

# 8862 Craniotomy Transducer

## 8863 Burr-Hole Transducer



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If you have comments about the user documentation, please write to us at the email address above. We would like to hear from you.

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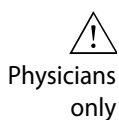
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English source version  
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## Introduction

This is the user guide for Craniotomy Transducer Type 8862 and Burr Hole Transducer Type 8863 and must be used together with *Care and Cleaning*, which contains important safety information.



**Caution:** Federal law in North America restricts this device to sale to, or on the order of, a physician

### Intended Use

The transducer is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.

### Indications for Use

Craniotomy Transducer Type 8862 is designed for intraoperative neurosurgical imaging, as well as neonatal cephalic<sup>1</sup>, spinal cord, intraoperative, and pediatric imaging. Needle guide UA1345 provides guidance of a needle for biopsy and drainage in the brain (following craniotomy).

Burr Hole Transducer Type 8863 is designed for intraoperative neurosurgical imaging of the brain through a burr hole. It can also be used for spinal cord and intraoperative imaging. Needle guide UA1346 provides guidance of a needle for biopsy and drainage in the brain.

### Contraindications



#### **WARNING**

To avoid causing injury to the eye, do not use type 8862 for fetal or ophthalmic use, or any application that causes the acoustic beam to pass through the eye.



Figure 1. Craniotomy Transducer Type 8862.

1. Neonatal cephalic imaging has not been licensed by Health Canada.

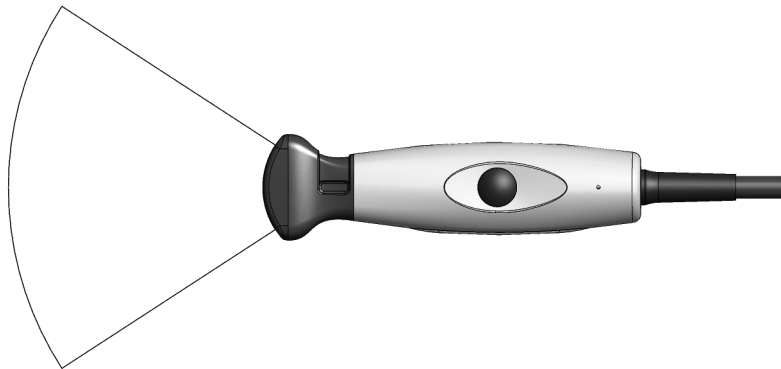


*Figure 2. Burr Hole Transducer Type 8863.*

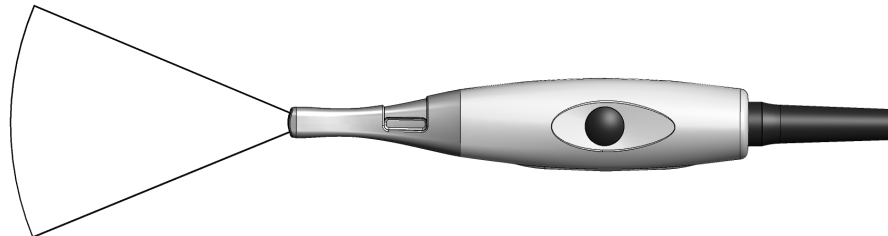
## Imaging Plane

The 8862 is a small curved array transducer with a penetration depth up to 120 mm and a 29 x 10 mm footprint size.

The 8863 is a small curved array transducer with a penetration depth up to 116 mm and a 10 x 8.6 mm footprint size.



*Figure 3. Imaging plane for Craniotomy Transducer Type 8862.*



*Figure 4. Imaging plane for Burr Hole Transducer Type 8863.*

## General Information

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 in Technical Data (BZ2100) that accompanies this user guide. A full explanation of acoustic output data is given in your system user guide.



#### **WARNING**

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

- Remove all transducers from contact with the patient.
- Turn off the system. Unplug the system from the wall and make sure it cannot be used until it has been checked.
- Do not try to repair the system yourself.
- 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.



Neonate or fetus

#### **WARNING**

To reduce the risk of thermal damage to tissues, be sure to keep the acoustic output as low as possible when you expose the head, brain, or spine of any neonate or fetus to diagnostic ultrasound.

## **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 and Cleaning*.

## **Cleaning and Disinfection**

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

Full details of cleaning and disinfection procedures can be found in *Care and Cleaning*, which 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 information.



#### **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 Imaging

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 system using the array transducer socket on the system. To connect, the transducer plug's locking lever should first be in a horizontal position. Align the plug to the system 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 multifrequency imaging (MFI) control enables you to select the imaging frequency. See the applicable system 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 sterile transducer cover. See the Product Data sheet for a list of available transducer covers.



**Caution:** Use only non-pyrogenic, sterile transducer sheaths (transducer covers) that are approved for intraoperative use. This means that in the USA they must be market cleared by the FDA, in Canada they must be licensed by Health Canada, and in Europe they must be CE-marked.



#### **WARNING**

Some transducer covers can contain latex. Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.



## For Intraoperative Applications

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

Pull the transducer cover over the transducer. Check for air bubbles between the cover and the transducer and even out if necessary before proceeding.



### WARNING

Use only water-based gel (sterile if you are using a sterile transducer cover). Products containing parabens, petroleum, or mineral oils may harm the transducer or transducer cover.

## Using the Transducer Control Button

The transducer has a control button that you can press to **Start** or **Stop** imaging (freeze frame). Press the button for more than one second to make a copy of the image.

Each time the button is pressed, a “beep” is emitted.

## Changing Orientation

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

## Neurosurgical Imaging with Types 8862 and 8863

The transducer should be enclosed in a sterile transducer cover during neurosurgical imaging.



### WARNING

Do not use Types 8862 and 8863 for neurosurgical applications if the patient is suspected of having Creutzfeldt-Jakob disease. If a neurosurgical transducer has been used on a patient suspected of or diagnosed as being Creutzfeldt-Jakob positive, the transducer must be destroyed, following approved procedures for your hospital.



### WARNING

If the transducer cover is damaged during interventional procedures, follow the policies of the hospital or clinic for treatment of the patient under such circumstances.



**Caution:** Use only non-pyrogenic, sterile transducer sheaths (transducer covers) that are approved for neurosurgical use. This means that in the USA they must be market cleared by the FDA, in Canada they must be licensed by Health Canada, and in Europe they must be CE-marked.

Pull the transducer cover over the transducer and irrigate the organ to be imaged with 0.9% sterile physiological saline solution.

## Puncture Facilities

Puncture and biopsy are possible with Types 8862 and 8863. The appropriate puncture attachments are illustrated in the following pages with a brief description of their uses and operating instructions.



### WARNING

It is essential for the patient's safety that only the correct equipment is used.

- Do not use other manufacturers' transducers with BK Medical ultrasound systems.
- Do not use BK Medical transducers with other manufacturers' systems.
- Do not use unauthorized combinations of transducers and puncture attachments.
- Do not use other manufacturers' puncture attachments with BK Medical transducers.

Needle guides UA1345 and UA1346 are supplied sterile in peel packs and are for single-use only. Contents are sterile only if the package is intact. The needle guide, inserts, and 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
- Packaged 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 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 and Cleaning* 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.

## Single-Use Needle Guide UA1345 for 8862

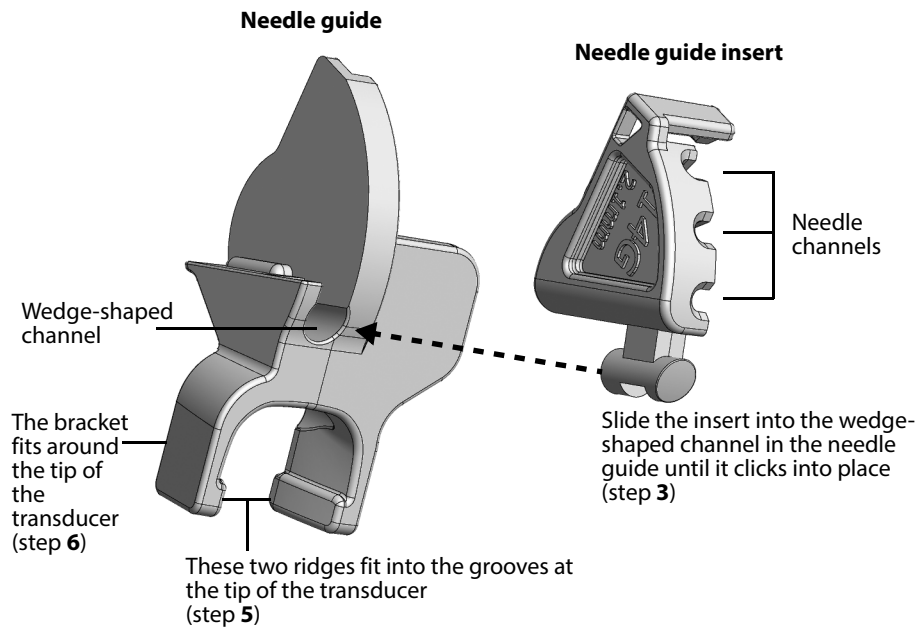


Figure 5. Needle Guide UA1345 for Craniotomy Transducer Type 8862; the numbered steps refer to the procedure on the following pages describing how to mount the needle guide.

Single-use Needle Guide UA1345 (see Figure 5) is for use with Craniotomy Transducer Type 8862 and is supplied together with two needle guide insert palettes (see Figure 6). Each palette contains a set of 9 needle guide inserts; one palette with 3-angle inserts and one palette with free-angle inserts.

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 8862.

The free-angle inserts are slotted to allow positioning of the needle at any angle between 25° and 65° to the image axis of the 8862 while making sure that the needle follows the plane of the image.

Puncture lines indicate expected needle path

The puncture line on the scan image is an indication of the expected needle path (see Figure 15). The distance from the guide channel entrance of the puncture attachment to the first dot on the scan image puncture line is approximately 7.5 mm (0.3 in) for 25°, 12 mm (0.5 in) for 45°, and 19 mm (0.7 in) for 65°. The distance between the dots is 5 mm (0.2 in).

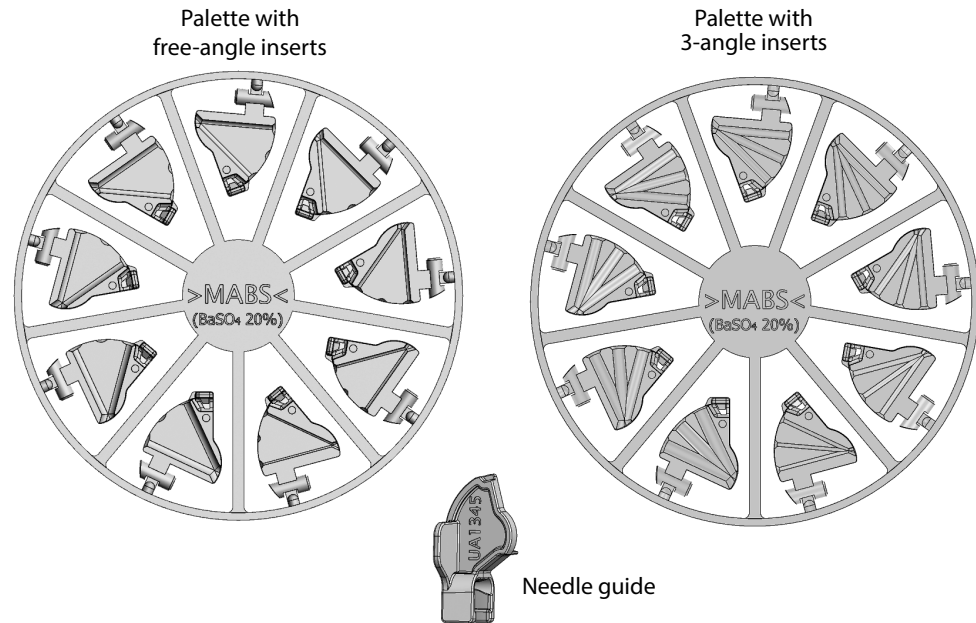
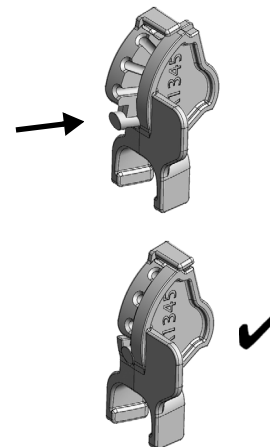


Figure 6. Two needle-guide insert palettes together with needle guide (UA1345).

### Assembling and Mounting the Needle Guide

#### To assemble and mount a needle guide on the Craniotomy Transducer Type 8862:

- 1 Apply a small amount of imaging gel to the tip of the transducer and carefully cover the transducer with a sterile cover.
- 2 Select the required needle guide insert by breaking it off the palette (see Figure 6).
- 3 Find the wedge-shaped channel in the needle guide, and slide the insert into the channel in the needle guide until it clicks into place and aligns with the needle guide.



- 4 Hold the assembled needle guide with the bracket pointing down.
- 5 Align the two grooves on the transducer with the two ridges on the needle guide.

- Carefully smooth and stretch the transducer cover along the face of the array and apply pressure until the needle guide clicks into place over the end of the transducer.

Figure 7 below shows the needle guide mounted on the transducer.

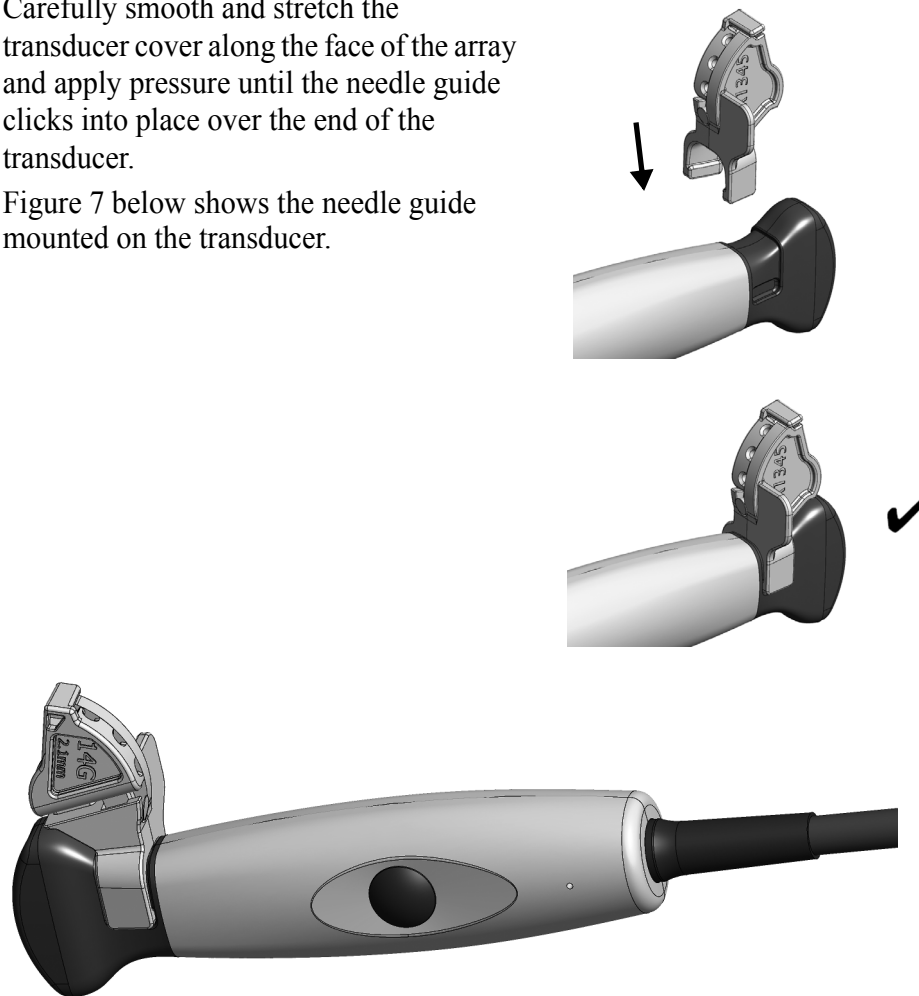


Figure 7. UA1345 mounted on transducer Type 8862 (shown here without transducer cover).



#### **WARNING**

Ensure the needle guide is positioned correctly.

- Carefully insert the needle into the needle channel.



**Caution:** Do not let the needle scrape the inside of the needle channel.

### **Attaching the 8862 Transducer and Needle Guide to a LEYLA Arm**

Needle guide UA1345 (for use with the Craniotomy Transducer Type 8862) has a tab that can be used to secure it to a LEYLA arm (see Figure 8).

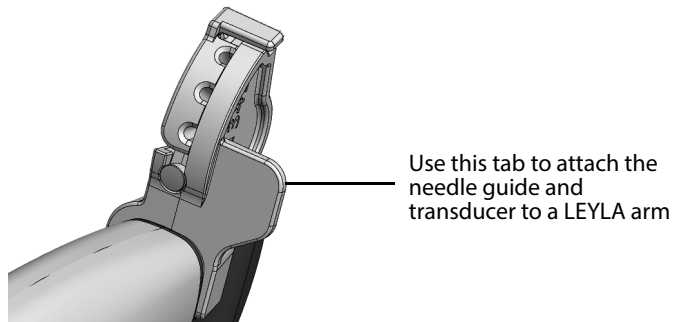


Figure 8. The 8862 transducer with needle guide can be attached to a LEYLA arm.



**Caution:** Ensure that the transducer and needle guide are attached firmly to the LEYLA arm so that they stay in position and do not fall off.

**NOTE:** Ensure that the transducer cable is secured so that it cannot move and pull the transducer out of position.

### 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.

#### How to release the needle guide on 8862:

- 1 Hold the transducer with your left hand. With your right hand, carefully push the needle guide insert sideways until it opens up (see Figure 9).

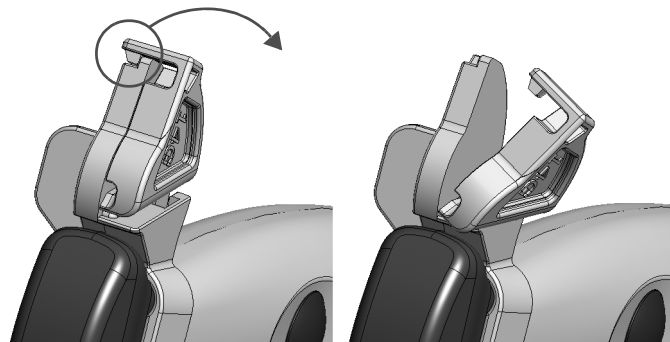


Figure 9. Push to release the needle guide on the Craniotomy Transducer Type 8862.

- 2 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.



#### **WARNING**

Be careful not to lose any parts of the needle guide inside the patient.

## Single-Use Needle Guide UA1346 for 8863

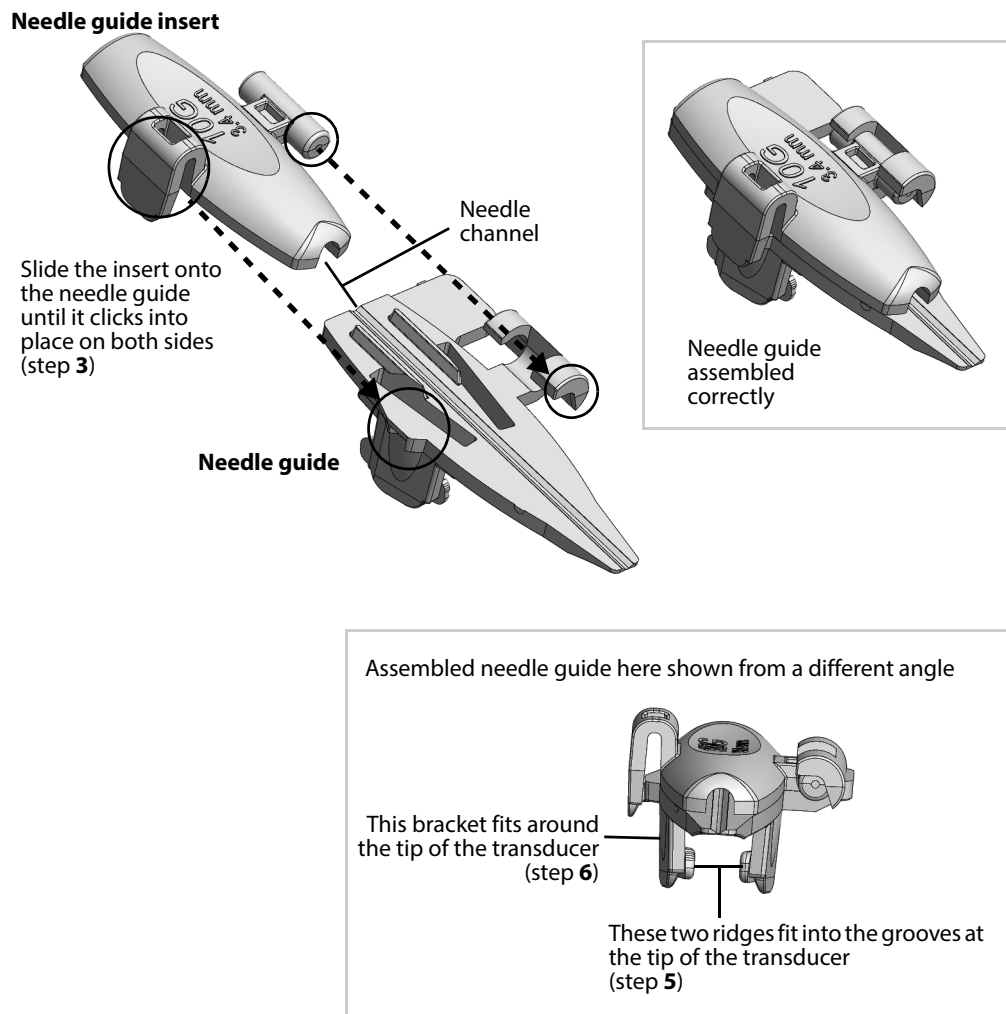


Figure 10. Needle guide UA1346 for Burr Hole Transducer Type 8863; the numbered steps refer to the steps in the procedure describing how to mount the needle guide on the following pages.

Needle guide UA1346 is supplied together with one needle guide insert palette. The palette contains a needle guide and a set of 9 needle guide inserts.

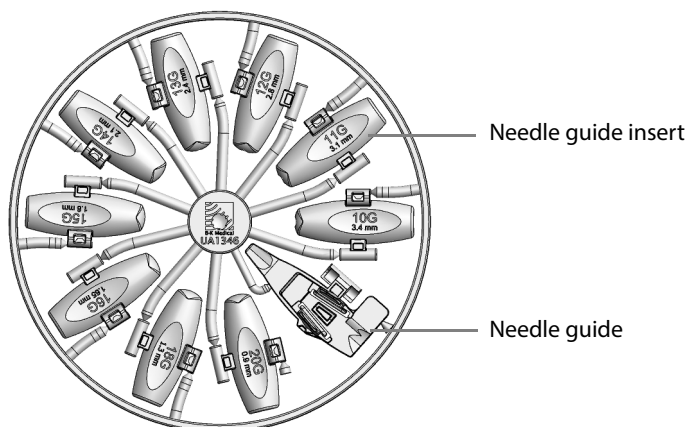


Figure 11. Palette with needle guide UA1346 and needle guide inserts.

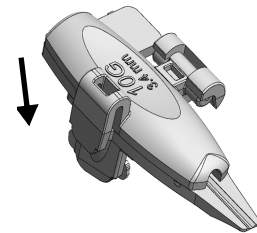
The guide channel is angled at 8° to the transducer's image axis.

The distance from the guide channel entrance of the puncture attachment to the first dot on the scan image puncture line is approximately 7 mm (0.3 in). The distance between the dots is 5 mm (0.2 in).

### Assembling and Mounting the Needle Guide

#### To assemble and mount a needle guide on the Burr Hole Transducer Type 8863:

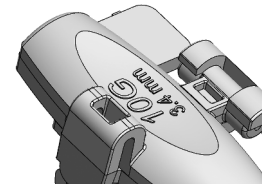
- 1 Apply a small amount of scanning gel to the tip of the transducer and carefully cover the transducer with a sterile cover.



- 2 Select the needle guide and the required needle guide insert by breaking them off the palette, see Figure 11.
- 3 Slide the insert onto the needle guide until it clicks into place on both sides, see Figure 10.



- 4 Hold the assembled needle guide with the bracket pointing down.



- 5 Align the two grooves on the transducer with the two ridges on the needle guide.
- 6 Carefully smooth and stretch the transducer cover along the face of the array while applying pressure until the needle guide clicks into place over the end of the transducer.
- 7 Figure 12 shows the needle guide mounted on the transducer.

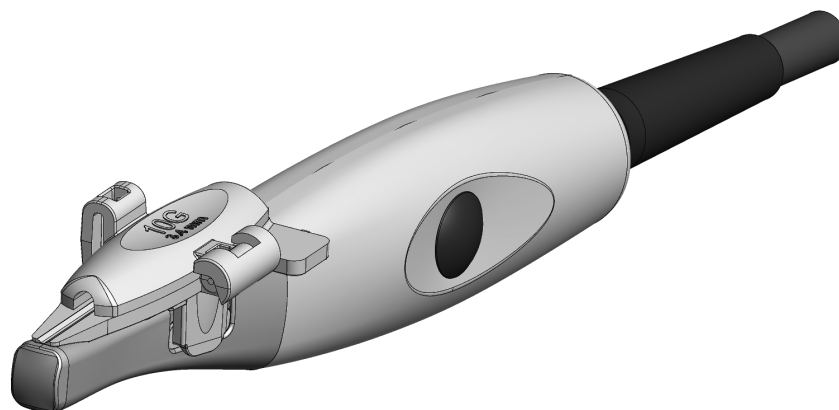


Figure 12. UA1346 mounted on transducer Type 8863 (shown here without transducer cover).



#### WARNING

Ensure the needle guide is positioned correctly.



8 Carefully insert the needle into the needle channel.



**Caution:** Do not let the needle scrape the inside of the needle channel.

### Attaching the 8863 Transducer and Needle Guide to a LEYLA Arm

Needle guide UA1346 (for use with the Burr Hole Transducer Type 8863) has a tab that can be used to secure it to a LEYLA arm (see Figure 13).

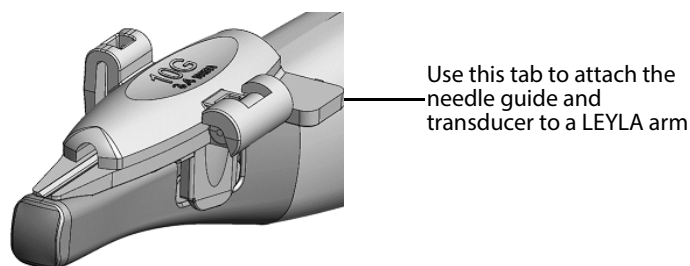


Figure 13. The 8863 transducer with needle guide can be attached to a LEYLA arm.



**Caution:** Ensure that the transducer and needle guide are attached firmly to the LEYLA arm so that they stay in position and do not fall off.

**NOTE:** Ensure that the transducer cable is secured so that it cannot move and pull the transducer out of position.

### 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.

#### How to release the needle guide on 8863:

- 1 Hold the transducer with your left hand. With your right hand, carefully push the needle guide insert sideways until it opens up, see Figure 14.

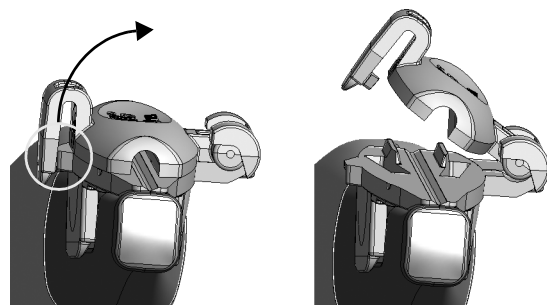


Figure 14. Push to release the needle guide on the Burr Hole Transducer Type 8863.

2 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.



**WARNING**

Be careful not to loose any parts of the needle guide inside the patient.

## Performing Puncture and Biopsy



**WARNING**

Before you start imaging, verify that the type number of the transducer and the type number or description of the puncture attachment you are using match the number displayed on the monitor. If they do not match, the puncture line on the monitor may not correspond to the true puncture path in the tissue. In case of any inconsistency, stop imaging, turn off the system, and contact your local BK Medical representative.



**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.

If the transducer is not sterilized, cover it with a sterile transducer cover.

If the transducer cover is damaged when attaching the puncture attachment, replace it with a new cover.



**Caution:** Use only non-pyrogenic, sterile transducer sheaths (transducer covers) that are approved for neurosurgical use. This means that in the USA they must be market cleared by the FDA, in Canada they must be licensed by Health Canada, and in Europe they must be CE-marked.

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

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

If more than one puncture line is available, refer to the applicable system 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.

**WARNING**

If the cover is damaged during interventional procedures, follow the policies of the hospital or clinic for treatment of the patient under such circumstances.

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

**WARNING**

Avoid unnecessary tissue damage. When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

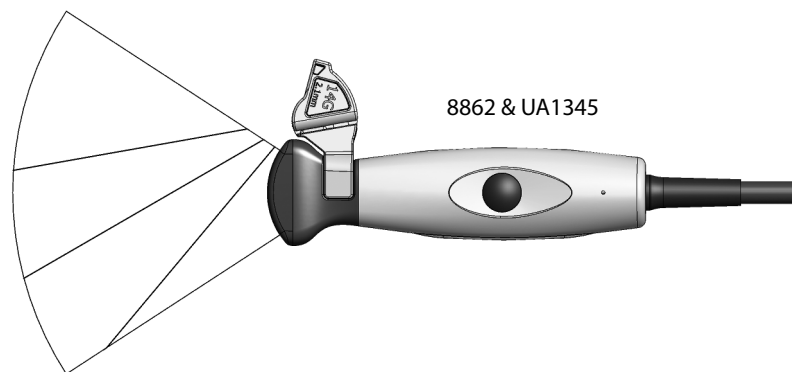


Figure 15. Illustration of the puncture lines for single-use needle guide UA1345 when mounted on the 8862. You must take extra care when taking a free-angle biopsy because the expected needle path is not shown on the screen image.

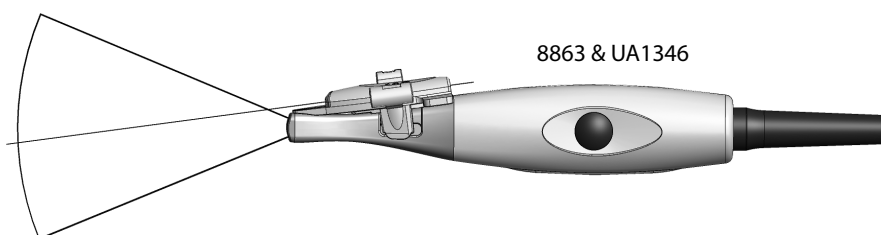


Figure 16. Illustration of the puncture line for single-use needle guide UA1346 when mounted on 8863.

## Cleaning after Puncture and Biopsy

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

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

## Disposal

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 system 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.



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