

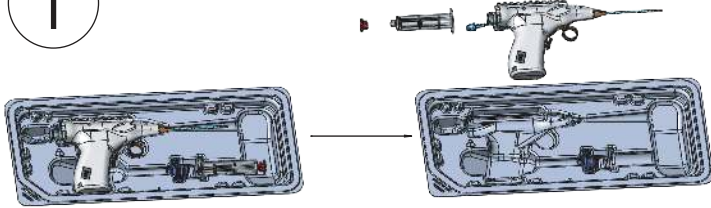


SpeedBird®
Universal

QUICK START GUIDE



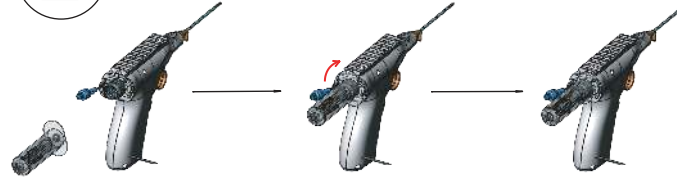
1



Carefully remove the device from its carton, remove the Tyvek lid and set the device in its thermoform tray on a stable surface.

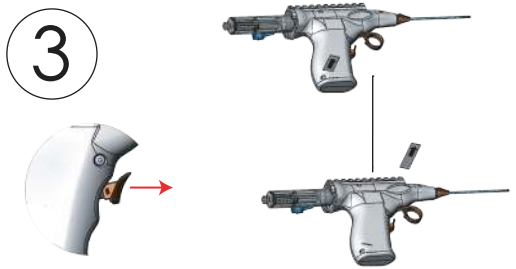
Remove the specimen collection assembly from the tray and remove the red sealing cap from the specimen collection assembly.

2



Attach the Specimen Collection Assembly to the rear of the device with a clockwise twist to secure.

3



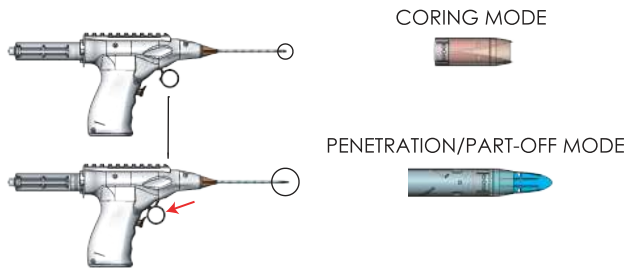
Ensure the power switch is in the disengaged OFF position.

Remove the battery pull tab.



Exercise caution when unpacking, preparing and using the device to ensure the precision needle is not damaged. Do not use the device if the needle or its tip appear damaged.

4



With the power OFF, pull and hold the trigger. Ensure the beaks at the end of the device are fully closed and undamaged to the naked eye. This is the penetration/partoff mode.

Release the trigger to its natural position and ensure that the beaks are fully open. This is the coring mode - the beak tips are open and will core tissue when the device is powered on.

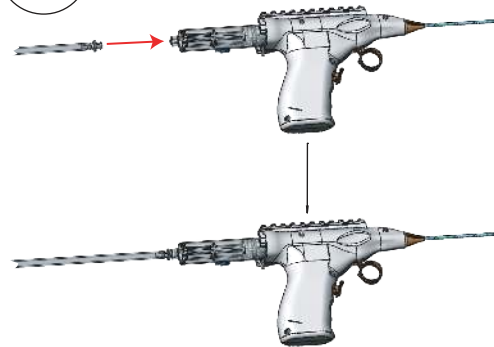
Turn the power ON by pressing the latching switch, and repeat this process to ensure device functions properly.

Turn the power OFF by pressing the latching switch again.



Power must remain on throughout the procedure.

5



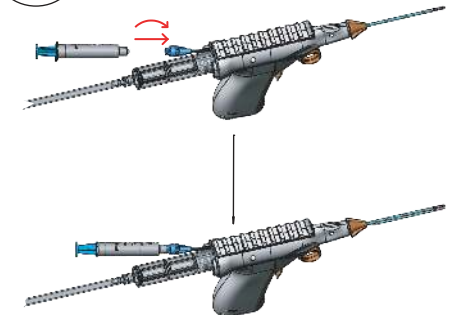
Attach the vacuum tube to the luer connection on the back of the Specimen Collection Assembly.

Attach the vacuum tube to the external vacuum source and test the vacuum for proper function before using the device.



Vacuum must remain on throughout the procedure.

6



Attach a syringe (with anesthetic and/or saline) or a flush infusion set to the flush port luer connection by simultaneously pushing and turning clockwise.

PRIME the device by injecting 2-3 cc of fluid into the device from the syringe or drip bag until you observe fluid being drawn by the vacuum.





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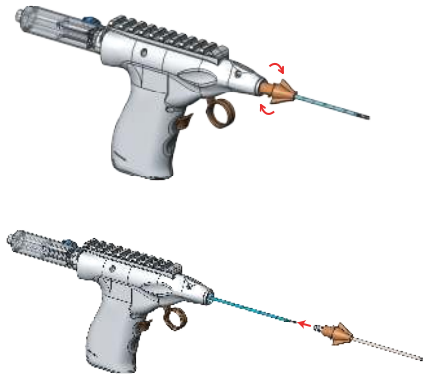
Zero5-based SIMC Device for Handheld, Ultrasound Guided Biopsy



The SpeedBird model SBU device is a single use, sterile, Single Insertion / Multiple Collection® (SIMC), vacuum assisted Forward Coring biopsy device. It has been designed for simplicity, ease of use, and patient comfort while delivering full diameter, operator-selectable length breast tissue specimens.

SBU devices feature full Active Fluid Management, anesthetic and flush fluid delivery options, and vacuum assisted tissue transport and collection in its Specimen Collection Assembly. The Specimen Collection Assembly features a vaporless tissue fixation system for ease of immediate tissue sample preservation post procedure as well as secure transport to the pathology laboratory for analysis.

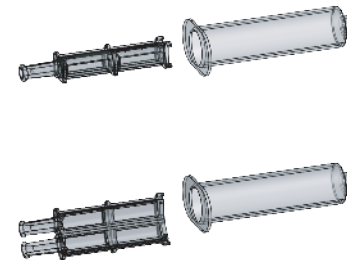
POST-PROCEDURE MARKER PLACEMENT



With the needle still at the target site:

1. Turn the device OFF.
2. Twist the wings of the nosecone 120 degrees counter-clockwise (from the back) to release the nosecone and non-rotating sheath from the device.
3. Remove the device and its needle, leaving the non-rotating sheath and nosecone in place (the nosecone need not stay attached to the non-rotating sheath).
3. Insert marker into the proximal end of the non-rotating sheath.

SPECIMEN INSPECTION



1. Slide the specimen capture magazine out of the transport tube.
2. Open the specimen capture magazine by pulling apart the edges opposite the mesh hinge.

Refer to separate guides for: - Vaporless Tissue Fixation - Tetherless Operation (VacuPac®)



Read the full Instructions For Use (IFU) before using the device for a clinical procedure. This guide is intended as a supplemental reference and should not be considered a substitute for the IFU.

