

Step by Step Description Use of Bonopty[®] Coaxial Bone Biopsy System



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.

Bonopty[®] is a registered trademark of Apriomed AB.
The product is protected by one or more of the following patents:
US 5,423,824; US 5,810,826;
US 5,868,684; EP 0 794 733;
JP 3710475; SE 470 177.

Developed, Designed and Manufactured by:
Apriomed AB Virdings Allé 28
SE-754 50 Uppsala, Sweden.
Tel: +46(0)18 430 14 40
Fax: +46(0)770 339972
E-mail: info@apriomed.com
www.apriomed.com

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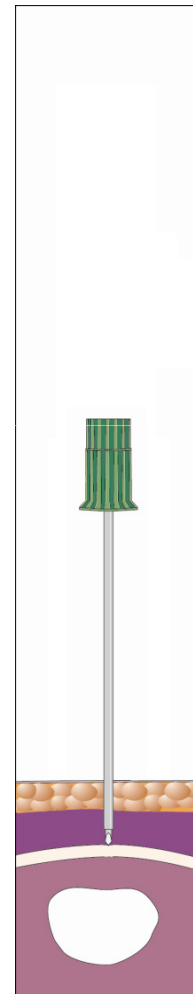
1. Bonopty Penetration Set (10-1072)

Plan the procedure carefully.

Administer anaesthetic at the puncture site.

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

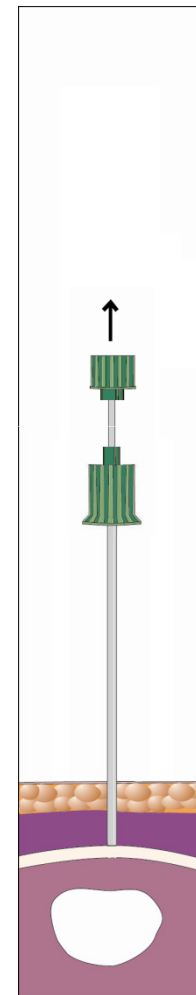
Press the penetration cannula with the stylet firmly down until the tip reaches the bone.



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2. Bonopty Penetration Set (10-1072) ct'd

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

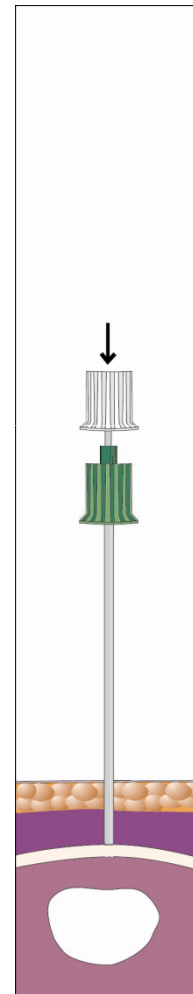


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3. Bonopty Penetration Set (10-1072) ct'd

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.



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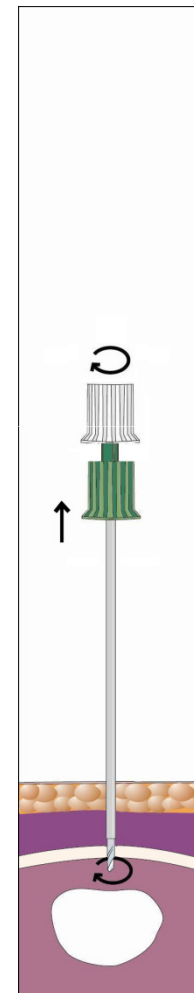
4. Bonopty Penetration Set (10-1072) ct'd

Before drilling, pull back the penetration cannula (retract the green cap) to allow the wobbling movement of the eccentric drill.

Continue to drill through the cortical bone. Use moderate axial pressure and as long turns as possible.

When the drill has passed the cortical bone, advance the penetration cannula (green cap) 2-3 mm into the cortex. Make sure that the penetration cannula is firmly anchored in the bone.

Remove the drill



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5. Bonopty Penetration Set (10-1072) ct'd

The anchored cannula now provides a passage for the desired intervention such as 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.



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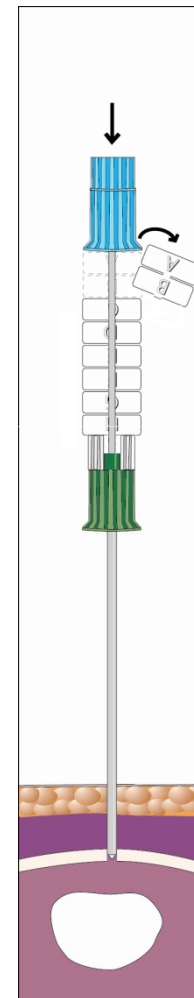
6. Bonopty Biopsy Set (10-1073)

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 of the Biopsy needle.

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

Click the depth gauge onto top of the penetration cannula hub (green cap). The tip of the biopsy needle (blue cap) will then align to the tip of the penetration cannula.

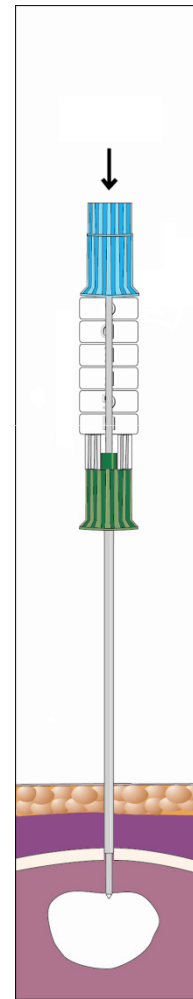
Break off the number of indicators needed (each indicator is 5 mm) to reach to target lesion.



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7. Bonopty Biopsy Set (10-1073) ct'd

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



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8. Bonopty Biopsy Set (10-1073) ct'd

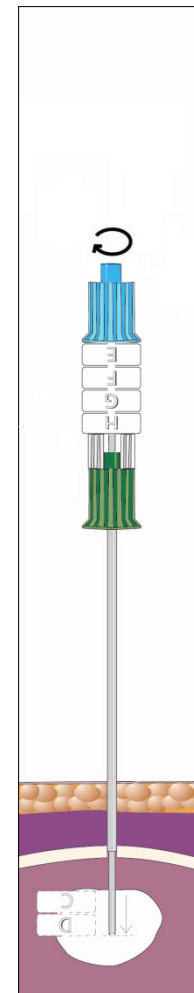
Break off the number of indicators corresponding to the desired length of the sample (maximum 15-20 mm).

Remove the stylet and push (“wiggle”) the biopsy needle (blue cap) to the stop.

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

Pull out the biopsy needle.

Please see the following slide for extraction of the sample.



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9. Bonopty Biopsy Set (10-1073) ct'd

The ejector pin (white cap) is inserted into the tip of the biopsy needle (blue cap).

The sample is pushed out through the luer opening of the cannula hub in order to it avoid crush artifacts.

For multiple sampling, repeat steps 6 to 8.

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



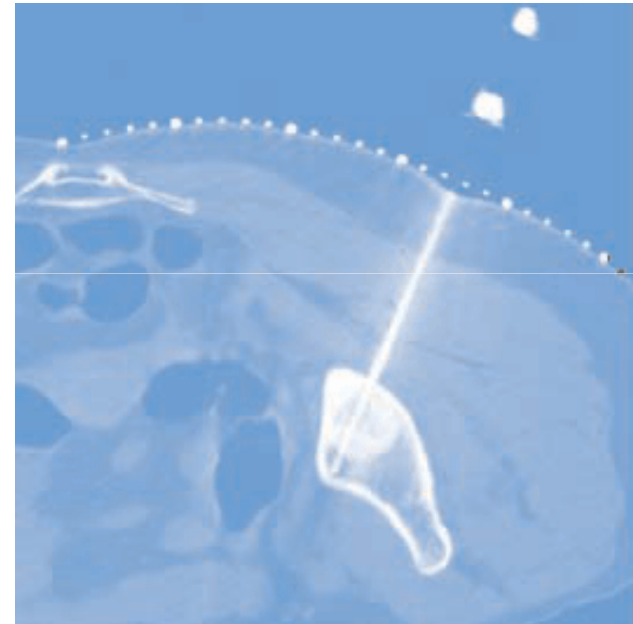
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10. Bonopty Extended Drill (10-1074)

When the penetration cannula (10-1072) is anchored in the cortex there may still be a need to reach further into the bone.

Use Bonopty® Extended Drill to:

- Pass or sample sclerotic lesions deeper in the bone
- Facilitate trans-osseous biopsies



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