CamPROBE

INSTRUCTIONS FOR USE

Read the entire leaflet carefully before you use the CamPROBE Prostate Biopsy device.
If it is your first use of the CamPROBE device it is advised that you also watch the tutorial video; see section 13 for the location of the webpage.

1. Device Intended Purpose

The CamPROBE device (Cambridge Prostate Biopsy Device) is intended to facilitate transperineal prostate biopsies under local anaesthetic.

2. Indications For Use

CamPROBE is indicated for use in adult males over the age of 18, with suspected or known prostate cancer and who need a prostate biopsy.

3. Principles of Operation and Mode of Action

The CamPROBE device is a surgically invasive, transient (less than 60 minutes use duration), single use, sterile device consisting of a stainless steel cannula and an integrated coaxial needle. The CamPROBE is inserted at 2 points on either side of the perineum mid-line. It is then advanced to the prostate with simultaneous targeted local anaesthetic (LA) infiltration to deeper structures (including pelvic muscles) using the integrated delivery needle and under transrectal ultrasound guidance. Once in position, the delivery needle is removed and the CamPROBE cannula can be used as an access sheath for prostate biopsies. The CamPROBE can be angled or repositioned to reach different areas without superficial or deep structure re-puncture.

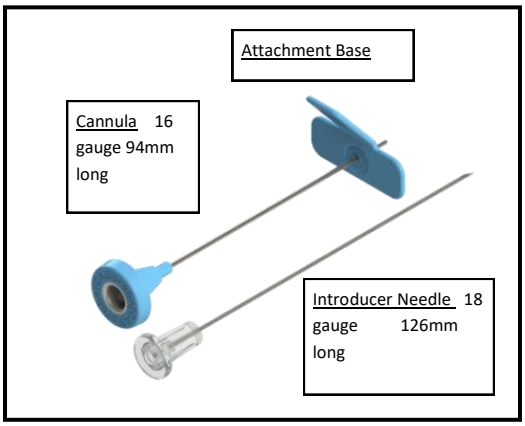

Figure 1 - CamPROBE Prostate Biopsy Device.

4. Contra-indications

Patients who do not meet the indication for use.
Patients with contra-indication to a prostate biopsy.
Patients with contra-indications to a prostate biopsy through the transperineal route.

5. Users

CamPROBE must only be used by qualified healthcare professionals appropriately trained in prostate biopsy procedures.

6. Use environment

DO NOT use the CamPROBE device outside the following use environments: surgical operating theatres, surgical day case procedure rooms or outpatient clinics.

7. Warnings and Precautions

- CamPROBE must only be used for prostate biopsies through the transperineal route.
- The CamPROBE device is for Single Use Only.
- DO NOT use product beyond printed expiry date on package.
- Inspect the CamPROBE device packaging and assess the condition of all components prior to the biopsy. Check packaging integrity and ensure that the sterile package has not been unintentionally opened. Non-sterile products may result in infection or other complications requiring patient treatment.
- If the CamPROBE device appears damaged/ faulty or malfunctions during use DO NOT USE the device. Replace the suspect device with a new device and follow your procedure for reporting device defects.
- Take precautions during the removal of the CamPROBE device from packaging to keep the device sterile and avoid accidental stick injury to patient/operator. Practice aseptic technique during the entire procedure, including removal of the device from its packaging. The healthcare assistant shall pass the device to the clinician who will remove the needle guard.
- Take precautions during the removal of the sharps protection on the CamPROBE device to avoid accidental stick injury.
- DO NOT re-cap the needle with the sharps protection. Needle stick injury to the user may occur.
- As with all surgical procedures, the CamPROBE device operator and clinical personnel should follow aseptic technique including the use of surgical gloves and protective clothing.
- If the device is dropped during the procedure or is involved in an accidental stick injury dispose of the device according to your infectious waste disposal procedure. Non-sterile product may result in infection or other complications.
- Ensure that the patient's perineum is properly sterilised using antiseptic wash and that the sterile field is properly maintained.
- Ensure the CamPROBE cannula and integrated needle are primed with saline before use on patient.
- Prime the CamPROBE needle and cannula directed at a sterile bowl in a safe direction away from the patient with no obstructions. Failure to do so may result in user or patient injury or accidental break in sterility.
- DO NOT insert the integrated LA delivery needle into a patient without the cannula. The needle with loaded syringe is ONLY intended to be used with the cannula as a guide.
- The CamPROBE device must be used ONLY with a biopsy gun deploying an 18-gauge needle.
- DO NOT adhere the Attachment Base to broken skin.
- After use, discard each CamPROBE device according to your infectious waste disposal procedure for single use surgical devices. Use yellow lidded sharps bin only.
- DO NOT re-sterilise or re-use the CamPROBE device. This will affect the functionality and sterility of the device resulting in potential injury and infection to the patient and the user.

8. Undesirable Side Effects

Potential side effects that may be experienced during and after the CamPROBE prostate biopsy procedure are those associated and common in prostate biopsy. These include:

- Procedural pain, post procedural discomfort and bruising of the skin;
- Haematuria, haematospermia, haematochezia and dysuria;
- Temporary erectile dysfunction, painful ejaculation, urethral bleeding and urinary retention;
- Urinary tract infection and septicaemia.

Qualified healthcare professionals must convey this information to the patient.

9. How to Conduct CamPROBE Procedure

9.1 Prepare standard equipment on a sterile tray/table including: swabs, Steri Strips or plasters, antiseptic wash, biopsy cassettes to receive the samples, sterile swabs and post procedure dressings, a No. 15 Scalpel Blade, a Luer slip syringe with appropriate local anaesthetic, a Luer slip syringe with sterile saline, orange needles and green needles. Ensure that a linear transducer endocavity probe and an appropriate 18-gauge prostate biopsy needle are available for use in the procedure. A disposable or reusable firing handle may be used. The procedure should occur under ambient low clinic noise levels, normal theatre or clinic setting lighting and ambient room temperature.

9.2 **Patient Preparation:** as per local standard practice with regards to use of antibiotics. Suppositories may be self-administered by the patient if required. No further patient preparation specific for CamPROBE is required.

9.3 Have patient adopt the standard lithotomy position with no extension. Patients are asked to hold their external genitalia up onto the abdomen with a slight degree of tension (Figure 2).

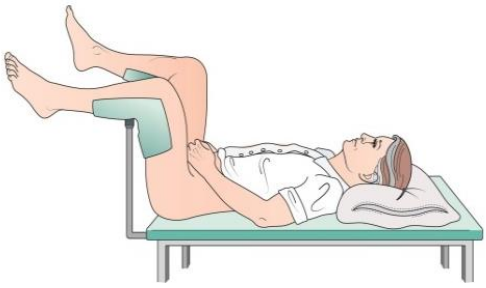

Figure 2 - The patient is placed in a modified lithotomy position, with patients supporting their own genitalia away from the operative field.

9.4 Prepare the perineum by shaving (if necessary) and then place a sterile drape over the lower abdomen and apply an antiseptic wash to the perineum.

9.5 Lubricate the linear transducer endocavity probe then insert into the rectum for a preliminary scan to visualise the prostate gland and its depth from the perineum.

9.6 Mark a point on the perineum approximately 1.5cm up from the anal verge in the mid line. The punctures will be made 1.5cm to the right and left of this point laterally (Figure 3). There will therefore be two perineal punctures, one on the left and one on the

right. A new CamPROBE device will be used for each puncture.

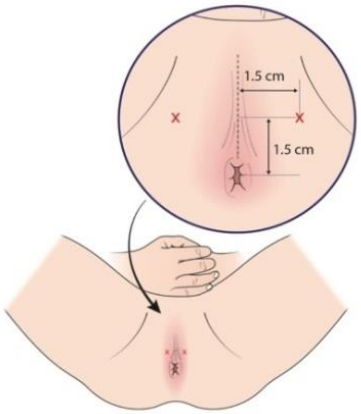

Figure 3 - After skin preparation and draping, two points are marked 1.5cm above and lateral to the anal verge and perineal midline. A small amount of local anaesthetic (1-2mLs) is injected into the skin before the device is inserted.

9.7 Numb the skin by injecting approximately 1mL of local anaesthetic in the two areas marked in Figure 3. Confirm the area is numb before proceeding.

9.8 Remove the CamPROBE device from the packaging and remove needle guard. The needle guard can be removed only by the specialist clinician. Do not remove the attachment base loaded onto the cannula.

9.9 Once the local anaesthetic syringe is prepared and attached to the device, under ultrasound image guidance by the operator, insert the assembled CamPROBE device with a 10mL local anaesthetic syringe into the previously anaesthetised skin area. A prior 2-3mm deep stab incision into the skin at these points using a No.15 scalpel blade is recommended as this can facilitate easier and smoother insertion of the sheathed coaxial CamPROBE needle and cannula device.

9.10 Unpeel backing from the attachment base and advance to the level of the prostate with LA infiltration along the track as needed (Figure 4A). As the device approaches the prostate capsule, about 2-3mLs of LA is delivered to the peri-prostatic space.

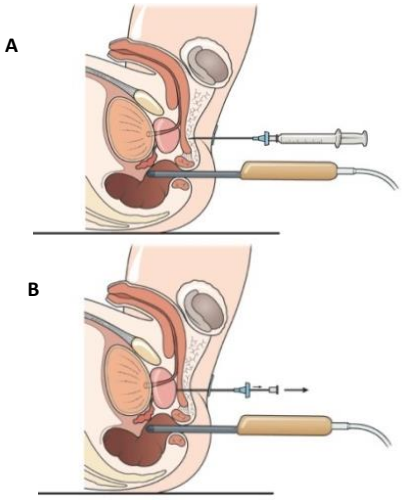

Figure 4- Sagittal diagrams demonstrating (A) CamPROBE insertion under ultrasound guidance with synchronous LA infiltration and (B) disarticulation of the integrated needle leaving the cannulation probe adjacent to the prostate.

9.11 Place attachment base onto the skin of the perineum. Orient the thumb tab away from the midline pointing towards the ipsilateral thigh, allowing the adhesive portion to be attached vertically.

9.12 Once deployed, the syringe and inner delivery needle is removed leaving the cannula ready for prostate biopsies (Figure 4B).

9.13 An appropriate 18 gauge biopsy needle is then inserted through the funnelled entrance of the cannula to take the biopsies.

9.14 The ultrasound probe is rotated and angled to visualise the needle direction and biopsy site for each acquisition. Biopsies can now be taken from the posterior and anterior prostate and mid and peripheral zones (typically 6 on each side) using a fan approach. When biopsies are taken at an angle, straighten the biopsy needle and cannula before withdrawal to avoid inadvertent displacement of the CamPROBE. The device can also be further stabilised by a thumb or finger on the wide funnel rim using the hand holding the US device.

9.15 If there is any further discomfort indicated by the patient, the integrated needle can be returned through the funnelled entrance of the cannula and further LA injected without the need for a further skin puncture.

9.16 Once all biopsies are taken, the biopsy needle is removed and the cannula withdrawn before removing the attachment base.

9.17 Standard Steri-Strips, plasters or a simple dressing is applied to the puncture sites.

9.18 The procedure (Steps 9.2-9.17) is then repeated on the contralateral side. **NOTE: use a new CamPROBE device for the contralateral side.**

Disposal: *Follow your infectious waste disposal procedure for single use surgical devices.*

10. Clinical benefit

CamPROBE facilitates transperineal biopsy acquisition using simultaneous local anaesthetic delivery through an integrated needle. It is an alternative to transrectal and other transperineal devices, using only two body entry puncture points, resulting in low pain scores, patient comfort and patient acceptability. Procedural access through the perineum reduces complications due to infections and sepsis, compared to transrectal procedures.

11. Post-Procedure Patient Care (Recommendations Only)

After the procedure, the patient can sit up and be observed for up to an hour to ensure full recovery before being allowed home.

Post-procedure protocols should follow each unit's local standard practice for use of antibiotics and passing urine.

12. Content of Individual sterile package and other Information

- The sterile package consists of one sterile barrier pouch containing the fully assembled CamPROBE device.
- Store the device in a dry, clean, well ventilated area at room temperatures between 15°C and 25°C, humidity levels of 40 – 60% and out of direct sunlight.

13. Further Information

A PDF version of this IFU is available at www.jeb-technologies.com

The Step by Step Guide video can be viewed here; https://www.youtube.com/watch?v=d4N_GHM5SzY&t=4s

Any serious incident that has occurred in relation to the CamPROBE prostate biopsy device should be reported to JEB Technologies Ltd and the competent authority of the Member State in which you are established (for example, the ***MHRA*** in the United Kingdom).

Symbols Key

Medical Device

Consult Instructions for Use

Date of Manufacture

Manufacturer

Use-by date

Batch Code

Catalogue number

Sterilised using ethylene oxide

Sterile barrier

Do not re-use

Do not use if package is damaged and consult instructions for use

Caution

Temperature limit

Humidity limit

Keep away from sunlight

Keep dry

The product complies with Medical Device Regulations (EU) 2017/745

The product complies with Part II of The Medical Device Regulations 2002 (UK)

**JEB Technologies Ltd, Hampstead Avenue,
Mildenhall, Suffolk,
IP28 7AS, United Kingdom**