

SwannShidi



*Bone Marrow Aspiration Needle
Surgical Technique*



AllianceSpineTM

Inspiring Solutions Through Innovation

Table of Contents

Indications for Use1
Device Description1
Key Features2
Instruments2
Surgical Technique3
Precautions/Contraindications/Adverse Effects6

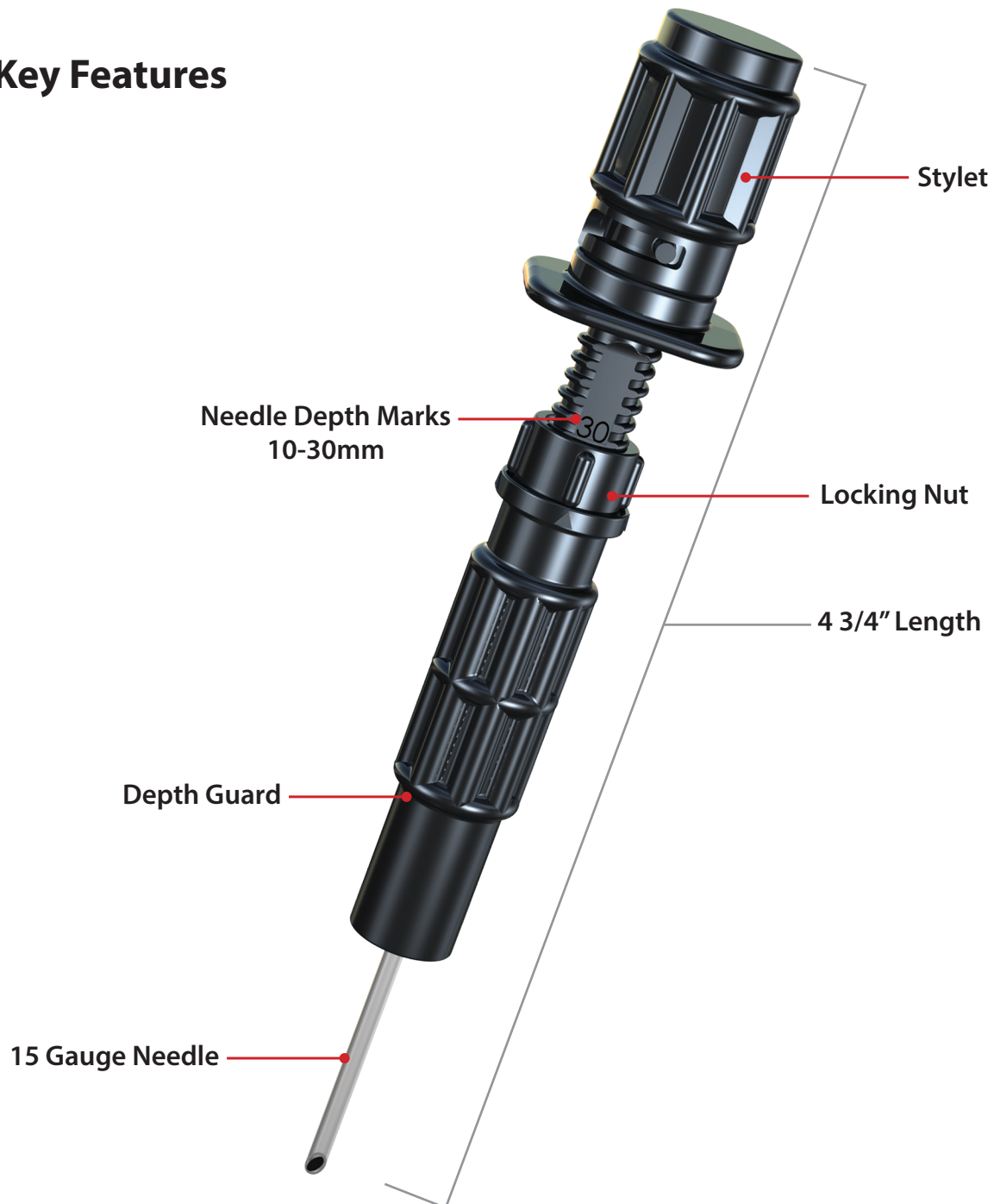
Indications for Use:

The SwannShidi Bone Marrow Aspiration Needle is to be used for aspiration of bone marrow or autologous blood by use of a standard syringe.

Device Description:

The SwannShidi Bone Marrow Aspiration Needle consists of a 15ga needle and an angled tip stylet of corresponding size. A depth gauge with graduated scale and additional locking mechanism allows for adjustment of the penetration section of the needle. A luer lock connection is provided to allow aspiration of bone marrow or autologous blood by use of a standard surgical syringe. The SwannShidi is a single use, disposable device that will be supplied sterile.

Key Features



SwannShidi **Bone Marrow Aspiration Needle** **Surgical Technique**

Step 1: Locate and Prepare the Surgical Site

Locate the site for bone marrow aspiration in the sternum, iliac crest or vertebral body.

Prepare the surgical site and anesthetize the area using sterile technique.

Step 2: Prepare Needle

Remove and reinsert the stylet one time to ensure that it can be easily separated from the cannula of the needle once it is inserted into the bone. To remove stylet rotate it 90 degrees counterclockwise and pull it straight out. Replace the stylet in the cannula and lock it back in place by rotating it 90 degrees clockwise so that it aligns with the slot on the lower portion of the stylet cap.

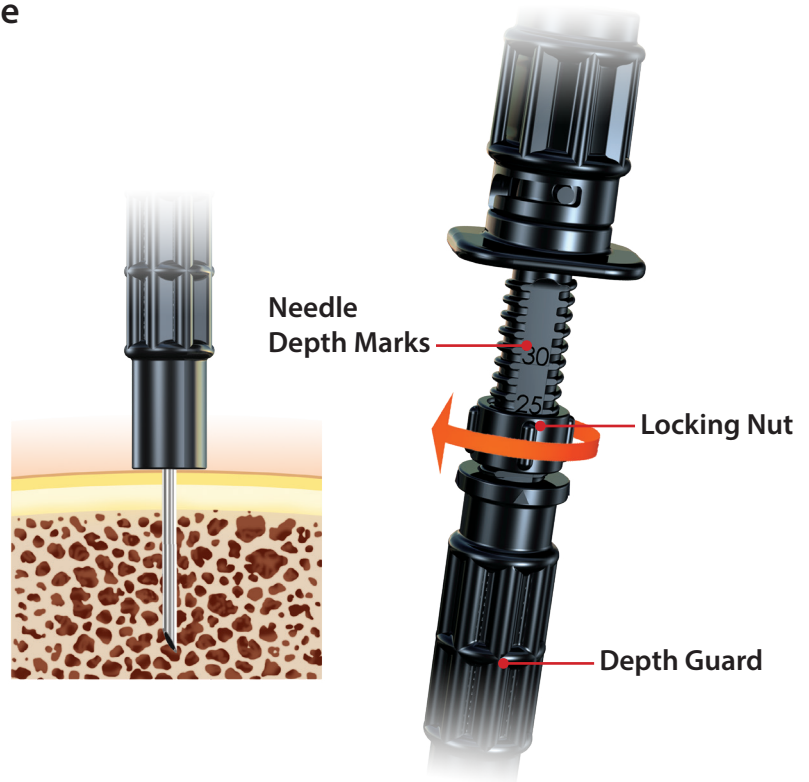
Remove the plastic guard from the aspiration needle.



Step 3: Introduce and Advance Needle

Adjust depth of needle by threading the depth guard up or down based on individual patient's anatomy and lock the nut in place by spinning it down in a clockwise direction to finger tight. If depth needs to be adjusted, unlock the locking nut by spinning the nut upward in a counterclockwise direction to its starting position at the top of the needle. Grasp the needle and introduce it through the prepared incision with the trajectory determined by the approach and anatomical site.

Advance the needle using gentle but firm pressure. Rotate the needle in alternating clock and counterclockwise motion or gently tap the needle using a mallet. Decreased resistance may be encountered upon the penetration of the cortex and entrance of the bone marrow cavity.



Step 4: Remove Stylet and Screw Syringe into Hub

Remove the stylet by rotating the cap 90 degrees counterclockwise and pulling straight out.

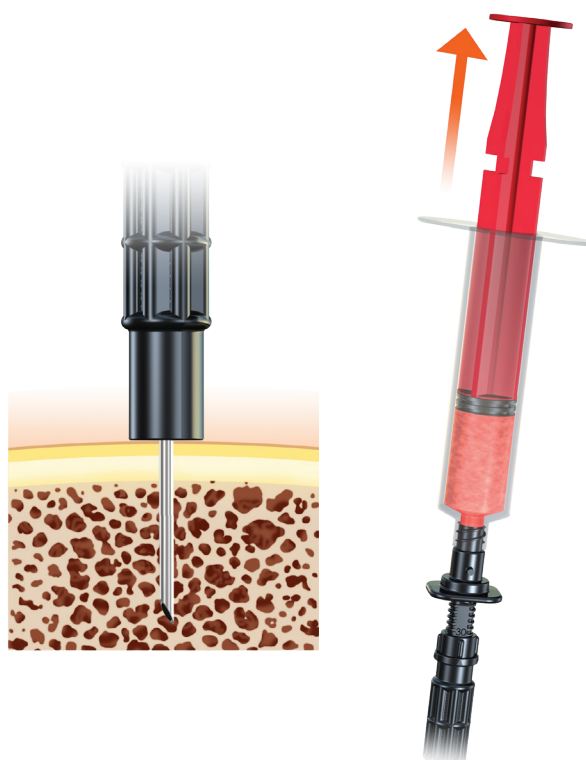
Screw the end of the included 10mL syringe filled with 1mL of anticoagulant to the hub of the bone marrow aspiration needle. Ensure a firm fit but do not over tighten.



Step 5: Aspirate Bone Marrow

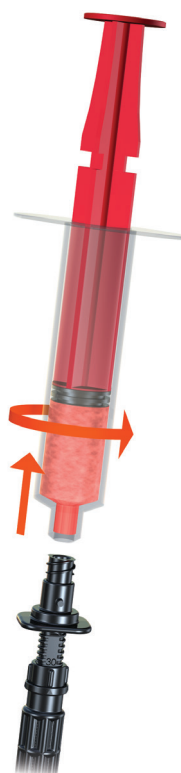
Withdraw the syringe plunger to draw out 2 through 10mL of bone marrow into the syringe chamber.

If bone marrow does not aspirate easily, reposition the needle slightly by rotating the needle either counterclockwise or clockwise or advancing the needle further into the vertebral body using fluoroscopy. If bone marrow still does not aspirate, remove the syringe from the needle, remove the needle from the incision, reinsert the stylet, and repeat steps 3 through 5 with a slight change in needle trajectory.



Step 6: Disengage Syringe

Disengage the syringe containing the aspirated bone marrow and dispose of the needle in accordance with applicable laws and regulations. Aspiration site may be sealed with hemostatic agent.



Precautions:

This device should only be used by a trained physician who is completely familiar with the indications, contraindications, and standard technique for the type of procedure that utilizes this device.

The introduction of the needle into the body should be carried out under fluoroscopy.

Before using, inspect the needle components for damage. Do not use if the needle components are damaged.

The device is for single patient use only. Do not reuse. Do not re-sterilize. Package integrity should be evaluated prior to opening the package and using the device. Damaged packages or products should not be used. Devices in packaging that exceeds the expiration date listed on the label should not be used.

Components of this system should not be used with components of any other system or manufacturer.

Additional warnings include, but are not limited to:

- Hemorrhagic disorders such as congenital coagulation factor deficiencies (e.g., hemophilia), disseminated intravascular coagulation and concomitant use of anticoagulants.
- Skin infection or recent radiation therapy at the sampling site.
- Bone disorders such as osteomyelitis or osteogenesis imperfecta.

Potential Adverse Effects:

Possible adverse events or complications include, but are not limited to:

1. Infection
2. Hemorrhage
3. Injury to vessels, heart (sternum aspiration)
4. Hematoma
5. Chronic pain at the site of the bone marrow aspiration and biopsy
6. Excessive bleeding

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. Please refer to the Instructions For Use included with the product for complete instructions, indications, contraindications, and warnings.

SwannShidi

Part Numbers	Description
1110I-1000	SwannShidi Bone Marrow Aspirate Needle



AllianceSpineTM

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14206 Northbrook Dr.
San Antonio, TX 78232

P:(210) 314-2525 • F:(210) 314-2524
E: info@alliance-spine.com • www.alliance-spine.com
MKT-104 Rev. C