

Brevera® Breast Biopsy System

Quick Reference Guide

Set Up and Use



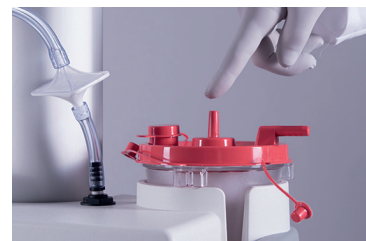
Power ON the system.



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



Log in to the system. On the *Startup* screen, select the **Patient List** button to go to the *Select Patient* screen. Enter or select a patient and procedure.



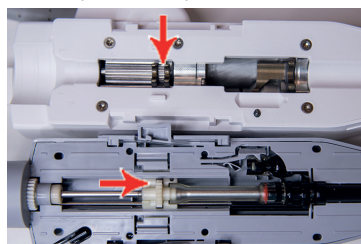
Place the assembled canister into the holder with the "PATIENT" port facing the right side.



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 the driver and biopsy needle are in the ready position before assembly. To rehome the driver, press the **Check** button. To reset the biopsy needle, manually slide the 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.



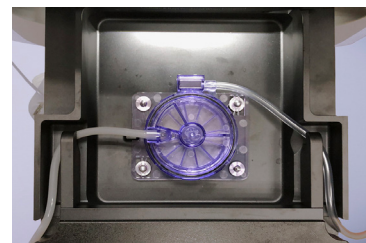
Connect the biopsy needle vacuum tubing to the "PATIENT" port of the canister lid.



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.



Insert the larger diameter section of the saline tubing into the saline pinch valve.



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



To complete setup, follow the on-screen prompts on the Technologist display.



Once the "Test" cycle is complete, you can follow the prompts to test "Arm" and "Fire" or you can proceed to "Standby".



To "Arm": press and hold the **Arm** button. To "Fire": press and hold the **Fire** button. The system defaults to "Standby" when complete.



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

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Select Biopsy mode and arm the biopsy device. Confirm the correct aperture (12mm or 20mm) and needle position are displayed on both screens. The device only arms and fires in Biopsy mode.



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



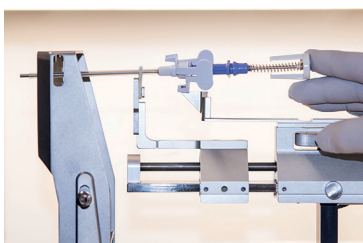
Press and hold the **Fire** button to advance the needle to the target. To begin tissue acquisition, press down and hold the footswitch.



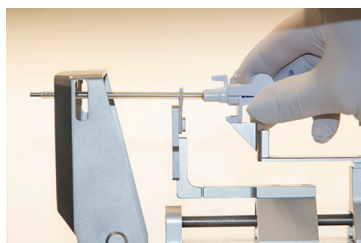
Once the biopsy is complete, select **Lavage** and saline is introduced to irrigate the biopsy cavity.



Select **Aspirate** to vacuum the biopsy cavity.



Select **Standby** to close the aperture. To deploy a site marker, slide the biopsy device from the adapter while leaving the introducer in place. Insert the marker into the introducer.



Dial the introducer and marker deployment device out of the breast. Pinch the tabs on the introducer to remove it from the adapter.



Open the drawer. Twist off the tissue filter assembly cover. Place a cap on the tissue filter. Remove the tissue filter and place in a formalin jar. Replace the 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.
	Needle Armed	
	Needle Fired	
	12mm Aperture	
	20mm Aperture	

Clean Up and Disposal



Once the procedure is complete, select **Close Procedure** on the Imaging display. Pinch the tabs on the biopsy needle and slide it to remove it from the driver.



Place the driver on the console. If the needle is removed in Standby mode, the driver will automatically reset to a ready state for a new needle.



Remove the saline tubing. Remove the vacuum tubing and disconnect it from the canister lid.
Disconnect the Vacuum Line Assembly from the canister lid and seal all ports.
Remove the saline bag from the hook.



Dispose of all consumables per your facility protocol.

Clean the top of the console and the driver with a mild detergent and disinfect per your facility protocol. Refer to the Brevera *User Guide* for detailed cleaning instructions.