

Step by step description - Use of Gangi-SoftGuard®

Indication for use: As a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, spleen, lymph nodes and various soft tissue lesions.

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.

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Introduction

Gangi-SoftGuard® is a coaxial biopsy needle provided with a trocar stylet and a spring loaded blunt stylet.

This step by step guide describes the function of the spring loaded blunt stylet and shows an example procedure where Gangi-SoftGuard® is used.

Introduction – Package contents

Each Gangi-SoftGuard[®] package contains:

Needle



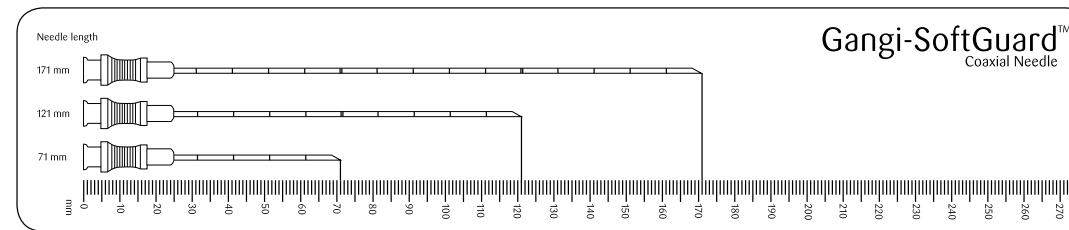
Trocar stylet



Spring loaded blunt stylet



Reference guide

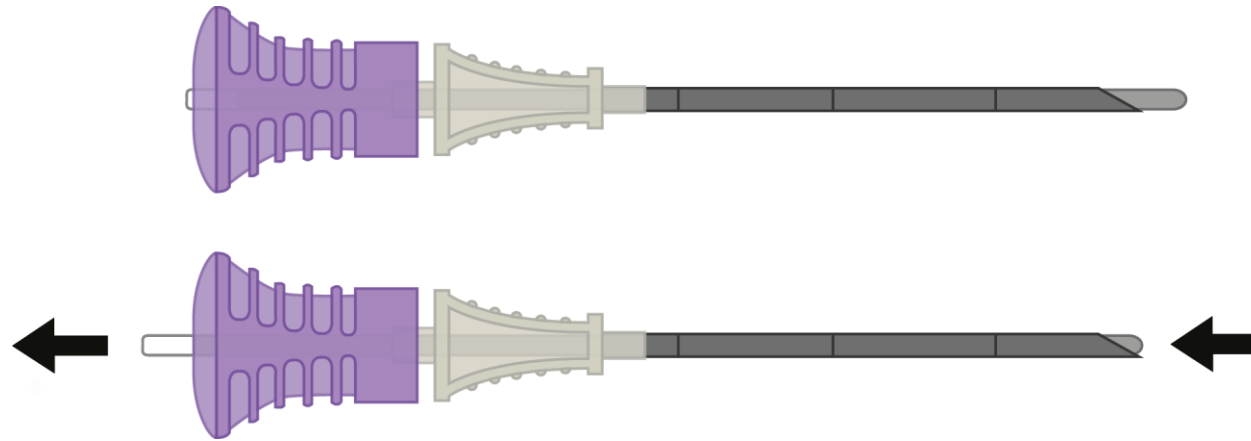


Introduction – The blunt stylet

The blunt stylet is spring loaded.

When resistance is met at the blunt tip, the tip retracts into the needle. This exposes the sharp needle, and cutting through tissue can be performed.

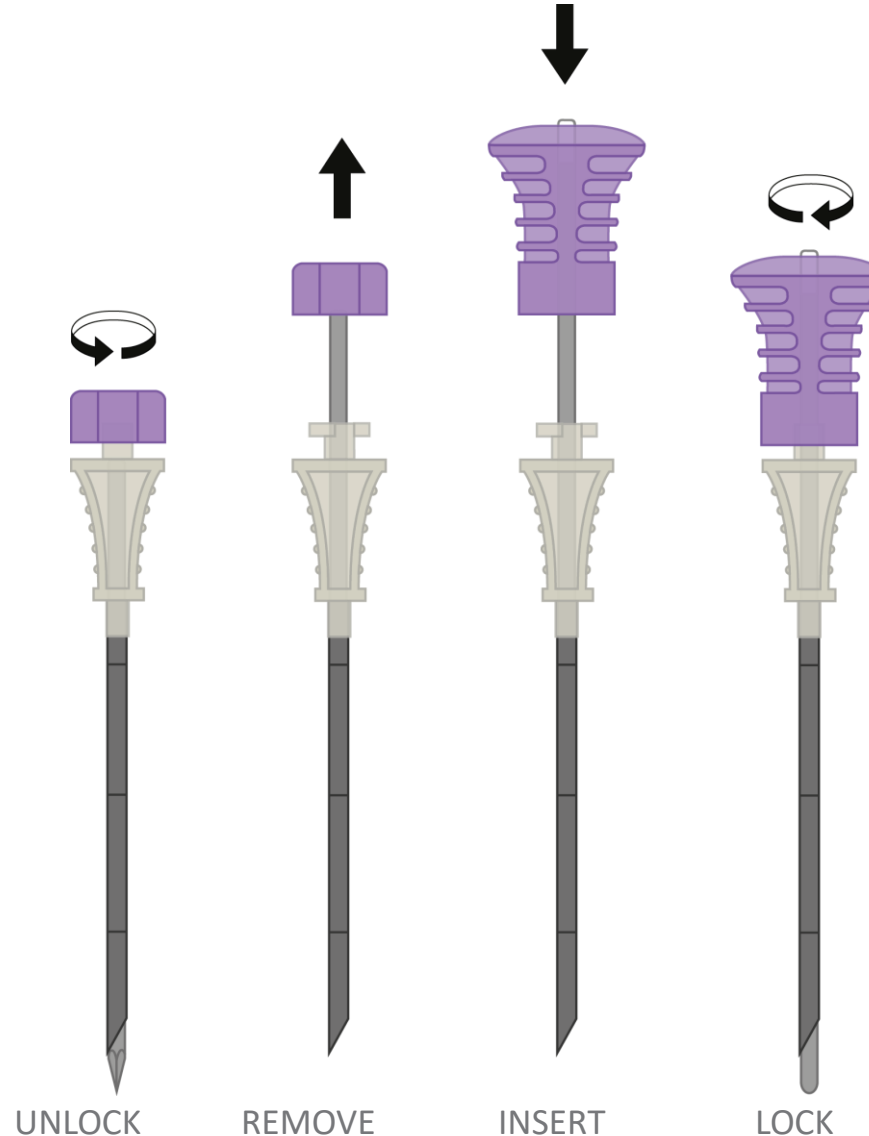
Simultaneously with the retracting tip, the pin at the needle hub springs back, giving visual and tactile feedback of the position of the blunt tip.



Introduction – Exchanging stylets

The device is provided with two stylets.

The stylets are easily exchanged and locked into position. Stylets can be exchanged before and during procedure.

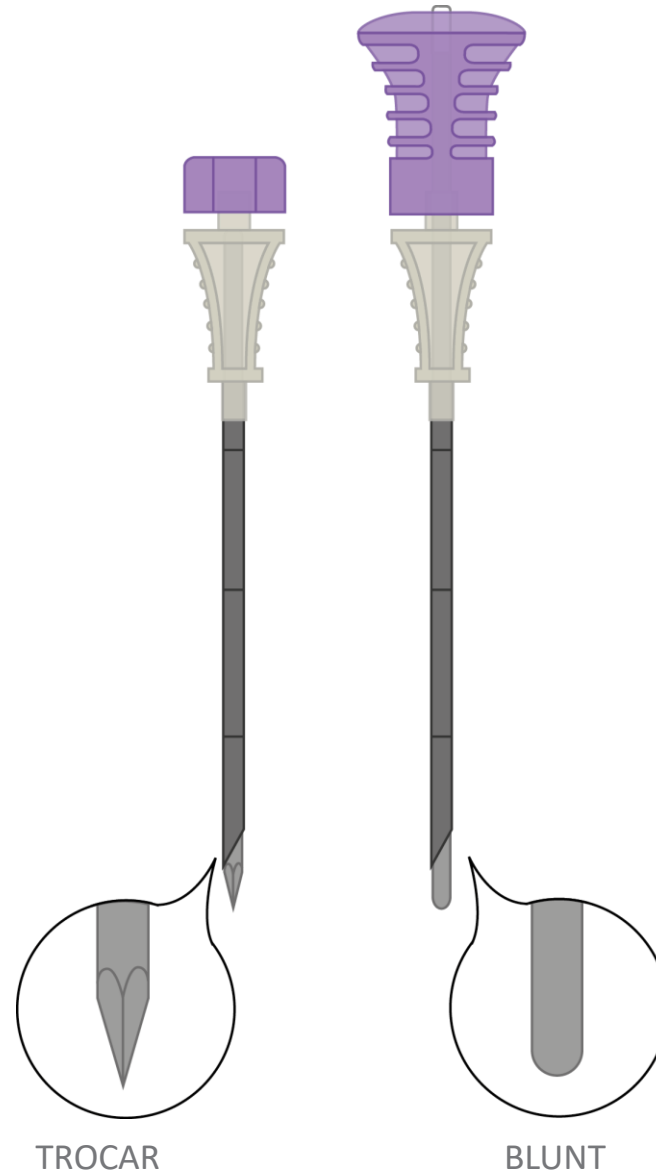


Step 1

Determine which stylet is preferred.

The needle is delivered with the trocar stylet inserted. If the blunt stylet is preferred, exchange stylets.

In this procedure, the trocar stylet is used for skin entry.

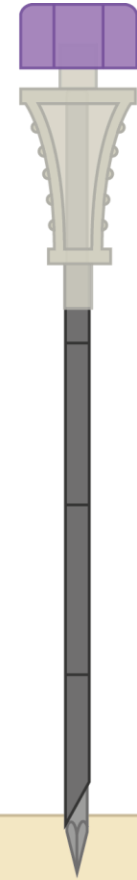


Step 2

Insert device superficially.

Monitor position using imaging technique.

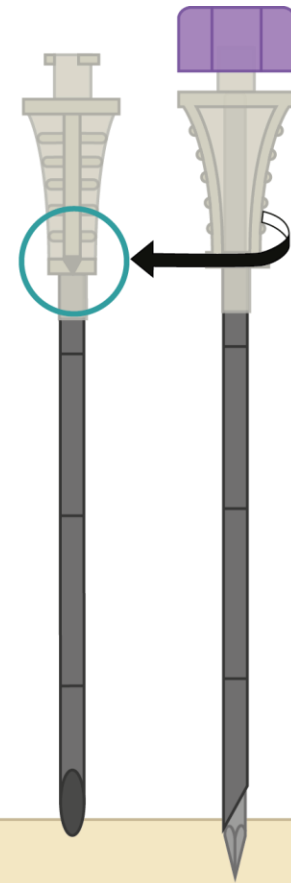
Note: If trocar stylet is not used, make a small skin incision using a scalpel to make penetration of skin easier.



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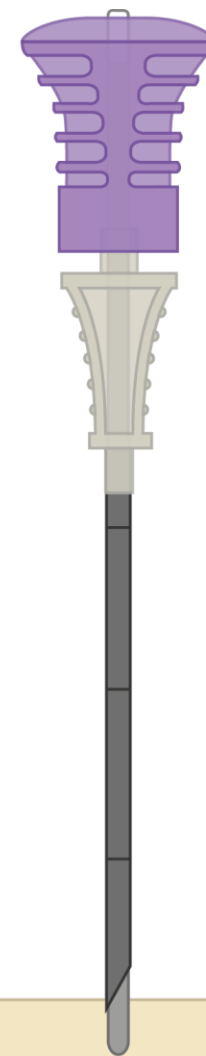
Note

The indicator on the needle hub reveals the bevel position at the needle tip.



Step 3

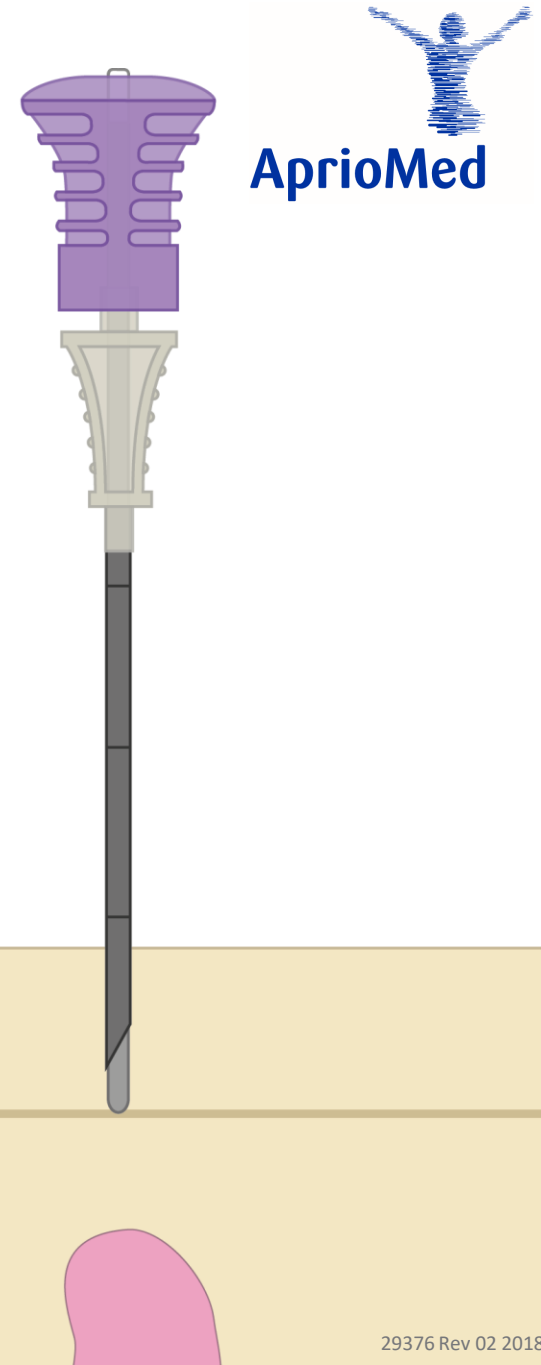
Exchange to blunt stylet.



Step 4

Advance device.

Monitor position using imaging technique.

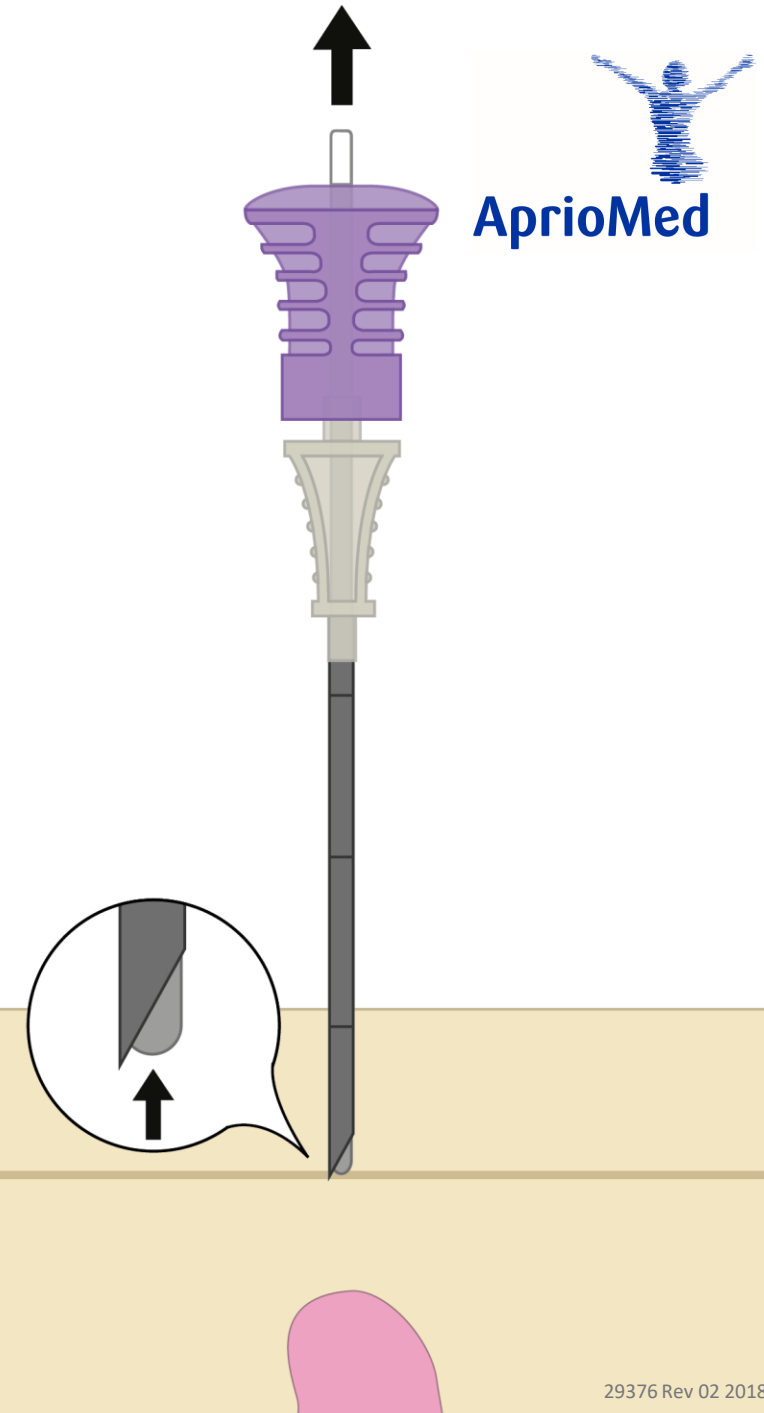


Step 5

If resistance is met at the blunt tip, the tip will retract into the needle and the sharp needle will be exposed.

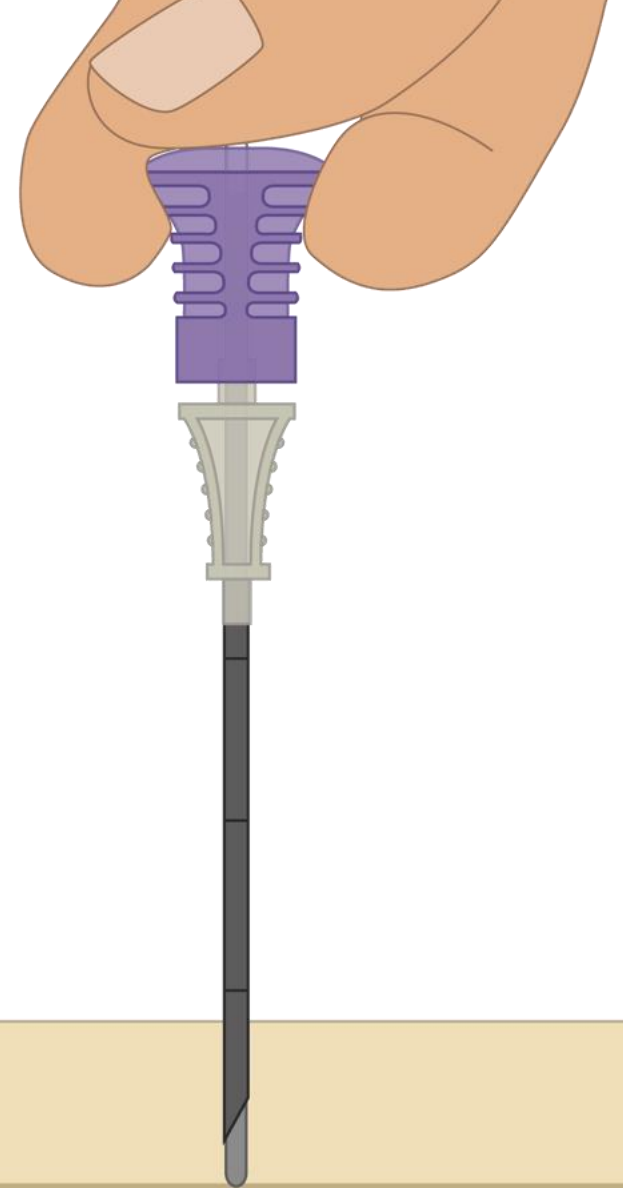
Simultaneously, the pin at the stylet hub will spring back indicating the position of the blunt tip.

If continuing to advance the device, the sharp needle will cut through the tissue causing the resistance.



Note

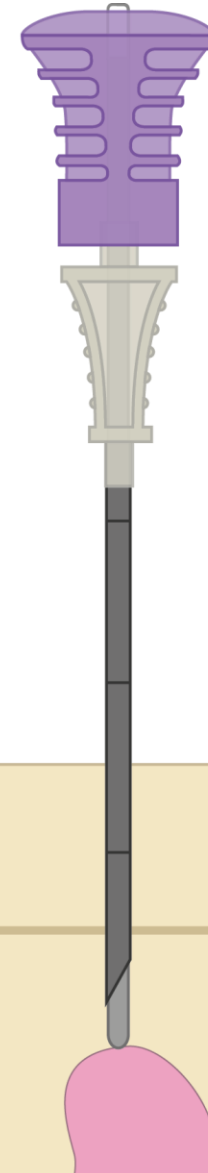
If exposure of the sharp needle is not wanted, the retraction of the blunt tip can be prevented by pressing the pin in the hub with your thumb.



Step 6

Advance device proximal to lesion.

Monitor position using imaging technique.

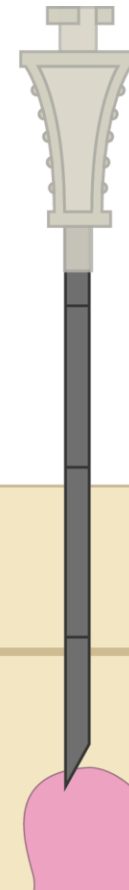


Step 7



Remove the stylet.

Perform biopsy as per normal routine.



About



AprioMed develops, manufactures, markets and sells innovative medical devices and related services within the field of interventional radiology. We aim to deliver, in close collaboration with healthcare practitioners, innovative, quality tools to achieve optimal solutions for radiologists worldwide.

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