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OptiCross™ X 40 MHz Coronary Imaging Catheter

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R ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Carefully read all instructions prior to use. Observe all contraindications, warnings, precautions and adverse events noted in these directions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

DEVICE DESCRIPTION

The OptiCross X 40 MHz Coronary Imaging Catheter is a sterile, short rail imaging catheter.

It consists of two main assemblies:

1. Imaging Core
2. Catheter Body

The imaging core is composed of a hi-torque, flexible, rotating drive cable with a radial looking 40 MHz ultrasonic transducer at the distal tip. An electro-mechanical connector interface at the proximal end of the catheter makes the connection to the Motordrive Unit (MDU5 PLUS) Instrument. The MDU5 PLUS-catheter interface consists of an integrated mechanical drive socket and electrical connection.

The catheter body is comprised of three sections:

1. Distal Imaging Window Lumen
2. Proximal Shaft Lumen
3. Telescoping Section

The distal imaging window lumen and proximal shaft lumen sections comprise the “working length” of the catheter, and the telescoping section remains outside of the guiding catheter.

The catheter body has a distal imaging window lumen with proximal exit at 1.6 cm from the distal end (Figure 1). A radiopaque (RO) marker is embedded in the catheter body at 0.5 cm from the distal tip. In addition, two insertion depth markers are located on the proximal shaft lumen at 90 cm and 100 cm from the distal tip to aid in estimating catheter position

relative to the distal guide catheter tip. The proximal shaft lumen is attached to the telescoping section via a strain relief connection.

The telescoping shaft (section) allows the imaging core to be advanced and retracted for 15 cm of linear movement. The corresponding movement of the transducer occurs from the proximal end of the guidewire exit port to the proximal end of the distal imaging window lumen. The telescope section has proximal markers for lesion length assessment, consisting of a series of marks spaced 1 cm apart on the telescope body.

A flush port with a one-way check valve (Figure 1) is used to flush the interior of the catheter body and maintain a flushed condition. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way check valve helps retain saline in the catheter during use.

Contents

OptiCross X 40 MHz Coronary Imaging Catheter
MDU5 PLUS Sterile Bag

17.78 cm (7 in) extension tube

3 cm³ (3 cc) and 10 cm³ (10 cc) syringes

4-way stopcock

INTENDED USE/INDICATIONS FOR USE

This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

CONTRAINDICATIONS

Use of this imaging catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. The contraindications also include the following:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for CABG surgery
- Patients disqualified for PTCA
- Severe hemodynamic instability or shock
- Use of the imaging catheter to cross a total occlusion

WARNINGS

- Do not use device after indicated ‘Use By’ date. Use of an expired device could result in patient injury due to device degradation.
- Intravascular ultrasound examination of coronary anatomy should be performed only by physicians fully trained in interventional cardiology or interventional radiology and in the techniques of intravascular ultrasound, and in the specific approach to be used, in a fully-equipped cardiac catheterization lab.
- The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. Using an altered catheter can result in poor image quality or patient complications.
- No modification of this equipment is allowed.
- Air entrapped in the catheter and flushing accessories can cause potential injury or death. Always verify that the catheter and flushing accessories have been properly cleared of air prior to inserting the catheter into the vasculature.
- **Do not pinch, crush, kink or sharply bend the catheter at any time.** This can cause poor catheter performance, vessel injury or patient complications. An insertion angle greater than 45° is considered excessive.
- Never advance or withdraw the imaging catheter without fluoroscopic visualization because it may cause vessel injury or patient complications.
- Do not advance the catheter if resistance is encountered. The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis. A catheter that is forcibly advanced may cause catheter damage resulting in vessel injury or patient complications.

- When advancing the catheter through a stented vessel, catheters that do not completely encapsulate the guidewire may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- If resistance is met upon withdrawal of the catheter, verify resistance using fluoroscopy, then remove the entire system simultaneously. A catheter that is forcibly removed may cause vessel injury or patient complications.
- When **re-advancing** a catheter after deployment of stent(s), at no time should a catheter be advanced across a guidewire that may be passing between one or more stent struts. A guidewire may exit between one or more stent struts when recrossing stent(s). Subsequent advancement of the catheter could cause entanglement between the catheter and the stent(s), resulting in entrapment of catheter/guidewire, catheter tip separation and/or stent dislocation. Use caution when removing the catheter from a stented vessel.
- Inadequately apposed stents, overlapping stents, and/or small stented vessels with distal angulation may lead to entrapment of the catheter with the stent upon retraction. When retracting the catheter, separation of a guidewire from an imaging catheter or bending of the guidewire may result in kinking of the guidewire, damage to the catheter distal tip, and/or vessel injury. The looped guidewire or damaged tip may catch on the stent strut resulting in entrapment.
- If multiple insertions are required, the catheter should not be disconnected from the MDU5 PLUS to avoid possible breach of catheter sterility.

PRECAUTIONS

- Do not attempt to connect the catheter to electronic equipment other than the designated Systems because the catheter may not function properly.
- Never attempt to attach or detach the catheter while the motor is running. To do so may damage the connector.
- If difficulty is encountered when backloading the guidewire into the distal end of the catheter, inspect the guidewire exit port for damage before inserting the catheter into the vasculature. The use of a damaged guidewire exit port could increase the resistance of catheter advancement or withdrawal.
- Never advance the imaging catheter without guidewire support because it can cause difficulty in reaching the intended region of interest or can cause the distal catheter tip to kink.
- Never advance the distal tip of the imaging catheter near the very floppy end of the guidewire. This part of the guidewire will not adequately support the catheter. A catheter advanced to this position may not follow the guidewire when it is retracted and cause the guidewire to buckle into a loop which the catheter may drag along the inside of the vessel and catch on the guide catheter tip. If this occurs, it may be necessary to remove the catheter assembly, guidewire and the guide catheter together. If the catheter is advanced too near the end of the guidewire, advance the guidewire while holding the imaging catheter steady. If this fails, withdraw the catheter and guidewire together.
- Never advance or withdraw the imaging catheter without the imaging core assembly being positioned at the most distal position of the imaging window because it may cause the catheter to kink.
- During and after the procedure, inspect the catheter carefully for any damage which may have occurred during use. Multiple insertions may lead to catheter exit port dimension change/distortion which could increase the chance of the catheter catching on the stent. Care should be taken when re-inserting and/or retracting catheter to prevent exit port damage.

- Always turn the MDU5 PLUS™ “OFF” before withdrawing the imaging catheter because it could cause the motor drive to overload.

ADVERSE EVENTS

The risks and discomforts involved in vascular imaging include those associated with all catheterization procedures. These risks or discomforts may occur at any time with varying frequency or severity. Additionally, these complications may necessitate additional medical treatment including surgical intervention and, in rare instances, result in death.

- Allergic reaction
- Angina
- Cardiac arrest
- Cardiac arrhythmias including, but not limited to ventricular tachycardia, atrial/ventricular fibrillation and complete heart block
- Cardiac tamponade/Pericardial effusion
- Death
- Device entrapment requiring surgical intervention
- Embolism (air, foreign body, tissue or thrombus)
- Hemorrhage/Hematoma
- Hypotension
- Infection
- Myocardial infarction
- Myocardial Ischemia
- Stroke and Transient Ischemic Attack
- Thrombosis
- Vessel occlusion and abrupt closure
- Vessel trauma including, but not limited to dissection and perforation

HOW SUPPLIED

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Operating Environment

Ambient Temperature: 10 °C to 40 °C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29 °C to 60 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 15 °C to 30 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

DIRECTIONS FOR USE

Note: Medical Electrical Equipment requires special precautions regarding Electromagnetic Compatibility (EMC). This equipment (device) needs to be installed and put into service according to the EMC information contained within the documents accompanying the system.

Note: Portable and mobile Radiofrequency (RF) communications equipment can affect Medical Electrical Equipment.

A. Inspection Prior to Use

Before use, inspect the packaging for any violation of the sterile barrier and inspect the catheter and accessories for any damage or defects. Do not use potentially contaminated or defective equipment. If the sterile barrier integrity is compromised or the contents damaged, contact your Boston Scientific representative. Prior to imaging, all equipment to be used during the procedure should be carefully examined to ensure proper performance. If device appears to be compromised, contact your Boston Scientific representative.

Prior to use, verify product is within labeled shelf life. Do not use product if the ‘Use By’ date has been exceeded. Dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

B. Preparation for Catheter Use

1. Refer to the setup section of the User’s Guide(s) or Direction for Use for iLab™ Imaging System, MDU5 PLUS, MDU5 PLUS Sterile Bag and Automatic Pullback Sled (if used).

Note: All of the following steps have to be performed using Sterile Technique

2. Using sterile technique, remove the catheter and accessories from tray. Retract the movable imaging core completely to the proximal position via the telescoping shaft. DO NOT pull too hard while retracting the imaging core.
3. Fill the 3 cm³ (3 cc) and 10 cm³ (10 cc) syringes with heparinized saline. Connect the 3 cm³ (3 cc) and 10 cm³ (10 cc) syringes to the 4-way stopcock, with the 3 cm³ (3 cc) syringe connected to the inline port of the 4-way stopcock. Then connect the assembly to the extension tube. Ensure that all air is expelled from the assembly (syringes, stopcock, and extension tubing) by flushing, using heparinized saline in syringes. Connect the extension tube to the one way valve on the catheter hub. The 10 cm³ (10 cc) syringe is to be used as a reservoir for refilling the 3 cm³ (3 cc) flushing syringe.
4. Flush the imaging catheter TWICE on the prep table continuously with 3 cm³ (3 cc) volume each time. DO NOT USE EXCESSIVE PRESSURE. Move the imaging catheter over to the procedure table. Ensure that all air is expelled from the system.
5. Connect the imaging catheter to the MDU5 PLUS by aligning the catheter hub and the MDU5 PLUS. Push the catheter hub and MDU5 PLUS together until the hub clicks into place. To ensure that the hub is fully seated in the MDU5 PLUS, gently tug on the hub. **If catheter identification is incorrect or missing: See Section G2.**
6. Remove catheter carefully from sterile hoop dispenser coil. Confirm the imaging core is in the fully retracted position and the catheter is not tightly coiled. Turn on the MDU5 PLUS and confirm proper function of the catheter by observing a pattern of partial bright concentric rings on the monitor (Figure 2).
7. While imaging with MDU5 PLUS, advance the imaging core to the fully distal position, via the telescoping shaft.

Note: Always turn the MDU5 PLUS “ON” before using the telescope to advance the imaging core within the catheter.

8. Turn off the MDU5 PLUS. The MDU5 PLUS should remain off from this point until the catheter is positioned in situ.
9. Refill the 10 cm³ (10 cc) syringe as needed and reattach to the stopcock without introducing air into the line.
10. To prevent air from being introduced into the catheter lumen, **DO NOT** retract the imaging core prior to catheter placement. Any amount of retraction of the imaging core prior to catheter placement will require additional flushing.

Note: Where pullback device use is desired, flush the catheter one more time while the imaging core is in the full distal position with the catheter installed on the pullback device.

Note: If flushing is difficult with the imaging core in the full distal position, then manually retract the imaging core 3 mm - 5 mm and re-flush. Then, manually advance the imaging core to the original full distal position.

Note: Exercise care not to kink catheter while handling.

C. Preparation for MDU5 PLUS Sterile Bag use

Refer to MDU5 PLUS Sterile Bag Directions for Use section.

D. Place Guide Catheter

1. Prepare the entry site with a sheath introducer according to standard practice.
2. Before insertion of the imaging catheter, ensure the patient has been prepared using standard procedure for interventional treatment.
3. Place the guide catheter and Y-adapter. Introduce the guidewire and advance it to the region of interest.

E. Introduce Imaging Catheter Into Guide Catheter

1. Wet the distal section (approximately 23 cm) of the imaging catheter sheath with heparinized saline to activate the lubricious coating. Always wipe down the guidewire with heparinized saline prior to loading the catheter onto the guidewire.

2. Backload the guidewire into the distal end of the imaging catheter (Figure 1). Advance the guidewire into the imaging catheter until the guidewire exits from the guidewire exit port.

Note: Guidewires that supply more stiffness near the distal tips are recommended.

3. Continue to advance the imaging catheter into the guide catheter up to the exit point using the appropriate proximal marker as a reference if needed. Tighten the hemostasis valve on the guide catheter’s Y-adapter. Tighten only enough to prevent fluid/blood leakage. **AN EXCESSIVELY TIGHTENED HEMOSTASIS VALVE MAY DISTORT THE IMAGE DUE TO BINDING OF THE ROTATING DRIVE CABLE.**
4. Turn on the MDU5 PLUS and check to see that the catheter produces an image. If the image is flickering, some air may still be present in the catheter. Flush the catheter again with the MDU5 PLUS “ON” (Imaging). DO NOT USE EXCESSIVE PRESSURE. The image should appear as a single bright concentric ring. After confirmation of stable image, press imaging button on MDU5 PLUS to stop imaging.

F. Catheter Placement and Imaging

1. With MDU5 PLUS “OFF” and using fluoroscopy, advance the imaging catheter over the guidewire until the distal marker crosses a minimum of 3 cm beyond the region of interest in the vessel/lesion.
2. Keeping the catheter body and guidewire fixed, turn MDU5 PLUS “ON” and retract the imaging core slowly along its length of travel (up to maximum of 15 cm) either manually or using the optional Automatic Pullback Sled to image the region of interest. Retract and advance as desired.

Note: Always turn the MDU5 PLUS “ON” before advancing or retracting the imaging core within the catheter.

Note: If the image fades: See Section G3 and G4.

3. When done imaging, fully advance the imaging core and turn “OFF” the MDU5 PLUS. Maintain the position of the guidewire and remove the imaging catheter.
4. If the imaging catheter is to be re-inserted, flush once with 3 cm³ (3 cc) volume syringe and coil the catheter and set aside the MDU5 PLUS and Automatic Pullback Sled, if used.

Note: If multiple insertions are required, the catheter should not be disconnected from the MDU5 PLUS to avoid possible breach of catheter sterility.

5. When ready to reinsert the imaging catheter, flush one more time with 3 cm³ (3 cc) volume syringe.
6. Inspect guidewire exit port prior to re-inserting to verify no damage occurred during withdrawal.
7. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

G. Troubleshooting

1. If there is vibration from the catheter telescope section during advancement of the imaging core, stop imaging. Adjust the location of the sheath such that the imaging window is as straight as possible. Reactivate MDU5 PLUS and re-advance the imaging core. Be aware of potential imaging core entanglement if catheter is utilized subsequently.
2. If imaging catheter is not recognized by the system, contact your Boston Scientific representative before proceeding.
3. If the image fades during use, or if shadowed areas persist after flushing *in situ*, the distal imaging window lumen may contain air bubbles. Remove catheter and repeat flushing procedure in Section B, Preparation for Catheter Use, step 4.
4. If the image cannot be recovered as a result of flushing, a drive cable failure or MDU5 PLUS disconnection may have occurred. Stop imaging and verify that the hub is fully seated in the MDU5 PLUS. If the hub is fully seated and the condition persists, withdraw the catheter. Restart the MDU5 PLUS and visually inspect for rotation of the imaging core. If it is not rotating, return the catheter to your Boston Scientific representative for analysis.

ACOUSTIC OUTPUT – COMPLIANCE TO US FDA GUIDELINES

ALARA Precaution

There is one scan parameter that can be varied which can cause a change in the radiated ultrasound field. The motor speed (frame rate) can vary downwards from its preset value of 30 frames per second. The maximum in situ intensities will be generated when the motor speed is 30 frames per second. It should also be noticed that the gain setting cannot change the in situ intensity.

Additional acoustic output information can be found in the operator’s manual or user’s guide.

Imaging Catheter Information

Acoustic Power Output varies between different models of imaging catheters. Each imaging catheter supplied by Boston Scientific Corporation is supplied with Directions for Use (DFUs) that include statements and tables specifying their acoustic power outputs.

US FDA guidelines for measurements and definitions of terms may be found in FDA publication: *Information for Manufacturers Seeking Market Clearance of Diagnostic Ultrasound Systems and Transducers* (September 9, 2008).

Where Mechanical and/or Thermal Indices are reported, the MI/TI is displayed on the lower right of the IVUS image next to the imaging catheter identification.

Calculation of Estimated in situ Intensities

The estimated spatial peak in situ intensities are calculated from the spatial peak water values using the following equation:

$$I_{in\ situ} = I_{water} \exp(-0.069f_c z_{sp})$$

where $I_{in\ situ}$ is the estimated in situ intensity, I_{water} is the measured intensity in water, f_c is the center frequency of ultrasound in MHz, and z_{sp} is the distance from the catheter surface to the measurement point in centimeters, 0.075 cm in this case. It should be noted that because of the complex acoustic properties of living tissue, the estimated in situ intensity may not be the same as the actual in situ intensity, and therefore, it should not be interpreted as such.

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: OptiCross™ X 40 MHz Coronary Imaging Catheter
 Operating Mode: B
 System Model: iLab™ Ultrasound Imaging System with MDU5 PLUS™
 Application(s): Fetal Imaging & Other

Note: The US FDA guidance document “Information for Manufacturers Seeking Market Clearance of Diagnostic Ultrasound Systems and Transducers” dated September 9, 2008 classifies intravascular ultrasound within the application(s) “Fetal Imaging & Other” to determine the maximum allowable acoustic output energy. **The catheter is not intended for fetal imaging.**

ACOUSTIC OUTPUT		MI	I _{SPTA,3} (mW/cm ²)	I _{SPPA,3} (W/cm ²)	
Global Maximum Value		0.302	5.89	100.01	
Associated Acoustic Parameters	p _{r,3} (MPa)	1.37			
	W ₀ (mW)		.026	.026	
	f _c (MHz)	40.30	40.30	40.30	
	z _{sp} (cm)	0.075		0.075	
	Beam Dimensions	x-6 (cm)			0.039
		y-6 (cm)			0.040
	PD (μsec)	0.054		0.054	
	PRF (Hz)	7680		7680	
	EDS	Az. (cm)		0.259	
Elev. (cm)			0.053		
Operating Control Conditions	No operator controls affecting acoustic output				

All intensities and total power have uncertainty of +28.7% to -23.4%.
 All pressure values have uncertainty of +14.3% to -11.7%.
 All center frequency values have uncertainty of +7.78% to -7.78%.

TERMINOLOGY		
Term	Definition	Units
MI	Mechanical Index, defined as $MI = p_{r,3}/(f_c^{1/2})$	n/a
I_{SPTA,3}	Derated Intensity, Spatial Peak Temporal Average	mW/cm ²
I_{SPPA,3}	Derated Intensity, Spatial Peak Pulse Average	W/cm ²
p_{r,3}	Derated Peak Negative Pressure at a location of the maximum derated pulse intensity integral	MPa
W₀	Total Power	mW
f_c	Center frequency	MHz
z_{sp}	Distance in the z axis direction where the measurements were taken	cm
x-6 and y-6	-6 dB dimensions for In Plane (azimuth) and Out of Plane (elevation) at the x-y plane where z _{sp} is obtained	cm
PD	Pulse duration	μs
PRF	Pulse repetition frequency	Hz
EDS	Entrance dimensions of scanning for azimuth and elevation to a plane	cm

Note: Since the iLab System are identical with respect to the ultrasound generator, the acoustic output values provided above also apply to the iLab System with MDU5 PLUS.

ACOUSTIC OUTPUT – COMPLIANCE TO IEC 60601-2-37

Prudent-Use Statement

It is the responsibility of the system operator to understand the risk of the acoustic outputs generated by the Imaging System and its associated imaging catheters. It is also the operator’s responsibility to act appropriately to mitigate such risks. To that end, Boston Scientific Corporation has reported Mechanical and/or Thermal Indices that may exceed the requirements of IEC 60601-2-37.

Please note that the Mechanical Index (MI) displayed on the system’s screen has not been corrected for finite amplitude effects.

Imaging Catheter Information

Acoustic Power Output varies between different models of imaging catheters. Each imaging catheter supplied by Boston Scientific Corporation is supplied with Directions for Use (DFUs) that include statements and tables specifying their acoustic power outputs.

IEC requirements for measurements and definition of terms may be found in IEC 60601-2-37 – “Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.”

Where Mechanical and/or Thermal Indices are reported, the MI/TI is displayed on the lower right of the IVUS image next to the imaging catheter identification.

ACOUSTIC OUTPUT REPORTING TABLE (In accordance with IEC 60601-2-37)			
Index Label		MI	TIS-Scan
Maximum index value		0.302	0.005
Associated Acoustic Parameters	p _{r,α} (MPa)	1.37	
	P (mW)		0.026
	min. of [P _α (z _s), I _{1α,α} (z _s)] (mW)		
	z _s (cm)		
	z _{bd} (cm)		
	z _b (cm)		
	z at max. I _{pi,α} (cm)	0.075	
	d _{eq} (z _b) (cm)		
	f _{awf} (MHz)	40.30	40.30
	Dim of A _{sprt}	X (cm) Y (cm)	0.055 0.057
Other Information	t _d (μsec)	0.054	
	prr (Hz)	7680	
	p _r at max. I _{pi} (MPa)	1.53	
	d _{eq} at max. I _{pi} (cm)		
	I _{pa,3'} at max. MI (W/cm ²)	100.01	
Operating control conditions	There are no user controls that affect the catheter values provided in this table.		

All intensities and total power have uncertainty of +28.7% to -23.4%.
 All pressure values have uncertainty of +14.3% to -11.7%.
 All center frequency values have uncertainty of +7.78% to -7.78%.

TERMINOLOGY		
Term	Definition	Units
MI	Mechanical Index, defined as $MI = \frac{p_{r,cz} f_{awf}^{-1/2}}{C_{MI}}$	n/a
C_{MI}	1 MPa MHz ^{-1/2}	n/a
$p_{r,cz}$	Attenuated peak-rarefactional acoustic pressure	MPa
f_{awf}	Acoustic working frequency	MHz
P	Output power	mW
TIS-Scan	Soft tissue thermal index	n/a
z	Distance from the source to a specified point	cm
A_{aprt}	-12 dB output beam area	cm ²
t_d	Pulse duration	μs
prr	Pulse repetition rate	Hz
p_r	Peak-rarefactional acoustic pressure	MPa
$I_{pa,cz}$	Attenuated pulse-average intensity	W/cm ²
I_{pi}	Pulse-intensity integral	J/m ²
$I_{pi,cz}$	Attenuated pulse-intensity integral	J/m ²

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

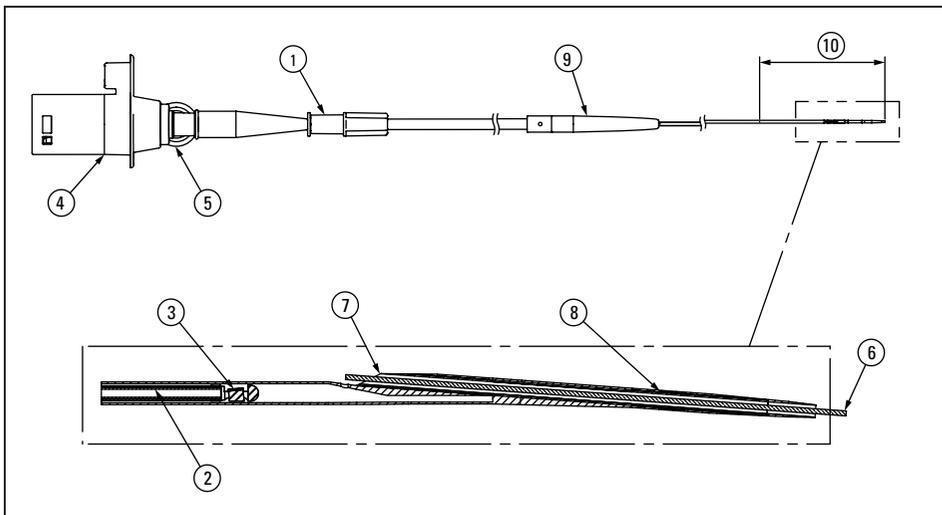


Figure 1. OptiCross™ X 40 MHz Coronary Imaging Catheter

1. Telescoping Shaft
2. Imaging Core
3. Transducer
4. Proximal Hub
5. Flush Port & Check Valve
6. Guidewire
7. Guidewire Exit Port
8. Radiopaque Marker
9. Distal Strain Relief
10. Hydrophilic Coating: 230 mm minimum

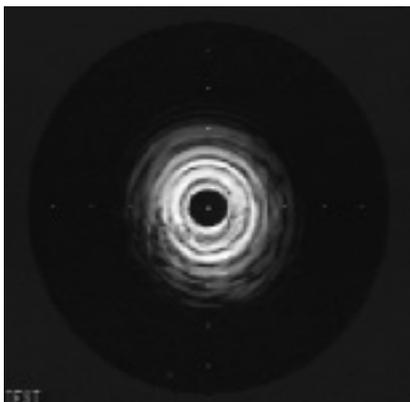


Figure 2. Normal test image

MDU5 PLUS™ Sterile Bag

Sterile Bag for MDU5 PLUS Motordrive Unit

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Carefully read all instructions prior to use. Observe all contraindications, adverse events, warnings, and precautions noted in these directions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

DEVICE DESCRIPTION

This device provides an efficient, conformal covering to fit the MDU5 PLUS motordrive.

Contents

MDU5 PLUS Sterile Bag (referred to as “bag”)

INTENDED USE/INDICATIONS FOR USE

The MDU5 PLUS Sterile Bag is intended to cover the motordrive during intravascular ultrasound procedures to maintain the sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker.

CONTRAINDICATIONS

None known.

WARNINGS

None known.

ADVERSE EVENTS

None known.

PRECAUTIONS

None known.

HOW SUPPLIED

Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

DIRECTIONS FOR USE

A. Inspection Prior to Use

Before use, inspect the packaging for any violation of the sterile barrier and inspect the bag for any damage or defects. Do not use potentially contaminated or defective equipment. If the sterile barrier integrity is compromised or the contents damaged, contact your Boston Scientific representative.

Prior to use, verify product is within labeled shelf life. Do not use product if the ‘Use By’ date has been exceeded. Dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

B. Covering the MDU5 PLUS

Covering the MDU5 PLUS requires two people – one inside and one outside the sterile field. Using appropriate sterile technique:

1. The non-sterile operator opens the pouch containing the bag.
2. The sterile operator removes the bag from the pouch.
3. The sterile operator unfolds the bag so the “Insert Here” sticker is on one end and the faceplate is on the opposite end.
4. The sterile operator places their hands into the innermost folds of the bag, opening the bag for MDU5 PLUS placement by the non-sterile operator. The “Insert Here” sticker can be used to easily locate the bag opening (Figure 3).

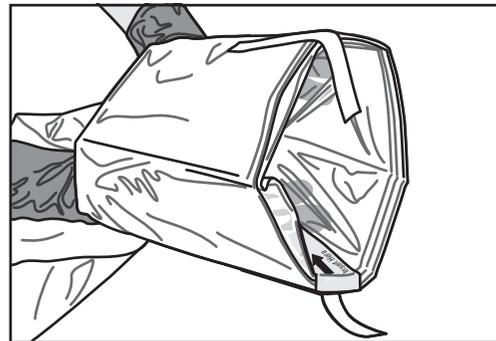


Figure 3. Opening the Bag

5. The non-sterile operator then places the MDU5 PLUS into the opening, positioning the MDU5 PLUS so that the top of the unit is aligned with the “This Side Up” sticker on the bag (Figure 4).

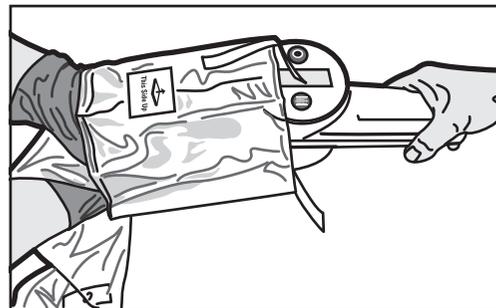


Figure 4. Inserting the MDU5 PLUS

6. The sterile operator then grasps the covered MDU5 PLUS. The non-sterile operator grips and pulls the tabs until the bag is unfolded to its full length (Figure 5).

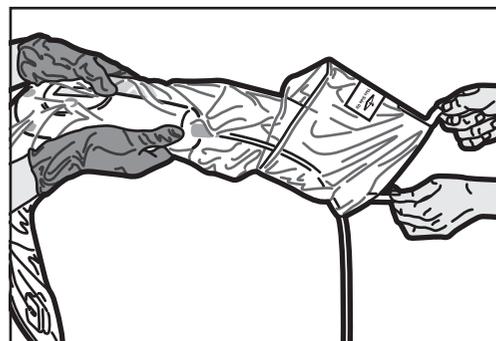


Figure 5. Unfolding the Bag

7. To position the bag, stop advancing the MDU5 PLUS into the bag as soon as a snug fit is obtained. The sterile operator does not need to advance the MDU5 PLUS all the way to the bag’s faceplate. It is normal to have space between the nose of the MDU5 PLUS and the faceplate on the bag (Figure 6).

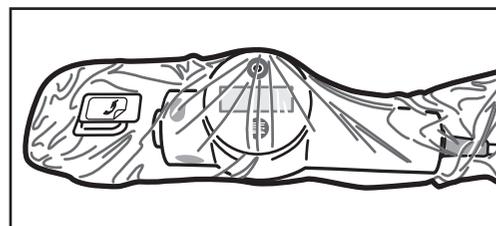


Figure 6. Positioned Bag

8. To attach the bag to the MDU5 PLUS, the sterile operator should align the bag’s faceplate with the nose of the MDU5 PLUS (Figure 7), and gently push to secure the connection. Do not trap material between the faceplate and the nose. Extra bag material around and beyond the connection is normal (Figure 8).

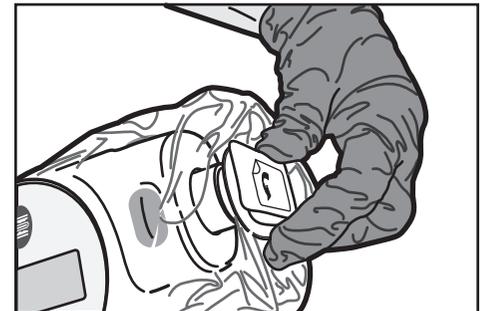


Figure 7. Attaching the Faceplate

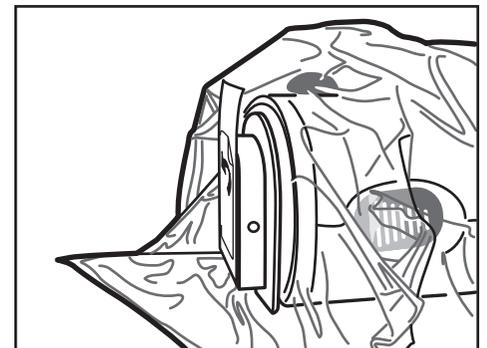


Figure 8. Attached Faceplate

9. When ready to insert the MDU5 PLUS compatible catheter, remove the sticker from the faceplate and discard appropriately (Figure 9).



Figure 9. Removing Sticker

10. The bagged MDU5 PLUS is now ready for use.

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