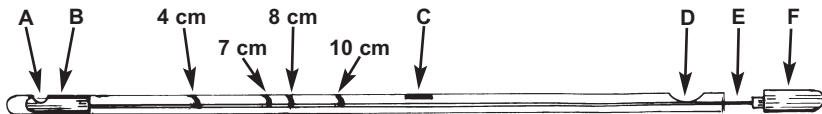
Directions for Use (English)

CE0086

DESCRIPTION

The Pipelle® is a single-use, sterile, disposable, suction curette for obtaining a histologic biopsy of the uterine mucosal lining or sample extraction of uterine menstrual content for microscopic examination or culturing.

The device consists of a clear, flexible, polypropylene sheath that is 26.5 cm (overall) 23.5 cm (effective) length with a 3.1 mm OD (Outside Diameter) and a 2.6 mm ID (Internal Diameter). The sheath is marked with colored, graduated markings from 4 cm to 10 cm, distance from the distal tip of the sheath to indicate the depth of insertion of the sheath into the uterus during use (see diagram below).



The 4, 7, 8, and 10 cm point depth markings on the sheath are accentuated and numbered. At 4 mm from the distal tip of the sheath is the center of the curette opening (A) which is 1.93 mm in diameter. This opening has sharp edges and leads to the lumen of the sheath. An EVA piston (B) affixed to the distal end of a soft acetal resin rod (E) can be moved forward and backward within almost the full length of the lumen of sheath. This is accomplished by manipulation of the knob (F) affixed to the proximal end of the piston rod which extends beyond the proximal end of the sheath. The piston is prevented from being totally pulled from within the sheath by means of an indentation (D) in the sheath located 1 cm from its proximal end. An orientation mark (C) indicates the position of the curette opening.

Rapid movement of the piston within the sheath from its fully inserted position to its maximum retracted position creates a negative pressure (suction) within the lumen of the sheath. This negative pressure draws the mucosal tissue through the curette opening and into the lumen of the sheath as the curette scrapes against the endometrial wall while it is maneuvered within the uterine cavity.

WARNINGS

In patients with amenorrhea, obtaining an endometrial biopsy with the Pipelle should be performed only after confirmation of the absence of detectable circulating HCG levels.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

Histologic biopsy of the epithelium and glandular mucosal layer (endometrium) of the uterine wall or sample extraction of uterine menstrual content for:

- Detection of endometrial carcinoma and precancerous conditions

- Determination of endometrial tissue response to hormonal influences by visual observation of the histologic sample, such as:
 - a. Endometrial dating
 - b. Periodic scrutiny of the effects of hormonal therapy on the uterine endometrium, particularly in patients receiving estrogen replacement therapy for menopausal symptoms and prophylaxis of osteoporosis
 - c. Luteal insufficiency (visually determined histologically from endometrial tissue obtained only during the secretory [progestational] phase of the menstrual cycle)
 - d. Functional metrorrhagia (contraception, pre-menopause)
 - Diagnosis of pathology associated with infertility
 - Bacterial culturing to specifically identify causative uterine pathogens

CONTRAINDICATIONS

The Pipelle® should not be used in patients who are pregnant or in patients suspected of being pregnant.

PRECAUTIONS

By virtue of its flexibility and small caliber, with the Pipelle a histologic endometrial biopsy can be performed with minimal danger of uterine wall perforation. However, care should be taken prior to its insertion to ascertain the depth of the uterus and any uterine retroflexion or antelexion present in individual patients. Best clinical judgement should be used to allow for any variations from anatomical norms during insertion and in no case should the instrument be forced against digitally felt resistance.

If passage of the Pipelle through the cervical canal is not found to be easily achievable, the instrument should not be forced and the possibility of the presence of pathologic cervical stenosis considered. With elderly patients in whom an extremely dry cervix may cause resistance to the instrument's passage, very slight lubrication of the sheath with a sterile water soluble gel may facilitate its insertion.

ADVERSE REACTIONS

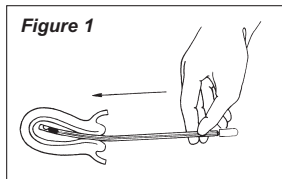
The following adverse reactions have been occasionally suspected or reported. The order of listing does not indicate frequency or severity.

- Injury to uterus (perforation)
- Cramping
- Uterine spasm

DIRECTIONS FOR USE

1. Prepare the vagina and cervix using currently accepted antiseptic techniques as you would for any intrauterine procedure.
2. With the vaginal speculum in place and open to expose the uterine cervix, gently probe the uterus for both its depth and direction with a uterine sound. **DO NOT USE** the Pipelle as a uterine sound. Then grasp the cervix with a very fine forceps or a tenaculum. If the uterus is anteverted, this grasp should be applied to the anterior lip of the cervix. If the uterus is retroverted, the grasp should be applied to the posterior lip of the cervix. If the uterus is normally positioned and the cervix is stable, it is possible that the use of forceps or a tenaculum may not be necessary.

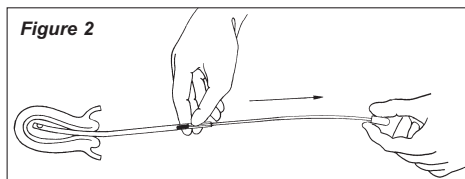
- Now withdraw the speculum approximately 2 cm and apply gentle traction to the forceps or tenaculum to straighten any cervical curvature and to stabilize the cervix.
- With the piston positioned at the extreme distal end of the sheath, the Pipelle® is then inserted into and gently passed through the cervical canal and into the cavity of the uterus to a depth that corresponds to that which was determined by uterine depth finding (**Figure 1**). Slight friction can usually be felt with the fingers as the Pipelle passes through the internal cervical os. **IN NO EVENT SHOULD FORCE BE USED** to obtain passage if resistance is encountered. Slight lubrication of the sheath with a sterile water soluble gel may facilitate its passage in patients with an extremely dry or narrow cervical canal. If, as is usually not the case, negotiation of the cervical canal proves painful, brief topical use of an anaesthetic agent may help facilitate introduction of the Pipelle.



- When the sheath is in position within the uterine cavity, discontinue any traction you have applied with a tenaculum or forceps. Then, while holding the sheath in position with one hand, with the other hand rapidly pull the piston firmly and without interruption (with one swift steady motion) toward the proximal end of the sheath as far as it will go (**Figure 2**).

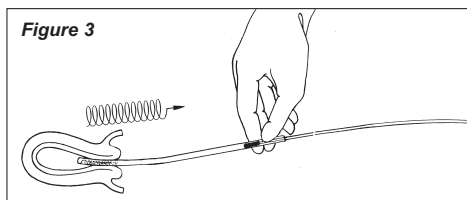
NOTE: Slow interrupted or partial withdrawal of the piston will not produce the amount of negative pressure (suction) necessary to obtain the maximum tissue biopsy.

An indentation in the wall of the sheath will prevent total withdrawal of the piston from within the sheath. This action creates a negative pressure (suction) within



the sheath that draws the tissue into the curette opening at the distal end of the sheath and captures the separated tissue within its lumen.

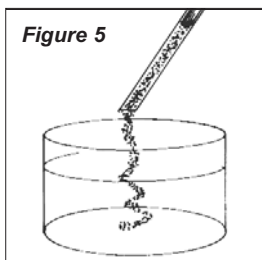
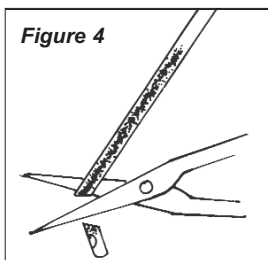
- Immediately after pulling the piston the full permissible distance, the sheath should be continuously rotated 360° by rolling or twirling between the fingers while moving the sheath laterally and back and forth (in and out) between the fundus and internal os at least 3 or 4 times to obtain sample. It should then be gently withdrawn from the uterus (**Figure 3**). Examination of the sheath should then reveal a specimen of the uterine mucosa of histologic quality clearly visible within the sheath. Bleeding, if it occurs at all, is usually minimal.



For Best Results:

At least 3 or 4 slow, spiralling passes between the fundus and internal os should be made before withdrawing the Pipelle from the uterus.

7. For histologic assessment of the specimen, the tip of the sheath should now be sectioned just proximal to its distal curette opening (**Figure 4**). The piston should then be advanced within the sheath to express the specimen from the sectioned sheath into an appropriate transport medium (**Figure 5**).



8. For bacterial culturing of the specimen, leave the piston in its fully withdrawn position and do not section the sheath at its distal curette opening. Immediately send the entire, intact instrument with the specimen captured within it to the laboratory with instructions to section the distal tip at a point at least 2 mm proximal to the distal curette opening and then to express the sample by use of the piston onto the appropriate culturing medium. Alternatively, immediately following biopsy, section the sheath just proximal to the distal curette opening and then, by advancing the piston, express the sample onto appropriate medium in a transport container and send it to the laboratory for culturing.

EXPLANATION OF SYMBOLS


REF Reorder Number

LOT Batch Code

 Use By

STERILE EO Ethylene Oxide Sterilized

 Latex Free

 Do Not Reuse

 **ATTENTION:**
See instructions for use.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

CE 0086 Product conforms to the Medical Device Directive 93/42/EEC

EC REP Authorized Representative in the European Community.

Pipelle® is a registered trademark of CooperSurgical, Inc.

© 2011 CooperSurgical, Inc.

CooperSurgical

Made in the USA

95 Corporate Drive • Trumbull, CT 06611 USA
Phone: (800) 243-2974 • Fax: (800) 262-0105

EC REP

Leisegang Feinmechanik GmbH
Leibnizstraße 32
D-10625, Berlin GERMANY

International:

Phone: (203) 601-9818
Fax: (203) 601-4747

www.coopersurgical.com

37219 • Rev. B • 3/11