LABELING SYMBOLS

1 -	REF	Reference#, Part# or Catalog#
2 -	LOT	Lot Number
3 -		Read Instructions for Use (IFU)
4 -	STERILE R	Sterile Product Radiation
5 -	EXP	Expiration or Use By Date
6 -	Single Use	Single Use, Single Patient
7 -		Manufactured By
8 -	Rx ONLY	Prescription Use Only
9 -	MR	Magnetic Resonance Unsafe

ARTERIOCYTE
Helping Patients Heal Faster™

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- DO NOT REUSE.
- DO NOT RESTERILIZE.
- Re-use of contents may cause cross contamination, leading to patient risk and complication(s).
- Check skin thickness before manual Cannula Set insertion on all patients.
- Special caution must be exercised in use with patients with BMI greater than 30.
- Rx Use Only
- Caution – Federal Law restricts this device to sale by or on the order of a physician.
- Storage: -18°C to 48°C (0°F to 120°F)
- The Lightning® Bone Marrow Aspiration Cannula System is unsafe in MR environments.
- Once used, this product may present a biohazard. Handle the Cannula Set in a manner which will prevent injury or contamination. Dispose of the Cannula Set and associated tray components in accordance with applicable laws and regulations.

INSERTION SITES:

- Anterior Iliac Crest
- Posterior Iliac Crest
- Proximal Humerus
- Proximal Tibia
- Lumbar Vertebral Body

INTENDED USE:

The Arteriocyte Medical Systems Lightning® Bone Marrow Aspiration Cannula System is intended for use in the intraosseous aspiration of viscous bone marrow material in the human body.

CONTRAINDICATIONS FOR USE:

- Fracture
- Excessive tissue (severe obesity and/or absence of adequate anatomical landmarks)
- Osteoporosis
- Infection at the area of insertion
- Previous, significant orthopedic procedure at the site, prosthetic limb or joint
- Intraosseous at site in the past 48 hours

WARNINGS:

- System should only be used by clinicians familiar with the complications, limitations, indications, and contraindications of bone marrow aspiration and biopsy.
- DO NOT USE for aspiration or biopsy at locations other than those indicated.
- DO NOT recap Cannula Sets or separate components.
- Use biohazard and sharps disposal precautions.
- Use aseptic sterile technique.
- Single Use Only

DEVICE DESCRIPTION:

The Arteriocyte Medical Systems Lightning® Bone Marrow Aspiration Cannula System is an 11-gauge Cannula needle system in various lengths (currently of 45, 80 & 105mm) that allows the use of a drill 'power driver' for hard bone insertion during a viscous bone marrow aspiration/collection procedure. The needles are packaged STERILE as a 'Cannula Set' to include a graduated Cannula Sleeve, a Trocar Drill and a Plunger. All metal components (Cannula Sleeve, Trocar Drill & Plunger) of the Lightning® System are manufactured from 304 surgical grade stainless steel. The hub materials are molded polyetherimide (Ultem).

The sterilization method is gamma-irradiation to meet an SAL of 10-6. The device is provided STERILE and re-sterilization of the device has not been validated. For 'Single Use' ONLY. Do not use if package is open or damaged.

Lightning Bone Marrow Aspiration Cannula Components

Lightning Needle™

Bone Marrow Aspiration Cannula

Instructions For Use

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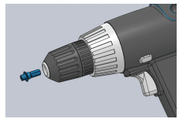
INSTRUCTIONS FOR USE:

IMPORTANT: The following instructions are NOT meant to define or suggest a medical or surgical technique. The clinician is responsible for the proper procedure(s), site(s) and technique(s) used with this device.

Utilizing Sterile Technique, perform the following steps:

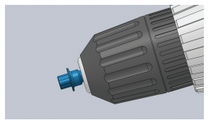
1. Palpate and locate entry point.*
2. Using aseptic technique, prep the skin.
3. If desired, apply local anesthetic to prepped area.
4. With a #11 or #15 blade sterile scalpel, make a small stab incision at the entry point.*
5. Remove the Lightning cannula assembly, plunger and driver adapter from their sterile packaging.
6. Properly secure the driver adapter to driver drill with the magnet tip exposed. To accomplish this:
   6a. Insert the hexagonal end (end opposite the magnet) of the driver adapter into the chuck of the driver drill. **See Figure 1.**

Figure 1: Driver adapter hexagonal end being inserted into driver drill.



   6b. Ensure that the driver adapter is engaged into the driver drill as much as possible (until round portion of driver adapter makes contact with front end of drill chuck jaws).
   6c. Tighten the jaws of the drill chuck around the driver adapter. **See Figure 2.**

Figure 2: Driver adapter engaged into drill chuck fully with jaws tightened.

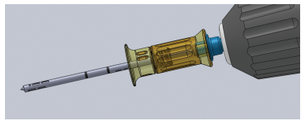


   6d. Ensure driver adapter is properly captured in driver drill chuck (attempt to pull driver adapter away from drill chuck). If driver adapter moves when pulled upon, retighten drill chuck until no movement in driver adapter is felt.
7. Leaving the Lightning cannula assembly intact, carefully remove the protective cap, then thoroughly coat the cannula shaft with 3 to 5cc's of anticoagulant.

IMPORTANT: Be careful to maintain sterile technique.

8. Securely attach the Lightning cannula assembly to driver adapter. **See Figure 3.**

Figure 3: Lightning cannula assembly attached to driver adapter.



9. Place the Lightning cannula assembly through the stab incision placing the trocar point on the cortical bone.*

IMPORTANT: Control the patient's movement prior to and during cannula assembly insertion.

10. Utilizing a drill with a speed range of 1000 to 3000 RPM (optimum speed of 1500 RPM), activate the driver drill and apply gentle, steady pressure until cortex is penetrated.
11. When cortical wall is penetrated, advance the Lightning cannula assembly an additional 2 to 2.5cm to assure the cannula's fenestrations lie within cancellous bone.
12. Remove driver drill with attached drill adapter from the Lightning cannula assembly.

IMPORTANT: To assure the Lightning cannula assembly remains properly seated, apply gentle downward finger pressure on the trocar hub while removing the drill.

13. Remove the trocar from the Lightning cannula assembly by turning the trocar hub counter-clockwise one and one half turns.
14. Insert the Lightning plunger through the cannula hub and seat fully. Plunger hub will abut the cannula hub when fully seated. Slight to medium pressure may be required to fully seat plunger.
15. Remove plunger.
16. Attach syringe to Luer Lock on the cannula hub. Begin marrow aspiration by gently pulling back on syringe plunger. Slight downward pressure on the cannula will assure its stability.

IMPORTANT: Do not pull back on syringe body as this may destabilize the cannula.

17. Repeat step #16 as needed to collect the desired amount of marrow.
18. When desired amount of marrow is obtained, remove the Lightning cannula by securely reattaching the trocar hub to the cannula hub Luer Lock. Once securely attached, apply gentle outward traction.

IMPORTANT: Do not rock or bend Lightning cannula assembly during removal.

19. Once the Lightning cannula assembly, plunger and drill adapter are no longer needed, discard all pieces in an appropriate sharps container.
20. Dress insertion site as needed.

*Refer to Individual Site Surgical Technique

SURGICAL TECHNIQUE – ANTERIOR ILIAC CREST

1) Position patent in supine position, palpate borders of anterior iliac crest.
2) Select entry point two (2) fingerbreadths cranial to anterior superior iliac spine. Choose a medial/lateral entry point in the widest portion of the iliac crest.
3) Using aseptic technique, prep the skin.
4) If desired, apply local anesthetic to the prepped area.
5) Make a stab incision with a #11 or #15 blade sterile scalpel.
6) Remove cannula assembly set and driver adapter from their sterile packages
7) Properly secure the driver adapter to driver drill with the magnet tip exposed. To accomplish this:
   7a. Insert the hexagonal end (end opposite the magnet) of the driver adapter into the chuck of the driver drill.
   7b. Ensure that the driver adapter is engaged into the driver drill as much as possible (until round portion of driver adapter makes contact with front end of drill chuck jaws).
   7c. Tighten the jaws of the drill chuck around the driver adapter.
   7d. Ensure driver adapter is properly captured in drill chuck (attempt to pull driver adapter away from drill chuck). If driver adapter moves when pulled upon, retighten drill chuck until no movement in driver adapter is felt.
8) Securely attach cannula assembly with protective cap to driver adapter.
9) Carefully remove the protective cap and position cannula assembly over the entry point at a 90-degree angle to the bone.

IMPORTANT: Be careful to maintain strict sterile technique.

IMPORTANT: Control the patient's movement prior to and during cannula assembly insertion.

IMPORTANT: Ensure at least 5mm of the cannula is visible.

10) Activate driver drill by squeezing the trigger. Insert the cannula assembly into the bone with gentle, steady downward pressure. Advance cannula assembly and penetrate cortical wall (slight release of pressure will be felt). Continue insertion to first etched depth line on cannula. Release drill trigger and stop insertion process.
11) Remove drill and driver adapter from cannula assembly by pulling outward. Slight downward pressure on the cannula will assure its stability.
12) Remove trocar from cannula assembly by turning trocar counter-clockwise one and one half turns and pull back. Confirm cannula stability.
13) Insert plunger into cannula, seat fully. Gently remove plunger.
14) Attach syringe to Luer lock hub on cannula, begin marrow aspiration by gently pulling on syringe plunger. Slight downward pressure on the cannula will assure its stability. **DO NOT PULL BACK ON SYRINGE BODY AS THIS MAY DESTABILIZE THE CANNULA.**
15) If additional marrow is required, attach and fill a second syringe or repeat steps 9-12. If performing a second drilling procedure the cannula may be placed approximately 1cm adjacent to first entry point.
16) Remove cannula from patient by attaching Luer lock syringe, continuously rotate clockwise while slowly and gently applying outward traction to cannula. **DO NOT ROCK OR BEND THE CANNULA DURING REMOVAL.**
17) Once removed, discard cannula assembly set in appropriate sharps container.
18) Dress site as appropriate.

SURGICAL TECHNIQUE – POSTERIOR ILIAC CREST

1) Position patient in prone position. Palpate midline L/S spine and posterior iliac crest.
2) Locate Posterior Superior Iliac Crest (PSIS) and iliac crest borders and select entry point in cranial third of iliac crest at the widest area from medial/lateral dimension. Avoid caudal third of iliac crest.
3) Using aseptic technique prep the skin.
4) If desired, apply local anesthetic to the prepped area.
5) Make a stab incision with a #11 or #15 blade sterile scalpel.
6) Remove the cannula assembly set and driver adapter from their sterile packages.
7) Properly secure the driver adapter to driver drill with the magnet tip exposed. To accomplish this:
   7a. Insert the hexagonal end (end opposite the magnet) of the driver adapter into the chuck of the drill.
   7b. Ensure that the driver adapter is engaged into the drill as much as possible (until round portion of driver adapter makes contact with front end of drill chuck jaws).
   7c. Tighten the jaws of the drill chuck around the driver adapter.
   7d. Ensure driver adapter is properly captured in drill chuck (attempt to pull driver adapter away from drill chuck). If driver adapter moves when pulled upon, retighten drill chuck until no movement in driver adapter is felt.
8) Securely attach cannula assembly with protective cap to driver adapter.
9) Carefully remove the protective cap and position cannula assembly over the entry point at a 90-degree angle to the bone.

IMPORTANT: Be careful to maintain strict sterile technique.

IMPORTANT: Control the patient's movement prior to and during cannula assembly insertion.

IMPORTANT: Ensure at least 5mm of the cannula is visible.

10) Activate driver drill by squeezing the trigger. Insert the cannula assembly into the bone with gentle, steady downward pressure. Advance cannula assembly and penetrate cortical wall (slight release of pressure will be felt). Continue insertion to first etched depth line on cannula. Release drill trigger and stop insertion process.
11) Remove drill and driver adapter from cannula assembly by pulling outward. Slight downward pressure on the cannula will assure its stability.
12) Remove trocar from cannula assembly by turning trocar counter-clockwise one and one half turns and pull back. Confirm cannula stability.
13) Insert plunger into cannula, seat fully. Gently remove plunger.
14) Attach syringe to Luer lock hub on cannula, begin marrow aspiration by gently pulling on syringe plunger. Slight downward pressure on the cannula will assure its stability. **DO NOT PULL BACK ON SYRINGE BODY AS THIS MAY DESTABILIZE THE CANNULA.**
15) If additional marrow is required, attach and fill a second syringe or repeat steps 9-12. If performing a second drilling procedure the cannula may be placed approximately 1cm adjacent to first entry point.
16) Remove cannula from patient by attaching Luer lock syringe, continuously rotate clockwise while slowly and gently applying outward traction to cannula. **DO NOT ROCK OR BEND THE CANNULA DURING REMOVAL.**
17) Once removed, discard cannula assembly set in appropriate sharps container.
18) Dress site as appropriate.

SURGICAL TECHNIQUE – PROXIMAL TIBIA

1) Palpate and locate the proximal Tibia tubercle.
2) Select optimal entry point approximately two (2) finger breaths distal and 1" medial to the proximal tibia tubercle.
3) Using aseptic technique, prep the skin.
4) If desired, apply local anesthetic to the prepped area.
5) Make a stab incision with a #11 or #15 blade sterile scalpel.
6) Remove cannula assembly set and driver adapter from their sterile packages
7) Properly secure the driver adapter to driver drill with the magnet tip exposed. To accomplish this:
   7a. Insert the hexagonal end (end opposite the magnet) of the driver adapter into the chuck of the driver drill.
   7b. Ensure that the driver adapter is engaged into the driver drill as much as possible (until round portion of driver adapter makes contact with front end of drill chuck jaws).
   7c. Tighten the jaws of the drill chuck around the driver adapter.
   7d. Ensure driver adapter is properly captured in drill chuck (attempt to pull driver adapter away from drill chuck). If driver adapter moves when pulled upon, retighten drill chuck until no movement in driver adapter is felt.
8) Securely attach cannula assembly with protective cap to driver adapter.
9) Carefully remove the protective cap and position cannula assembly over the entry point at a 90-degree angle to the bone.

IMPORTANT: Be careful to maintain strict sterile technique.

IMPORTANT: Control the patient's movement prior to and during cannula assembly insertion.

IMPORTANT: Ensure at least 5mm of the cannula is visible.

10) Activate driver drill by squeezing the trigger. Insert the cannula assembly into the bone with gentle, steady downward pressure. Advance cannula assembly and penetrate cortical wall (slight release of pressure will be felt). Continue insertion to first etched depth line on cannula. Release drill trigger and stop insertion process.
11) Remove drill and driver adapter from cannula assembly by pulling outward. Slight downward pressure on the cannula will assure its stability.
12) Remove trocar from cannula assembly by turning trocar counter-clockwise one and one half turns and pull back. Confirm cannula stability.
13) Insert plunger into cannula, seat fully. Gently remove plunger.
14) Attach syringe to Luer lock hub on cannula, begin marrow aspiration by gently pulling on syringe plunger. Slight downward pressure on the cannula will assure its stability. **DO NOT PULL BACK ON SYRINGE BODY AS THIS MAY DESTABILIZE THE CANNULA.**
15) If additional marrow is required, attach and fill a second syringe or repeat steps 9-12. If performing a second drilling procedure the cannula may be placed approximately 1cm adjacent to first entry point.
16) Remove cannula from patient by attaching Luer lock syringe, continuously rotate clockwise while slowly and gently applying outward traction to cannula. **DO NOT ROCK OR BEND THE CANNULA DURING REMOVAL.**
17) Once removed, discard cannula assembly set in appropriate sharps container.
18) Dress site as appropriate.

SURGICAL TECHNIQUE – PROXIMAL HUMERUS

1) Palpate and locate the proximal humerus tubercle.
2) Select optimal entry point.
3) Using aseptic technique, prep the skin.
4) If desired, apply local anesthetic to the prepped area.
5) Make a stab incision with a #11 or #15 blade sterile scalpel.
6) Remove cannula assembly set and driver adapter from their sterile packages
7) Properly secure the driver adapter to driver drill with the magnet tip exposed. To accomplish this:
   7a. Insert the hexagonal end (end opposite the magnet) of the driver adapter into the chuck of the driver drill.
   7b. Ensure that the driver adapter is engaged into the driver drill as much as possible (until round portion of driver adapter makes contact with front end of drill chuck jaws).
   7c. Tighten the jaws of the drill chuck around the driver adapter.
   7d. Ensure driver adapter is properly captured in drill chuck (attempt to pull driver adapter away from drill chuck). If driver adapter moves when pulled upon, retighten drill chuck until no movement in driver adapter is felt.
8) Securely attach cannula assembly with protective cap to driver adapter.
9) Carefully remove the protective cap and position cannula assembly over the entry point at a 90-degree angle to the bone.

IMPORTANT: Be careful to maintain strict sterile technique.

IMPORTANT: Control the patient's movement prior to and during cannula assembly insertion.

IMPORTANT: Ensure at least 5mm of the cannula is visible.

10) Activate driver drill by squeezing the trigger. Insert the cannula assembly into the bone with gentle, steady downward pressure. Advance cannula assembly and penetrate cortical wall (slight release of pressure will be felt). Continue insertion to first etched depth line on cannula. Release drill trigger and stop insertion process.
11) Remove drill and driver adapter from cannula assembly by pulling outward. Slight downward pressure on the cannula will assure its stability.
12) Remove trocar from cannula assembly by turning trocar counter-clockwise one and one half turns and pull back. Confirm cannula stability.
13) Insert plunger into cannula, seat fully. Gently remove plunger.
14) Attach syringe to Luer lock hub on cannula, begin marrow aspiration by gently pulling on syringe plunger. Slight downward pressure on the cannula will assure its stability. **DO NOT PULL BACK ON SYRINGE BODY AS THIS MAY DESTABILIZE THE CANNULA.**
15) If additional marrow is required, attach and fill a second syringe or repeat steps 9-12. If performing a second drilling procedure the cannula may be placed approximately 1cm adjacent to first entry point.
16) Remove cannula from patient by attaching Luer lock syringe, continuously rotate clockwise while slowly and gently applying outward traction to cannula. **DO NOT ROCK OR BEND THE CANNULA DURING REMOVAL.**
17) Once removed, discard cannula assembly set in appropriate sharps container.
18) Dress site as appropriate.

SURGICAL TECHNIQUE – LUMBAR VERTEBRAL BODY

1) Locate pedicle entry point (as per placement of pedicle screws).
2) Remove cannula assembly set and driver adapter from their sterile packages
3) Properly secure the driver adapter to driver drill with the magnet tip exposed. To accomplish this:
   3a. Insert the hexagonal end (end opposite the magnet) of the driver adapter into the chuck of the driver drill.
   3b. Ensure that the driver adapter is engaged into the driver drill as much as possible (until round portion of driver adapter makes contact with front end of drill chuck jaws).
   3c. Tighten the jaws of the drill chuck around the driver adapter.
   3d. Ensure driver adapter is properly captured in drill chuck (attempt to pull driver adapter away from drill chuck). If driver adapter moves when pulled upon, retighten drill chuck until no movement in driver adapter is felt.
4) Securely attach cannula assembly with protective cap to driver adapter.
5) Carefully remove the protective cap and position cannula assembly over the entry point at a 90-degree angle to the bone.

IMPORTANT: Be careful to maintain strict sterile technique.

IMPORTANT: Control the patient's movement prior to and during cannula assembly insertion.

IMPORTANT: Ensure at least 5mm of the cannula is visible.

6) Activate driver drill by squeezing the trigger. Insert cannula assembly into vertebral body via pedicle with gentle, steady downward pressure. Cannula assembly is seated when most proximal fenestrations are within the intraosseous space. Fluoroscopy or x-ray control is recommended. Release drill trigger to stop insertion process.
7) Remove drill and driver adapter from cannula assembly by pulling outward. Slight downward pressure on the cannula will assure its stability.
8) Remove trocar from cannula assembly by turning trocar counter-clockwise one and one half turns and pull back. Confirm cannula stability.
9) Insert plunger into cannula, seat fully. Gently remove plunger.
10) Attach syringe to Luer lock hub on cannula, begin marrow aspiration by gently pulling on syringe plunger. Slight downward pressure on the cannula will assure its stability. **DO NOT PULL BACK ON SYRINGE BODY AS THIS MAY DESTABILIZE THE CANNULA.**
11) If additional marrow is needed, repeat steps 3-10 at an adjacent level or opposite pedicle.
12) Remove cannula from patient by attaching Luer lock syringe, continuously rotate clockwise while slowly and gently applying outward traction to cannula. **DO NOT ROCK OR BEND THE CANNULA DURING REMOVAL.**
13) Once removed, discard cannula assembly set in appropriate sharps container.