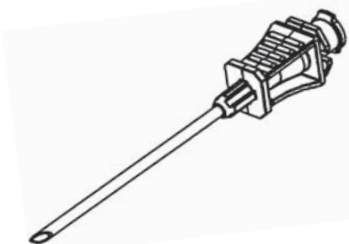


PRECISION POINT™ Transperineal Access System

Perineologic™ Access Needle

Instructions for Use



Description

The Perineologic™ Access Needle is a sterile, single use, disposable, biopsy needle guide intended to be used for soft tissue and tumor biopsies of the prostate and other organs. The Perineologic™ Access Needle is provided in various lengths from 7 cm – 20 cm and diameters of 14 gauge – 20 gauge.

Material

The Perineologic™ Access Needle is fabricated from medical grade stainless steel and medical grade polymers.

Indications for Use

The Perineologic™ Access Needle is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue and tumors of such organs as liver, kidney, spleen, lymph nodes, prostate, lung and various soft tissue lesions.

Contraindications

- Do not use in regions where there is an active infection.
- Not intended for use in bone.

Sterility

The Perineologic™ Access Needle is sterilized by ethylene oxide [EO].

Storage and Handling

Store at 15 – 30°C (59 – 86°F). Keep package dry.

Warnings and Precautions

- Discard and do not use previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged containers.
- FOR SINGLE USE ONLY
- Do not use if there is loss of sterility of the device.
- Do not re-sterilize.
- Do not use after expiration date.
- Before using, inspect the needle for damaged point, bent shaft or other imperfections that would prevent proper function. If the needle components are damaged or bent, DO NOT USE.
- Patients on anticoagulants and/or patients with bleeding disorders may present risks of post-surgical bleeding.
- This product should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of core needle biopsy, in particular, those relating to the specific organ being biopsied.
- The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.).

Possible Adverse Effects

Infection	Hemoptysis
Pain	Hemothorax
Hematoma	Adjacent tissue injury
Hemorrhage	Pneumothorax
Bleeding	Non-target tissue, organ or vessel perforation

Directions for Use

Preparation

1. Determine the appropriate gauge and length of Perineologic™ Access Needle required for the specific biopsy procedure.
2. Choose an appropriately sized/matched biopsy needle to be used with the Perineologic™ Access Needle.

NOTE: The biopsy needle is not provided by Corbin Clinical Resources, LLC.


3. Using aseptic technique, carefully remove the Perineologic™ Access Needle from the sterile package and from the protective sheath.

Biopsy Procedure

1. The biopsy procedure must be performed using appropriate aseptic technique
2. Prepare the operative site per standard protocol, to include the administration of antiseptic solutions and appropriate anesthesia to the region to be treated.
3. Insert the Perineologic™ Access Needle into the anatomy to be biopsied.
4. Using imaging guidance, insert the tip of the Perineologic™ Access Needle proximal to the lesion to be biopsied.
5. Place the appropriate biopsy needle (not provided) through the Perineologic™ Access Needle to the lesion to be biopsied.
6. Perform the biopsy and remove the biopsy needle from the Perineologic™ Access Needle, leaving the Perineologic™ Access Needle in place.
7. For multiple samples, reposition the Perineologic™ Access Needle using imaging guidance and repeat steps 4, 5, and 6 above.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

SYMBOL	DEFINITION
	Reference number
	Expiration date
	Storage temperature conditions
	Caution, consult accompanying documents
	Manufacturer
	Do not Reuse. For single use only.
	Do not Resterilize
	Sterilized with Ethylene Oxide
	Lot number / batch code


 Manufactured for:
Corbin Clinical Resources, LLC
 110 Luteman Road
 Cumberland, MD 21502
 TEL: 240-727-7662
www.perineologic.com

900687 Rev A