

**Lead Delivery System Accessory Kit, LV-1
(CRM Model 7610)**

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

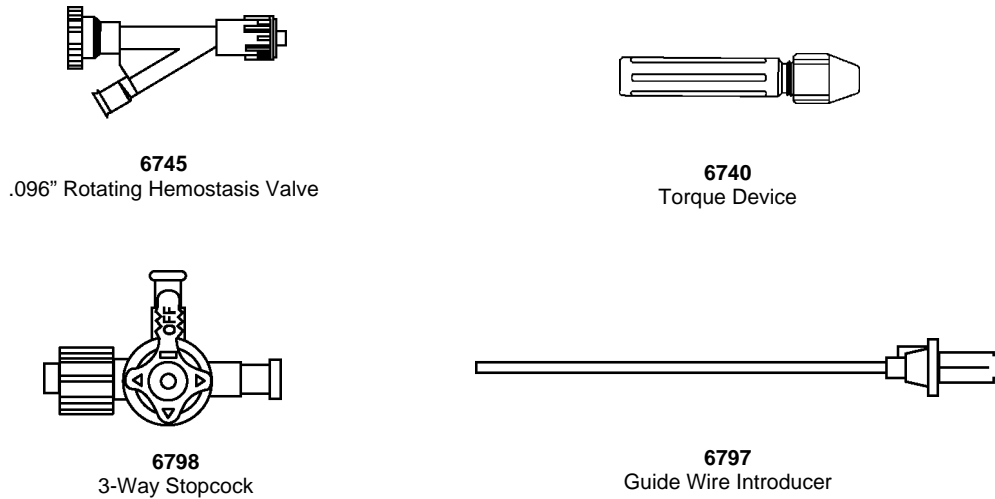
CAUTION: Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.

HOW SUPPLIED

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

CONTENTS. Two (2) .096" Rotating Hemostasis Valves (6745); 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 .096" Rotating Hemostasis Valve (6745) is recommended for maintaining a fluid-tight seal around a dilatation catheter during percutaneous transluminal angioplasty.

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.

CONTRAINDICATIONS

There are no known contraindications for these devices.

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

.096" Rotating Hemostasis Valve (RHV) 6745

If using a dual-catheter RAPIDO™ 6F assembly, insert the RAPIDO™ 6F guiding catheter into the 8F guiding catheter

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).

Insert the desired device into the guiding catheter through the .096" RHV according to the manufacturer's instructions.

To remove the guiding catheter, disconnect the hemostasis valve from the catheter if applicable. Remove the guiding catheter.

Torque Device 6740

Loosen the cap of the Torque Device.

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.

Rotate the Torque Device to steer the guide wire to the desired position.

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

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.

Adjust the cap on the hemostasis valve to seal around the Guide Wire Introducer in order to minimize fluid loss.

Carefully insert the distal tip of the guide wire through the Guide Wire Introducer and into the guiding catheter or sheath.

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.

Guidant Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

24-Hour Consultation
1-800-CARDIAC (1-800-227-3422)
Worldwide: 651-582-4000
www.guidant.com

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**Graphical Symbols For
Medical Device Labeling**

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