

Step by step description - Use of Bonopty[®] Bone Biopsy System, 12 gauge

Before use, please read the Instructions For Use which accompany the product for indications, contraindications, warnings and precautions.

Caution: Federal law restricts this device to sale by or on the order of a physician.

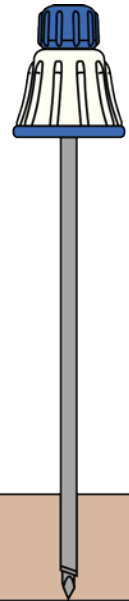
Step 1

Plan the procedure carefully.

Administer local anesthetic at the puncture site.

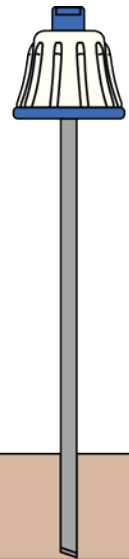
Make a small incision with a scalpel to make the penetration of the skin easier.

Press the penetration cannula with the stylet firmly down until the tip reaches the bone.



Step 2

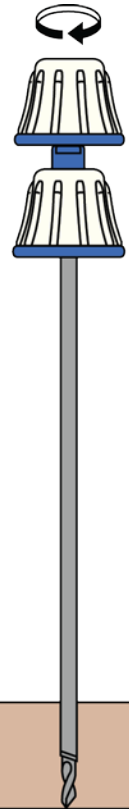
Remove the stylet while holding the penetration cannula firmly against the bone to maintain the position.



Step 3

Insert the eccentric drill into the penetration cannula and rotate it a few turns until the drill tip catches the bone.

Verify the position and direction of the drill with diagnostic imaging. It is easy to correct the position and direction at this point.

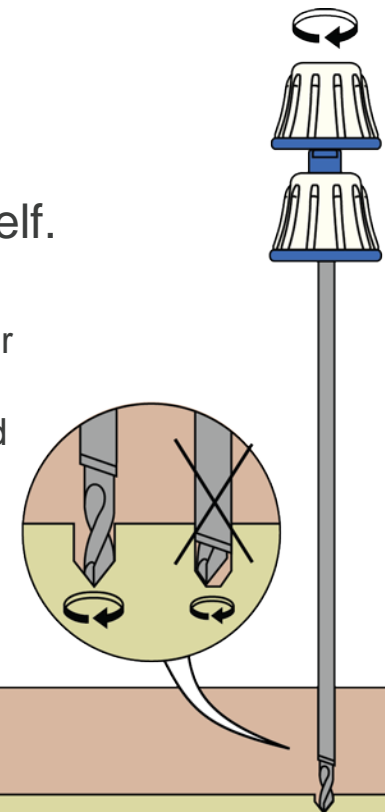


Step 4

Before drilling, retract the penetration cannula to allow the wobbling movement of the eccentric drill.

From an engineering standpoint, retracting the cannula exposes the eccentric drill tip, which allows the drill to make a hole that is larger than the drill itself.

⚠ Warning: During drilling, do not push the cannula forward over the drill. This hinders the "wobbling" movement of the eccentric drill and prevents the transportation of bone material out from the drilled hole.

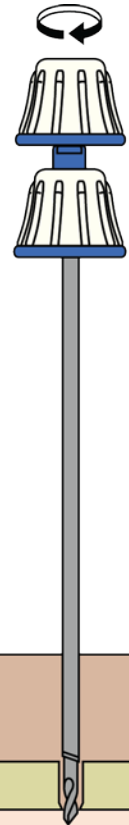


Step 5

Continue to drill through the cortical bone. Use moderate axial pressure and as long turns as possible. This may take several minutes. When the drill has passed the cortical bone, advance the penetration cannula 2-3 mm into cortex.

Make sure that the penetration cannula is firmly anchored into the bone.

Remove the drill.



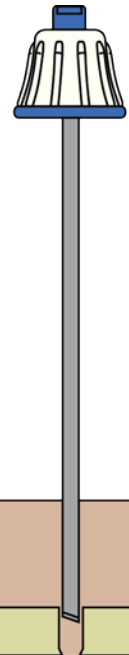
Step 6

The anchored cannula now provides a passage for the desired intervention, such as an ablation, injection or biopsy.

The use of Bonopty® Biopsy Set is described in the following slides.

Please note: If any other device besides the Bonopty® Biopsy Set is to be used through the penetration cannula, compatibility in length and size must be checked first.

⚠ Warning: The penetration cannula is designed for anchorage, and is not intended for passage through thick intact cortical bone.

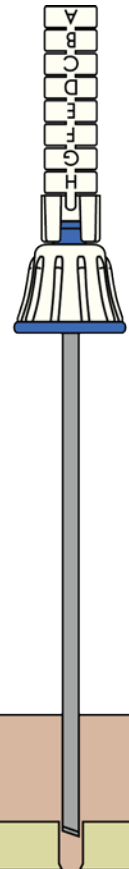


Step 7

The biopsy needle is designed for successful sampling of somewhat sclerotic lesions. More lytic lesions are also possible to sample by using a syringe attached to the Luer-Lok fitting.

For increased accuracy and precision during sampling, use of the Depth Gauge is recommended.

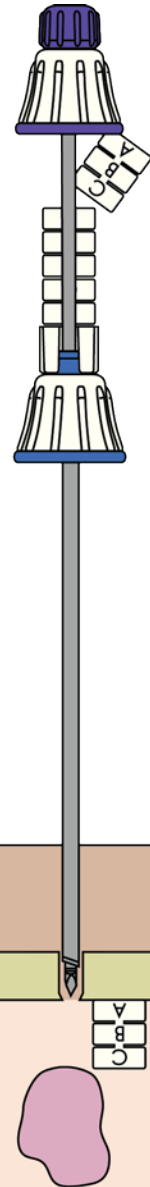
Snap the Depth Gauge on to the top of the penetration cannula.



Step 8

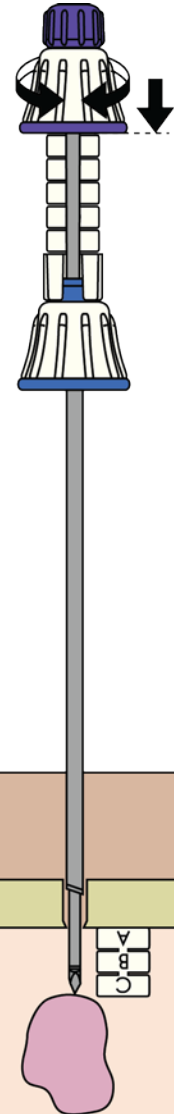
Insert the biopsy needle. The tip of the biopsy needle will then align with the tip of the penetration cannula.

Break off the number of indicators on the Depth Gauge needed to reach the target lesion (each indicator is 5 mm).



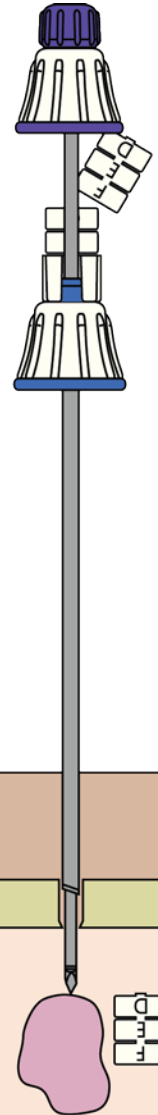
Step 9

Advance the biopsy needle, with the stylet inserted, to the stop. The tip of the biopsy cannula is now at the targeted lesion.



Step 10

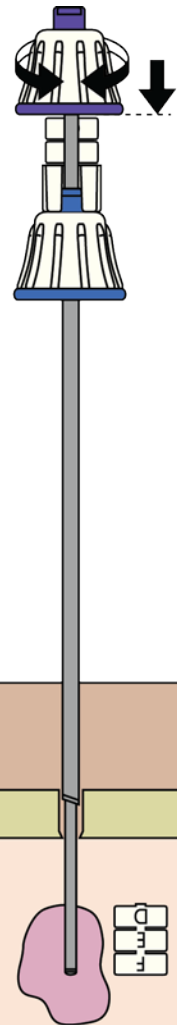
Break off the number of indicators corresponding to the desired length of the sample.



Step 11

Remove the stylet and rotate or wiggle the biopsy needle while applying slight pressure until the hub reaches to the stop.

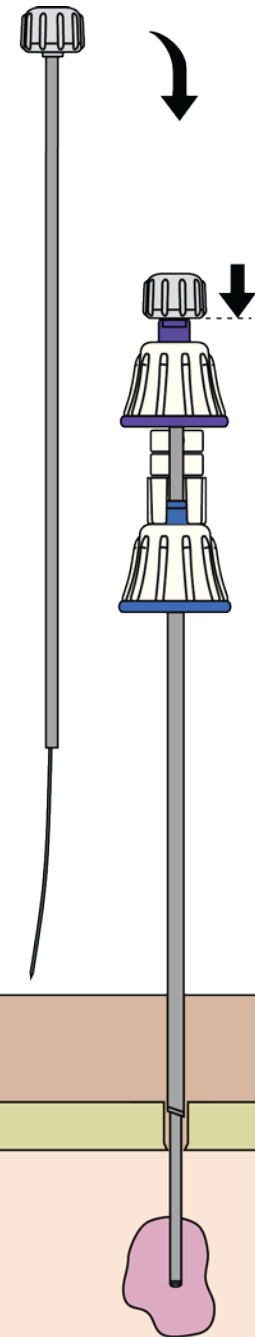
⚠ Warning: The system is not suitable for very sclerotic or purely lytic lesions. If a target or trajectory proves to be too hard to sample or penetrate using the Bonopty® biopsy cannula, stop the procedure and remove the cannula.



Step 12

Insert the Core Lock.

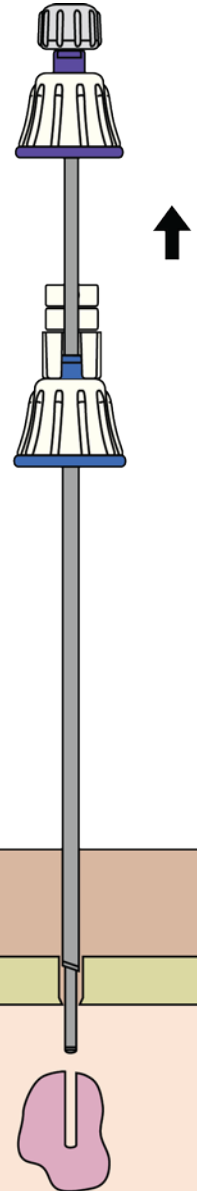
The Core Lock will trap the specimen in the distal tip of the biopsy cannula. This will keep the sample intact during retrieval.



Step 13

Remove both the biopsy cannula and the Core Lock at once.

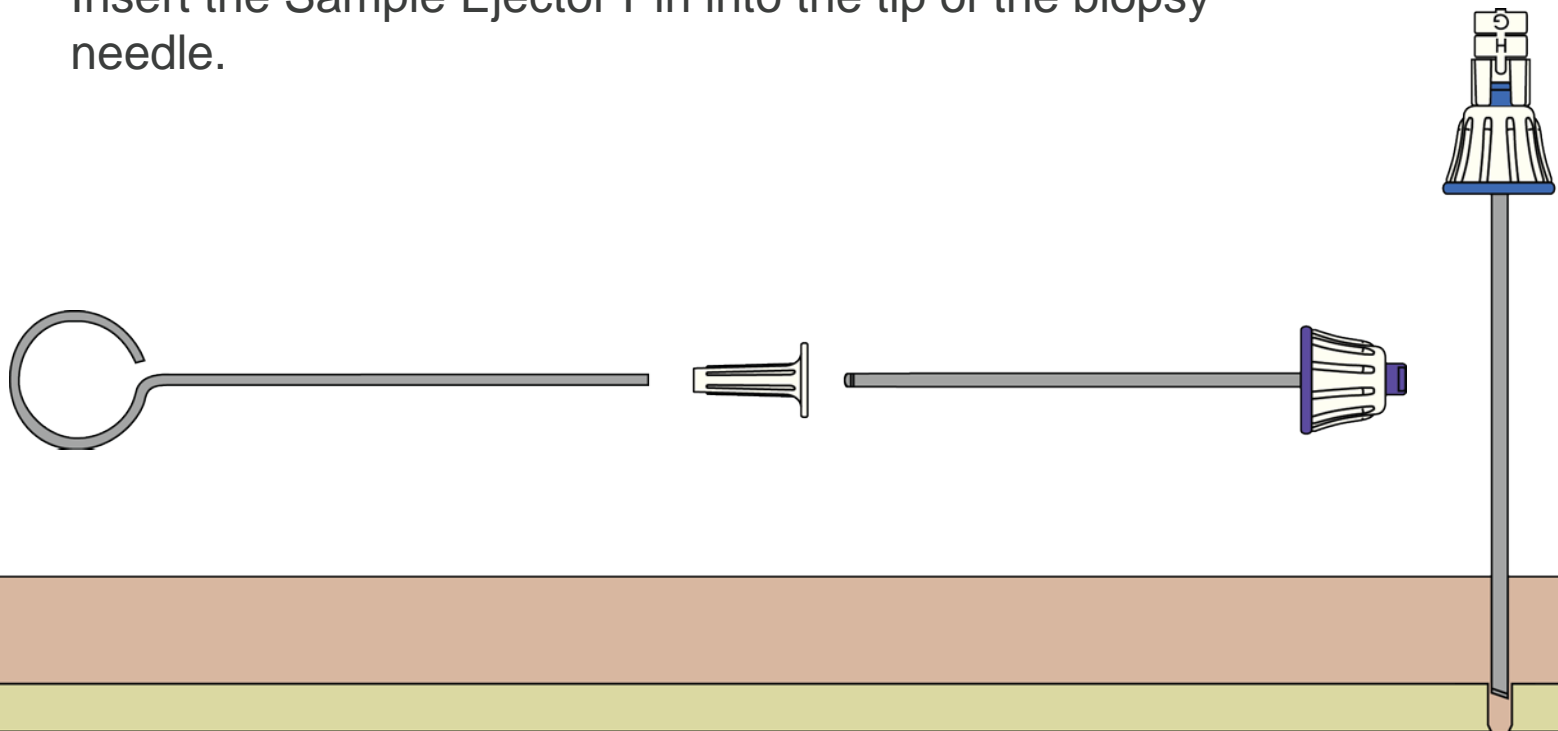
Remove the Core Lock from the cannula.



Step 14

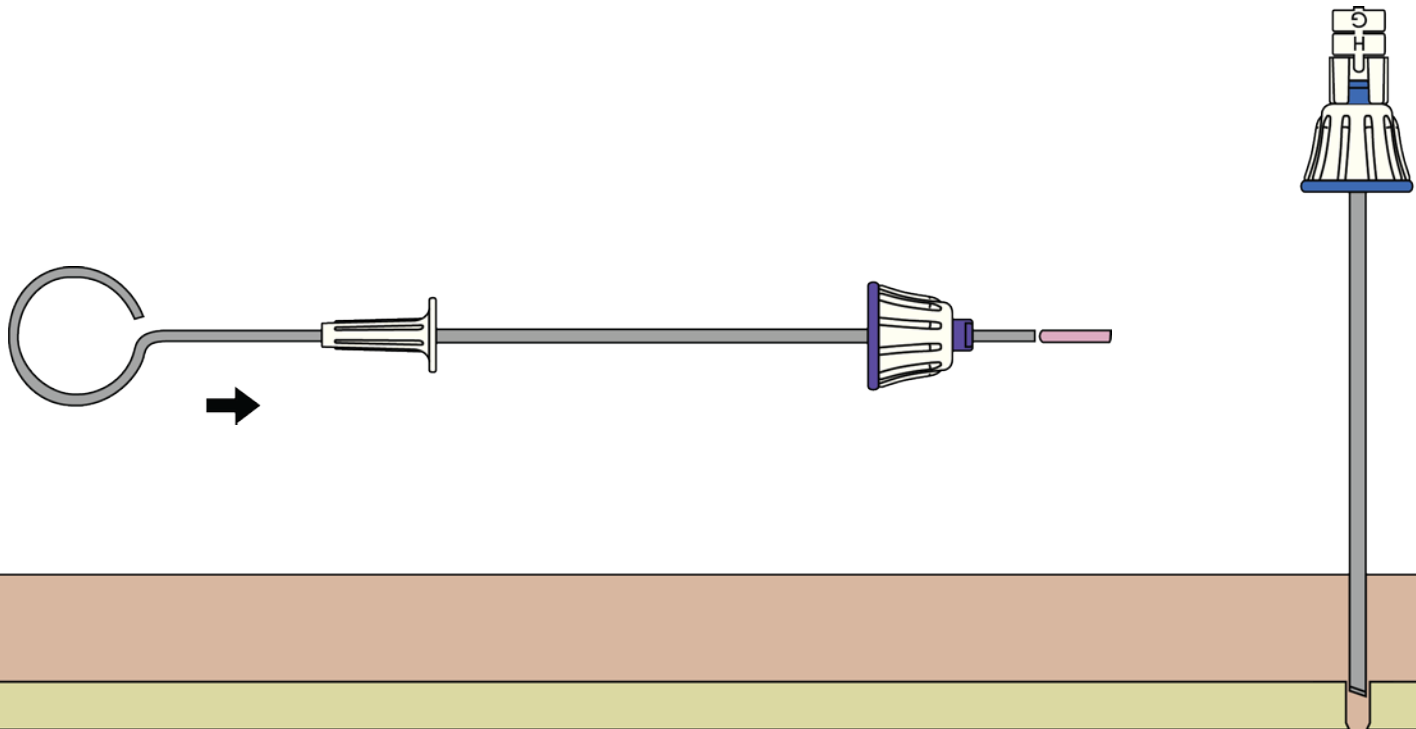
In order to obtain the sample, place the Sample Ejector Guide on the distal tip of the biopsy cannula.

Insert the Sample Ejector Pin into the tip of the biopsy needle.



Step 15

Push the sample out through the Luer opening of the hub in order to avoid crushed artifacts.



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Step 16

For multiple sampling, repeat steps 7 to 15.

The stylet should remain in the biopsy needle until the new sampling location is reached in order to avoid contamination of the following samples.

