

Biopsy Procedure

7. Prepare the biopsy site appropriately and locate the target area.
8. **Optional use of co-axial introducer needle with biopsy instrument:** Under imaging guidance, advance the co-axial introducer needle to a position proximal to the lesion. For applicable 18- and 20-gauge catalog numbers, a blunt tip stylet is available for use in addition to a trocar tip stylet. Position the adjustable needle stop (the spring clip) proximal to the skin. Remove the stylet from the co-axial introducer needle, leaving the cannula in place.
9. Charge the device by pulling back on the plunger until a noticeable click is felt at either the first stop, indicating the 10mm notch size position, or the second stop, indicating the 20mm notch size position (user selectable). Verify the device is charged by looking at the sample notch window and confirming either a "10" or a "20" is present.

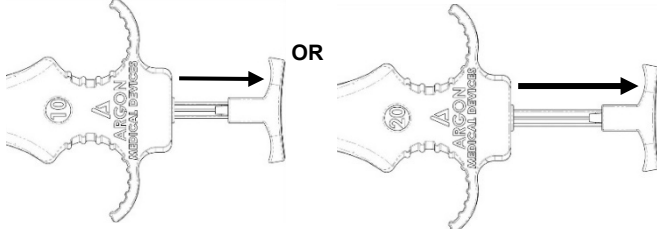


Figure 3: Pull Back Plunger to Charge

10. With stylet fully retracted (specimen notch completely covered by cannula), under imaging guidance, insert needle percutaneously or through the co-axial introducer needle to a location proximal to area to be sampled. Carefully advance the biopsy instrument needle, monitoring the position throughout the insertion process. When using a co-axial introducer needle, insert the biopsy instrument until the co-axial adapter meets the co-axial cannula hub (see Figure 4), monitoring the position of the biopsy instrument needle during the insertion to ensure that it does not over-shoot its target and that its final placement is correct. **See Precautions section for Step 10 precautions.**

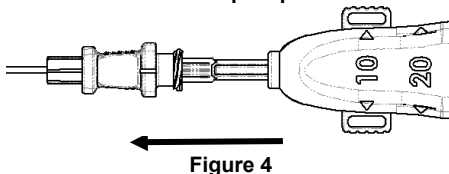


Figure 4

11. Press the plunger to advance the inner stylet into the tissue. When the fire ready indicator begins to enter the device, the cannula is about to be fired. To trigger the cannula to close, continue pressing plunger, pushing the fire ready indicator into the device. The cannula will prolapse the specimen in the sample notch.
12. Carefully draw the biopsy instrument needle out.
13. Pull back the plunger to the 10mm or 20mm position, recharging the spring. Push the plunger forward, exposing the specimen notch. Remove the tissue specimen from the notch in the stylet. **See Precautions section for Step 13 precautions.**
14. If additional biopsies are required, pull back plunger to withdraw the inner stylet and repeat steps 10-13.
15. If a co-axial introducer needle was used, carefully remove the co-axial introducer needle from the patient.

Disposal

After use, the biopsy instrument and co-axial introducer needle (if used) are potential biohazards. Handle the device(s) in a manner which will prevent accidental puncture, percutaneous injuries, or exposure to blood-borne pathogens. Dispose the device(s) in accordance with hospital policies and procedures and applicable law concerning sharps and biohazard materials and waste.

Storage

Store at controlled room temperature.

NOTE: In the event a serious incident related to this device occurs, the event should be reported to Argon Medical at quality.regulatory@argonmedical.com as well as to the competent health authority where the user/patient resides.



SuperCore Advantage™ Semi-Automatic Biopsy Instrument & Co-Axial Needle

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The symbols glossary is located electronically at www.argonmedical.com/symbols

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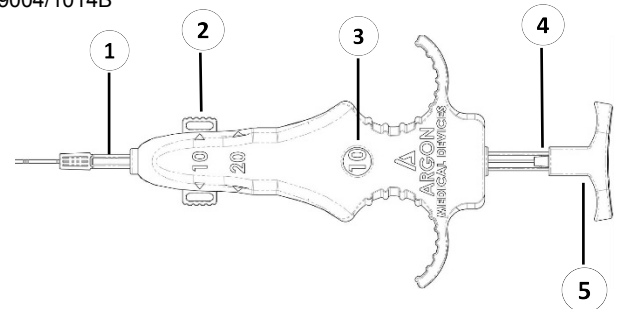


Figure 1: Biopsy Device

1. Co-axial Adapter
2. Co-axial Adapter Tabs
3. Sample Notch Size Window
4. Fire Ready Indicator
5. Plunger

Intended Use/Purpose

The **SuperCore Advantage™ Semi-Automatic Biopsy Instrument** and associated Co-Axial Introducer Needle are intended for percutaneous insertion and removal of tissue samples for diagnostic purposes. They are not intended for use in bone.

Device Descriptions

The **SuperCore Advantage™ Semi-Automatic Biopsy Instrument** is used to obtain soft tissue biopsies. It is composed of a spring-loaded biopsy needle fitted into a plastic handle permitting single handed specimen collection. The position of the needle may be visualized by x-ray, CT, or ultrasound.

Device Descriptions (continued)

The needle has numerically ordered centimeter markings to facilitate precise depth placement. The adjustable instrument allows for a specimen notch size of 10mm or 20mm, providing clinical flexibility. The device has an adjustable co-axial adapter built into the device for either the 10mm or 20mm notch settings. The stylet travels up to 27mm from when the device is in a fully charged position (prepared for a collection with the 20 mm notch size) to when the stylet is fully extended. The needle has an echogenic tip. The **SuperCore Advantage™ Semi-Automatic** biopsy instrument is available in several needle gauge sizes and lengths. The plunger is color coded according to the various gauge sizes, e.g., green=14-gauge, purple=16-gauge, pink=18-gauge, and yellow=20-gauge.

The optional Co-Axial Introducer Needle is used to support obtention of soft tissue biopsies. If a Co-Axial Introducer Needle is not provided with your biopsy instrument, a compatible one can be purchased from Argon Medical Devices. Compatible Co-Axial Introducer Needles are not available for biopsy instruments having needles 6cm in length. The introducer needle includes a stylet and cannula, which terminate in a trocar tip. For applicable 18- and 20-gauge catalog numbers, a blunt tip stylet is also available. The introducer needle is introduced proximal to the target biopsy site and then the stylet is removed. The hollow cannula allows for introduction of the biopsy instrument. The position of the introducer needle may be visualized by x-ray, CT, or ultrasound. The needle has numerically ordered centimeter markings to facilitate precise depth placement. The introducer needle has an echogenic tip. The introducer needle mates with an adjustable co-axial adapter built into the biopsy instrument. Each introducer needle has an adjustable needle stop in the shape of a spring clip, which allows the user to restrict the forward movement of the introducer needle.

Indication for Use

The **SuperCore Advantage™ Semi-Automatic** Biopsy Instrument and associated Co-Axial Introducer Needle are used to obtain samples from soft tissue such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, pancreas, and other masses.

Contraindications for Use

- These devices shall not be used in bone.

Caution: Do not use these devices in a manner contrary to their Indication for Use. Safety and effectiveness have not been evaluated for alternate uses.

Potential Complication

Potential complications associated with core biopsy procedures and co-axial guided biopsy procedures are site specific. They include, but are not limited to: hematoma; hemorrhage; infection; fever, swelling, adjacent tissue injury; pain; bleeding; hemoptysis; hemothorax; non-target tissue, organ or vessel perforation; pneumothorax; hematuria; dysphagia; dysphonia; edema; pseudoaneurysm; vasovagal reaction; vertebral puncture; carotid injury; tracheal puncture, nerve injuries; and air embolism.

Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

Warnings

- Physician judgement is required when considering biopsy on patients with bleeding disorders or receiving anti-coagulant medications.
- These instructions are NOT meant to define or suggest any medical or surgical technique (e.g. how to advance a needle through tissue to a position proximal to a lesion). The individual practitioner is responsible for the proper medical or surgical techniques to be used with these devices.
- When used for breast biopsy, the biopsy instrument is for diagnosis only.

Precautions

- Contents are supplied sterile and are intended for single use only. Do not re-sterilize.
- These devices should be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of soft tissue biopsy.

Precautions (continued)

- During Step 10, after charging device, be careful not to press plunger until the biopsy instrument needle is positioned in the appropriate location, proximal to the lesion. Verify proper location of needle prior to pushing plunger and advancing the inner stylet.
- During Step 10, the co-axial adapter may be damaged if the co-axial introducer needle is placed on it or removed from it too forcefully.
- During step 13, while retrieving a tissue specimen from the notch, be careful not to trigger the cannula and do not push the fire-ready indicator into the device.
- Before use, verify the integrity of the biopsy instrument and the co-axial introducer needle (if being used). If any parts are damaged, replace the device(s).
- Before use, verify that any protective tips or sheaths are secured to their associated components. If any parts are not properly secured, replace all contents of the pouch with a new device.
- Reuse or reprocessing has not been evaluated and may lead to device failure and subsequent patient illness, infection or other injury. DO NOT reuse or reprocess these devices.
- Do not use if package(s) is/are open or damaged or if the expiry date(s) has/have been exceeded.
- Do not continue to use if any of the components are damaged during the procedure. When used repeatedly in the same patient, the biopsy instrument should be inspected for damage or wear after each sample is taken.
- The introduction of the biopsy instrument needle (and the co-axial introducer needle, if applicable) into the body should be carried out under imaging guidance (ultrasound x-ray, or CT).
- Handle devices in a manner that will prevent accidental puncture.
- If using a separately packaged Argon co-axial introducer needle, ensure that the catalog number of the Argon introducer needle corresponds with the catalog number of the Argon biopsy instrument.
- Other manufacturer's co-axial introducer needles have not been tested for compatibility with the biopsy Instrument.
- Noises generated when operating biopsy instrument may startle patient, causing patient movement during use.
- The stylet travels up to 27mm from when the device is in fully a charged position (prepared for a collection with the 20 mm notch size) to when the stylet is fully extended. Use caution when operating device near sensitive tissue or vasculature.

Directions for Use

Preparation Procedure

1. Inspect package integrity prior to use.
2. Remove the device(s) from their package(s).
3. Before use, verify that any protective tips or sheaths are secured to their associated components. If any parts are not properly secured, DO NOT USE.
4. Remove the protective needle sheath/tip protector from needle and (if applicable) co-axial introducer needle (including from the additional blunt stylet for applicable 18- and 20-gauge catalog numbers).
5. Before using the biopsy instrument, inspect the stylet and cannula of the needle and (if applicable) the stylet(s) and cannula of the co-axial introducer needle for damaged point(s), bent shaft(s) or other imperfections that would prevent proper function. If the needle(s) is/are observed damaged, DO NOT USE.
6. If using a co-axial introducer needle, adjust the co-axial adapter on the biopsy instrument to the appropriate setting (each setting corresponds to either a 10mm or 20mm notch size) by simultaneously pressing the tabs and moving the adapter. Use device markings to confirm the adapter position is at either "10" or "20".

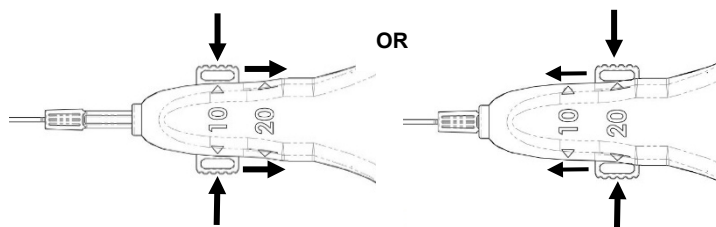


Figure 2: Co-axial Adapter Adjustment