

Brevera® Breast Biopsy System

User Reference Guide

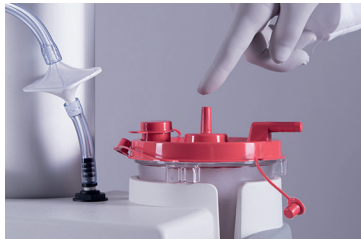
Set Up and Use



Plug biopsy driver into console.



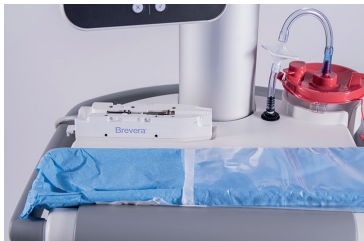
Power the system on.



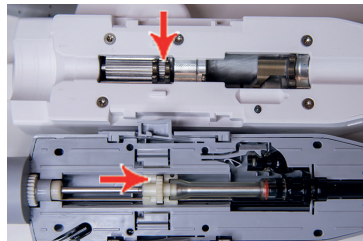
Place the assembled canister into the holder with the "PATIENT" port facing the right side.



Securely connect the blue fitting of the Vacuum Line Assembly to the "VACUUM" port.



Place the biopsy needle package into the tray on the top of the console and open the sterile pack.



Ensure biopsy needle and driver are in the ready position before assembly. To reset driver (if needed), disconnect and plug into the console. To reset biopsy needle, manually slide white gear forward until it clicks into place.



With the biopsy needle lined up over the driver, carefully move the biopsy needle straight down matching the notches. The needle should slide forward smoothly until it clicks.



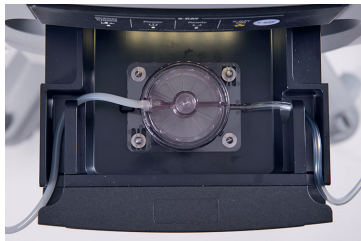
Spike the saline bag, gently squeeze to ensure unobstructed flow, and hang the bag on the saline hook located on the side of the console.



Guide saline tubing counter-clockwise around the tubing management plate and insert clear section of saline tubing into the saline pinch valve. Place gray vacuum tubing into the tubing guide.



Connect the biopsy needle vacuum line to the "PATIENT" port of the canister lid.



Open the drawer and click the tissue filter assembly into place, routing the tubing through the guides. Ensure tissue filter cap is secure. Close the drawer.



Unwind foot switch and place it on the floor in front of the console.



To complete set up follow on screen prompts on the smaller technologist display screen.



Once the "Test" cycle is complete, the user may follow prompts to test "Arm" and "Fire" the device or proceed to "Standby".

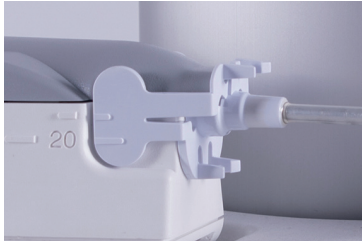


OPTIONAL: To "Arm" press and hold Arm button. To "Fire" press and hold Fire button. System will default to "Standby" when complete.



On the larger imaging display, select Log In. Follow the prompts to enter a patient and procedure.

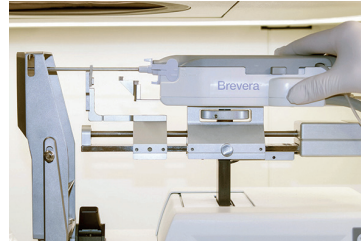
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To begin biopsy, place introducer onto needle in the 20mm or 12mm aperture position. System will not function if introducer is not installed.



Select "Biopsy" mode and "Arm" device. Confirm appropriate aperture (12mm or 20mm) and needle position is displayed on both screens. The device will only "Arm" and "Fire" in "Biopsy" mode.



Attach Brevera adapter to imaging guidance system. Slide the biopsy device onto the adapter until it clicks in place. Confirm appropriate settings on the imaging system for the chosen biopsy needle.



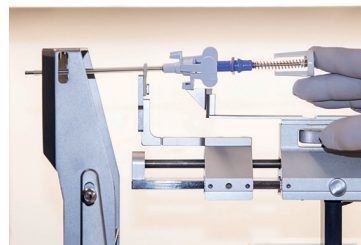
Press and hold "Fire" to advance the needle to target. To begin tissue acquisition, press down and hold footswitch.



Once the biopsy is complete, select "Lavage" and saline will be introduced and aspirated to irrigate the biopsy cavity.



Select "Aspirate" to vacuum the biopsy cavity.



Press "Standby" to close the aperture. To deploy a site marker slide the biopsy device from the adapter while leaving the introducer in place and insert the marker into the introducer.

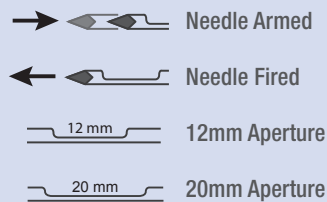


Dial introducer/marker out of the breast. To remove introducer/marker assembly from adapter, pinch tabs to release.



Open drawer. Twist off the tissue filter assembly cover. Place a cap on the tissue filter. Remove filter and place in a formalin jar. Replace the tissue filter assembly cover.

Symbols Legend



	Standby	Vacuum is off and aperture of biopsy needle is closed. The device cannot be fired and images cannot be taken.
	Test	Confirms vacuum, initiates saline flow and tests the cutting cycle.
	Biopsy	Depressing footswitch activates a cutting cycle and releasing footswitch stops the device after the cycle is complete. Aperture is open.
	Lavage	Vacuum is on and saline is used to irrigate the cavity. Aperture is open.
	Aspirate	Vacuum is on and the cavity is aspirated without saline. Aperture is open.

Clean Up and Disposal



Once the procedure is complete, press "Close Procedure" on the console.

Pinch tabs on biopsy needle and slide to remove from driver.



Place driver on console.

If the needle is removed in "Standby", the driver will automatically reset to a ready state for a new needle.



Disconnect the Vacuum Line Assembly from the canister lid and seal all ports.

Remove the silicone tubing section of the biopsy needle saline line and the vacuum tubing from the canister lid.

Remove the saline bag from the hook.



Dispose of all consumables per your facility's protocol.

Clean top of console and biopsy driver with a mild detergent and disinfect per your facility's protocol. Refer to Brevera User Manual for detailed cleaning instructions.