

ARROW® OnControl®

POWERED BONE ACCESS



Bone Marrow Aspiration System Bone Marrow Biopsy System

Instructions for Use

Teleflex®

APPLICATION & PRECAUTIONS

DESCRIPTION:

The Arrow® OnControl® System utilizes a lithium battery-powered driver to penetrate the cortical layer of bone while providing controlled insertion of the needle set. Patented needle sets facilitate the successful collection of an aspirate or a core. The comprehensive biopsy tray is available in select markets and includes additional components necessary to perform the sterile procedure.

INDICATIONS FOR USE:

The Arrow® OnControl® Bone Marrow Aspiration System is intended for bone marrow aspiration of the iliac crest of adult and pediatric patients. The Arrow® OnControl® Bone Marrow Biopsy System is intended for bone marrow core biopsy of the anterior or posterior iliac crest of adult patients.

CONTRAINDICATIONS FOR USE:

The Arrow® OnControl® Bone Marrow Aspiration and Biopsy Systems should not be used by clinicians unfamiliar with the complications, limitations, indications, and contraindications of bone marrow aspiration and biopsy.



WARNINGS & PRECAUTIONS:

CAUTION: Use aseptic technique.

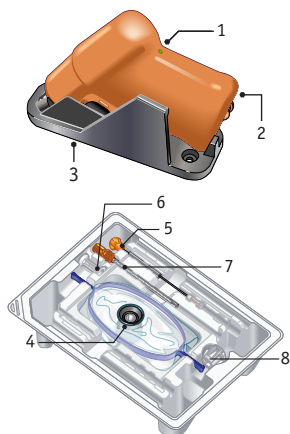
CAUTION: Do not recap needle sets or separated components. Use biohazard and sharps disposal precautions.

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

Sterile Needle Tray:

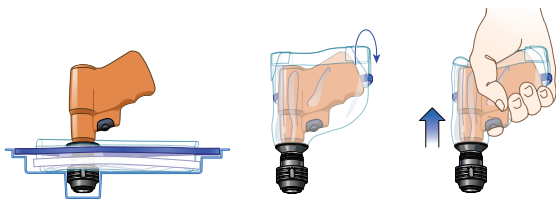
4. Connector with Sterile Sleeve
5. Ejector Rod (bone marrow biopsy only)
6. Alignment Guide (bone marrow biopsy only)
7. Aspiration Needle (purple) or Biopsy Needle (orange) with Depth Gauge
8. Manual Handle (ported biopsy needle only)

| Needle Sets | Gauge | Lengths |
|--|-------|-------------------------|
| Bone Marrow Biopsy: For bone marrow core biopsy and aspiration of the anterior and posterior iliac crest in adult patients. The needle also features a core capturing thread at the distal tip. | 11 ga | 102 mm 152 mm |
| Ported Bone Marrow Aspiration: For bone marrow aspiration of the anterior and posterior iliac crest in adult patients. The ported needle features 5 ports at the distal end, two proximal black lines indicating the location of the ports. | 11 ga | 102 mm |
| Bone Marrow Aspiration: For bone marrow aspiration of the iliac crest in pediatric and adult patients. | 11 ga | 102 mm |
| | 15 ga | 90 mm 68 mm 25 mm |

INSTRUCTIONS FOR USE

BONE MARROW ASPIRATION

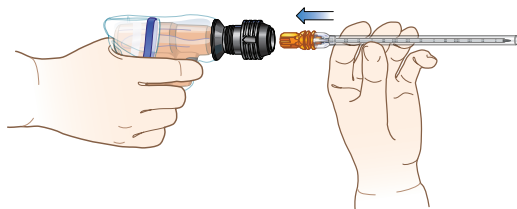
1. Prepare patient.
2. Attach power driver to connector with sterile sleeve and seal the sterile sleeve closed.



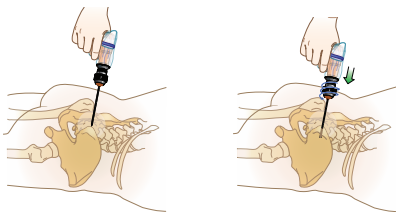
3. Tighten stylet and hub of the needle.



4. Attach needle set to connector. Note: When correctly inserted you will feel it secure into place with a "click".



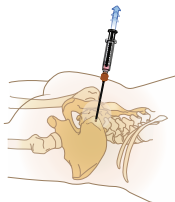
5. Locate insertion site with needle set on the periosteum. Note depth marking. Squeeze trigger to penetrate cortex to medullary space. **DO NOT APPLY EXCESSIVE FORCE TO DRIVER/NEEDLE SET.**



6. Detach power driver from needle set and remove stylet.



7. Collect aspirate. If using the ported needle, you may rotate the needle using the manual handle after the initial aspirate to collect additional bone marrow. Two black lines near the needle hub indicate the location of the ports.



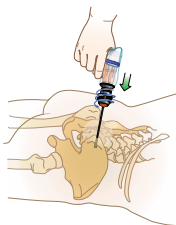
INSTRUCTIONS FOR USE

BONE MARROW BIOPSY

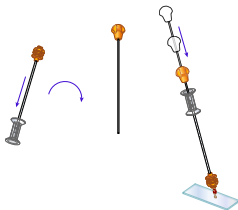
8. Prior to biopsy, stabilize cannula and slide depth guide down to the desired depth. Proceed with biopsy. *This device is not a stopping mechanism; it is intended to be used as a visual guide.*



9. Proceed with core biopsy, stabilize cannula, re-attach power driver to hub (Note: When correctly inserted you will feel it secure into place with a “click”), move depth guide, squeeze trigger, and with a continuous motion, advance cannula to desired depth. **Then with the trigger still engaged,** pull up on power driver until cannula is completely removed from patient.



10. Insert cannula tip into the alignment guide and insert ejector rod in the other end. Tap until the sample is loose.



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

Teleflex®

Customer Service: 1.866.479.8500

 Manufactured for:
Teleflex Medical
IDA Business & Technology Park,
Dublin Rd, Athlone,
Co. Westmeath, Ireland



Do Not Use if
Package is Damaged



Single Use



Do Not
Resterilize



Keep Away
From Sunlight



Keep Dry



Caution



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



Consult Instructions
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