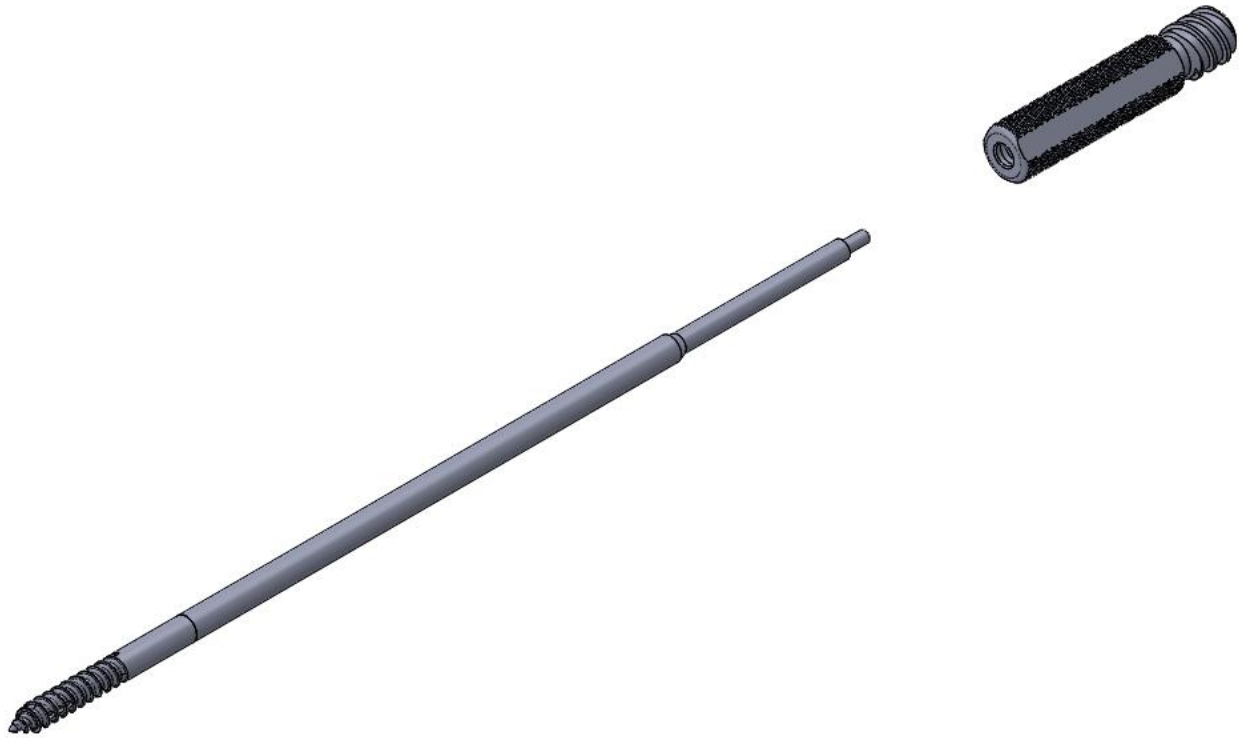


Cannulated Aspiration Screw and Luer Lock



Cannulated Aspiration Screw Surgical Technique



AllianceSpineTM

Inspiring Solutions Through Innovation

Cannulated Aspiration Screw & Luer Lock Surgical Technique

This instructions for use is designed to serve only as a general guideline. It is not intended to supersede institutional protocols or professional clinical judgement concerning patient care. Alliance- Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Indications for Use:

The Cannulated Aspiration Screw is intended to be used for bone marrow biopsy/aspiration.

Device Description:

The Cannulated Aspiration Screw consists of a Cannulated Aspiration Screw, Stylet and Luer Lock. The luer lock is intended to allow bone marrow biopsy/aspiration. The components of this device are composed of surgical grade stainless steel per ASTM F899.

Contraindications:

The instruments are contraindicated and should not be used for, including but not limited to, patients with the following:

- Active systemic infection or an active infection at the operative site
- Previous history of infection
- Excessive local inflammation
- Foreign body sensitivity
- Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)
- Any condition that precludes the possibility of fusion, e.g., kidney dialysis, metabolic disorders or osteopenia
- Patients having inadequate tissue coverage of the operative site

Warnings:

Only clinicians who have been properly trained in this procedure, including patient preparation, and samples preservation, should use this device. The instructions are not intended to define or suggest surgical protocol. It is the physician's responsibility to determine the appropriate protocol and techniques required based on the needs of the patient.

Good medical judgement should be exercised if instrument should be used and use of image guidance based on location and patient anatomy.

Good medical judgement should be exercised in considering on patients who are receiving anticoagulant therapy or who have bleeding disorders.

Do not use for a sternal procedure. Due to screw length, internal thoracic organs or blood vessels may be punctured or otherwise damaged.

Precautions:

Prior to insertion, inspect the Cannulated Aspiration Screw, Stylet and Luer for damage.

Surgical Technique

1. Place the patient in an appropriate position for the procedure.
2. Locate and mark the appropriate insertion site.
3. Using sterile technique, prepare the site.
4. Infiltrate the skin, especially the periosteum, with local anesthetic.
5. A skin puncture may be created prior to inserting the Cannulated Aspiration Screw.
6. Insert the Stylet into the Cannulated Aspiration Screw until it's fully seated. Refer to **Figure 1**.

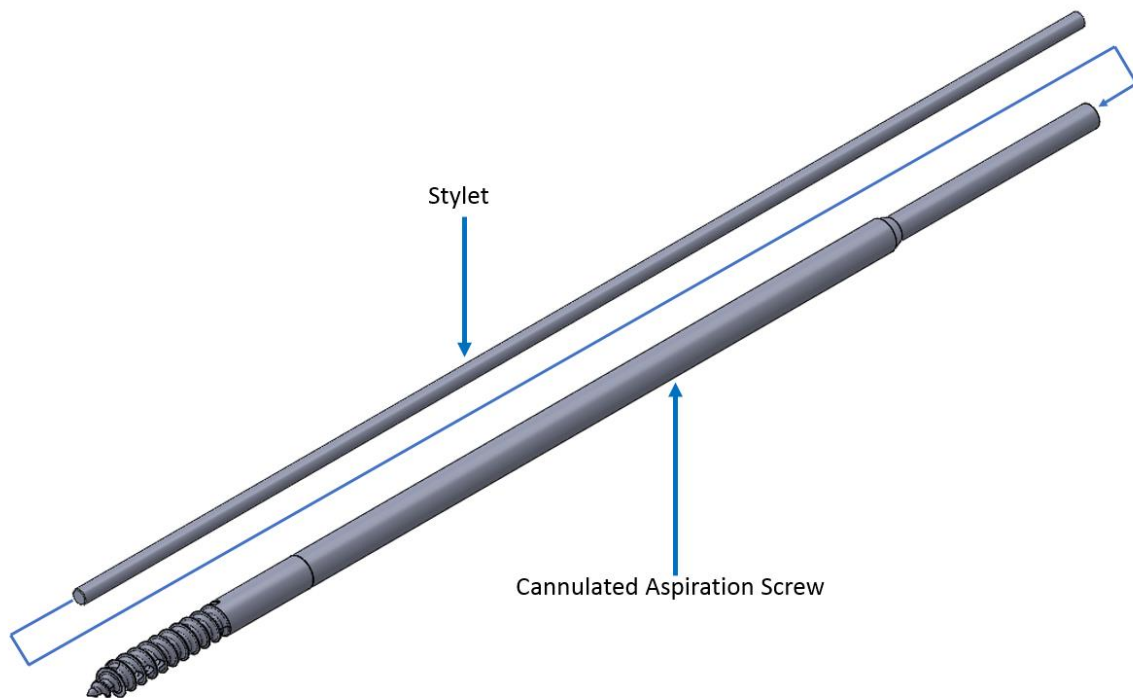


Figure 1

7. Introduce the Cannulated Aspiration Screw and stylet through the incision, and using firm pressure, advance the screw in a clockwise motion until the proper depth of bone penetration is reached. Refer to **Figure 2**.



Figure 2

NOTE: Care should be taken regarding the depth of penetration of the Cannulated Aspiration Screw to avoid potential patient harm.

8. Detach and remove the stylet. Refer to **Figure 3**.



Figure 3

9. Attach Luer Lock in orientation as shown to proximal end of Cannulated Aspiration Screw until its fully seated. Refer to **Figure 4**.



Figure 4

10. Prepare the Syringe with 1mL of anticoagulant.

11. With one hand holding both the Cannulated Aspiration Screw and Luer Lock thread the Syringe on to the Luer Lock in a clockwise direction and firmly tighten. Refer to **Figure 5**.

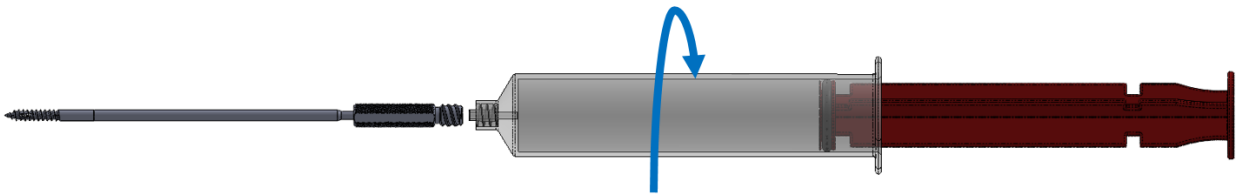


Figure 5

12. Push the Syringe and Luer Lock towards the Cannulated Aspiration Screw to ensure its fully seated.

13. While applying downward pressure on the Syringe, withdraw the syringe plunger to draw out into the syringe chamber until the desired amount of aspirate is obtained. Refer to **Figure 6**.



Figure 6

NOTE: If does not aspirate easily, reposition the Cannulated Aspiration Screw slightly by rotating either counterclockwise or clockwise.

NOTE: If the still does not aspirate, remove the syringe and Luer Lock, insert stylet into the Cannulated Aspiration Screw, attach and remove the Cannulated Aspiration Screw from the patient's bone, and repeat steps 6 through 12, with the exception of step 10 with a slight change in screw trajectory noted in step 7.

14. Detach the syringe by unthreading the syringe in a counterclockwise direction while holding the Luer Lock and remove the aspirated specimen. Refer to **Figure 7**.

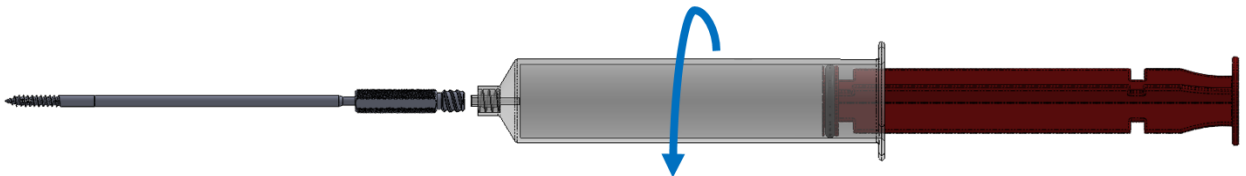


Figure 7

15. Detach the Luer Lock. Refer to **Figure 8**.



Figure 8

16. Reinsert the Stylet to strengthen the Cannulated Aspiration Screw before removal. Refer to **Figure 9**.



Figure 9

17. To remove the Cannulated Aspiration Screw, rotate in a counterclockwise direction until it is disengaged from the patient's bone.

Cannulated Aspiration Screw and Luer Lock

Part Number	Description
1170-1505	Cannulated Aspiration Screw Assembly
1170-1506	Luer Lock



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