

INDICATION FOR USE

Percutaneous injection and aspiration procedures and tissue sampling in liver, kidney, muscle and subcutaneous tissue.

CONTRAINDICATIONS

No known contraindications.

WARNINGS

- W1. Verify that the 21G Needle and the Steerable Stylet are used together. Use of Steerable Stylet without 21G Needle may cause stylet breakage.
- W2. Only use the 21G Needle supplied in the package. Use of a too short needle may cause permanent stylet deformation and harm surrounding tissue. Use of a too long or larger gauge needle may cause incorrect behavior of needle.
- W3. Verify the device location using imaging techniques after every device adjustment and before injection or aspiration. Depending on the tissue structure, 21G Needle adjustments and advancements may vary.
- W4. Be careful when approaching hard surface. If the 21G Needle kinks, retract both the Steerable Stylet and the 21G Needle together. A kinked needle may cause tissue damage.
- W5. If the 21G Needle kinks, stop the procedure and retract both the Steerable Stylet and the 21G Needle together. Applying additional force to a kinked needle may cause needle breakage and result in materials remaining in the body.
- W6. Relax the Steerable Stylet by turning the lever to its original upright position before rotating the Steerable Stylet. Rotating without relaxing the Steerable Stylet may result in change of location of the 21G Needle.
- W7. Relax the Steerable Stylet by turning the lever to its original upright position before retracting the Steerable Stylet or the device. Retracting without relaxing the Steerable Stylet may cause scratching and damage to the surrounding tissue.
- W8. Do not use Morrison Steerable Needle™ in Magnetic Resonance Imaging (MRI) equipment. The device is magnetic and exposure to MRI may cause unintended device movement.




PRECAUTIONS

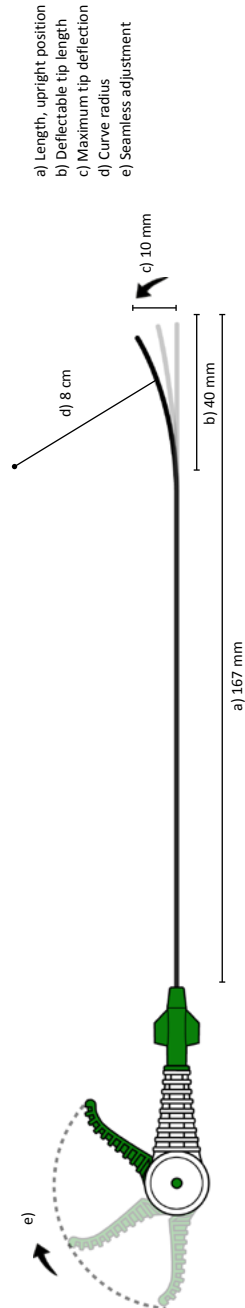
Note that the device curves in one direction. Device will curve in same plane as lever turns.




Before use together with other equipment, check the compatibility in length and gauge together with Morrison Steerable Needle™.

After use, the components may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

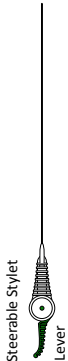

Rx only Morrison Steerable Needle™ should only be used by, or under the supervision of, a physician trained in percutaneous injection and aspiration procedures and tissue sampling.

-  Single use. After use, the product performance and characteristics may degrade, and can cause infection in patient.
-  Do not re-sterilize. Re-sterilization may have impact on product characteristics and performance.
-  Do not use if package is damaged. Product in damaged package may be contaminated and can cause infection in patient.

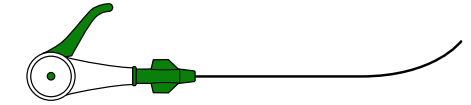


TIP CONFIGURATION	Steerable Stylet	21G Needle	Protruding Steerable Stylet length
			

Morrison Steerable Needle™ consists of the following parts:

STEERABLE FNA BIOPSY NEEDLE	REF 13550		
		ID	0.68 mm
		OD	0.82 mm
		Length	167 mm
			

Morrison Steerable Needle™



Morrison Steerable Needle™
Steerable FNA biopsy needle

Instructions for use



Symbols explained in IFU

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

Morrison Steerable Needle™ is a trademark of AprioMed AB. Patents pending.

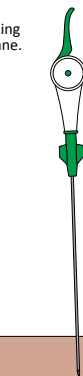
AprioMed

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Fig.

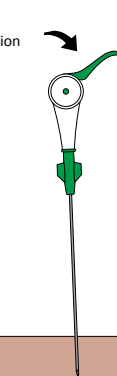
① ⚠
W1, W2, W8

Insert device superficially, aligning the device with the imaging plane.



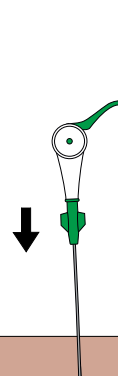
②

Turn lever in direction of target or away from danger. The 21G Needle tip will remain in position until the device is advanced or retracted.



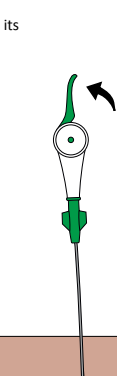
③ ⚠
W3, W4, W5

Advance device. Monitor position using imaging technique.



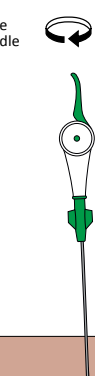
④

Before making adjustments, return lever to its original position.



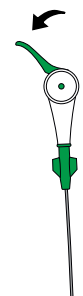
⑤ ⚠
W6

If a change of direction is desired: rotate Steerable Stylet while keeping 21G Needle in place.



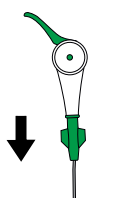
⑥

Turn lever to desired degree of deflection.



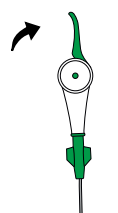
⑦ ⚠
W3

Advance device. Monitor position using imaging technique.



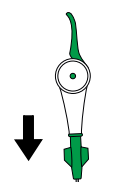
⑧

Further adjustments can be made if necessary.



⑨ ⚠
W3

Advance device to target. Monitor position using imaging technique.



⑩ ⚠
W7

Remove Steerable Stylet. Perform injection, aspiration or biopsy.



Directions for use

