bk ultrasound
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User Guide
Type 8826

Pro*ART*™
Robotic Drop-in Transducer

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CE 0543
For Professional Users Only

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The serial number of a BK Medical product contains information about the year of manufacture. To obtain the date of manufacture of a product, please contact your BK Medical representative or write to us at the email address above, including the product's serial number (SN number).

BK Medical Customer Satisfaction

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.

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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Introduction

This is the user guide for Pro***ART***™ Robotic Drop-in Transducer Type 8826 and must be used together with your system user guide and *Care, Cleaning & Safety* which contains important safety information.

Indications for Use

Pro***ART*** Robotic Drop-in Transducer Type 8826 is designed for intraoperative imaging. The transducer is ideal for ultrasound-guided robotic surgery procedures (such as *Liver, Pancreas, Uterus* and *Kidney*)

Patient Population

The patient population is adults and children.

*Figure 1. Pro**ART** Robotic Drop-in Transducer Type 8826.*

Imaging Plane

The 8826 is a small laparoscopic transducer with a curved array. The transducer has a penetration depth up to 125 mm (depending on system) and a 9 x 33.2 mm footprint size.

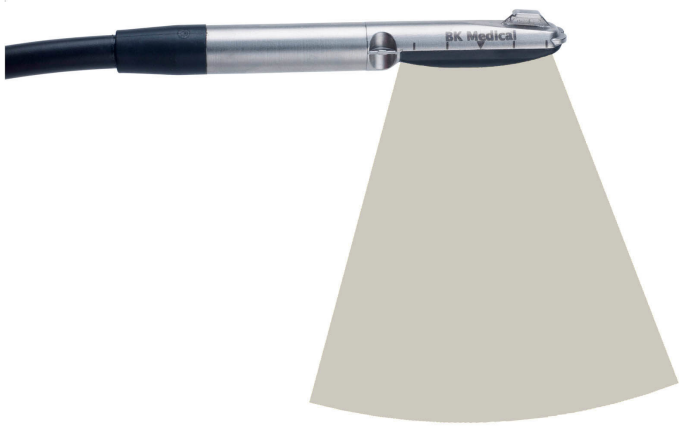

*Figure 2. Imaging plane for Pro**ART** Robotic Drop-in Transducer Type 8826.*

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.

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

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, 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 cover is 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. A transducer that is used intraoperatively must be sterilized. If sterilization is not possible, it must be processed to achieve high-level disinfection and then covered with a sterile transducer cover. See discussion of levels of disinfection and sterilization in *Care, Cleaning & Safety*.

Connecting the Transducer

WARNING

To prevent electrical shock, 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 Multi-Frequency Imaging (MFI) facility enables you to select the imaging frequency. The 8826 has a frequency range of 12-5 MHz for the *flex* **Focus** 800 system and 12-4 MHz for the Pro Focus UltraView 800 system. See the applicable system user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

WARNING

Transducer covers must not be used for robotic surgery because the covers may be damaged when handled by the robot tools. For use in robotic surgery, the transducer must be sterilized.

If the transducer is used for non-robotic surgery, it should be enclosed in a sterile transducer cover, and sterile gel should be used.

WARNING

Some transducer covers can contain latex. 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 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-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover material.

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.

Changing Orientation

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

Imaging with Type 8826

The Pro***ART*** Robotic Drop-in Transducer Type 8826 can be used together with a *flex* **Focus** 800 Ultrasound System, or a Pro Focus UltraView 800 System if you want to use Contrast Enhanced Ultrasound (CEUS). Both systems can be operated by wireless Remote Control UA1237 for use with the *da Vinci* Surgical System®.

WARNING

When you use cautery instruments together with the transducer, you must be particularly careful. To avoid damaging the transducer and possibly the patient, keep the transducer at a safe distance from the cautery instruments. Otherwise the instruments may damage the cable shield or the acoustic surface of the transducer resulting in an electrical connection to ground. This may present an electrical hazard for the patient. There may also be a risk of contamination from damage to plastic parts.

Connecting to the Robotic Surgical System

The following step by step instruction describes how to connect the 8826 transducer to the *da Vinci* Surgical System using a *flex* **Focus** 800 or a Pro Focus UltraView 800, and a wireless Remote Control UA1237.

1. Connect *flex* **Focus** 800 or Pro Focus UltraView 800 to the *da Vinci* Surgical Console* with a Digital Visual Interface (DVI) or an analog SVGA cable (depending on ultrasound system) for integration of picture-in-picture images with TilePro™.
2. Pair wireless Remote Control UA1237 with the ultrasound system. Once the remote control is paired with the system, you have full control of all system features. For further instructions on how to use Remote Control UA1237 refer to the applicable user guide.
3. Connect the 8826 transducer to the ultrasound system. Make sure the transducer is properly sterilized before use. Full details of cleaning and disinfection procedures can be found in *Care, Cleaning & Safety* that accompanies this user guide.
4. Gently place the 8826 transducer in a standard 12 mm trocar before imaging. Imaging can be controlled by wireless Remote Control UA1237 which interacts with the ultrasound system.
5. When imaging is completed, gently remove the 8826 transducer by pulling it back through the trocar.

* First generation *da Vinci* Surgical Systems use an analog S-Video output signal. See Technical Data (BZ2100) that accompanies this user guide for more information on the electromagnetic compatibility of the BK Medical ultrasound systems. For a list of suitable adaptors, see the 'Safety Information' chapter in the *flex* **Focus** User Guide (BB1756).

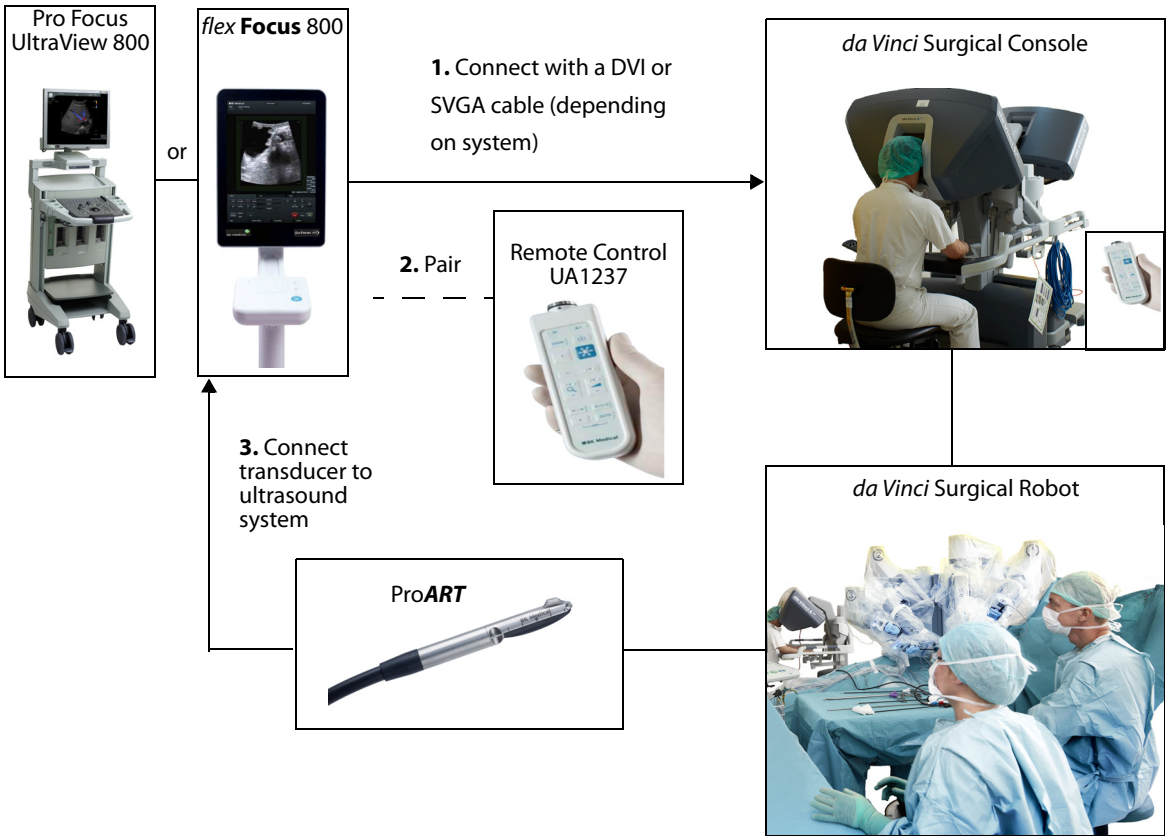

Figure 3. System overview. Numbers refer to the steps in the procedure on page 9.

Grasping the Transducer with the Robot Tools

WARNING

Check the transducer for sharp edges, especially at the grasper sites, before use.

The Pro***ART*** Robotic Drop-in Transducer Type 8826 is designed for use with the ProGrasp Forceps™ which are manipulated from the *da Vinci* console by the surgeon.

Fig. 4 illustrates where to grab and handle the 8826 transducer with the robot tools.

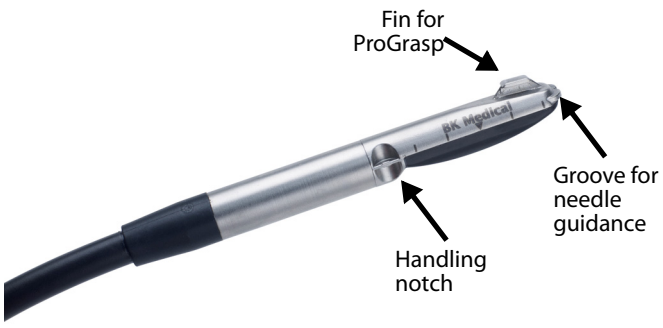

*Figure 4. Pro**ART** Robotic Drop-in Transducer Type 8826*

When grasping the 8826 transducer with the the ProGrasp Forceps, you can use the handling notches to stabilize the transducer. The transducer fin must be grasped from the back of the transducer.

Fig 5. illustrates how to grasp the transducer fin from the back of the transducer with the ProGrasp Forceps.

Figure 5. Grasping the transducer fin with the ProGrasp Forceps

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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