Instructions for Use

**BARD® MARQUEE™**
Disposable Core Biopsy Instrument

**BARD® MARQUEE™**
Disposable Core Biopsy Instrument Kit
Instructions for Use

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. Device Description

The Bard® Marquee™ Disposable Core Biopsy Instrument is a single use core biopsy device. See Figure 1. It is available in 12 gauge with 10cm and 13cm needle lengths. The coaxial cannula release is colored light blue to indicate 12 gauge.

The Bard® Marquee™ Disposable Core Biopsy Instrument is available as a biopsy instrument only and as a kit, which includes the Bard® Marquee™ Disposable Core Biopsy Instrument and compatible Coaxial Biopsy Needle. See Figure 2. The Bard® Marquee™ Disposable Core Biopsy Instrument Kit will herein be referred to as the “Kit”.

![Figure 1: Bard® Marquee™ Disposable Core Biopsy Instrument](image1)

- 1. Stylet
- 2. Cutting cannula
- 3. Centimeter marks
- 4. Energizing slide
- 5. Coaxial cannula release
- 6. Penetration depth switch
- 7. Automatic “A” mode trigger
- 8. Single “S” mode trigger
- 9. Fire ready indicator

![Figure 2: Coaxial Biopsy Needle included as part of the Kit](image2)

- 10. Centimeter marks
- 11. Coaxial cannula
- 12. Trocar stylet

<table>
<thead>
<tr>
<th>Bard® Marquee™ Disposable Core Biopsy Instrument</th>
<th>Catalogue Number</th>
<th>Gauge Size and Needle Length</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MQ1210</td>
<td>12g x 10cm</td>
</tr>
<tr>
<td></td>
<td>MQ1213</td>
<td>12g x 13cm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bard® Marquee™ Disposable Core Biopsy Instrument Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalogue Number</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>MQK1210</td>
</tr>
<tr>
<td>MQK1213</td>
</tr>
</tbody>
</table>
The following is applicable to all catalogue numbers.

The Instrument has an 18mm and 25mm penetration depth.

The length of the sample notch for the 18mm penetration depth is 17mm.

The length of the sample notch for the 25mm penetration depth is 19mm.

B. How Supplied

The product is supplied sterile and non-pyrogenic unless the package has been opened or damaged. Sterilized using Ethylene Oxide. For single patient use only. Do not reuse. Do not resterilize.

C. Indications for Use

The Bard® Marquee™ Disposable Core Biopsy Instrument and Kit are intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

D. Contraindications

Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding problem.

E. Warnings

1. Post-biopsy patient care may vary with the biopsy technique utilized and the individual patient’s physiological condition. Observation of vital signs and other precautions should be taken to avoid and/or treat potential complications that may be associated with biopsy procedures.

2. The collection of multiple core biopsy samples may help to ensure the detection of any cancer tissue. A “negative” biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma.

3. The Instrument and Kit have been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.

4. Do not resterilize the Instrument or Kit. After re sterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or re sterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

Note: Inspect Instrument and Kit needle components for damaged point, bent shaft or other imperfections prior to use and after each sample is collected. DO NOT USE the device if any imperfection is noted.

Note: After use, the Instrument and Kit may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations.

F. Precautions

1. The Instrument and Kit 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 tissue being biopsied.

2. The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT, etc.).

Note: This product has not been tested for MR Imaging compatibility.

3. Never test the Instrument by firing into the air. Damage may occur to the Instrument needle tip and could result in patient and/or user injury.
4. Unusual force applied to the stylet or unusual resistance against the stylet while extended out of the cutting cannula may cause the stylet to bend at the sample notch. A bent sample notch may interfere with needle function.

G. Potential Complications

Potential complications associated with core biopsy procedures are site specific and may include, but are not limited to: hematomas; hemorrhage; infection; adjacent tissue injury; pain; bleeding; hemoptysis; hemothorax; non-target tissue, organ or vessel perforation; pneumothorax; and air embolism. Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

H. Equipment Required

- Appropriate imaging modality accessories
- Surgical gloves and drapes
- Local anesthetic
- Coaxial (Optional, available as part of the Kit)
- Scalpel
- Sample collection container
- Other equipment as necessary

I. Directions for Use

Device Preparation
1. Using aseptic technique, remove the Instrument and Coaxial (when applicable) from its package.
2. Remove the protective needle sheath(s).
3. Before using the Instrument or Coaxial, inspect each needle for damaged point, bent shaft or other imperfections that would prevent proper function. If the needle is damaged or bent, DO NOT USE.
4. Energize (cock) the Instrument by pulling back on the energizing slide twice to lock the cutting cannula and stylet in place (See Figure 4-A).
5. Using the penetration depth switch, select the desired penetration depth (18mm or 25mm). The default setting is 25mm. Changing the penetration depth is only possible when the Instrument is energized. (See Figure 4-C)

Note (Kit only): Prior to performing the procedure, ensure the trocar stylet can be separated from the coaxial cannula without difficulty by loosening the hubs. Retighten the trocar stylet into the coaxial cannula and ensure the trocar stylet is fully seated in the coaxial cannula prior to insertion into the patient.

Biopsy procedure

The biopsy procedure must be performed using appropriate aseptic technique. Prepare site as required. Adequate anesthesia should be administered prior to incision of the skin. For ease of insertion, puncture the skin with a scalpel at the entry site.

1. Bard® Marquee™ Disposable Core Biopsy Instrument

Catalogue Numbers: MQ1210, MQ1213

A. Verify the Instrument is energized (cocked) by looking at the fire ready indicator (See Figure 4-F).
B. Using imaging guidance, insert the Instrument proximal to the lesion to be biopsied.
C. Fire the Instrument in either Automatic or Single mode.
   i. Automatic Mode – Press the “A” trigger to sequentially fire the stylet and cutting cannula to automatically capture the biopsy specimen (See Figure 4-D).
   ii. Single Mode – Press the “S” trigger to fire only the stylet (See Figure 4-E). With imaging, the user can verify the sample notch is in the target area to be biopsied. When ready to capture the biopsy specimen, press the “A” trigger to advance the cutting cannula (See Figure 4-D).
D. Remove the Instrument from the patient.
E. Pull back on the energizing slide once to lock the cutting cannula and expose the sample notch to acquire the biopsy specimen.
F. If additional biopsies are required, pull back on the energizing slide once more to lock the stylet and repeat steps A through E.
Kit Option 1 – Target the lesion using the Coaxial

A. Using imaging guidance, insert the Coaxial proximal to the lesion to be biopsied.

B. While holding the coaxial cannula hub, turn the trocar stylet hub counterclockwise and remove leaving the coaxial cannula in place to retain the tract.

C. Verify the Instrument is energized (cocked) by looking at the fire ready indicator (See Figure 4-F).

D. Insert the Instrument into the coaxial cannula.

E. Fire the Instrument in either Automatic or Single mode.
   i. Automatic Mode – Press the “A” trigger to sequentially fire the stylet and cutting cannula to automatically capture the biopsy specimen (See Figure 4-D).
   ii. Single Mode – Press the “S” trigger to fire only the stylet (See Figure 4-E). With imaging, the user can verify the sample notch is in the target area to be biopsied. When ready to capture the biopsy specimen, press the “A” trigger to advance the cutting cannula (See Figure 4-D).

F. While holding the coaxial cannula hub, remove the Instrument leaving the coaxial cannula in place (remove coaxial cannula if no additional biopsies are required).

Note: If desired, pull back on the coaxial cannula release or twist the Instrument to detach the Instrument from the coaxial cannula (See Figure 4-B).

G. Pull back on the energizing slide once to lock the cutting cannula and expose the sample notch to acquire the biopsy specimen.

H. If additional biopsies are required, pull back on the energizing slide once more to lock the stylet and repeat steps C through G.

Kit Option 2 – Target the lesion using the Instrument and attached coaxial cannula

A. Turn the trocar stylet hub counterclockwise to remove the trocar stylet from the coaxial cannula.

B. Insert the Instrument into the coaxial cannula.

C. Install the coaxial cannula to the Instrument’s coaxial cannula release hub (See Figure 4-B).

D. Verify the Instrument is energized (cocked) by looking at the fire ready indicator (See Figure 4-F).

E. Using imaging guidance, insert the Instrument with attached coaxial cannula proximal to the lesion to be biopsied.

F. Fire the Instrument in either Automatic or Single mode.
   i. Automatic Mode – Press the “A” trigger to sequentially fire the stylet and cutting cannula to automatically capture the biopsy specimen (See Figure 4-D).
   ii. Single Mode – Press the “S” trigger to fire only the stylet (See Figure 4-E). With imaging, the user can verify the sample notch is in the target area to be biopsied. When ready to capture the biopsy specimen, press the “A” trigger to advance the cutting cannula (See Figure 4-D).

G. While holding the coaxial cannula, pull back on the coaxial cannula release or twist the Instrument to detach the Instrument from the coaxial cannula (See Figure 4-B). Remove the Instrument leaving the coaxial cannula in place (remove coaxial cannula and Instrument if no additional biopsies are required).

H. Pull back on the energizing slide once to lock the cutting cannula and expose the sample notch to acquire the biopsy specimen.

I. If additional biopsies are required, pull back on the energizing slide once more to lock the stylet and insert the Instrument into the coaxial cannula and repeat steps D through H.

Recommendation (Kit only): When collecting multiple samples, wipe the Instrument needle with sterile moist gauze prior to reinsertion into the coaxial cannula. This will aid in proper movement of the Instrument needle within the coaxial cannula.
**Figure 4:** Bard® Marquee™ Disposable Core Biopsy Instrument

Key Features for Use

A. **Energizing slide**
   - Pull back once to lock cutting cannula and expose sample notch
   - Pull back second time to lock the stylet

B. **Coaxial cannula release**
   - If desired, pull back to release coaxial cannula from Instrument

C. **Penetration depth switch**
   - Select 18mm or 25mm penetration depth after the Instrument is fully energized

D. **“A” trigger**
   - Fires Instrument in Automatic mode
   - Fires cutting cannula after stylet has been fired in Single mode

E. **“S” trigger**
   - Fires Instrument in Single mode (stylet only)

F. **Fire ready indicator**
   - Instrument is fully energized when both indicators are shown

**Warranty**

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular’s sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

**TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.**

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and revision number for these instructions are included for the user’s information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.