

Endovaginal Endfire 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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Input from our customers helps us improve our products and services. As part of our customer satisfaction program, we contact a sample of our customers a few months after they receive their orders. If you receive an email message from us asking for your feedback, we hope you will be willing to answer some questions about your experience buying and using our products. Your opinions are important to us. You are of course always welcome to contact us via your BK Medical representative or by contacting us directly.

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Introduction

This is the user guide for the Endovaginal Endfire Transducer Type 8819, and must be used together with *Care and Cleaning* which contains important safety information.

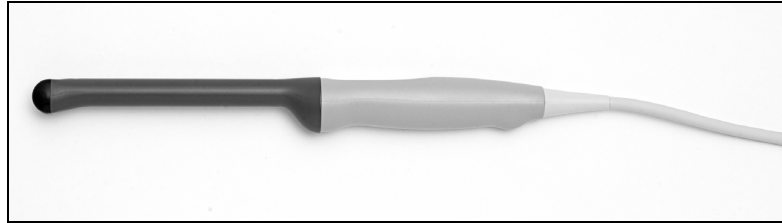


Fig. 1. Endovaginal Endfire Transducer Type 8819

Indications for Use

8819 is an endovaginal transducer suitable for gynecological examinations, fetal studies in early pregnancy and for ultrasound-guided interventional procedures.

Needle guides UA1282 and UA1350 provide guidance for needles or other interventional devices during an ultrasound-guided procedure. UA1282/UA1350 positions 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.

Scanning Plane

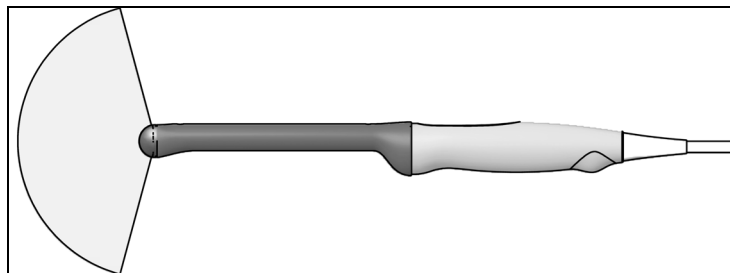


Fig. 2. Scanning plane Type 8819

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 the *Technical Data (BZ2100)* 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.

Fetal Scanning

When you use the transducer for fetal scanning, it is important to make sure that the default settings are appropriate and to reset to the default setting before scanning a new patient. A full explanation of acoustic output is given in your scanner user guide.

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*.

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.

Cleaning and Disinfection

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 the *Care and Cleaning* guide 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

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 on 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.



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.

Apply gel to the tip of the transducer. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer.

Gel also creates a good acoustic contact between the skin and the transducer; therefore, apply a small amount to the outside of the cover prior to scanning. Re-apply the gel frequently to ensure good screen images.



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.

Puncture Facilities

Puncture and biopsy are possible with Type 8819. The needle guides are illustrated in the following pages with a brief description of their use and operating instructions.

For hygiene reasons, the transducer should be enclosed in a transducer cover or a standard condom. When sterile conditions are required, cover the transducer with a sterile transducer cover.



WARNING

It is essential for the patient's safety that only the correct needle guide is used with Type 8819. Never use unauthorized combinations of transducers and needle guides or other manufacturers' needle guides.

Needle Guide UA1282

This metal needle guide (see Fig. 3) is intended for transvaginal puncture and biopsy with Endovaginal Endfire Transducer Type 8819.

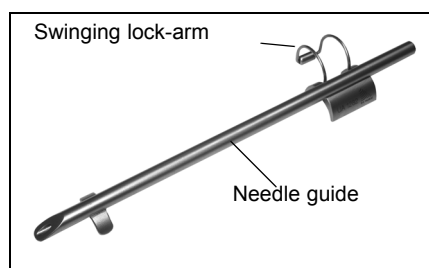


Fig. 3. Needle guide UA1282.

The needle guide is equipped a swinging lock-arm. The needle guide has an inner diameter of 1.8 mm, suitable for up to 14 gauge needles.

The needle guide is angled 0.9° towards the long axis of the transducer (i.e. towards the mid-axis of the scan image). The distance from the entrance to the needle guide and the first puncture line dot on the scan image is 173 mm. The dots are 5 mm apart, see Fig. 6 for details.

All parts of the puncture attachment can be autoclaved or disinfected by immersion in a suitable solution.

To mount UA1282 (as shown in Fig. 4):



Fig. 4. Type 8819 with needle guide UA1282

- 1 Hold the transducer with the groove on the handle uppermost.
- 2 Align the two raised nodules on the underside of the attachment with the two holes on the upperside of the probe's rod.
- 3 Lock the swinging arm into position over the bottom of the transducer. An audible click indicates when the needle guide is securely attached.

Caution:

Ensure that the tip of the needle guide lies close to the front end of the probe, if not the needle guide may be damaged and require realignment by BK Medical technicians.

Caution:

Ensure UA1282 is positioned correctly.

To remove the needle guide, unlock the swinging arm and lift the needle guide off the transducer.

Single-Use Sterile Needle Guide UA1350

Needle guide UA1350 is supplied sterile in peel packs and is for single-use only. Contents are sterile only if the package is intact. The needle guide must be discarded after use.

NOTE:

*When using the UA1350, the needle guide number on the monitor will be **610-958**.*



WARNING

Single-use 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.



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.

The sterile-packed needle guides must be stored at a temperature range from +5°C (+41°F) to +25°C (+77°F) and a storage humidity of 0% to 80%.

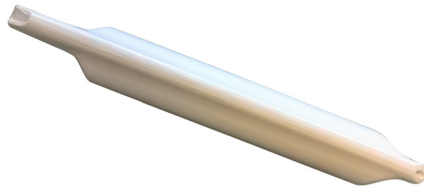


Fig. 5. Single-use needle guide UA1350.

To take a biopsy:

1. Enclose the transducer in a transducer cover.
2. Click the needle guide into place.
3. Insert a needle into the needle guide.

Ensure the needle guide is securely in place and the tip of the needle guide lies close to the front of the transducer.

Performing Puncture and Biopsy

Transvaginal Biopsy



WARNING

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

Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the puncture attachment 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.

Cover the transducer with a sterile transducer cover.

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

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.

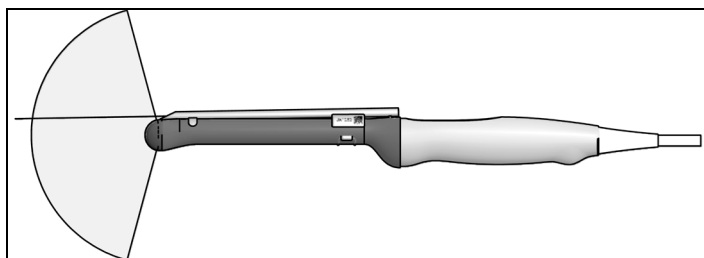


Fig. 6. Illustration of puncture line for puncture attachment UA1282



WARNING

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

Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer or needle guides, disinfection and sterilization processes may not be effective. Therefore, you must clean puncture needle guides 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 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 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.

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