

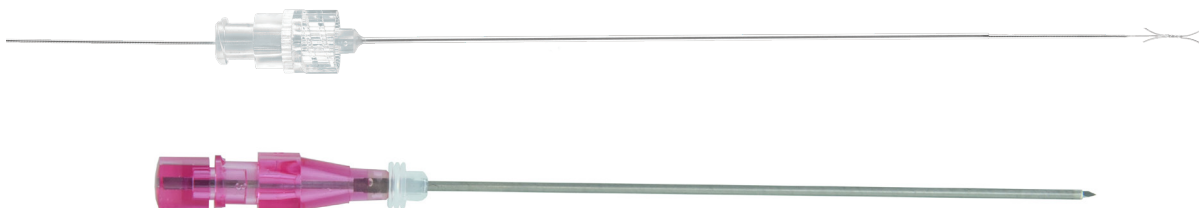
## V Breast Lesion Localization Needle

- V Used for preoperative marking of nonpalpable breast lesions
- V
  - The X-shaped hook provides **excellent fixation** and is intended to **limit migration** before the procedure
- V
  - The 3 cm long stiff portion of the needle is **easily palpated** during the procedure
  - The soft, flexible wire portion of the shaft is **comfortable** for the patient
  - The reinforced wire is **easy to locate** during the procedure
  - The reinforced wire is intended to **reduce the possibility** of accidentally cutting the wire
- V Supplied sterile in peel-open packages. Intended for one-time use only.

p.d.12 Kruties naviku lokalizacijos žymeklis skirtas prieš operaciją krutu pažeidimu žymėjimui. X formos kabliukas užtikrina puikų fiksavimą ir yra skirtas apriboti migraciją prieš procedūrą. Procedūros metu lengvai apčiuopiama 3 cm ilgio standi vielos dalis. Sustiprinta viela lengva rasti procedūros metu. Sustiprinta viela skirta sumažinti galimybes netysia nupjauti vielą. Tiekiamas sterilioje, vienkartinėje pakuotėje. Rinkini sudaro:

- Dviejų dalių pozicionavimo adatas su TROCAR įvedimo kaniule; Kabliuko viela;

Kabliukas patalpintas isorinėje kaniulėje. Isorinės kaniulės diametras 18G, ilgis 5 cm arba 9 cm pasirinktinai.



## ORDER INFORMATION

## X-Reidy - Standard Needles

SET ORDER NUMBER	OUTER CANNULA GAUGE • LENGTH	GLOBAL PROD. NO.
NEEDLE		
DXRBL-19.5-5.0-S	19.5G • 5 cm	G19617
DXRBL-19.5-9.0-S	19.5G • 9 cm	G19533
DXRBL-19.5-15.0-S	19.5G • 15 cm	G19589
SET		
V DXRBL-18-5.0	18G • 5 cm	G19418
V DXRBL-18-9.0	18G • 9 cm	G19380

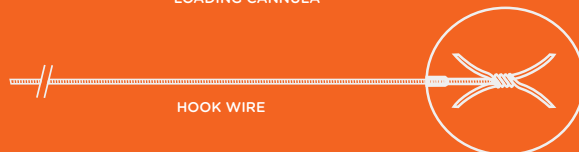
P.D.12. Kruties naviko  
lokalizacinis žymeklis



Trokaras



Kaniule



Kabliuko viela



Not all parts numbers shown may be approved for sale in all regulatory jurisdictions. Parts and configurations are subject to change without notification. Please consult with your Account Representative for details.

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## X-Reidy Breast Lesion Localization Needle Sets

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## X-Reidy nålesæt til lokalisering af brystlæsioner

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## X-Reidy Brustläsions- Lokalisationskanülen-Sets

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## ΣΕΤ βελόνων εντοπισμού βλάβης μαστού X-Reidy

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## Equipos de agujas de localización de lesiones mamarias X-Reidy

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## Sets d'aiguille X-Reidy pour localisation de lésion mammaire

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## Set con ago per localizzazione delle lesioni mammarie X-Reidy

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## X-Reidy sets met lokalisatienaald voor borstlaesies

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## Zestawy igły do lokalizacji zmian w piersi X-Reidy

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## Conjuntos de agulha X-Reidy para localização de lesão mamária

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## X-Reidy nålset för bröstlesionslokalisering

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## X-Reidy乳腺病灶定位针套装

使用说明

## X-REIDY BREAST LESION LOCALIZATION NEEDLE SETS

**CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).**

### DEVICE DESCRIPTION

The X-Reidy Breast Lesion Localization Needle Sets consist of a needle; and a hook wire with a palpable 3 cm stiff segment just proximal to the X-shaped hook, for easy palpation during surgery. The remaining part of the hook wire is soft and flexible, for patient comfort. A slide clamp is provided for use as a skin marker.

Sets with an “-S” suffix in the order number contain a bevel-tipped needle. Sets without an “-S” suffix in the order number contain a two-part positioning needle with a trocar point and a loading cannula for the hook wire.

Hook wire lengths are proportionate to the needle lengths, for example:

5.0 cm needle	26 cm hook wire
9.0 cm needle	30 cm hook wire
15.0 cm needle	36 cm hook wire

### INTENDED USE

X-Reidy Breast Lesion Localization Needle Sets are intended for preoperative marking of nonpalpable breast lesions, where the hook wires serve as a guide for the surgeon.

### CONTRAINDICATIONS

None known

### WARNINGS

Under no circumstances should a hook wire engaged in tissue be pulled out without surgical intervention.

### PRECAUTIONS

- X-Reidy Breast Lesion Localization Needle Sets are intended for use by physicians trained and experienced in breast lesion localization techniques. Standard techniques for placement of hook wires should be employed.
- Following hook wire placement, the portion protruding outside of the breast should be taped to the skin to prevent inadvertent movement.
- Final hook wire position should be confirmed by appropriate imaging modality.
- The hook wire should be used as a guide for the surgeon, not as a retractor.
- The slide clamp is intended as a skin marker for identification of the entry point only. It should not be used as an anchoring device.

### INSTRUCTIONS FOR USE

1. Introduce the needle into the lesion.
2. Check the position of the needle.  
**NOTE:** If using a set containing the two-part positioning needle, remove the stylet.
3. Insert the loading cannula with the preloaded hook wire, and lock the hubs together.
4. Advance and release the X-shaped hook wire for fixation.
5. Remove the needle.
6. Place the slide clamp on the wire at the skin entry point and tape the flexible hook wire to the skin.
7. Verify final hook wire position.

### HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

### REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.