ARGON MEDICAL DEVICES

Instructions for Use

PARACERVICAL / PUDENDAL BLOCK TRAY

Intended Use:

To provide anesthesia for gynecological procedures.

Contraindications:

This tray should be used by a physician familiar with the possible side effects, typical findings, and limitations associated with Paracervical/Pudendal Block. The value of the procedure should always be weighed against the risks before procedure is performed.

Cautions:

- **Rx Only**: Federal Law (USA) restricts this device to sale by or on the order of a physician. Read instructions prior to use.
- The Paracervical / Pudendal Block Tray is designed for single use only.
- Do not re-use, re-process, or re-sterilize the tray or any items provided in the tray.
- Re-use, re-processing, or re-sterilization may compromise the structural integrity and the intended function of the product which could result in patient injury.
- Verify the integrity of all items in the tray before use. Do not use the contents if package is open or damaged.

Warnings:

- These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.
- To avoid needle breakage, do not attempt to straighten a bent needle; discard and complete the procedure with a replacement needle.
- Do not re-shield used needles.
- Ensure all connections are tight without overtightening.
- The following situations should be considered when doing procedure planning, and the clinician should proceed with caution:
  - Patient’s inability to cooperate
  - Patient’s sensitivity to local anesthetics
  - Presence of infection in the ischiorectal space or the adjacent structures, including the vagina or perineum
  - Uteroplacental insufficiency
  - Preexisting fetal distress
  - Nonreassuring fetal heart tracing
  - Imminent delivery
  - Coagulopathy and/or presence of anticoagulants

Potential Complications:

Paracervical / Pudendal Block should not be attempted by physicians unfamiliar with the possible complications.
Possible complication may include, but are not limited to the following:

- Transient fetal bradycardia
- Intravascular or intrafetal injection
- Prolonged second stage of labor

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- Laceration of the vaginal mucosa
- Systemic anesthetic complications including palpitation, tinnitus, dysarthria, drowsiness, confusion, loss of consciousness, convulsions, hypotension and bradycardia
- Infection/abscess
- Hematoma
- Edema

How Supplied:

The Paracervical / Pudendal Block Tray is supplied sterile by ethylene oxide gas as a single use product. The tray is surrounded by a wrap and sealed in a plastic pouch. Do not use the tray if package is open or appears to be damaged or defective. The tray has no components made of natural rubber latex.

Preparation and Instructions for Use:

- Open hospital wrap using sterile technique and position pad under patient.
- Fill syringe with local anesthetic.
- Attach a 20 G x 6” needle to the syringe, utilize needle guide as desired.
    - Determine the desired needle penetration depth:
        - For 5 mm depth use the spacer provided in the tray
        - For 10 mm depth do not use the spacer
- Position needle guide and needle.
- Aspirate to ensure no blood vessel perforation then inject anesthetic into the desired locations.
- If increased needle penetration is desired, remove the spacer from needle guide.
- Additional anesthetic may be injected as the needle is withdrawn to ensure nerve block.

Handling and Disposal:

Handle in a manner which will prevent accidental puncture, percutaneous injuries and exposure to bloodborne pathogens. After use, this product may be a potential biohazard. Dispose in accordance with applicable laws and regulations.

Storage:

Store at standard ambient temperature.

Symbols:

	Sterilized using Ethylene Oxide		Use Before Date		Do not Re-Sterilize	RxOnly	Prescription Use Only
	Consult instructions for use		Single Use Only		Catalogue number		Manufacturer
	Do Not Use if Open or Damaged		Not made with natural rubber latex		Batch Code		

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