

Step by step description - Use of Bonopty[®] Bone Biopsy System, 14 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.

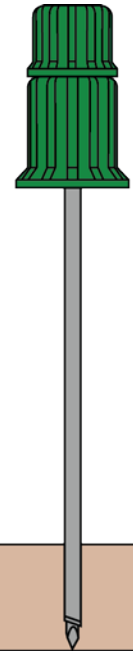
Step 1

Plan the procedure carefully.

Administer local anesthetic at the puncture site.

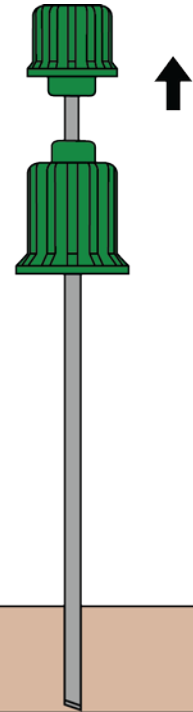
Make a small incision with a scalpel to make the penetration of the skin easier.

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



Step 2

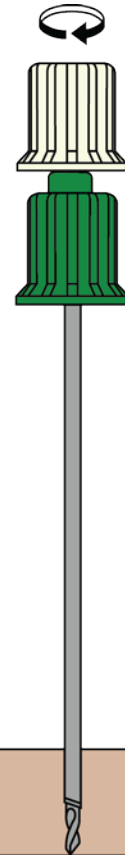
Remove the stylet while holding the penetration cannula firmly against the bone to maintain the position.



Step 3

Insert the eccentric drill (white cap) into the penetration cannula (green cap) 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.

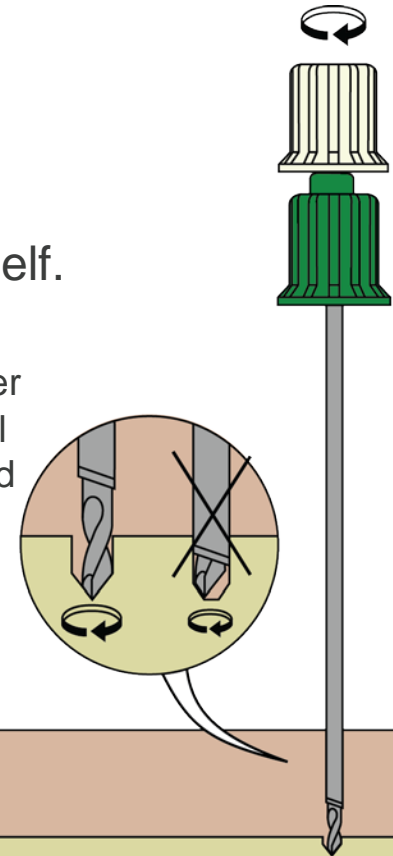


Step 4

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.

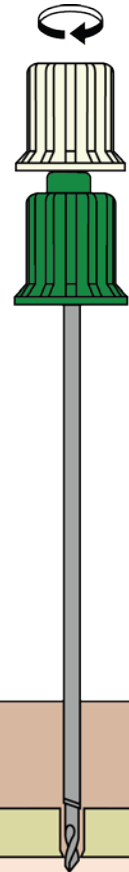


Step 5

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.



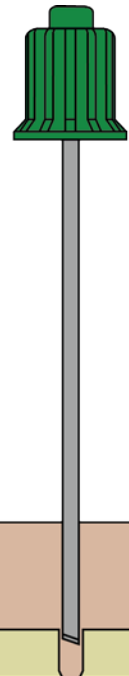
Step 6

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

The use of Bonopt[®] Biopsy Set is described in the following slides.

Please note: If any other device besides the Bonopt[®] 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.

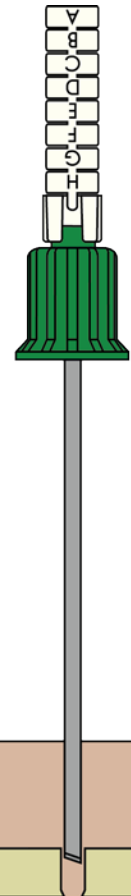


Step 7

The biopsy needle (blue cap) is designed for successful sampling of somewhat sclerotic lesions. More lytic lesions are also possible to sample by using a syringe pressed on to the Luer fitting.

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

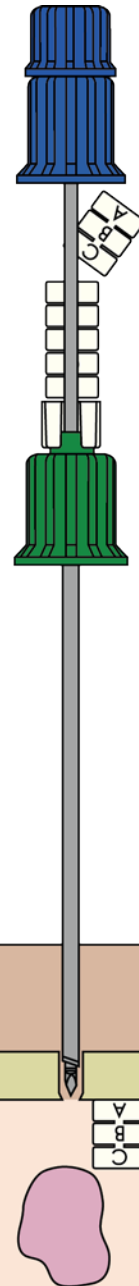
Snap the Depth Gauge on to the top of the penetration cannula (green cap).



Step 8

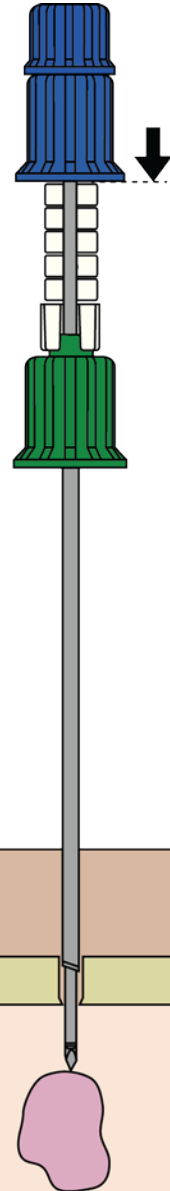
Insert the biopsy needle. The tip of the biopsy needle will then align with the tip of the penetration cannula.

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



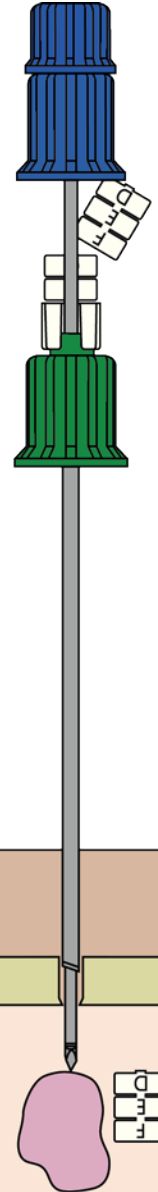
Step 9

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.




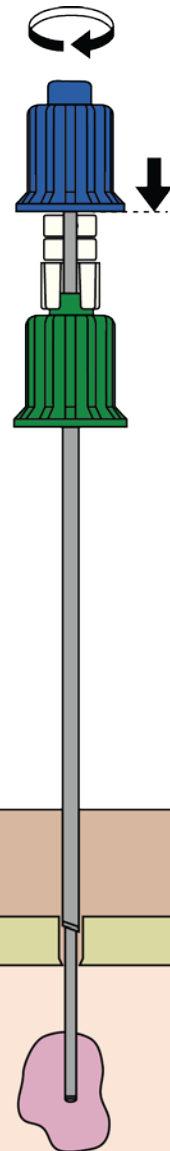
Step 11

Remove the stylet and push and turn the biopsy needle (blue cap) while applying slight pressure until the hub reaches the stop.

Turn the biopsy needle (blue cap) to retrieve the sample.

Pull out the biopsy needle.

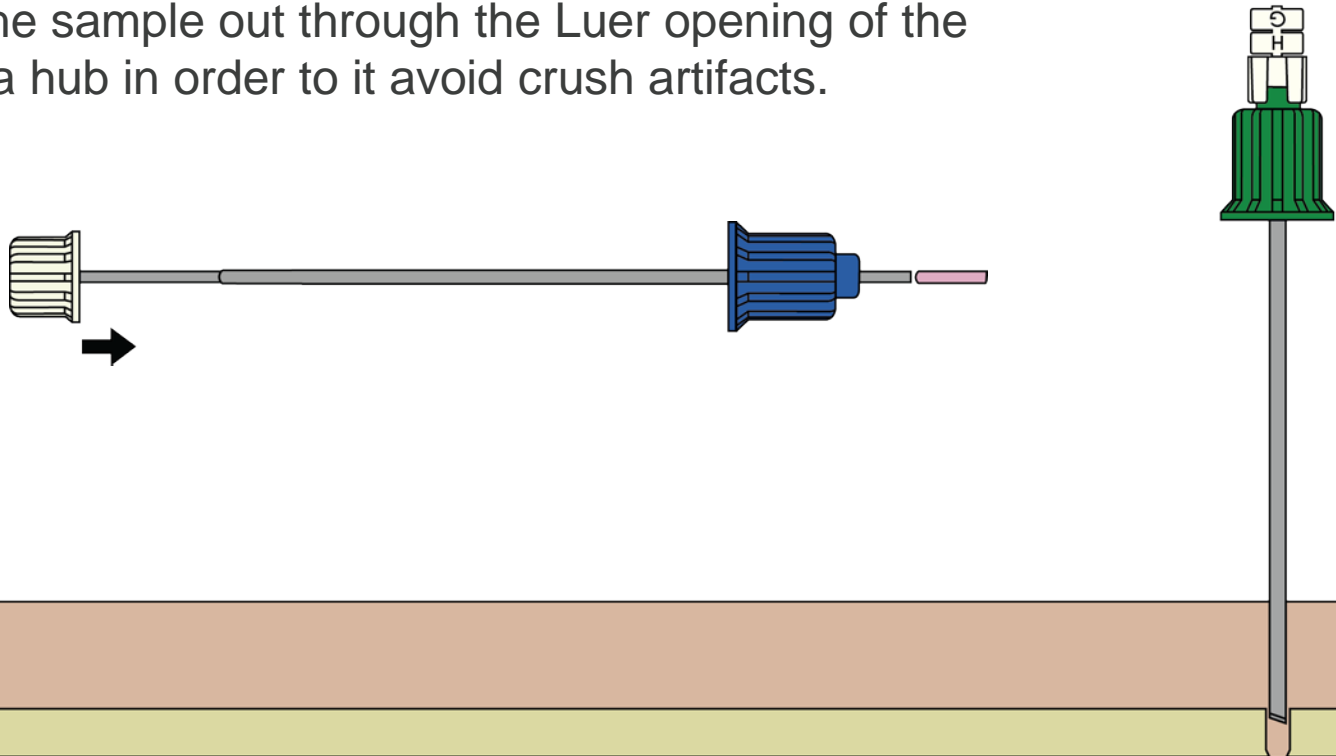
 Warning: The system is not suitable for very sclerotic or purely lytic lesions. If a target or trajectory proves to be too hard to sample or penetrate using the Bonopty® biopsy cannula, stop the procedure and remove the cannula. It may be possible to sample using the extended drill instead, please see the IFU.



Step 12

Insert the ejector pin (white cap) into the tip of the biopsy needle (blue cap).

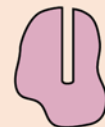
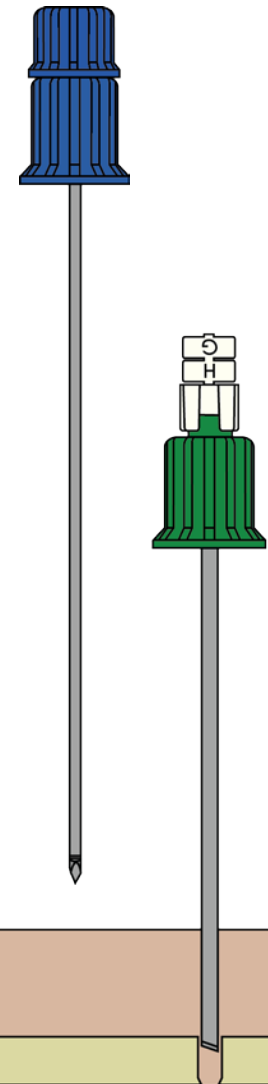
Push the sample out through the Luer opening of the cannula hub in order to it avoid crush artifacts.



Step 13

For multiple sampling, repeat steps 7 to 12.

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



Step 14

When the penetration cannula is anchored in the cortex there may still be a need to reach further into the bone.

Use Bonopt[®] Extended Drill to pass or sample sclerotic lesions deeper in the bone.

