

Preparing for a Biopsy



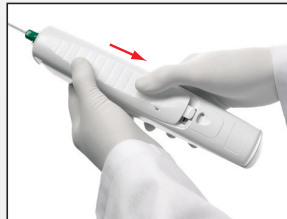
Ensure driver is sufficiently charged
Before loading probe into driver, press **SAMPLE** button to check battery charge level. A green light indicates driver is sufficiently charged. A red light or no light indicates driver requires charging.



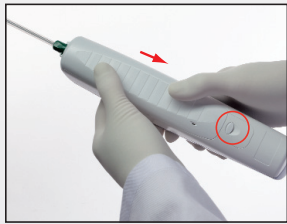
Insert probe into driver



Remove red retaining pin
Pull pin straight out, don't turn or twist pin.



Slide probe carriage back



Visually check to make sure the probe is fully engaged
Check that the oval tab securely locks into place and the probe is fully engaged with the driver.



Remove probe protective sleeve
The driver sounds one beep and the **PRIME/PIERCE** and **SAMPLE** indicator lights display green, indicating the probe is properly inserted.

Performing a Biopsy



To pierce dense breast tissue (optional)
Press **PRIME/PIERCE** button to retract probe 20-22mm. Using ultrasound guidance, position probe in the breast and press **PRIME/PIERCE** button a second time to release probe.



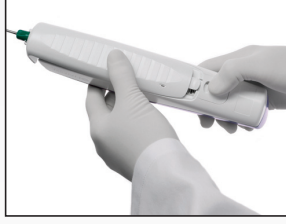
To acquire multiple samples
Using ultrasound guidance, confirm probe position. Press **SAMPLE** button to acquire a tissue sample. Press **SAMPLE** button again to acquire an additional sample. Repeat as desired.



To place a BARD ULTRACLIP® breast tissue marker
With probe in the breast, detach integrated coaxial cannula, remove probe and introduce tissue marker down through coaxial cannula.



To remove samples from the sample container
Remove lid from the sample container by twisting counter clockwise.




To remove the probe from the driver
Press down on locking tab, push carriage forward and pull probe from driver.

Cleaning/Maintenance



- After each use, clean driver thoroughly with a germicidal wipe or a damp cloth moistened with a 10% bleach solution.
- Do not spray driver with any fluids, submerge it in fluids, autoclave, or expose it to heat over 54°C (129°F).

Charging Instructions

	Battery Indicator Light	Description
	Steady Green	Battery is fully charged.
	Flashing Green	Battery is sufficiently charged to perform at least one biopsy procedure.
	Steady Red	Battery charging. Full charge takes approximately 120 min.

Place driver in charging stand when not in use.

Service and Repair

For technical assistance with product hardware, please contact:
Tel: (800) 592-9871, select Option #4 Fax: (800) 950-9278

Field Assurance

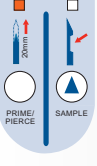
To report a product issue or complaint, please contact:
Tel: (800) 592-9871, select Option #2 Fax: (800) 950-9278

Ordering Information

Part Number	FINESSE® ULTRA Breast Biopsy System
F01BLU	Biopsy Driver-Blue
F01CVR	Biopsy Driver-Sterile Instrument Cover
F14105US	Ultrasound Biopsy Probe 14g x 105mm

Part Number	ULTRACLIP® Dual Trigger Breast Tissue Marker
862017D	Ultrasound Enhanced Wing Marker 17g x 10cm Needle
863017D	Ultrasound Enhanced Ribbon Marker 17g x 10cm Needle
864017D	Ultrasound Enhanced Coil Marker 17g x 10cm Needle

For important additional information, please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

KEYPAD LIGHTS	BEEPS	CONDITION	ACTION REQUIRED
 No lights	None	No probe loaded or driver in sleep mode if not moved for 120 seconds.	Move driver or place driver on charging stand. PP and S lights will turn solid green. •If the indicator lights do not turn on after loading a probe into the driver, ensure the probe cover and locking tab are securely in place and ensure the probe is new and has never been used before. •If the above conditions are satisfied, remove the probe and check to see if the driver has sufficient charge by pressing and holding the S button. If the Battery indicator light indicates sufficient charge, replace the probe with a new probe. •If the indicator lights do not turn on after properly inserting a new probe, contact Bard Service and Repair. See section J, Driver Charging, for Battery light and charging stand instructions.
 PP and S Green Solid	1 beep (only when loading probe)	Probe loaded in driver.	Driver ready to perform biopsy. Option to either “Prime” or “Sample.”
 PP and S Orange Flashing Alternating	None	Sample container removed.	Ensure sample container is installed in probe.
 PP and S Orange Flashing Simultaneously	2 beeps	Tissue sample stuck in sample chamber or probe chamber is open and probe is stuck in driver.	If procedure is not yet complete, detach coaxial from probe to maintain location in breast. Remove probe from the breast. •If sample chamber is closed, press the PP and S buttons simultaneously for at least 3 seconds until the chamber opens. Remove any tissue from sample chamber and then press and hold the PP and S buttons simultaneously for at least 3 seconds. If both the PP and S lights are solid green, the biopsy can be continued. Insert the probe and reattach the coaxial to continue the biopsy. •If the sample chamber is open, remove any tissue from the chamber and then press and hold the PP and S buttons simultaneously for at least 3 seconds. If both the PP and S lights are solid green, the biopsy can be continued. If the PP and S lights are flashing red after holding the PP and S buttons simultaneously for at least 3 seconds, discard the biopsy probe, reset the driver, and replace with a new probe if additional samples are required.
 PP and S Orange Flashing Simultaneously	Multiple beeps	Keypad button held down after completing prime, pierce, or sample acquisition sequence.	Release the keypad button. Either PP or PP and S button(s) will turn solid green, and the biopsy procedure can be continued.
 PP and S Orange Flashing Alternating	5 beeps	Probe inserted before driver has reset.	Remove probe from driver, allow driver to reset and reload probe after driver has reset.
 PP and S Red Flashing Alternating	3 beeps	Probe or driver failure.	Remove and discard probe. Reset driver by pressing the PP and S button simultaneously for at least 3 seconds until the motors engage. If reset does not occur and lights remain flashing red, place driver on charging stand and wait for driver to reset (PP and S lights will cycle from red to orange to green to off). If the indicator lights do not turn off or the probe cannot be removed, contact Bard Service and Repair.
 PP Green Solid	None	Driver primed (probe retracted).	Press “PP” when in desired location to pierce target.
 PP Orange Solid	None	Device is performing either the prime or pierce function.	Wait for driver to complete function and indicator light to turn solid green before moving or repositioning.
 S Orange Solid	None	Device is engaged in sample acquisition sequence.	Wait for driver to complete sample acquisition sequence and indicator light to turn solid green before moving or repositioning.
 S Orange Flashing	2 beeps	Sample cup obstructed.	Remove sample cup. Inspect cup base and below cup and remove any tissue outside cup. Replace sample cup. S light will flash green when obstruction is resolved. Press and hold S button for 3 seconds to reset probe. If S light remains flashing orange, discard the biopsy probe, reset the driver, and replace with a new probe if additional samples are required.
 S Green Flashing	None	Sample cup has been reinserted (observed after S orange / flashing error).	Press and hold sample button for at least 3 seconds to reset probe. S will turn solid orange while reset occurs. When reset is complete both PP and S will be solid green and the biopsy can be continued.

Service and Repair

For technical assistance with product hardware, please contact:
Tel: (800) 592-9871, select Option #4 Fax: (800) 950-9278

Field Assurance

To report a product issue or complaint, please contact:
Tel: (800) 592-9871, select Option #2 Fax: (800) 950-9278

For important additional information, please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.