

ProART™ Robotic Transducer

USES

- Robotic Assisted Partial Nephrectomy (RAPN) procedures
- Upper gastrointestinal procedures
- Gynecological surgery
- Intraoperative imaging
- Contrast imaging*

BENEFITS

- Uncompromised image quality for Robotic Assisted Partial Nephrectomy
- Superb control – grasping fin directly over array
- Curved linear array for best field of view
- Uncompromised image quality
- Fully integrated with robotic surgery equipment
- “Extension of the surgeon’s hand”
- Fits through a standard 12-mm trocar
- Easily maneuverable
- Maximum organ contact
- Maximum imaging contact
- Reduces procedure times
- Compatible with modern sterilization methods



Robotic Transducer Type 8826 for insertion through a 12-mm trocar

General Description

8826 is a small laparoscopic transducer with a convex array, designed for use with BK Medical’s ultrasound systems.

Applications

8826 is ideal for intraoperative procedures. Common applications are the investigation of key structures such as the kidney, pancreas, uterus and liver.

Unmatched Transducer Design

The design of the 8826 is completely unique. The transducer features a 36° field of view, the largest on the market today for a transducer of this type and size.

The transducer also features a unique fin situated over the array. This fin placement means that the transducer can be easily gripped by the ProGrasp™ forceps of a robot. This grip is secured because of the fin’s position and also allows for maximum security and maneuverability even in the demanding environment of robotic or laparoscopic surgery.

The transducer is easily maneuverable so the surgeon, or robot, can easily move the transducer to any angle necessary. The transducer’s design also facilitates maximum imaging contact between the array and the anatomy.

Flexible Imaging Options

8826 can transmit at 12, 10, 7.5 and 5 MHz, allowing penetration and resolution to be optimized for each application. The transducer also features superior Spectral Doppler capabilities as well as excellent B-Mode, Color and Power Doppler.

Cleaning and Sterilization

The 8826 can be disinfected by immersion in the solutions listed under Specifications.

8826 can be processed by using STERRAD® 50, 100S, 200, NX and 100NX. The transducer can also be processed using STERIS SYSTEM 1^{***} and STERIS SYSTEM 1E (when a watertight plug protection device is fitted).

Sterile transducer cover is available.

Safety

8826 is designed and tested in accordance with EN60601-1 (IEC 60601-1), “Medical Electrical Equipment, General Requirements for Safety.” When used with BK Medical’s ultrasound systems, Type BF requirements are met.

* In the USA, contrast-enhanced ultrasound has not been market cleared by the FDA, with the exception of only select cardiac imaging applications.

** STERIS SYSTEM 1 is not market cleared in the USA.

The 8826 transducer is not licensed by Health Canada.

Specifications 8826

<p>SAFETY When used with BK Medical's ultrasound systems, this transducer complies with Safety Standard EN60601-1 (IEC60601-1) Type BF.</p> <p>FREQUENCY RANGE 12–4 MHz (depending on system)</p> <p>ENVIRONMENTAL Operating pressure: 700–1060 hPa (normal atmospheric pressure) Operating Temperature: +10 to 40 °C (+50 to 104 °F) Storage Temperature: -25 to 70 °C (-13 to 158 °F) Watertight Immersion Temperature: Max. 40 °C (104 °F) Watertight Immersion Time: Max. 15 hours per 24 hours</p> <p>STERILIZATION AND DISINFECTION Complete details and procedures can be found in <i>Care, Cleaning & Safety</i>. RESISTANCE TO CHEMICALS DURING DISINFECTION Sterilization processing* 8826 can be processed using: <ul style="list-style-type: none"> • STERIS SYSTEM 1*** and SYSTEM 1E • STERRAD® 50, 100S and 200 systems • STERRAD NX™ and 100NX™ systems • Ethylene oxide gas† (max. temperature 55 °C (131 °F), min. pressure 100 hPa (1.5 psi)) </p>	<p>Immersion (with covered plug) Immersion for less than 10 minutes in each hour in: <ul style="list-style-type: none"> • Chlorhexidine gluconate (5–20%) • Ethanol (70% in water) • Propanol (70% in water) </p> <p>For less than 15 hours in each 24 hours in the following solutions: <ul style="list-style-type: none"> • Glutaraldehyde (2-3.4% in water) Follow manufacturer's instructions for use.</p> <p>The following disinfectants can also be used (but not exceeding maximum watertight immersion time specified for this transducer): <ul style="list-style-type: none"> • Cidex® OPA • Korsolex® Basic • Korsolex® Extra • PeraSafe® • Tristel® </p> <p>Wiping <ul style="list-style-type: none"> • Ethanol (70% in water) </p> <p>Follow manufacturer's instructions for use.</p> <p>POWER SUPPLY Internally from system</p> <p>CABLE LENGTH 3.5 m (11.5 ft)</p>	<p>TRADEMARKS</p> <ul style="list-style-type: none"> • STERIS SYSTEM 1 and STERIS SYSTEM 1E are registered trademarks of STERIS Corporation. • STERRAD is a registered trademark and NX and 100NX are trademarks of Advanced Sterilization Products (ASP), a Johnson & Johnson Company. • Cidex OPA is a registered trademark of Advanced Sterilization Products (ASP), a Johnson & Johnson Company. • Korsolex is a registered trademark of Bode Chemie GmbH. • PeraSafe is a registered trademark of Antec International. • Tristel is a registered trademark of Tristel Pharmaceutical. <p>* Sterilization processes are harsh and can shorten the life of the product. ** STERIS SYSTEM 1 is not market cleared in the USA. † A specific EO process for sterilization has not been validated by BK Medical.</p>
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	Units	8826							
		Pro Focus UltraView 2202†				Flex Focus 1202††			
B-Mode Frequency	MHz	12	10	7.5	5	12	10	7.5	5
Doppler Frequency	MHz	10 - 7.5 - 6 - 5							
Tissue Harmonic Frequency	MHz	8.5							
Contrast Frequency	MHz	4.3 - 4				-			
Number of Elements		95							
Radius of Curvature	mm	48							
Transverse Plane Aperture	mm	5							
Transverse Focal Length	mm	23							
Image Plane Aperture	mm	20							
Axial Resolution (Measured at 20 mm)*	mm	0.4	0.5	0.5	0.6	0.4	0.5	0.6	0.6
Lateral Resolution (Measured at 20 mm)*	mm	0.4	0.5	0.6	0.7	0.4	0.5	0.6	0.7
Image Field		Sector 36°							
Basic Imaging Modes		B, M, Doppler, CFM, Tissue Harmonic Imaging, Contrast Imaging‡				B, M, Doppler, CFM, Tissue Harmonic Imaging			
Penetration Depth*	mm	81	105	120	125	87	104	122	125
Frame Rate (Max)	Hz	>150							
Contact Surface (Acoustic)	mm	5 x 29.9							
Contact Surface (Overall)	mm	9 x 33.2							
Size of Transducer	mm	80 x 12.2							
Weight (Approximate)	g	25							
Applications (Typical)		Intraoperative							

† Only available on UltraView and UltraView 800.

†† Only available on Flex Focus 800

* Measurements according to IEC/TS 61390 and JIS T 1501. Penetration depth is measured in an ultrasound phantom and recalculated corresponding to a realistic tissue attenuation of 0.5 dB/cm/MHz.

‡ In the USA, contrast-enhanced ultrasound has not been market cleared by the FDA, with the exception of only select cardiac imaging applications. For definition of terms, refer to Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. AIUM/NEMA, 2004.

Ordering Information 8826

ACCESSORIES INCLUDED

KE4320: Carrying Case

ACCESSORIES AVAILABLE

UA1404: Leakage Testing kit

TRANSDUCER COVERS

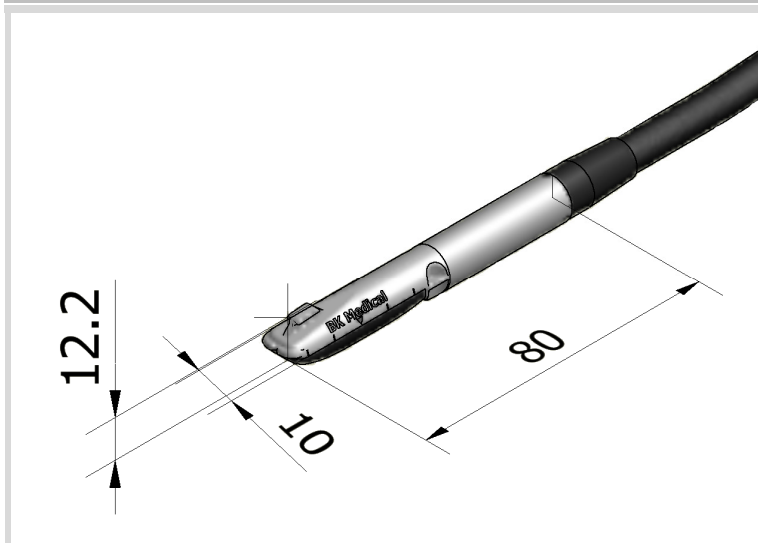
UA0067: NeoGuard® Sterile Covers, latex-free
(pack of 12)

TRADEMARKS

NeoGuard is a registered trademark of CIVCO
Medical Instruments Co., Inc.

8826 Technical Drawing

All measurements are in mm.



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Innovative Solutions for Life

Analogic Corporation creates innovative technology to improve the health and ensure the safety of people around the world. We are committed to providing ultrasound solutions under the BK Medical brand name that advance medicine and save lives.



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