

## 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 re-sterilize



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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B05103 Rev.4/11-15

# OSTY CUT<sup>®</sup>

## Disposable Bone 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 OSTY CUT<sup>®</sup> Disposable Bone Biopsy Needle is a two-part puncture needle consisting of a threaded cannula and a trocar point stylet with a cutting edge capable of penetrating bone. Also included are a 10 cc luer tipped aspiration syringe for drawing up the biopsy sample and a ring obturator to push the biopsy specimen out of the cannula.

#### Indications for Use:

The OSTY CUT<sup>®</sup> Disposable Bone Biopsy Needle is intended for use in bone biopsy procedures.

#### 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 OSTY CUT<sup>®</sup> Disposable Bone 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 OSTYCU<sup>®</sup> Disposable Bone 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 OSTYCU<sup>®</sup> Disposable Bone 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 bone 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:**

Potential complications of bone biopsy are hematoma, hemorrhage, infection and pain.

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## **Directions for Use:**

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#### **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.

#### **Biopsy Procedure:**

The biopsy procedure must be performed using appropriate aseptic techniques.

1. Anesthetize the entire area between skin and periosteum.  
**Note:** To keep the level of pain to an absolute minimum, the periosteum must be well anesthetized. The position of the needle can be controlled using image guidance.
2. Leave the thin anesthesia needle in position as a guide for the parallel puncture with the trocar point OSTYCU<sup>®</sup> Disposable Bone Biopsy Needle. Introduce the OSTYCU<sup>®</sup> Disposable Bone Biopsy Needle (cannula and stylet) through the incision until contact is made with the area to be biopsied.
3. With the OSTYCU<sup>®</sup> Disposable Bone Biopsy Needle tip at the bone surface, advance the cannula into the bone under firm pressure while rotating it clockwise.
4. Leave the trocar stylet in place to prevent the cannula from drifting out of the biopsy area. As soon as the threaded part of the cannula obtains a grip in the bone, hold the needle hub in place and withdraw the stylet.
5. Slowly advance the cannula further into the bone using the same firm pressure and clockwise motion as in step 3 above.
6. After having reached and traversed the lesion, attach the 10 cc luer tip syringe to the female end of the outer cannula hub. Withdraw plunger to create negative pressure.
7. With applied vacuum, remove the cannula.
8. Remove syringe from the cannula. To remove biopsy specimen, insert the ring obturator into the cannula.

#### **Caution:**

In case the OSTYCU<sup>®</sup> Disposable Bone Biopsy Needle cannula cannot be removed smoothly from the punctured bone area, do not attempt to loosen the OSTYCU<sup>®</sup> Disposable Bone

Biopsy Needle cannula by oscillating movement of the cannula. Instead, it is advised to loosen and remove the OSTYCU<sup>®</sup> Disposable Bone Biopsy Needle cannula from the punctured bone area by simultaneously applying counter-clockwise rotation and traction.

#### **How supplied:**

The OSTYCU<sup>®</sup> Disposable Bone Biopsy Needle is a sterile, disposable, bone biopsy needle for single use. The needle is sterile unless the package has been opened or damaged. Do not reuse. Do not resterilize. It is available in several needle gauge sizes and lengths.

#### **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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