

**Lead Delivery System Accessory Kit, IS-1
(CRM Model 7611)
Information for Users**

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

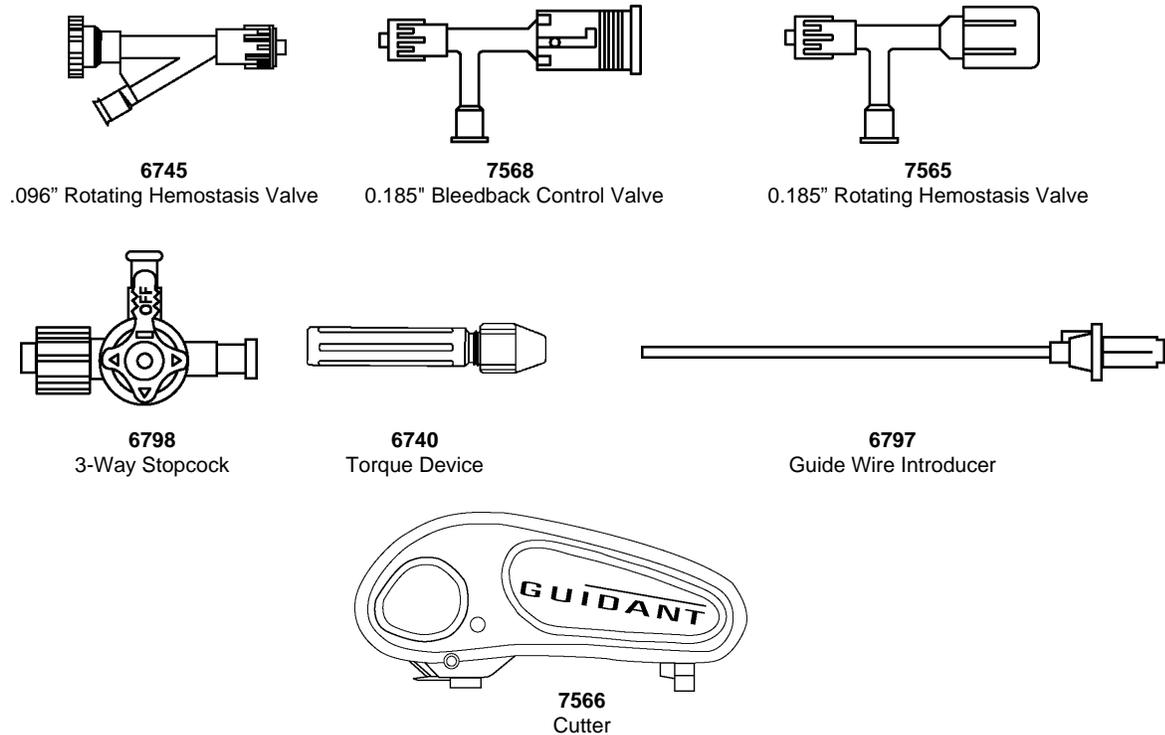
CAUTION: Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.

HOW SUPPLIED

STERILE. Sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or damaged.

CONTENTS. One (1) 0.185" Bleedback Control Valve (7568), One (1) 0.185" Rotating Hemostasis Valve (7565); One (1) .096" Rotating Hemostasis Valve (6745); One (1) Cutter (7566), One (1) Guide Wire Introducer (6797); One (1) Torque Device (6740); Two (2) 3-Way Stopcocks (6798).

Figure 1.0



STORAGE. Store in a dry, dark, cool place.

INDICATIONS

The Guidant Bleedback Control Valve (7568) is intended for maintaining a seal around diagnostic / interventional devices, with an outside diameter of less than 0.185" in the venous anatomy only, during interventional procedures.

The Guidant 0.185" Rotating Hemostasis Valve (7565) is intended for maintaining a fluid-tight seal around devices, including implantable coronary venous leads, during the implant procedure.

The Guidant .096" Rotating Hemostasis Valve (6745) is recommended for maintaining a fluid-tight seal around a dilatation catheter during percutaneous transluminal angioplasty.

The Guidant Cutter (7566) is intended to facilitate RAPIDO® Cut-Away® or RAPIDO® ADVANCE™ Guiding Catheter removal after the Guidant coronary venous lead is positioned.

The Guidant Guide Wire Introducer (6797) is recommended for use during vascular procedures in conjunction with interventional and / or diagnostic devices (e.g. balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to assist with the introduction of the guide wire.

The Guidant Torque Device (6740) is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g. balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to facilitate steering of the guide wire within the vascular anatomy.

The Guidant 3-way Stopcock (6798) is designed to provide control of fluid direction and shut off.

INTENDED USE

The Guidant 0.185" Bleedback Control Valve, 0.185" Rotating Hemostasis Valve, and Guidant Cutter are only intended to be used with the Guidant RAPIDO® Cut-Away® and RAPIDO® ADVANCE™ Guiding Catheters.

CONTRAINDICATIONS

The Guidant Bleedback Control Valve is not intended for use with pressure injections of greater than 30 psi.

WARNINGS

These devices are distributed STERILE, NON-PYROGENIC and are intended for one-time use only. Do NOT resterilize and / or reuse them, as this can potentially result in compromised device performance and risk of inappropriate sterilization and cross-contamination.

PRECAUTIONS

Prior to use each component in the kit should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

INSTRUCTIONS FOR USE**0.185" Bleedback Control Valve (BBCV) 7568**

1. Attach the BBCV to the guiding catheter proximal hub. Attach the stopcock to the side arm of the hemostasis valve, with the stopcock closed.
2. Attach a 10 –12 cc luer lock syringe filled with sterile heparinized normal saline to the stopcock.
3. Open the BBCV control valve by pushing on the cap and rotating it clockwise to the locked open position.
4. Place finger over the distal guiding catheter tip, and flush until fluid fills and exits the BBCV cap.
5. Rotate the cap counterclockwise to unlock and return the valve to a closed position.
6. Remove finger from the distal guiding catheter tip and continue to flush until fluid exits the distal tip of the guiding catheter.
7. Turn the stopcock lever to a closed position.
8. Slightly compress the cap when introducing a device. Release the cap to its normal position to maintain hemostasis while advancing a device.
9. To disconnect the BBCV from the guiding catheter, open the BBCV valve by pushing on the cap and rotating it clockwise to the locked open position.
10. Secure the guiding catheter hub in one hand. Loosen the rotating luer connection with the other hand by rotating it counterclockwise until it is freed from the guiding catheter hub.
11. Maintain the lead position at all times; slide the BBCV carefully over the proximal end of the lead.

0.185" Rotating Hemostasis Valve (RHV) 7565

1. Attach the RHV to the guiding catheter proximal hub. Attach the stopcock to the side arm of the hemostasis valve, with the stopcock closed.
2. Attach a 10 –12 cc luer lock syringe filled with sterile heparinized normal saline to the stopcock.
3. Open the RHV by rotating the cap in a counterclockwise direction.
4. Place finger over the distal guiding catheter tip, and flush until fluid fills and exits the RHV cap.
5. Rotate the cap clockwise to a closed position.
6. Remove finger from the distal guiding catheter tip, and continue to flush until fluid exits the distal tip of the guiding catheter.
7. Turn the stopcock lever to a closed position.
8. Rotate the cap counterclockwise to introduce and advance a device.
9. Once a device is in position, close the RHV by rotating the cap clockwise. Only tighten enough to maintain hemostasis.
10. To disconnect the RHV open the RHV by rotating the cap counterclockwise.
11. Secure the guiding catheter in one hand. Loosen the rotating luer connection with the other hand by rotating it counterclockwise until it is freed from the guiding catheter hub.
12. Maintaining the lead position at all times, slide the RHV carefully over the proximal end of the lead and finishing wire assembly.

.096" Rotating Hemostasis Valve (RHV) 6745

1. If using a dual-catheter RAPIDO™ 6F assembly, insert the RAPIDO™ 6F guiding catheter into the 8F guiding catheter
2. If desired, place the .096" RHV on the 6F inner catheter. Flush the guiding catheter assembly.

Note: If using a dual-catheter assembly, remove the 6F inner catheter prior to inserting any device larger than 0.063" (1.6 mm).

3. Insert the desired device into the guiding catheter through the .096" RHV according to the manufacturer's instructions.
4. Remove the guiding catheter, disconnect the hemostasis valve from the catheter if applicable. Remove the guiding catheter.

Torque Device 6740

1. Loosen the cap of the Torque Device.
2. Insert the proximal end of the guide wire into the funnel-shaped hole on the distal end of the Torque Device cap. Once positioned at the desired location, tighten the cap to secure the Torque Device to the guide wire.
3. Rotate the Torque Device to steer the guide wire to the desired position.
4. To move the Torque Device to a new position, loosen the cap, slide the device along the guide wire to the desired position, and tighten the cap.

Guide Wire Introducer 6797

1. Insert the Guide Wire Introducer, shaft-end first, into the proximal opening of the hemostasis valve that is attached to the end of the guiding catheter or sheath. Advance the Guide Wire Introducer until its tip is distal to the seal in the hemostasis valve.
2. Adjust the cap on the hemostasis valve to seal around the Guide Wire Introducer in order to minimize fluid loss.
3. Carefully insert the distal tip of the guide wire through the Guide Wire Introducer and into the guiding catheter or sheath.
4. After the guide wire has been positioned at the desired location, the Guide Wire Introducer may be removed.

3-Way Stopcock 6798

Attach the stopcock to the desired device. Align the 'OFF' handle with the port that is to be shut off or closed. The other two ports will be open to each other.

Cutter 7566

Reference instructions supplied with the RAPIDO® Cut-Away® or RAPIDO® ADVANCE™ Guiding Catheter Systems regarding the use of this accessory.

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Graphical Symbols For Medical Device Labeling

	
Manufacturer	Sterilized using Ethylene Oxide
REF	
Catalogue Number	Date of Manufacture
F	
French Size	Use By
	
Consult Instructions for Use	Batch Code
	
Contents (Numeral represents quantity of units inside.)	
	
Do Not Reuse	