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# Ultra ICE™ Plus - PI

**9 MHz**

## Peripheral Imaging Catheter

### Rx ONLY

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

Carefully read all instructions prior to use. Observe all contraindications, 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.

### 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.

### DEVICE DESCRIPTION

The Ultra ICE Plus - PI Catheter is an 8.5F (2.82 mm) diameter and 9 MHz frequency peripheral intravascular imaging catheter which is 110 cm in length. The catheter is supplied fully assembled.

The Ultra ICE Plus - PI Catheter is constructed with an inner core and proximal connector. The catheter has a distal imaging window and an inserted rotatable imaging core with a distal ultrasound transducer.

The 8.5F (2.82 mm) / 9 MHz Ultra ICE Plus - PI Catheter can be used with iLab™ Ultrasound Imaging Systems.

Ultra ICE Plus - PI relies on the rotational fidelity of the internal transducer and driveshaft assembly to accurately coincide with the position sensing electronics located in the Motordrive Unit (MDU5 PLUS™). This arrangement is necessary in order to reduce the overall diameter of the catheter and to ensure that image information is displayed correctly on the screen. Although the transducer and driveshaft assembly is relatively rugged, its performance depends on free rotation of the shaft within the catheter body. Pinching, crushing and extremely sharp bends are to be avoided during use and handling.

Although the catheter body will adequately protect and guide the internal rotating assembly, care should be taken so that the catheter body is not abraded, cut, or used to pull the motor assembly into position. The catheter body is formed at its distal tip so that the ultrasound energy is efficiently emitted and received. Design and functional constraints require that the distal tip be less strong, rendering it more susceptible to crushing and bending than the proximal portions. For this reason, it is strongly recommended that the tip be carefully inspected visually prior to use and after removal.

### Contents

- Ultra ICE Plus - PI 9 MHz Peripheral Imaging Catheter
- MDU5 PLUS Sterile Bag
- 26 gauge needle
- 10 ml (10 cc) syringe

### INTENDED USE/INDICATIONS FOR USE

The Ultra ICE Plus - PI 9 MHz peripheral imaging catheter is indicated for patients with vascular occlusive disease for which angioplasty, atherectomy, the placement of stents, or other intervention is contemplated.

### CONTRAINDICATIONS

This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization.

This device is not to be used in the coronary arteries.

This device is not intended for fetal use.

### 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
- Device Entrapment requiring surgical intervention
- Embolism (air, foreign body, tissue or thrombus)
- Hemorrhage/Hematoma
- Hepatic dysfunction
- Hypotension and/or Bradycardia (Transient Hemodynamic Instability)
- Infection/Sepsis
- Peripheral Ischemia
- Renal insufficiency/failure
- Stroke/Cerebrovascular Attack and Transient Ischemic Attack
- Thrombosis/thrombus
- Vasospasm
- Vessel Occlusion
- Vessel trauma (including perforation, trauma, rupture, dissection and pseudoaneurysm)

### WARNINGS

- 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.
- If resistance is met upon withdrawal of the catheter, verify resistance using fluoroscopy, then remove the entire system simultaneously.
- When utilizing a steerable guide sheath, it is not recommended to articulate the sheath tip beyond 55 degrees. Over articulation may result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result.
- Utilizing a fixed curve guide sheath with an angle greater than 55 degrees is not recommended. This could result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result.
- A guide sheath with an inner diameter less than 2.84 mm must never be utilized. Utilization of such a guide sheath could cause separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result.
- When utilizing the catheter, it is not recommended to place the transducer assembly within the curve of the guide sheath while imaging. This could result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result.
- No modification of this equipment is allowed.

### PRECAUTIONS

- Contents supplied STERILE using a e-beam 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.
- This device should be used by physicians thoroughly trained in the techniques of vascular interventions and in the specific approach to be used.
- After the procedure, inspect the catheter carefully for any damage which may have occurred during use.
- The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. Do not attempt to connect the catheter to electronic equipment other than the designated systems.
- Never attempt to attach or detach the catheter while the motor is running. To do so may damage the connector.
- Turn the MDU5 PLUS "OFF" before withdrawing the catheter, or when advancing the catheter in the body.
- Avoid any sharp bends, pinching or crushing of the catheter.
- **Do not kink or sharply bend the catheter at any time.** This can cause drive cable failure. An insertion angle greater than 45° is considered excessive.
- Prior to utilizing the catheter, verify there are not kinks in either the catheter or guide sheath. Utilization of a kinked catheter and/or guide sheath could compromise the functionality of the catheter, leading to device failure.

### 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

#### A. Inspection Prior to Use

The Ultra ICE Plus - PI Catheter is supplied sterile in a sealed package. Carefully inspect the package for any breach of the sterile seal and for any damage to the catheter. Also, the tip of the catheter should be carefully inspected visually prior to use and after removal.

#### B. Preparation for Use

1. Fill the supplied syringe with sterile water. **DO NOT USE SALINE.**
2. Insert the supplied needle (26 gauge, non-coring) or Fluid Dock™ into the tip of the catheter. The needle or Fluid Dock should be inserted through the center of the self-sealing septum (the white seal at the distal tip of the catheter). If using the supplied needle, keep the needle or Fluid Dock aligned with the catheter, taking care to avoid puncturing the sonolucent window with the needle. Insert the needle only enough so that the tip clears the septum and becomes visible on the other side of the septum (See Figure 1). **DO NOT TOUCH THE TRANSDUCER WITH THE NEEDLE.**

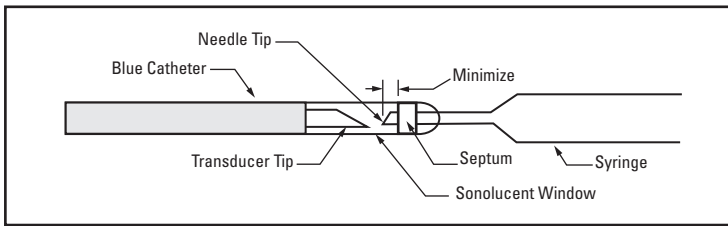


Figure 1.

- With the catheter tip pointed down, and holding the proximal hub much higher, using a full 10 cm<sup>3</sup> (10 cc) luer lock syringe or Fluid Dock™, inject **sterile water** into the catheter until water is expelled from the flush port. Continue injecting at a minimum 3 more cm<sup>3</sup> (cc) after water is expelled.

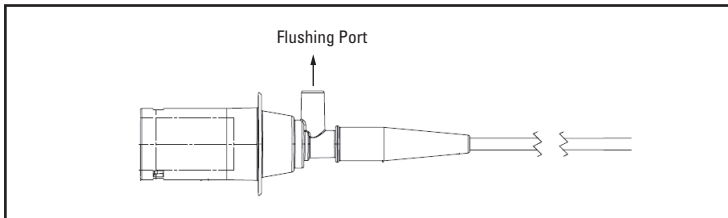


Figure 2.

- Remove the needle or the Fluid Dock, hold the catheter with the distal tip pointed down about 10 cm / 20 cm from the tip and flick the end of the catheter vigorously. Continue to move your fingers 10 cm closer to hub and repeat the motion until you reach the end of the catheter. This should free air bubbles from adhering to the catheter shaft and displace air bubbles proximally, away from the tip.
- Hold the catheter about 30 cm / 50 cm from the tip and vigorously swirl the distal catheter section around. This should force the water column to the tip and displace air bubbles proximally, away from the tip.
- Examine the distal tip and acoustic window area, if persistent bubbles remain visible, repeat steps 4 and 5 above. **DO NOT PROCEED IF DAMAGE IS OBSERVED.**
- Connect the 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.

**NEVER ATTEMPT TO ATTACH OR DETACH THE CATHETER WHILE THE MOTOR IS RUNNING. TO DO SO MAY DAMAGE THE CONNECTOR.**

**OBSERVE THE POSITION OF THE MDU5 PLUS AND CATHETER DURING THE PROCEDURE. AVOID BENDING THE CATHETER NEAR THE MDU5 PLUS.**

**DO NOT PULL THE MDU5 PLUS BY THE CATHETER. THERE IS A RISK OF DAMAGE IF THE CATHETER IS USED TO PULL THE MDU5 PLUS.**

**IF THE MDU5 PLUS IS PLACED BETWEEN THE PATIENT'S LEGS, KEEP THE NOSE OF THE MDU5 PLUS TILTED UPWARDS TO PREVENT THE PROXIMAL PART OF THE CATHETER FROM KINKING.**

**HOWEVER, IT IS RECOMMENDED TO ELEVATE THE MDU5 PLUS WITH RESPECT TO THE CATHETER TIP IN ORDER TO ENSURE TIP FILL.**

### C. Catheter Placement

- The Ultra ICE™ Plus - PI Catheter is introduced through a standard 9F (3 mm) / 10F (3.3 mm) venous or arterial access system. The catheter is then advanced under fluoroscopy to the desired position and imaging may commence.
- The directionality of the catheter tip may be enhanced by using a pre-curved long sheath, or guiding catheter.

**Note: Imaging through a long sheath or guiding catheter may compromise image depth and may affect measurement accuracy.**

**DO NOT** use excessive force to pass the ultrasound catheter through introducers or other ancillary equipment. The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis. **DO NOT** advance the catheter if resistance is encountered.

- Once the catheter is in the desired position, begin imaging. When imaging is complete, first shut off the motor and then withdraw the catheter.
- Inspect the catheter for any damage that may have occurred during use.
- To detach the hub of the catheter from the MDU5 PLUS, press the blue button on the MDU5 PLUS and pull the connector out of the MDU5 PLUS.

### 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 ultrasound 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, 0.47 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:	9 MHz 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 <sup>2</sup> )	$I_{SPPA,3}$ (W/cm <sup>2</sup> )
<b>Global Maximum Value</b>			0.695	8.49	133.44
<b>Associated Acoustic Parameters</b>	$p_{r,3}$	(MPa)	1.831		
	$W_0$	(mW)		2.068	2.068
	$f_c$	(MHz)	9.40	9.40	9.40
	$z_{sp}$	(cm)	0.468		0.468
	Beam Dimensions	x-6 (cm)			0.1146
		y-6 (cm)			0.1056
	PD	(µsec)	0.195		0.195
	PRF	(Hz)	7680		7680
	EDS	Az. (cm)			0.843
		Elev. (cm)			0.196
<b>Operating Control Conditions</b>	No operator controls affecting acoustic output				

All intensities and total power have uncertainty of +17.32% to -15.49%.  
All pressure values have uncertainty of +8.66% to -7.74%.  
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 <sup>2</sup>
$I_{SPPA,3}$	Derated Intensity, Spatial Peak Pulse Average	W/cm <sup>2</sup>
$p_{r,3}$	Derated Peak Negative Pressure at a location of the maximum derated pulse intensity integral	MPa
$W_0$	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

**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 their 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 ultrasound image next to the imaging catheter identification.

ACOUSTIC OUTPUT REPORTING TABLE (In accordance with IEC 60601-2-37)				
Index Label			MI	TIS-Scan
<b>Maximum index value</b>			0.695	0.089
<b>Associated Acoustic Parameters</b>	$p_{r,\alpha}$	(MPa)	1.831	
	P	(mW)		2.068
	min. of $[P_{\alpha}(z_2), I_{ta,\alpha}(z_3)]$	(mW)		
	$z_s$	(cm)		
	$z_{bp}$	(cm)		
	$z_b$	(cm)		
	z at max. $I_{pi,\alpha}$	(cm)	0.468	
	$d_{eq}(z_b)$	(cm)		
	$f_{awf}$	(MHz)	9.40	9.40
	Dim of $A_{aprt}$	X (cm)		0.193
	Y (cm)		0.190	
<b>Other Information</b>	$t_d$	(µsec)	0.195	
	prr	(Hz)	7680	
	$p_r$ at max. $I_{pi}$	(MPa)	2.131	
	$d_{eq}$ at max. $I_{pi}$	(cm)		
	$I_{pa,3}$ at max. MI	(W/cm <sup>2</sup> )	133.44	
<b>Operating control conditions</b>	There are no user controls that affect the catheter values provided in this table.			

All intensities and total power have uncertainty of +17.32% to -15.49%.  
 All pressure values have uncertainty of +8.66% to -7.74%.  
 All center frequencies have uncertainty of +7.78% to -7.78%.

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

**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.**

# 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).

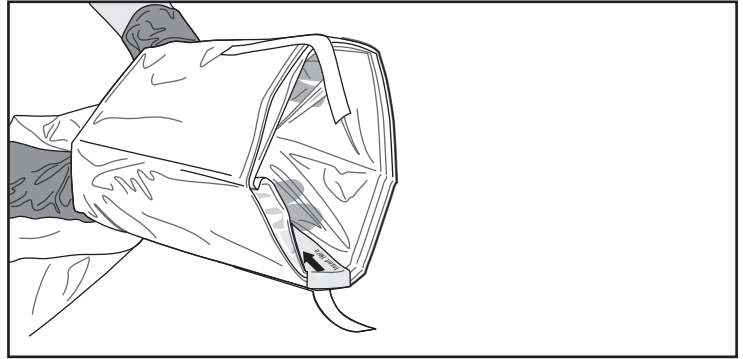


Figure 3. Opening the Bag

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).

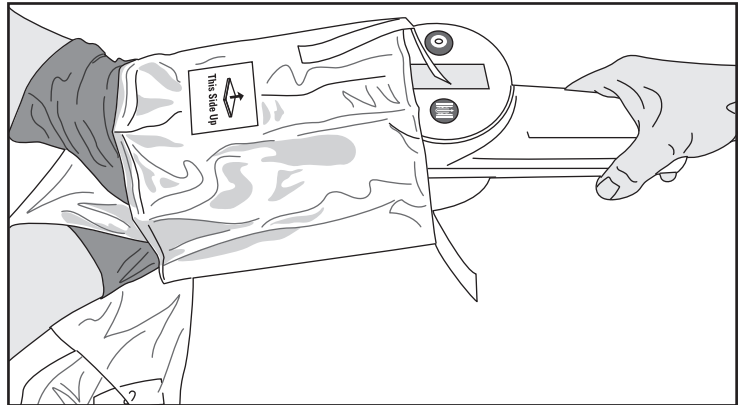


Figure 4. Inserting the MDU5 PLUS

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).

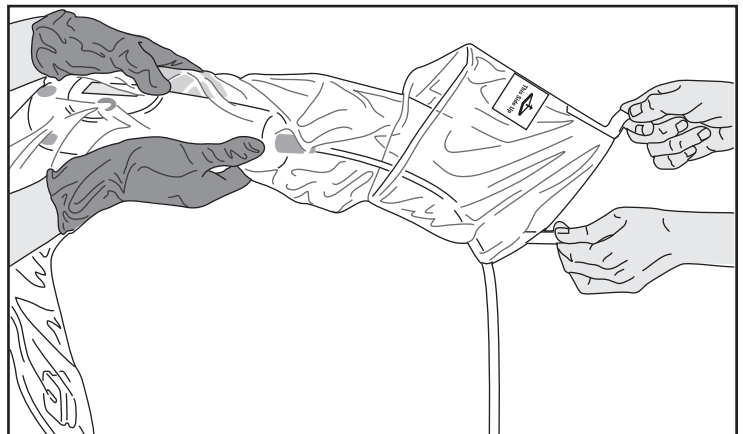


Figure 5. Unfolding the Bag

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).

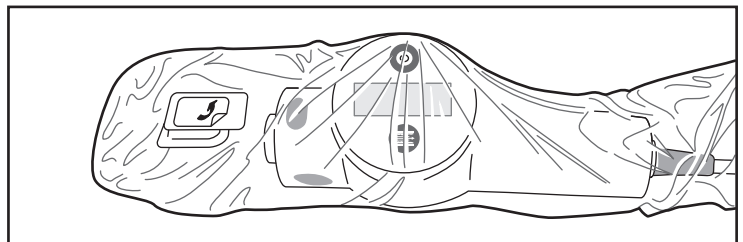


Figure 6. Positioned Bag

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).

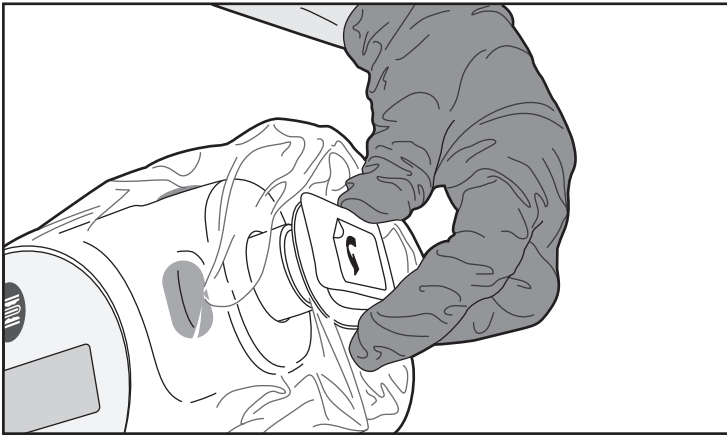


Figure 7. Attaching the Faceplate

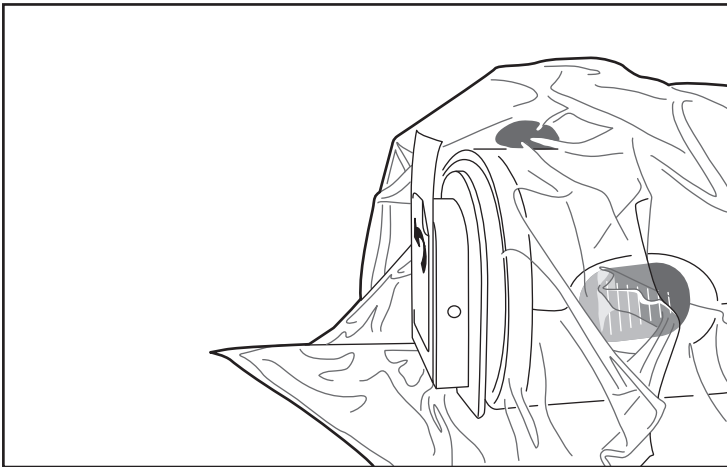


Figure 8. Attached Faceplate

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

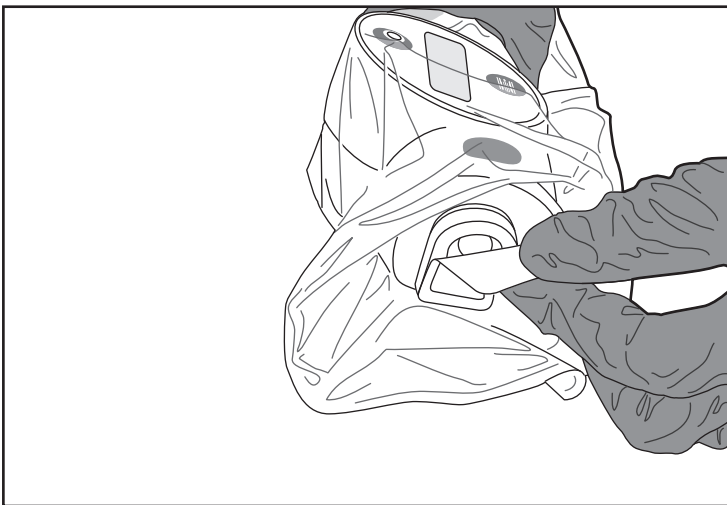


Figure 9. Removing Sticker

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

#### 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.**

**EC REP** **EU Authorized Representative**

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