EXPLANATION OF SYMBOLS

REF	Reorder Number
LOT	Batch Code
	Use-by date
STERILE R	Sterilized using irradiation
	Do not reuse
STERILISE	Do not resterilize
	Do not use if package is opened or damaged
LATEX	Not made with natural rubber latex
	Caution
	Consult instructions for use
R_x Only	**Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician

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Potocky Needle®

INSTRUCTIONS FOR USE

Product Numbers

Potocky Needle
#6066 • Box of 6

Potocky Luer Lock Needle
(For use with your own syringe)
#6166 • Box of 6

CooperSurgical

DESCRIPTION

The Potocky Needle® is designed for injection of solutions (such as 2% Lidocaine with or without 1:100,000 epinephrine) into the cervix and vaginal wall. Local anesthetics are indicated in office diagnostic and therapeutic procedures such as electroexcision, electrofulguration, CO2 laser excision and vaporization, and in some patients, endocervical curettage and cervical biopsies.

The disposable 27 gauge Potocky Needle® measures 9cm in length and has a reinforced shaft to prevent bending during injection. The needle is used in the application of intracervical and intravaginal blocks. The threaded Potocky Needle® is used in conjunction with a cartridge dental-type metal syringe. The luer-lock hub Potocky Needle® is used with medical syringes accepting luer-lock fittings.

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

CONTRAINDICATIONS

Absolute contraindications include known hypersensitivity to a wide type of local anesthetic solutions.

WARNINGS

Practitioners should be familiar with anesthetic agents and patient history. Read all warnings stated in pharmaceutical literature prior to administration of drug. Hypotensive shock may occur in rare situations soon after introducing the local anesthetic solution into the general blood circulation. Equipment and medication for cardio-respiratory resuscitation should be available in the physician's office.

PRECAUTION

- Inquire about allergic reactions to local anesthetic solutions in the past, i.e. at a dentist's office.
- Areas to be anesthetized should be cleansed with appropriate disinfectant solution and perfect visualization of the area must be achieved before the anesthetic procedure begins.
- A cartridge dental-type syringe does not aspirate, therefore penetration into blood vessels cannot be determined. The tip of the needle should not extend deeper than the subepithelial connective tissue (about 1-2 mm). This technique will reduce the risk of delivering anesthetic solutions directly into the bloodstream.
- The patient should be warned about discomfort of 1 to 3 minutes duration when entering the subepithelial tissue with the needle and when expelling the anesthetic solution.
- Take extra precautions with HIV positive patients; use double gloves and use needle under direct, preferably colposcopic view.
- Never leave used needles unsheathed.

INSTRUCTIONS FOR USE • General Operation

- Clean cervix and vagina with appropriate solution.
- Apply Lugol's strong iodine solution over lesional areas
- Visualize the lesion area using bright light source and, preferably, magnification. Place needle tip on epithelium adjacent to lesional tissue.
- Push needle just beneath the epithelium and expel the anesthetic by pushing on the plunger of the syringe.
- For cartridge syringes—ensure that the grip thumb hold is tightly screwed on the distal end of the plunger before the anesthetic procedure. This will provide stability to the syringe, the needle and proper emptying of the lidocaine-containing cartridge.
- Intracervical block is obtained by injecting 0.5 ml of 2% lidocaine solution with epinephrine in a concentration of 1:100,000 at the 12, 3, 6 and 9 o'clock positions.
- For large cervical lesions and those found in the vagina, more than four perilesional injection sites may be needed.
- Single vaginal lesions are simply "elevated" by the subepithelial anesthetic infiltrate.
- An Iris hook may be needed to stabilize and better visualize the area to be anesthetized, particularly the vaginal vault.
- Usually a total amount of 1 ml to 3.6 ml of 2% lidocaine solution provides an anesthetic block of the cervix and/or vagina. A larger volume of anesthetic solution may be needed for extensive external anogenital lesions.
- Wait approximately 1 to 3 minutes to obtain desired anesthesia effect.

CARE

The Potocky Needle® is disposable, designed for single use only, and should be discarded in accordance with Federal, State and local Medical / Hazardous waste practices.. Cartridge syringes should be clean and sterilized between use. Follow manufacturer's instructions for proper syringe care. As with all needles, handle according to your bloodborne pathogens procedure. **Ampules used in cartridge syringes with residual anesthetic solution should not be reused in another patient and must be discarded.**