LIFEMED®
The Essentials™ Kit

• Avenue™ Insertion Tool
• GateWay™ PLUS Y-Adapter
• TD2™ Torque Device

INSTRUCTIONS FOR USE

Indications & Description:
The Essentials™ Kit is intended for general intravascular procedures and is made up of the Avenue™ Insertion Tool, the GateWay™ PLUS Y-Adapter, and the TD2™ Torque Device. These individual devices may also be sold separately. This Instructions for Use applies to the Essentials Kit as well as the Avenue Insertion Tool and TD2 Torque Device.

This is a sterile, single-use product and is not designed for re-sterilisation. Do not reuse, reprocess or re-sterilise.

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

Contraindications:
None known

AVENUE INSERTION TOOL

Description:
The Avenue Insertion Tool is a guide wire insertion tool with a plastic hub tapering down to the inside of a longer stainless steel tube.

Indications:
The Avenue Insertion Tool is used to facilitate the introduction of a guide wire during general intravascular procedures.

Operational Instructions:
1. Carefully remove the plastic protective tubing from the stainless steel tubing which is at the distal end of the Avenue Insertion Tool.
2. Examine the stainless steel tube to ensure that it is not kinked or bent.

NOTE: The following three (3) steps should be executed in rapid succession to minimize backbleeding if the distal end of the catheter is being used in the vasculature.
3. Carefully open the Y-Adapter hemostatic valve on the proximal end of the guiding catheter or the balloon dilatation catheter manifold.
4. Insert the Avenue™ Insertion Tool’s stainless steel tube through the hemostatic valve of the Y-Adapter until a slight resistance is felt as the stainless steel tube seats against the interior of the PTCA catheter manifold or against the interior of the Y-Adapter attached to the guiding catheter.
5. Carefully close the hemostatic valve of the catheter onto the stainless steel tube of the Avenue Insertion Tool.
6. Insert the distal end of the guide wire into the hub of the Avenue Insertion Tool and advance until the guide wire is well within the catheter.
7. Loosen the hemostatic valve on the catheter and slide the Avenue Insertion Tool proximally, holding the guide wire in position, until the Avenue Insertion Tool is out of the catheter manifold.
8. Retighten the hemostatic valve of the Y-Adapter attached to the guiding catheter onto the guide wire to prevent backbleeding.
9. Remove the Avenue Insertion Tool off the proximal end of the guide wire.
GATEWAY™ PLUS Y-ADAPTER

Description:
The GateWay PLUS Y-Adapter employs a Tuohy-Borst type valve to provide hemostasis during general intravascular procedures. The GateWay PLUS Y-Adapter consists of a straight lumen with an inside diameter of 0.118 in.(3 mm). An adjoining curved lumen is used for pressure monitoring and manual infusion. The curved sideport terminates with a standard female luer fitting. A rotating male luer terminates the distal end of the straight lumen.

Indications:
The GateWay PLUS Y-Adapter is recommended for providing hemostasis around balloon dilatation catheters, guide wires, and other therapeutic devices during general intravascular procedures.

Precautions:
- Prior to angioplasty, all equipment to be used for the procedure, including the dilatation catheter, should be carefully examined to verify proper function.
- This device should be used only by physicians thoroughly trained in angioplasty procedures.
- Before use of this device, administer appropriate anticoagulant.
- Do not overtighten the adjustable valve. Excessive tightening may inhibit the ability to manipulate the balloon dilatation catheter, guide wire or other therapeutic device and may also significantly increase dilatation catheter inflation/deflation times.
- Since therapeutic devices are fragile, exercise care during handling to reduce the possibility of accidental breakage.
- If resistance is felt during manipulation, discontinue further movement and determine the cause.
- Ensure that the balloon dilatation catheters are completely deflated before inserting or withdrawing the balloon through the GateWay PLUS Adapter.

Operational Instructions:
1. Attach connective tubing between the fluid manifold and the curved sideport of the GateWay PLUS Y-Adapter. Flush the assembly with normal saline to remove trapped air. To flush the valve segment, open the adjustable valve (counterclockwise rotation), and continue to fill the assembly.
2. Connect the rotating male luer adapter to the proximal end of the guide catheter.
3. Attach the pressure monitor/manual infusion device or manifold to the curved sideport. Aspirate any air that may have entered the system during the connection and flush with normal saline.
4. Open the valve, insert the balloon dilatation catheter, guide wire, or other therapeutic device through the valve and advance to an appropriate distance into the vasculature. Close the valve around the shaft of the device so that the valve forms a liquid-tight seal around the shaft yet does not inhibit device movement.
5. Advance the balloon dilatation catheter, guide wire, or other therapeutic device into the vasculature and perform the interventional procedure according to the manufacturer’s recommendations.
6. Withdraw the balloon dilatation catheter, guide wire, or other therapeutic device to within 25 cm of the proximal end of the guide catheter. Open the adjustable valve then withdraw the dilatation catheter completely.
7. Close the adjustable valve and follow the recommended procedure for performing post dilatation arteriography of the treated vessel.

TD2™ TORQUE DEVICE

Description:
The guide wire TD2 Torque Device employs a plastic body and cap to tighten a metal collett onto the guide wire.

Indications:
The TD2 Torque Device is used for guide wire manipulation during general intravascular procedures.

Precautions:
- Do not over tighten the polymer cap. Excessive tightening may abrade the guide wire coating and make loosening difficult.
- Should the cap be accidentally removed from the TD2 Torque Device, the collett must be seated in the body before the cap can be put on again.

Operational Instructions:
Preset the TD2 Torque Device for use by rotating the yellow body clockwise into the winged cap until snug.
Rotate the body counter-clockwise one full turn before loading the guide wire. Insert the proximal end of the guide wire through the cap on the distal end of the TD2 Torque Device. Move the device to the desired location on the guide wire. Tighten the device onto the guide wire by screwing the cap and body of the TD2 Torque Device together.

**Storage and Use:**

**Storage:** Store in a cool, dry place away from direct sunlight, preferably in original box.

**Shelf Life:** Refer to the Expiry Date printed on each pack label.

Sterile unless package is opened or damaged. If damage is found call your local Bard Australia Pty Ltd representative.

Pack is a single use device. Dispose of all unused components immediately after pack use.

**STERILE EO**

Sterilised by Ethylene Oxide

**MANUFACTURER:**

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