PROSTATIC BIOPSY NEEDLE

Guides & instruction for use

CAUTION: Federal law (USA) restricts this device to sale by or on the order of physician.

INDENTED USE:
To take a biopsy from Prostate only.

WARNING:
- For single product and patient use only.
- Do not use if any sign of product damage is visible.
- Do not re-use, reprocess or re-sterilize. Reuse may lead to infection and Pyrogencity. Reprocessing or Re-sterilization may damage the product and affect its integrity which when re-used may lead to possible deterioration in health and safety of patients.

PRECAUTIONS:
- Puncture of surrounding structure.
- Hematuria
- Infection

DEVICE DESCRIPTION:
It is a tissue sampling device, comprising a stylet having a notch therein and a cannula partially surrounding the stylet. The notch has an exposed portion for receiving tissue to be sampled, and the cannula is adjustable relative to the stylet to vary the size of the exposed portion and therefore the amount of tissue to be sampled. The device also comprises a trigger mechanism operatively connected to at least one of the cannula and the stylet. Activation of the trigger mechanism causes relative movement of the stylet with respect to the cannula for collection of a tissue sample.

Product range codes:

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<th>BIOLOGY NEEDLE &quot; FOR AUTOMATIC GUN&quot;</th>
<th>BIOLOGY NEEDLE &quot;FOR SEMIAUTOMATIC&quot;</th>
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METHOD OF APPLICATION:

1- Biopsy needle for automatic gun
   1. Identify the biopsy site preferably under US or CT.
   2. Using the sterile technique, prepare the skin with antiseptic and drape.
   3. If necessary, infiltrate the selected area with local anaesthetic.
   4. Open the needle pouch and remove protective sheath from the needle.
   5. Set the needle into the biopsy gun.
   6. Follow the instructions provided by the biopsy gun manufacturer.

Note: 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.
II- Semi-Automatic Biopsy Needles

1. Identify the biopsy site preferably under US or CT.
2. Using the sterile technique, prepare the skin with antiseptic and drape.
3. If necessary, infiltrate the selected area with local anaesthetic.
4. Open the needle pouch and remove protective sheath from the needle.
5. Charge Biopsy needle by pulling back hard on color coded plunger in a horizontal direction until a clicking sound is heard.
   *This needle has two advancements: 1cm and 2cm. The first clicking sound indicates setting of the 1cm option, and the second 2 cm option.
6. Insert the biopsy needle and advance into the targeted area while the plunger is in backward position.
   Warning: Avoid pushing the plunger during insertion of the needle
7. Move the plunger with thumb to advance the stylet and expose the specimen notch.
   *After insertion of the stylet into position it is possible to collect specimen more successfully by moving the plunger back and forth a few mm.
8. Press plunger past stop with thumb. This will automatically trigger the cannula to close sample notch and trap the specimen.
9. Draw needle out. Pull back on color coded plunger until it is locked. Push plunger firmly to expose the specimen notch.

Remove the biopsy specimen from notch in stylet.

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Information for patient

Indications for Prostate Biopsy
Prostate biopsy is indicated in case of suspected prostate cancer:
- Increased or rising PSA-concentration
- Suspicious digital-rectal examination

Technique of Prostate Biopsy

Patient Preparation
- Discontinuation of anticoagulant agents (aspirin, warfarin, ticlopidine ...)
- Exclusion or treatment of a urinary tract infection
- Perioperative antibiotic prophylaxis: long-acting fluoroquinolones should be given orally for 1–3 days: for example ciprofloxacin 500 mg 1-0-1. The antibiotic prophylaxis is not necessary in perineal prostate biopsy.

Anesthesia for Prostate Biopsy
The minimum is the application of rectal lidocaine gel 2% for 10 min before the prostate biopsy. This should be combined with a diclofenac 100 mg suppository 1 h before biopsy.
To achieve a good better effective anesthesia for the patient, infiltration anesthesia with local anesthetic, preferably in combination with a diclofenac suppository. 10–20 ml of local anesthetic is infiltrated on both sides of the prostate in the region of the neurovascular bundles before the biopsy. For prostate biopsies with high number of samples, a spinal or general anesthesia is useful.

Prostate Biopsy:
Prostate biopsy is performed with either a transrectal or transperineal technique. Prostate cores are gained with a 18G true cut biopsy needle under transrectal ultrasound imaging control.

Number and location of the prostate samples:
The minimum of prostate samples are six cores (sextant biopsy), three from each prostate lobe (apical, middle and basal) [sextant prostate biopsy] (Hodge et al, 1989). The EAU guidelines on prostate cancer recommend at least 10 prostate cores [Heidenreich (Eur Urol 2008)]

Localization of biopsy cores in sextant prostate biopsy
Suspicious (hypoechoic) lesions of the prostate should be biopsied in addition. This increases the likelihood of prostate cancer detection. The prostate cores are sent separately to the pathologist, this enables later conclusions for e.g. nerve sparing radical prostatectomy.

Biopsing the prostate in the region of the prostate capsule, sextant prostate biopsy can detect more cancers (Stamey, 1995). The biopsy needle advances 2 cm into the tissue; this must be anticipated before biopsy. Especially apical biopsies can injure the dorsal venous plexus of the prostate.

Prospective studies demonstrated an improved sensitivity by increasing the prostate core number. The additional sampling should be obtained near the organ capsule of the prostate and from the transitional zone [fig increased
sampling in prostate biopsy]. Not all randomized trials have demonstrated this effect. Additionally, increased sampling may detect more clinically insignificant prostate cancers.

80% of prostate cancers are diagnosed with the first prostate biopsy, 10% with the second prostate biopsy, 7% with the third prostate biopsy and 3% with the fourth prostate biopsy.

**Extended Prostate Biopsy:**
Localization of the cores of prostate biopsy with 12 biopsies

**Complications of Prostate Biopsy**
Mild complications are relatively common (over 50%), serious complications are very rare.

**Infections after prostate biopsy:**
Acute prostatitis rare infectious complications are sepsis (1%) there are reports about fatal sepsis due to anaerobic bacteria.

**Bleeding:**
50% of patients have minor hematuria for up to seven days. Hematospermia in 30%, this can last up to a month. Severe rectal bleeding can be managed with rectal packing or endoscopic coagulation.

**Other complications of prostate biopsy:**
- Urinary retention (1–2%)
- Vasovagal reaction (5%)
- Adverse reactions from the local anesthetic, such as dizziness, nausea, syncope, cardiac arrhythmias or seizures.

**ADVANTAGE:**
- Suitable to be seen under fluoroscopic or ultrasound
- Pre-determining biopsy length (10-20mm) by pilling the firing part for one or two clicks.
- Stylet completely retractable from the cannula left in situ: control of specimen size and possibility of multiple biopsies (prostate mapping).
- Color coded for easier needle size (gauge) determination.

**COMPLICATIONS:**
- Infections
- Septicemia
- Hemorrhages
- Tumor dissemination
- Bladder perforation
- Urinary obstruction
- Severe pain
- Erectile dysfunction
- Loss of desire and reduced sexual activity

**HOW SUPPLIED:**
The devices are sterilized by ethylene oxide. Contents are sterile, non-pyrogenic in unopened or undamaged package. Do not use the device if package has been damaged or has been opened.

**STORAGE:**
Store at room controlled temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that devices are used prior to expiration date on the package label.

**PRODUCT SAFE DISPOSAL:**
*Used device should be disposed in sanitary container to prevent possible contamination and cross infection.*

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