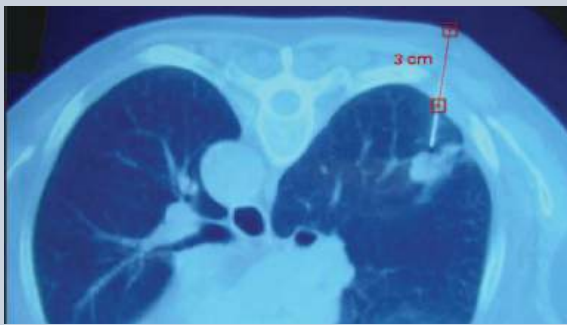


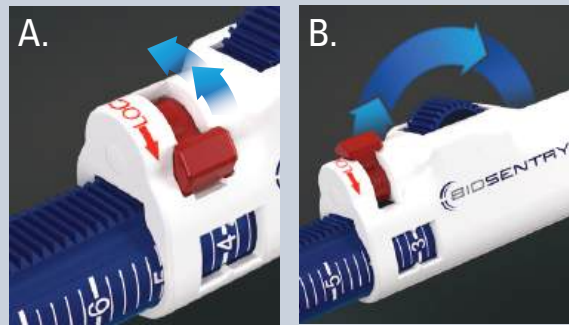
INSTRUCTIONS FOR USE:



1. Determine Depth Setting

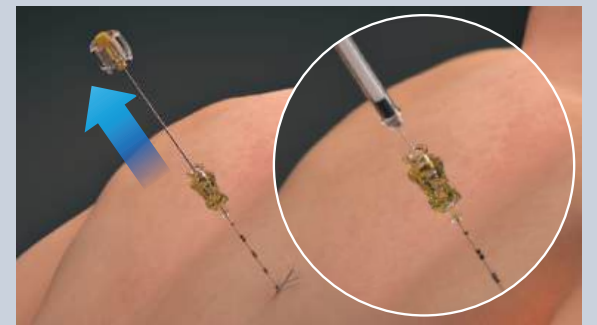
Following a percutaneous needle lung biopsy and using a 17 or 19G coaxial introducer needle, compute the distance of the skin to the pleural surface in the needle tract using appropriate imaging technique.

Note: The measured distance must be between 1cm and 7cm in order to use the BioSentry Tract Sealant System.



2. Prepare the Delivery Device

Remove the tip protector, (A) unlock the red lock arm and (B) adjust the depth wheel to set the measured distance at the arrows in the depth marking window (within 2mm increments). Re-lock the device. The delivery device is now prepared for use.



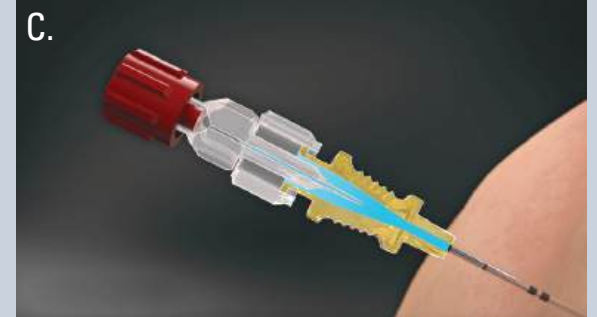
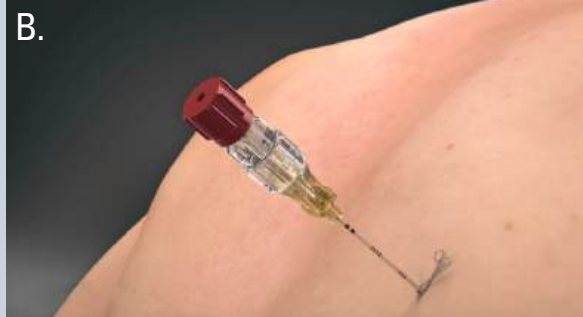
3. Prepare the Coaxial Introducer

Remove the stylet and fill the needle hub with drops of saline if fluid is not already present in the hub.

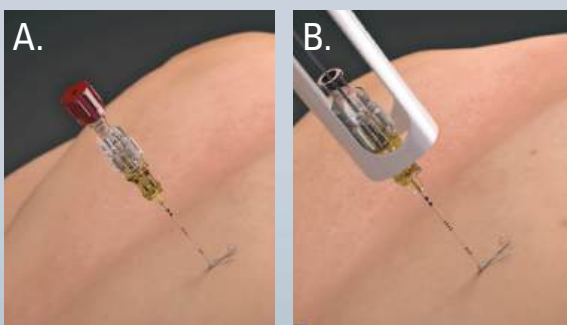


4. Prepare the Plug

(A) Remove the red nose cap on the coaxial adapter and visually inspect the adapter to verify it contains a plug. (B) Attach the adapter to the coaxial introducer needle hub and tighten. (C) The plug is now in contact with fluid and pre-hydration begins.

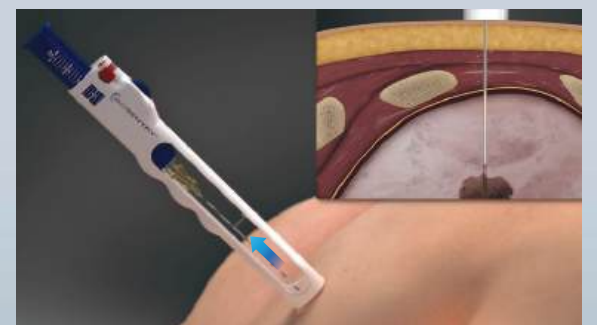


Next steps should be completed within 30 seconds.



5. Deploy the Plug

(A) Remove the red Luer cap from the coaxial adapter. Remove the yellow stabilization clip. Now insert the BioSentry delivery device plunger stylet into the coaxial adapter and coaxial introducer needle assembly. (B) Align the device around the spring clip on the coaxial introducer needle and advance the delivery device until (C) it contacts the patient's skin.



6. Expose the Plug

While maintaining slight downward pressure on the delivery device, **retract the coaxial introducer needle and adapter** assembly by reaching through the opening in the BioSentry delivery device and pulling the assembly away from the skin until the adapter fully enters the blue plunger. This action "unsheathes" and exposes the plug, leaving the plug across visceral pleura.

7. Remove the System

Remove the delivery device, coaxial adapter, and coaxial introducer needle together in one motion to complete the procedure. Discard any remaining components from the kit after the procedure is complete.

A MAJOR ADVANCE IN THE PREVENTION OF PERCUTANEOUS LUNG BIOPSY-RELATED PNEUMOTHORAX AND CHEST TUBE PLACEMENTS



INDICATIONS FOR USE: The BioSentry TRACT SEALANT SYSTEM is indicated for sealing pleural punctures to significantly reduce the risk of pneumothoraces (air leaks) associated with percutaneous, transthoracic needle lung biopsies and to provide accuracy in marking a biopsy location for visualization during surgical resection.

Warning: The BioSentry TRACT SEALANT SYSTEM can only be used with a 17 and 19 gauge coaxial introducer needle. This instrument should only be used by a physician familiar with the possible side effects, typical findings, limitations and contraindications of lung biopsies. Physician judgment is required when considering biopsy on patients with bleeding disorders, receiving anti-coagulant medications, or with bullous emphysema at or near the biopsy site.

Please refer to Directions for Use for further information pertaining to risks/contraindications. CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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