



# Intraoperative Transducer

## User Guide

| Types 8515-S and 8815 |



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# Intraoperative Transducer Types 8515-S and 8815

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## Introduction

This is the user guide for Intraoperative Transducer Types 8515-S and 8815 and must be used together with *Care, Cleaning & Safety* which contains important safety information.



Fig. 1. Intraoperative Transducer Types 8515-S and 8815

## Indications for Use

8515-S and 8815 are intraoperative transducers suitable for ultrasound-guided interventional procedures.

Needle guides UA1265 and UA1336 provide guidance for needles or other interventional devices during an ultrasound-guided procedure. They position the needle relative to the transducer, so that the needle image is in a specified position in the ultrasound image during procedures that require precise needle placement or biopsy.

### WARNING

*Do not use the transducer for applications where it may come in direct conductive contact with the patient's heart.*

### FDA WARNING for the United States of America

*8515-S and 8815 are **not** for fetal use.*

## Scanning Plane

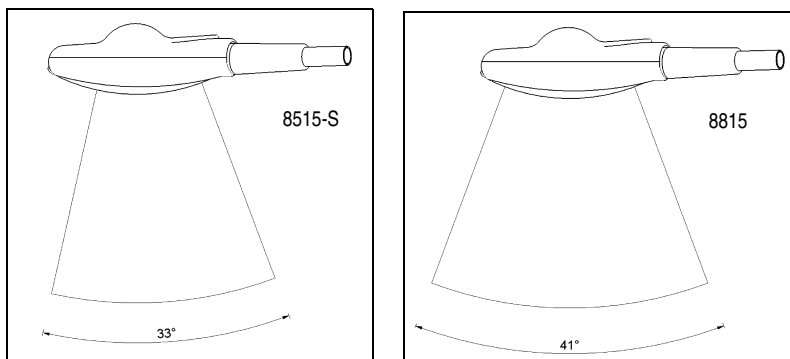


Fig. 2. Scanning plane of 8515-S and 8815

## General Information

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Product specifications for this transducer can be found in the Product Data sheet that accompanies this user guide.

Acoustic output data and data about EMC (electromagnetic compatibility) for this transducer are on the Technical Data CD that accompanies this user guide. A full explanation of acoustic output is given in your scanner user guide.

### WARNING

*If at any time the scanner malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the scanner is not functioning correctly:*

- *Remove all transducers from contact with the patient.*
- *Turn off the scanner. Unplug the scanner from the wall and make sure it cannot be used until it has been checked.*
- *Do not remove the scanner cover.*
- *Contact your BK Medical representative or hospital technician.*

### WARNING

*Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.*

## Service and Repair

### WARNING

*Service and repair of BK Medical electromedical equipment must be carried out only by the manufacturer or its authorized representatives. BK Medical reserves the right to disclaim all responsibility, including but not limited to responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. After service or repairs have been carried out, a qualified electrical engineer or hospital technician should verify the safety of all equipment.*

## Caring for the Transducer

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface. It should also be checked thoroughly once a month following the procedure in *Care, Cleaning & Safety*.

## Cleaning and Disinfection

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To ensure the best results when using BK Medical equipment, it is important to maintain a strict regular cleaning routine.

Full details of cleaning and disinfection procedures can be found in *Care, Cleaning & Safety* that accompanies this user guide. A list of disinfectants and disinfection methods that the transducer can withstand are listed in the Product Data sheet.

Sterile covers are available. See the Product Data sheet for more details.

**WARNING**

*Users of this equipment have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies for personnel and equipment established for your office, department or hospital.*

## Starting Scanning

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All equipment must be cleaned and disinfected before use.

### Connecting the Transducer

**WARNING**

*Keep all plugs and sockets absolutely dry at all times.*

The transducer is connected to the scanner using the array Transducer Socket on the scanner. To connect, the transducer plug's locking lever should first be in a horizontal position. Align the plug to the scanner socket and insert securely. Turn the locking lever clockwise to lock in place.

When connected the transducer complies with Type BF requirements of EN60601-1 (IEC 60601-1).

### Changing Frequency

The Multi-Frequency Imaging (MFI) facility enables you to select the scanning frequency. See the applicable scanner user guide for instructions. The selected frequency is displayed at the top of the screen.

### Using a Transducer Cover

The transducer should be enclosed in a transducer cover or a standard condom. See the Product Data sheet for a list of available transducer covers.

**Note:** Sterile, disposable sheaths are recommended for intraoperative use. In the United States of America, it is recommended that probe sheaths have been market-cleared. In Canada, use only licensed probe sheaths.

**WARNING**

*Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.*

**Note: For Intraoperative Applications**

Apply sterile gel to the tip of the transducer or fill the cover with 1 to 2ml of sterile water. This improves the screen images by preventing image artifacts caused by air bubbles.

## 8515-S and 8815 • Holding the Transducer for Intraoperative Scanning

Pull the transducer cover over the transducer.

### WARNING

*Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover material.*

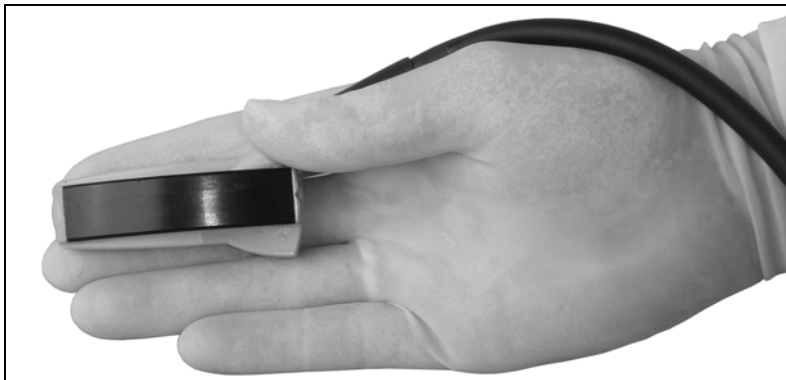
## Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable scanner user guide for instructions.

# Holding the Transducer for Intraoperative Scanning

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Hold the transducer between two fingers and the thumb (see Fig. 3.) or any position which is comfortable for your hand and move the transducer smoothly over the surface of the organ to produce the best screen image.



*Fig. 3. Holding 8515-S and 8815 for scanning*

## Puncture Facilities

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Intraoperative transducers 8515-S and 8815 are designed to support biopsy and other interventional procedures using reusable needle guide UA1265. The 8815 also supports single-use needle guide UA1336. The needle guides are illustrated in the following pages with a brief description of their use and operating instructions.

### WARNING

*It is essential for the patient's safety that only the correct needle guides are used with 8515-S and 8815. Never use unauthorized combinations of transducers and needle guides or other manufacturers' needle guides.*

### Single-use Needle Guide UA1336 - 8815 Only

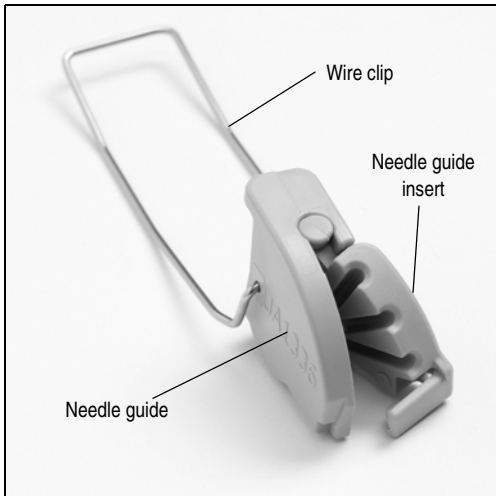


Fig. 4. Needle guide UA1336 assembled with 3-angle insert

Needle guide UA1336 is supplied together with two needle guide insert palettes. Each palette contains a set of 9 needle guide inserts, one 3-angle and one free-angle.

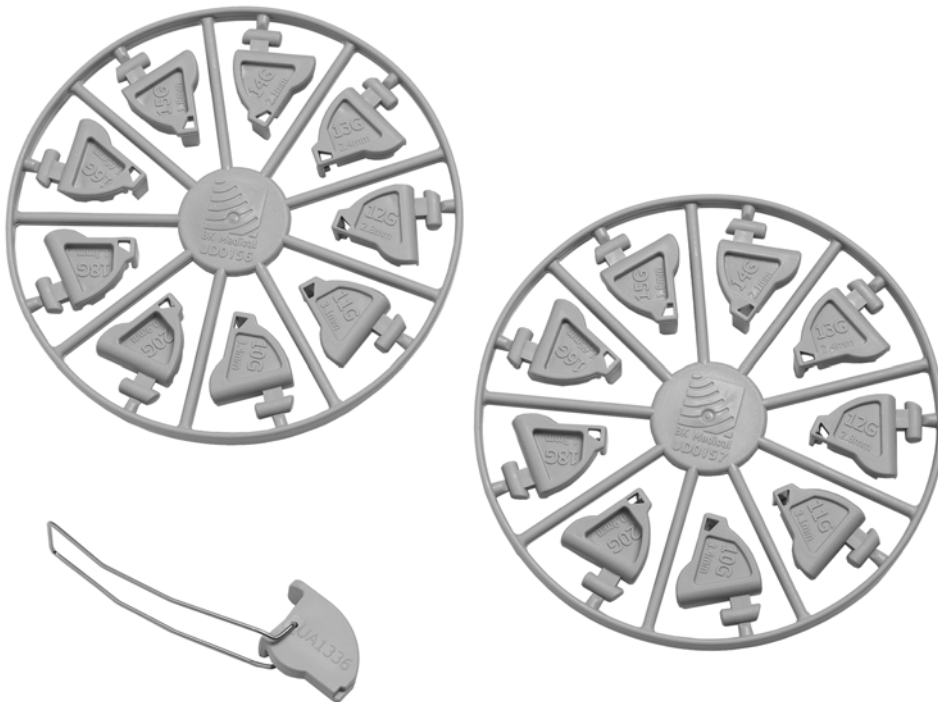


Fig. 5. Two needle guide insert palettes supplied together with needle guide UA1336

The 3-angle inserts each contain three channels. These channels allow the needle to be positioned at 25°, 45° or 65° to the image axis of the 8815.

## 8515-S and 8815 • Puncture Facilities

The free-angle inserts are slotted to allow the positioning of the needle at any angle between 25° and 65° to the image axis of the 8815 while making sure that the needle follows the plane of the image.

The puncture line pattern is shown in Fig. 7. The distance between the guide channel of the needle guide to the first dot on the scan image puncture line is 12-15mm depending on which angle is chosen. The distance between the dots is 5mm.

### Sterile Needle Guide UA1336

Needle guide UA1336 and the needle guide insert palettes are supplied sterile in peel packs and are for single-use only. Contents are only sterile if the package is intact. The needle guide, the inserts and both palettes **must** be discarded after use.

#### WARNING

*Disposable components are packaged sterile and are intended for single-use only.*

*Do not use if:*

- integrity of packaging is violated*
- expiration date has passed*
- package label is missing*

The sterile-packed needle guides must be stored at a temperature range from +15°C (+57°F) to +25°C (+77°F) and at a storage humidity of 30% to 80%.

#### WARNING

*Sterile-packed components must be stored in a safe environment and kept out of direct sunlight. Large temperature changes during storage may cause condensation and violate the integrity of the packaging.*

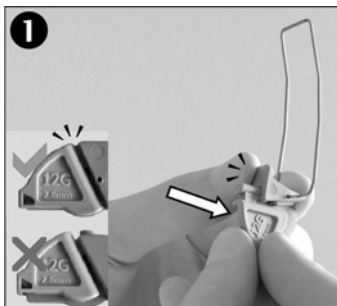
Please refer to *Care, Cleaning and Safety* for an example of how to open a sterile-packed product.

#### WARNING

*For contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department or hospital.*

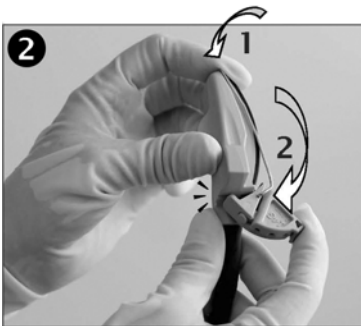
## Assembling the Needle Guide and Mounting it on the Transducer

Apply a small amount of scanning gel to the tip of the transducer and carefully cover the transducer with a sterile cover (for readability, the transducer here is shown without transducer cover).



Select the required needle guide insert by breaking it off the palette.

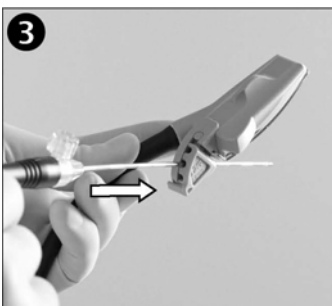
Find the wedge shaped channel in the needle guide and slide the insert into the channel in the needle guide from above until it clicks into place and aligns with the needle guide.



Taking care not to damage the transducer cover or the surface of the transducer array, gently place the wire clip over the small nodule on the tip of the transducer. Gently place and clip the needle guide into place as shown.

**Caution**

*Ensure the needle guide is positioned correctly.*



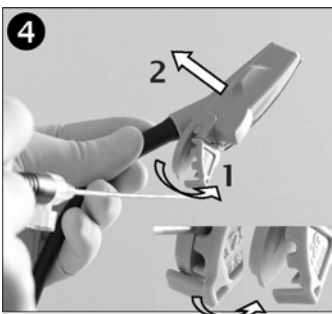
Carefully insert the needle into the needle channel.

**Caution**

*Do not let it scrape the inside of the needle channel.*

## Releasing the Needle During Biopsy

You can release the needle during biopsy so that the needle guide and transducer can be removed from the patient, leaving only the needle in place.



Hold the transducer with your left hand. With your right hand, carefully push the needle guide insert sideways until it opens up. Carefully move the transducer and needle guide away from the needle.

**WARNING**

*If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover before reattaching the needle guide.*

## Reusable Needle Guide UA1265

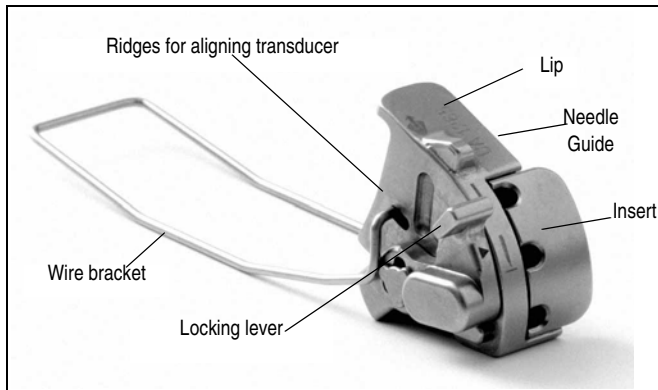


Fig. 6. Needle Guide UA1265 and 3-angle insert UA1318

Needle guide UA1265 (see Fig. 6.) is supplied together with a set of 6 needle guide inserts.

- 20 gauge 3-angle insert (UA1316)
- 18 gauge 3-angle insert (UA1317)
- 13 gauge 3-angle insert (UA1318)
- 20 gauge free-angle insert (UA1319)
- 18 gauge free-angle insert (UA1320)
- 13 gauge free-angle insert (UA1321)

The 3-angle needle guide inserts each contain three channels. These channels allow the needle to be positioned at 25°, 45° or 65° to the image axis of the 8815. The needle can be positioned at 29°, 49° or 69° to the image axis of the 8515-S.

The free-angle needle guide inserts are slotted to allow the positioning of the needle at any angle between 25° and 65° for 8815, and between 29° and 69° for 8515-S to the image axis while making sure that the needle follows the plane of the image.

The puncture line pattern is shown in Fig. 7. The distance between the needle channel of the needle guide to the first dot on the scan image puncture line is 12-15 mm depending on which angle is chosen. The distance between the dots is 5 mm.

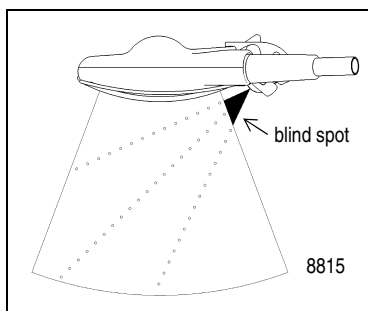


Fig. 7. Illustration showing the puncture line and blind spot (See 3rd “WARNING” on page 12)

Needle guide UA1265 and inserts UA1316-UA1321 are non-sterile when supplied, and must be sterilized. They can be autoclaved or disinfected by immersion in a suitable solution.

## Mounting the Needle Guide Onto 8515-S and 8815

1. Apply a small amount of scanning gel to the tip of the transducer and carefully cover the transducer with a sterile transducer cover.
2. Hold the transducer in your right hand with the cable towards you and the contact surface of the array facing up.
3. Hold the needle guide in your left hand with the lip at the bottom and pointing away from you.
4. Lift the wire bracket so that it is pointing up.
5. Align the two grooves on the transducer with the two ridges on the needle guide (see Fig. 8.). The lip of the needle guide should fit snugly underneath the transducer housing (see Fig. 8.)



Fig. 8. Mounting needle guide UA1265 (transducer shown without cover).

6. Taking care not to damage the transducer cover or the surface of the transducer array, gently lower the bracket over the transducer array.
7. Carefully smooth and stretch the transducer cover along the face of the array while applying firm pressure until the bracket clicks into place over the lug situated at the end of the transducer (see Fig. 9.).



Fig. 9. Smooth and stretch transducer cover when mounting needle guide UA1265

### Caution:

*Ensure the bracket is positioned correctly.*

## Attaching the Insert to the Needle Guide

1. Hold the transducer in your left hand with the contact surface of the array facing down and the cable pointing towards you.
2. Make sure the needle guide locking lever is pushed forward in the release position (see Fig. 11.).
3. Select the required needle guide insert.
4. Find the wedge shaped channel on the needle guide.
5. Hold the lip of the needle guide insert between thumb and forefinger of your right hand so that the grooves/slot face left and the narrow end of the insert points down (see Fig. 10.).
6. Slide the insert into the channel in the needle guide from above.
7. Once the insert is fully in place, it must be locked in place by pulling the attached locking lever all the way backwards (see Fig. 11.). When the locking lever is in this position the needle guide hole is closed.
8. Ensure the insert is securely in position and check the transducer cover is not damaged.



Fig. 10. Attaching the insert to needle guide UA1265

### WARNING

*If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover before reattaching the needle guide.*

Needle guide UA1265 includes a locking mechanism that prevents involuntary advancement of the needle into tissue while positioning the transducer in difficult to access areas inside the abdomen (see Fig. 11.).

The tip of the needle may be inserted into the needle guide and manually held in place against the locking mechanism while the transducer is maneuvered into position.

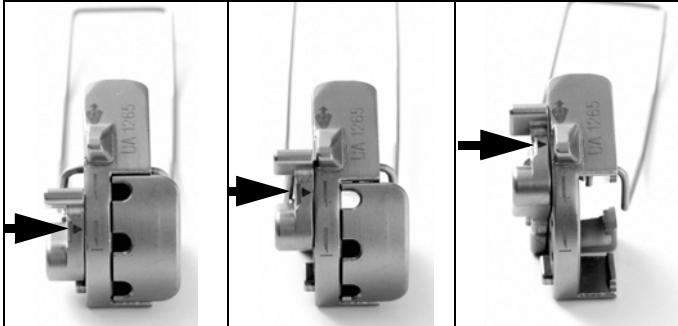


Fig. 11. The locked, open and release position of needle guide UA1265

To open the needle guide, move the locking lever forward one notch until it clicks into place.

Advancing the locking lever further will release the needle guide insert and allow the transducer to be removed from the patient during biopsy while leaving the needle in place.

**Caution**

*Take care not to lose the insert inside the patient when removing it.*

**Taking Apart Needle Guide UA1265 for Cleaning and Disinfection**

**Remove the Needle Guide from the Transducer:**

1. Gently lift the needle guide up and away from the transducer until the wire bracket is released from the transducer.

**Remove the Locking Lever:**

2. Remove the needle guide insert (if still attached) by pushing the locking lever all the way to the release position (see Fig. 11.).
3. Make sure that the shaped hole in the locking lever is lined up with the similarly shaped end of the pivot shaft. (See Fig. 12.)

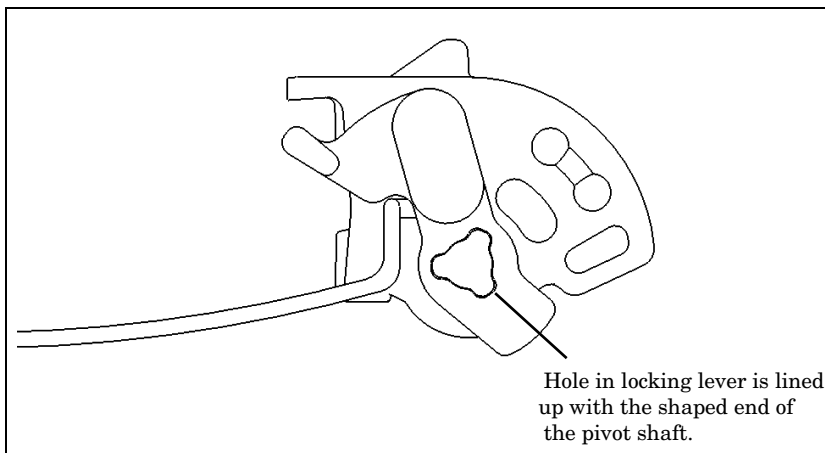


Fig. 12. Lining up the locking lever with the shaped end of the pivot shaft on needle guide UA1265 ready for removal.

4. Lift the locking lever off the end of the shaft.

**Remove the Wire Bracket from the Needle Guide:**

5. Hold the needle guide so that the hooked ends are lined up with the oval holes in the side of the needle guide (see Fig. 13.).

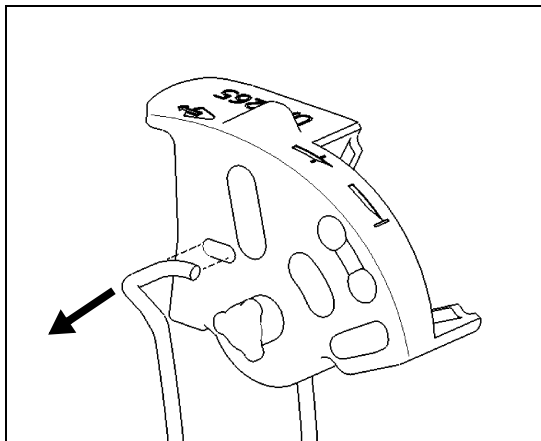


Fig. 13. Removing the wire bracket from needle guide UA1265

6. Gently pull the legs of the wire bracket apart. If the hooked end is correctly aligned it will easily slide out of the hole.

## Performing Puncture and Biopsy

**WARNING**

*It is essential for the patient's safety that only the correct needle guide, as described in this guide, are used. Never use unauthorized combinations of transducers and needle guide or other manufacturers needle guide.*

*Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the needle guide match exactly those displayed on the scanner monitor.*

**WARNING**

*The puncture line on the scan image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected. You must take extra care when taking a free-angle biopsy because the expected needle path is not shown.*

**WARNING**

*The 8515-S and 8815 transducers cannot monitor the first 1.2-1.5 cm of the puncture line (the blind spot, see Fig. 7.). Extra care should be taken during insertion until the needle tip echo can be seen on the image.*

Cover the transducer with a sterile transducer cover.

If the transducer cover is damaged when attaching the needle guide, replace it with a new cover.

**Note:** Sterile, disposable sheaths are recommended for intraoperative use; and in the U.S.A. it is recommended that probe sheaths have been market-cleared. In Canada, use only licensed probe sheaths.

See the Product Data sheet for a list of available transducer covers.

Press the scanner **Puncture** or **Biopsy** control button to superimpose a puncture line on the scan image.

If more than one puncture line is available, refer to the applicable scanner user guide for instructions on how to change which one appears.

Move the transducer until the puncture line transects the target. Insert the needle and monitor it as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.

**WARNING**

*If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover.*

To remove the puncture line from the scan image, refer to the applicable scanner user guide for instructions.

## RF Ablation

When performing RF ablation, you must always follow the instructions provided by the manufacturer of the RF ablation equipment. Be sure to pay attention to all warnings.

Do not use excessive force when you insert the needle into the needle guide.

Do not tighten adjustable needle guides so much that they can damage the needle.

If possible, carefully release and remove the needle guide from the transducer after you insert the RF needle into the patient and before you energize the needle.

If you use metal needle guides to guide RF ablation, you must make sure that the insulation on the needle is not damaged when the needle is moved back and forth in the needle guide.

**WARNING**

*Carefully examine the RF needle before each insertion, to make sure that the insulation is intact. Make sure that the needle is not damaged during insertion. If the insulation is scratched, replace the needle with a new RF needle.*

## Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer or needle guide, disinfection and sterilization processes may not be effective. Therefore, you must clean needle guide and transducers immediately after use.

Use a suitable brush to make sure that biological material and gel are removed from all needle guides and other channels and grooves. See *Care, Cleaning & Safety* for cleaning instructions

## Disposal

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When the transducer is scrapped at the end of its life, national rules for the relevant material in each individual land must be followed. Within the EU, when you discard the transducer, you must send it to appropriate facilities for recovery and recycling. See the applicable scanner user guide for further details.

**WARNING**

*For contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department or hospital.*