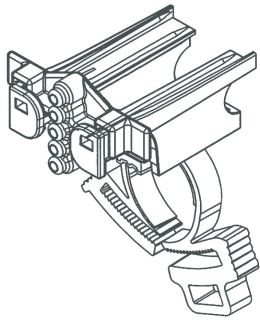


# PRECISION POINT™ Transperineal Access System

## Biopsy Needle Guide

### Instructions for Use



#### Description

The Perineologic™ PrecisionPoint™ Biopsy Needle Guide (PPBNG) is a sterile, single use, disposable, needle guide consisting, of a Carriage and a Rail/Clamp Assembly, that is intended for use with a cylindrical style transrectal ultrasound transducer (0.7" to 0.85" diameter BK #8658 or equivalent) associated with a BK ProFocus ultrasound system, a Perineologic™ Access Needle and a biopsy needle. The PrecisionPoint™ Biopsy Needle Guide is designed to stabilize a Perineologic™ Access Needle on the anatomy as a means to properly guide the anatomical placement of a biopsy needle into the prostate or other soft tissues through the use of ultrasound-assisted guidance.

#### Material

The Perineologic™ PrecisionPoint™ Biopsy Needle Guide is fabricated from medical grade polymers.

#### Indications for Use

The intended use of the Perineologic™ PrecisionPoint™ Biopsy Needle Guide when used in conjunction with a BK ProFocus 2202 ultrasound system and attached to the ultrasound system's transrectal transducer, is to facilitate proper needle placement to access anatomical structures.

#### Sterility

The Perineologic™ PrecisionPoint™ Biopsy Needle Guide 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.
- The Perineologic™ PrecisionPoint™ Biopsy Needle Guide is designed for use with a cylindrical style transrectal ultrasound transducer (0.7" to 0.85" diameter BK #8658 or equivalent) associated with a BK ProFocus ultrasound system.
- To aid in locking, avoid putting ultrasound gel on the probe in the area where the clamp will be placed.
- Do not use the Perineologic™ PrecisionPoint™ Biopsy Needle Guide with ultrasound transducers that do not fit into the Needle Guide Clamp or fail to be secured with the Needle Guide Clamp.
- The clamp on the PPBNG must be fully engaged to prevent the rotation of the PPBNG on the ultrasound probe and aligning the PPBNG in the correct orientation in relation to the ultrasound transducers. This is critical to the proper alignment of the biopsy needle in relation to the prostate gland image during the procedure.
- The clamp on the PPBNG, once engaged will prevent rotation of the PPBNG on the ultrasound probe. The user will align the PPBNG on the ultrasound probe at the midline position which is lined up with the sagittal transducer. This position will ensure proper alignment for proper visualization of the access needle and the biopsy needle.

#### Recommended Transducers and Ultrasound Systems

The Perineologic™ PrecisionPoint™ Biopsy Needle Guide is recommended for use with the following Ultrasound systems and transducer probes:


- BK ProFocus 2202 ultrasound system or equivalent.
- 0.7" to 0.85" diameter bi-plane, linear, cylindrical style transrectal ultrasound transducer (BK #8658 or equivalent).

#### Recommended Techniques

- See the User Manual for the PrecisionPoint™ Transperineal Access System at: [www.perineologic.com/usermanual](http://www.perineologic.com/usermanual)

**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


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