

Symbols used on Labeling



Keep away from
sunlight



Manufacturer



Keep dry



Date of manufacture



The Green Dot



Catalogue number



Recyclable



Lot number



Single use



Sterilized using
ethylene oxide



Do not resterilize



Consult instructions
for use



Contents



Do not use if package
is damaged



Use by

Labeling issue date: 11/15

In the event 3 years have elapsed between this date and the product use, the user should contact Bard to see if additional product information is available.

Assembled in Germany.

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VACU-CUT®

Disposable Aspiration Biopsy Needle

Information for Use:

Caution:

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

Description:

The VACU-CUT® Disposable Aspiration Biopsy Needle is a two-part puncture needle consisting of a cannula with a sealing membrane located in the needle-hub and a stylet. The sealing membrane forms a seal with the stylet that permits the creation of a vacuum sufficient to draw a tissue sample into the lumen of the cannula when the stylet is withdrawn.

The VACU-CUT® Disposable Aspiration Biopsy Needle is a sterile, disposable aspiration biopsy needle for single patient use. It is available in several needle gauge sizes and lengths.

Indications for Use:

The VACU-CUT® Disposable Aspiration Biopsy Needle is 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.

Contraindications:

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

Warnings:

After use, the VACU-CUT® Disposable Aspiration Biopsy Needle may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The VACU-CUT® Disposable Aspiration Biopsy Needle is not designed for puncturing the skin. Puncture the skin with a scalpel before inserting the needle.

Post-biopsy patient care may vary with the biopsy technique utilized and the individual patient's physiological conditions. Observation of vital signs and other usual precautions to avoid the serious potential complications associated with any biopsy procedure may be indicated.

Precautions:

The VACU-CUT® Disposable Aspiration Biopsy Needle should be used by a physician who is completely familiar with the indications, contraindications, precautions, limitations, typical findings and possible side effects of aspiration biopsy.

Before using, inspect the needle components for damaged point, bent shaft or other imperfections that would prevent proper function. If the needle components are damaged, bent or do not move together easily, DO NOT USE. Notify your Customer Service Representative.

Potential Complications:

Some potential complications of aspiration biopsy are hematoma, hemorrhage, infection and pain.

Directions for Use:

Needle Preparation:

1. Prior to use, determine the appropriate gauge and length for the specific biopsy to be performed. Using aseptic technique, remove needle from package and from protective sheath.
2. Insert the stylet through the sealing membrane and into the cannula, up to the base plate so that the needle is assembled.

Biopsy Procedure:

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Prepare site as required. Adequate anesthesia should be administered prior to incision of the skin.
2. Puncture the entry site using a scalpel for easier needle insertion.
3. Introduce the assembled needle through the incision until needle point reaches the area to be biopsied.
4. Holding cannula to stabilize needle, swiftly pull back the stylet to create negative pressure within the cannula. Do not remove the stylet.
5. Advance the cannula into the tissue to be biopsied using a quick, precise movement.
6. Remove the VACU-CUT® Disposable Aspiration Biopsy Needle from the body.
7. Remove biopsy specimen by slowly re-inserting the stylet into the cannula. The specimen should be fixed in formaldehyde solution and processed for routine cytology, and stained with hematoxylin and eosin.

How Supplied:

The VACU-CUT® Disposable Aspiration Biopsy Needle is supplied sterile unless package has been opened or damaged. **For single patient use only. Do Not Reuse. Do Not Resterilize.**

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.

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