

ARROW® OnControl®

POWERED BONE ACCESS



Bone Lesion Biopsy System

Instructions for Use

Teleflex®

APPLICATION & PRECAUTIONS

DESCRIPTION:

The Arrow® OnControl® Powered Bone Access System utilizes a lithium battery-powered driver to penetrate the cortical layer of bone while providing controlled insertion of the cannula. Patented needle sets facilitate the successful collection of a core biopsy.

INDICATIONS FOR USE:

The Arrow® OnControl® Bone Lesion Biopsy System is intended for bone biopsy of the vertebral body and bone lesions.

CONTRAINDICATIONS FOR USE:

The Arrow® OnControl® Bone Access System should only be used by clinicians familiar with the complications, limitations, indications, and contraindications of the indicated procedures.



WARNINGS & PRECAUTIONS:

CAUTION: Use aseptic technique.

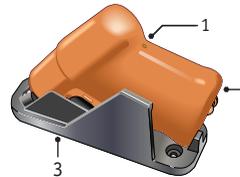
CAUTION: Do not recap needle sets or separated components. Use biohazard and sharps disposal precautions.

CAUTION: Needle sets are single use only; serious medical consequences (e.g. life-threatening infection) and reduced performance (e.g. blunted needles) may occur if compliance to this warning is not followed. For a complete listing of these serious medical and performance consequences, please contact Teleflex.

STORAGE:

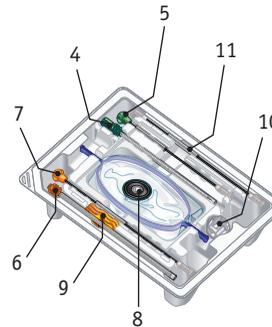
Store in a cool dry place.

COMPONENTS



Power Driver with Cradle:

1. Battery Indicator Light
2. Power Driver
3. Cradle



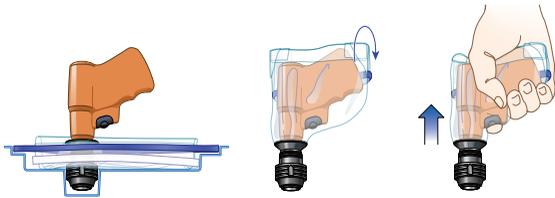
Bone Lesion Biopsy Tray:

4. Bone Access Needle Set
5. Bone Access Ejector Rod
6. Bone Lesion Biopsy Needle
7. Bone Lesion Biopsy Ejector Rod
8. Connector with Sterile Sleeve
9. Ejector Assist
10. Manual Handle – for minor adjustments
11. Transfer Rod – for marking the access point in the bone
12. Fenestrated Drape (not shown)

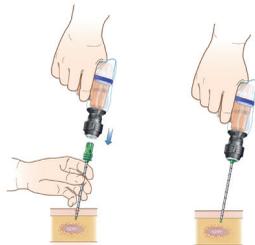
INSTRUCTIONS FOR USE

1. Prepare patient. Confirm proper anatomical landmarks. Diagnostic imaging guidance is recommended.
2. Attach power driver to connector with sterile sleeve and seal the sterile sleeve.

Note: When correctly inserted you will feel the connector secure into place on driver with a “click”.



3. Tighten styllet and hub of the bone access needle set.
4. Insert bone access needle set into intended location using the correct angle. Attach driver to needle set. When correctly inserted, the needle set will secure into connector with a “click”.
5. Find location on bone, note depth marking and squeeze trigger to activate driver. **DO NOT APPLY EXCESSIVE FORCE TO DRIVER/ NEEDLE SET.** Squeeze trigger until bone access needle set has reached the desired location to be biopsied.



6. Detach power driver from the bone access needle set.

7. Remove styllet. If needed, use the manual handle for minor adjustments of the bone access cannula. **BONE LESION BIOPSY NEEDLE SET SHOULD ALWAYS BE USED INSIDE THE ACCESS NEEDLE. DO NOT USE THE BONE LESION BIOPSY NEEDLE SET INDEPENDENTLY OF THE ACCESS NEEDLE.**

8. Place the bone lesion biopsy needle inside the bone access cannula.
9. For bone lesion, attach power driver to bone lesion biopsy needle hub, use depth markers as guide.
10. In one continuous motion, squeeze trigger, and advance bone lesion biopsy needle (up to 1.5 cm as allowed by the bone access cannula); with the trigger still engaged, pull up on power driver until bone lesion biopsy needle is completely removed from patient.

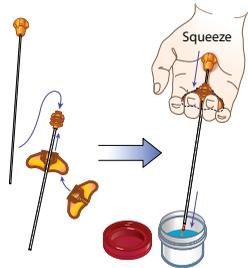


11. Detach power driver from the bone lesion biopsy needle set.

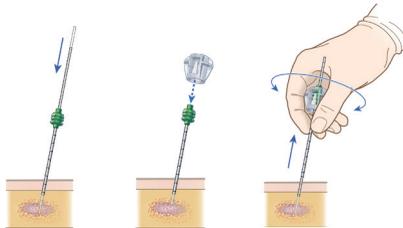
LIMITED EXPRESS WARRANTY AND DISCLAIMERS

12. Insert bone lesion biopsy ejector rod into the hub of the bone lesion biopsy needle to push the sample out of the distal tip of the needle.

Note: Attach the Ejector Assist handle to the hub to provide additional leverage.



13. If needed, use the transfer rod to mark the access point in the bone after the procedure. The manual handle can be used to assist in the removal of the bone access cannula.



14. To remove the bone access cannula from the patient: Re-attach power driver to hub of the bone access cannula.

Note: When correctly inserted you will feel it secure in place with a “click”.

Squeeze trigger and gently pull straight out of patient.



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For more information about the
Arrow® OnControl® Powered Bone Access System
visit ArrowOnControl.com

Teleflex®

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 Manufactured for:
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STERILE O

Sterilized Using
Ethylene Oxide



Do Not Use if
Package is Damaged



Single Use



Do Not
Resterilize



Keep Away
From Sunlight



Keep Dry



Caution

Rx
ONLY

This device is restricted
for sale by or on order
of a physician.

CE
0086

The System Conforms
to the Medical Device
Directive (93/42/EEC)



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