Read this entire booklet before opening inner pack.
INTENDED USE
The intra-aortic balloon catheter and accessories are used to provide counterpulsation therapy in the aorta, whereby balloon inflation during diastole and deflation during systole increases blood supply to the heart muscle and decreases the work of the left ventricle.

PRODUCT STORAGE AND HANDLING REQUIREMENTS
- Keep away from sunlight
- Do not resterilize
- Do Not Reuse
- Do not use if package is damaged

EXPLANATION OF SYMBOLS ON PACKAGE LABELING
- Catalog Number
- Serial Number
- Batch Code
- Date of Manufacture
- Use By
- Sterilized using Ethylene Oxide
- Consult Instructions for Use
- Caution
- Manufacturer

LIMITED WARRANTY
Datascope Corp. warrants that all its IAB catheters are free from defects in workmanship and materials for a period of three years from the date of purchase or until the expiration date is reached or until the date of use, whichever comes first. Datascope Corp. shall not be liable for any incidental, special or consequential loss, damage, or expense directly arising from the use of this product. Liability under this warranty and the buyer’s exclusive remedy is limited to replacement of the product which, under normal use and service, shall have been found by the Company to be defective in materials or workmanship. It shall be the buyer’s obligation to return any such product to the Company for examination for replacement liability.

No agent, employee, or representative of Datascope Corp. has any authority to bind Datascope Corp. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation, or warranty made by any agent, employee or representative shall not be enforceable by the buyer.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER.

Damage to any product or parts through misuse, neglect, accident, or by affixing any nonstandard accessory attachments or by any customer modification voids this warranty. Datascope Corp. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories, which are claimed to be defective, be returned when authorized by Datascope, freight prepaid, to Datascope Corp., 15 Law Drive, Fairfield, New Jersey 07004. Datascope Corp. shall not have any responsibility in the event of loss or damage in transit.
1. INDICATIONS FOR USE
   A. Acute Coronary Syndrome.
   B. Cardiac and non-cardiac surgery.
   C. Complications of heart failure.

2. CONTRAINDICATIONS
   A. Severe aortic insufficiency.
   B. Abdominal or aortic aneurysm.
   C. Severe calcific aorta-iliac disease or peripheral vascular disease.
   D. Introduction of the IAB catheter without the use of an introducer sheath is not recommended in patients with severe obesity, scarring of the skin or other contraindications to percutaneous insertion.

3. SUMMARY OF WARNINGS AND PRECAUTIONS

   A. WARNINGS
   1. If you continue to pump an IAB with a leak, gaseous embolic injury of organs may result or a large blood clot may form within the balloon membrane requiring surgical removal of the IAB catheter.
   2. Do not inflate the IAB using a syringe or any other means if a balloon membrane leak is suspected.
   3. Perforation of a balloon membrane may indicate that the patient's vascular condition may induce abrasion or perforation in subsequent balloon membranes.
   4. The practitioner must be aware of adverse effects associated with percutaneous sheath insertion including bleeding at the insertion site, limb ischemia, infection, vessel trauma, and thrombosis.
   5. The practitioner must be aware of the potential for an embolism associated with open needles, shunts, or catheter lumens in the patient's vasculature.
   6. Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body fluid precautions in the care of all patients.
   7. Do not cut the guidewire.
   8. Do not withdraw the guidewire against the needle bevel to avoid possibly severing or damaging the guidewire.
   9. If you encounter difficulty while inserting the IAB catheter without the use of an introducer sheath, remove the IAB catheter and insert the supplied introducer over the guidewire. From that point, continue with the remainder of the instructions to insert the IAB catheter with the use of an introducer sheath and guidewire.

   B. PRECAUTIONS
   1. Whenever possible, use fluoroscopy during guidewire and introducer sheath insertion.
   2. Use only the 0.025” (0.06 cm) guidewire with the LINEAR IAB Catheters.
   3. Use care to prevent kinking of the introducer during insertion.
   4. Pinching or kinking the reinforced introducer sheath may damage it, preventing insertion of the IAB catheter.
   5. Do not remove the introducer or packaging stylet until immediately prior to insertion.
   6. Take care not to kink or place undue force on the IAB catheter.
   7. The stylet wire provides support to the IAB. Handle the IAB with care and be sure to support during the T-handle so as not to kink or place undue force on the catheter.
   8. Remove the IAB catheter from the T-handle by pulling STRAIGHT away from the IAB catheter.
   9. When using a check X-ray to identify the position of the IAB Catheter, it is recommended to place the IAB in an unsteady to improve visualization while the X-ray is taken and then immediately resume pumping.

   C. Severe calcific aorta-iliac disease or peripheral vascular disease.
   B. Cardiac and non-cardiac surgery.
   A. Acute Coronary Syndrome.

IV. ADVERSE EFFECTS

A. Balloon Membrane Perforation
   Balloon membrane perforation may be caused by:
   - Contact with a sharp instrument.
   - Fatigue failure due to unusual (kniaval) folding of the balloon membrane during use.
   - Contact with calcified plaque resulting in abrasion of the surface and eventual perforation. If perforation occurs, blood may be visible in the IAB catheter. If balloon membrane perforation is suspected, as may be evidenced by: 1) IAB pump leak alarms, 2) diastolic blood pressures or miscellaneous fluid seen in the extracorporeal tubing or catheter extender or 3) a sudden change in the diastolic augmentation pressure waveform, the following procedure must be performed immediately:
   1. Stop pumping.
   2. Remove the IAB catheter.
   3. Place the patient in the Trendelenburg position should be considered if a leak is suspected.

   B. Limb Ischemia
   During or after IAB therapy, limb ischemia may occur. It can be caused by an obstruction of flow due to:
   - Thrombus formation.
   - Creation of an intimal layer separation or flap.
   - The presence of the introducer sheath or IAB catheter.
   After IAB catheter removal, if limb ischemia is observed, a vascular procedure may be indicated. Monitor distal limb for the development of compartment syndrome.
C. Bleeding at the Insertion Site
Bleeding at the insertion site may be caused by:
- Trauma to the artery during insertion of the IAB.
- Excision catheter movement at the insertion site.
- Anticoagulation.
Bleeding at the insertion site may be controlled with direct pressure at the insertion site, assuming adequate distal blood flow. If bleeding persists, surgical repair of the insertion site may be indicated.

D. Infection
Infection may occur due to interruption of normal skin integrity at the IAB catheter insertion site. Sterile technique should be used during IAB catheter insertion and during dressing changes.

E. Thrombocytopenia
Thrombocytopenia may develop due to mechanical damage to the platelets. Monitor platelet count and replace platelets, if necessary.

F. Aortic Dissection
Aortic dissection may occur during insertion of the IAB catheter. Symptoms can include back and/or abdominal pain, a decreased hematocrit, and hemodynamic instability.

G. Thrombosis
Thrombus formation may occur during counterpulsation. The symptoms associated with thrombosis formation and treatment will depend on the organ system involved.

V. EQUIPMENT REQUIRED
The following is a list of compatible consoles for the MAQUET LINEAR IAB catheters at heart rates not exceeding 140 BPM. The use of MAQUET catheters on some consoles at higher heart rates may result in decreased augmentation.

The following sterile equipment is required for insertion of the IAB catheter. Inspect all components prior to use.

The following items are supplied by MAQUET and are associated with thrombosis formation and treatment will depend on the organ system involved.

<table>
<thead>
<tr>
<th>IAB Catheters</th>
<th>MAQUET/Datascope Systems</th>
<th>Arrow Pumps</th>
</tr>
</thead>
<tbody>
<tr>
<td>LINEAR 7.5Fr.</td>
<td>98™, 98XT™, CS100®, CS300™ and CARDIOSAVE®</td>
<td>Available at 7 WAVE</td>
</tr>
</tbody>
</table>

The following items are supplied by MAQUET and are associated with thrombosis formation and treatment will depend on the organ system involved.

- One sterile one-way valve and 30cc syringe (included with IAB catheter)
- One sterile Insertion Kit which includes:
  - One 18-gauge angiographic needle
  - One vessel dilator
  - One introducer sheath with hemostasis valve
  - One introducer dilator
  - One three-way stopcock
  - One luer cap
  - One Catheter Extender
  - Pressure Tubing: Two 4 ft. (1.2 m) lengths of pressure tubing
  - Guidewire: One 0.025" (0.6 cm) x 145 cm PTFE coated guidewire

Optional items:
- One Sterile Arrow Pump Adapter

The following items are not supplied by MAQUET:
- Local anesthetic with syringe and needle
- One sterile scalpel and blade
- Radiographic contrast material
- One sterile 20cc syringe
- Sterile lint free sponges
- One 50cc luer lock syringe

IAB CATHETER SIZING
Select the most appropriate size IAB catheter for the patient from the following balloon membrane sizing table.

<table>
<thead>
<tr>
<th>Balloon Membrane Volume (cc)</th>
<th>Balloon Membrane Dimensions</th>
<th>Patient Height</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>0.025&quot; x 0.6 cm</td>
<td>&lt;40 kg</td>
</tr>
<tr>
<td>34</td>
<td>0.03&quot; x 0.8 cm</td>
<td>40-50 kg</td>
</tr>
<tr>
<td>40</td>
<td>0.045&quot; x 1.0 cm</td>
<td>&gt;50 kg</td>
</tr>
</tbody>
</table>

NOTE: This information is to be used only as a guideline. Clinical judgment and patient factors (i.e., torsa length) should be considered when selecting the most appropriate size IAB catheter.

VI. INSTRUCTIONS
A. IAB CATHETER INSERTION

NOTE: Insertion technique is for SHEATHLESS INSERTION of the IAB unless otherwise indicated.

1. Make the customary preparations for percutaneous catheterization and administer appropriate local anesthesia.
2. Insert the angiographic needle into the common femoral artery at a 45 degree or less angle. (See Figure 1)
3. Insert the J-tip end of the supplied 0.025" (0.6 cm) guidewire through the angiographic needle and advance into the thoracic aorta.

WARNINGs
- Do not cut the guidewire.
- Do not withdraw the guidewire against the needle bevel to avoid possibly severing or damaging the guidewire.

PRECAUTION
- Use only the 0.025" (0.6 cm) guidewire with the LINEAR 7.5Fr. IAB Catheters.
- Keep the guidewire in place, remove and discard the needle.
- Wipe the blood from the guidewire with a wet, lint-free sponge.
- Make a small incision at the exit of the guidewire to facilitate inserting the vessel dilator through the skin.
- Place the tapered end of the vessel dilator over the exposed guidewire and dilate the artery by pushing the vessel dilator into the arterial lumen.
- Keep the guidewire in place, remove and discard the vessel dilator. Apply pressure at the wound site to control bleeding.
- Wipe the blood from the guidewire with a wet, lint-free sponge.
- For sheathless insertion: Spread the tissue at the incision with a tissue dilator.

WARNING
- If you encounter difficulty while inserting the IAB catheter using sheathless insertion, remove the IAB catheter and insert the supplied introducer sheath over the guidewire. From that point, continue with the remainder of the instructions to insert the IAB catheter with the use of an introducer sheath.

A.1. INSTRUCTIONS FOR INSERTING THE INTRODUCER SHEATH

1. Make the customary preparations for percutaneous catheterization and administer appropriate local anesthesia.
2. Insert the angiographic needle into the common femoral artery at a 45 degree or less angle. (See Figure 1)
3. Insert the J-tip end of the 0.025" (0.6 cm) guidewire through the angiographic needle and advance into the thoracic aorta.
4. Keep the guidewire in place, remove and discard the needle.

WARNING
- Do not withdraw the guidewire against the needle bevel to avoid possibly severing or damaging the guidewire.

PRECAUTION
- Use care to prevent kinking of the introducer during insertion.
- Pinching or kinking the reinforced introducer sheath may damage it, preventing insertion of the IAB catheter.

NOTE: During insertion of the IAB catheter, after removal of the introducer dilator, some blood leakage may be observed past the hemostasis valve. This blood leakage will subside as the IAB catheter is advanced into the introducer sheath. Do not kink or pinch the reinforced introducer sheath to control bleeding.

WARNINGs
- Whenever possible, use fluoroscopy during IAB catheter insertion to ensure proper placement.
- Do not insert the IAB catheter unless the inner lumen is supported by a guidewire.

NOTE: Maintain vacuum on the IAB catheter throughout insertion. Do not remove the one-way valve.

12. Remove the IAB catheter tray from the sterile packaging.
13. Firmly attach the one-way valve to the male luer fitting of the extracorporeal tubing. (See Figure 3)
14. With the 30cc syringe, slowly aspirate at least 30cc. (See Figure 3) Remove the syringe while leaving the one-way valve in place.
15. Carefully remove the extracorporeal tubing, Y-fitting and IAB catheter WITH T-handle from the tray. (DO NOT disconnect one-way valve when removing the extracorporeal tubing from the tray.) (See Figure 4)

Figure 2
7. Remove the dilator leaving the sheath in place.
8. Continue from Step 11 of Section A: IAB CATHETER INSERTION

PRECAUTIONs
- Use care to prevent kinking of the introducer during insertion.
- Pinching or kinking the reinforced introducer sheath may damage it, preventing insertion of the IAB catheter.

NOTE: Maintain vacuum on the IAB catheter throughout insertion. Do not remove the one-way valve.

12. Remove the IAB catheter tray from the sterile packaging.
13. Firmly attach the one-way valve to the male luer fitting of the extracorporeal tubing. (See Figure 3)
14. With the 30cc syringe, slowly aspirate at least 30cc. (See Figure 3) Remove the syringe while leaving the one-way valve in place.
15. Carefully remove the extracorporeal tubing, Y-fitting and IAB catheter WITH T-handle from the tray. (DO NOT disconnect one-way valve when removing the extracorporeal tubing from the tray.) (See Figure 4)
Inflate Volume

1. While controlling the proximal end of the guidewire, advance the IAB catheter over the guidewire into the artery. Always ensure the operator has complete control of the guidewire.

2. Once the catheter is in place, aspirate and discard 3cc of blood from the inner lumen and cap the female luer hub with the supplied luer cap.

NOTE: If you are not using the inner lumen for pressure monitoring, aspirate 3cc of blood from the inner lumen and cap the female luer hub with the supplied luer cap.

WARNING
- Do not use excessive force when inserting the IAB catheter. If you use excessive force when inserting the IAB catheter, arterial tearing, dissection, or balloon membrane damage may occur.
- Always advance in short, continuous, one inch (2.5 cm) strokes to avoid kinking the IAB catheter while maintaining complete control of the guidewire.

WARRNIGS
- Any kinking or damage to the inner lumen may result in subsequent fatigue failure to the inner lumen when pumping.
- Do not insert the IAB catheter unless the inner lumen is supported by a guidewire.

3. Advance the IAB catheter to the proper position in the descending thoracic aorta, with the IAB catheter tip just distal (approximately 2 cm) to the left subclavian artery. (See Figure 8)

NOTE: If it becomes necessary to reposition the IAB catheter, hold the sheath seal in one hand, grasp the catheter through the STAT-GARD sleeve with the other hand, and reposition under aseptic conditions. Do not attempt to reposition the IAB catheter by moving the sheath.

4. Push the Universal Sheath Seal into the hub of the introducer sheath (See Figure 11).

5. If blood is seen passing the sheath seal following insertion through a sheath, disengage the sheath seal from hemostasis valve.

6. If after a few cycles of counterpulsation, it appears that the balloon membrane or flexing of the inner lumen, aspirate 3cc of blood from the inner lumen and cap the female luer hub.

WARNING
- NEVER INJECT AIR INTO THE INNER LUMEN (female luer hub).

PRECAUTION
- If the inner lumen has been capped off DO NOT attempt to re-access the inner lumen.

3. After IAB insertion has been completed, remove the one-way valve from the male luer of the extracorporeal tubing. (See Figure 12)

A2. WHEN USING INTRODUCER SHEATH

WARNING
- If the balloon membrane has not entirely exited the introducer sheath, it will not inflate and deflate properly.

NOTE: Either during advancing or once the catheter is correctly positioned, confirm that the IAB catheter membrane has fully exited the sheath. (See Figure 9)

1. The first single band from the IAB catheter tip indicates that the entire balloon membrane has exited from the 6" (15.2 cm) introducer sheath/hemostasis valve and may now be inflated.

2. Single bands follow at 3/4" (1.9 cm) increments.

21. Invert the supplied 0.025" (0.6 cm) guidewire through the inner lumen. (See Figure 7) Advance the IAB catheter over the guidewire until the guidewire exits the female luer hub. Always ensure the operator has complete control of the guidewire.

WARNING
- Do not handle the IAB membrane or wipe the catheter prior to insertion.

NOTE: During insertion of the IAB catheter, arterial blood under pressure may run down the length of the folds in the balloon membrane and drip or be expelled under arterial pressure from the balloon membrane/catheter junction. THIS “CHANNELING” IS NOT A LEAK. As the IAB catheter is advanced the bleeding will diminish.

22. While controlling the proximal end of the guidewire, advance the IAB catheter over the guidewire into the artery. Always grasp the IAB catheter no more than one inch (2.5 cm) from the insertion site or sheath hub and advance in short continuous strokes to avoid kinking the IAB catheter while maintaining complete control of the guidewire.

PRECAUTIONS
- Always advance in short, continuous, one inch (2.5 cm) strokes to avoid kinking the IAB Catheter.
- Do NOT twist the catheter during insertion.

A3. INSTRUCTIONS FOR USE OF SHEATH SEAL WITH INTRODUCER SHEATH

PRECAUTION
- Do not place any sutures or ligatures around the outside diameter of the introducer to avoid damaging it.

WARNING
- Do not inject any portion of the Universal Sheath Seal below the skin line.

1. If blood is seen passing the sheath seal following insertion through a sheath, disengage the sheath seal from hemostasis valve.

3. After IAB insertion has been completed, remove the one-way valve from the male luer of the extracorporeal tubing. (See Figure 12)

4. Connection of the IAB catheter to the pump.

NOTES
- Ensure that all connections are leak-free.
- All catheter extenders are sterile and should only be used one time.
- Use one catheter extender when connecting the IAB catheter to the IAB pump.

When a MAQUET/Datascope IAB pump is used:

Connect the IAB catheter’s male luer fitting to the female luer fitting of the provided catheter extender. Connect the male luer fitting of the catheter extender to the safety chamber/disk.

When an Arrow IAB pump is used:

Connect the IAB catheter’s male luer fitting to the female luer fitting of the provided catheter extender. Connect the male luer fitting of the provided catheter extender to the male luer fitting of the Arrow Pump Adapter. Connect the Arrow Pump Adapter to the appropriate system. Adjust the volume setting on the Arrow pump, according to the operating instructions, to match the IAB catheter volume.

5. Follow the IAB pump operating instructions to initiate pumping. If augmentation is not within the desired range, see Appendix A Factors Affecting Augmentation.

6. If after a few cycles of counterpulsation, it appears that the balloon membrane is not fully open, perform the following procedure:

WARNING
- Do not perform manual inflation of the IAB with the catheter extender tubing. (See Figure 13)

a. Detach the catheter extender from the IAB catheter’s male luer fitting.

b. Attach the supplied 3-way stopcock and syringe to the IAB catheter's male luer fitting.

c. Attach the provided catheter extender to the safety chamber/disk.

NOTE: Push the Universal Sheath Seal into the hub of the introducer sheath (See Figure 11).

D. INITIATING IAB PUMPING (IABP)

NOTE: Do not raise the head of the bed greater than 45°.

1. After positioning the IAB catheter, remove the guidewire.

2. Once the catheter is in place, aspirate and discard 3cc of blood from the inner lumen and then immediately perform a manual flush using a syringe filled with 3cc to 5cc of flush solution. This will minimize the chances of stagnant blood clotting in the inner lumen.

3. If blood is seen passing the sheath seal following insertion through a sheath, disengage the sheath seal from hemostasis valve.

NOTE: If you are not using the inner lumen for pressure monitoring, aspirate 3cc of blood from the inner lumen and cap the female luer hub with the supplied luer cap.

WARNING
- NEVER INJECT AIR INTO THE INNER LUMEN (female luer hub).

PRECAUTION
- If the inner lumen has been capped off DO NOT attempt to re-access the inner lumen.

1. After insertion has been completed, remove the one-way valve from the male luer of the extracorporeal tubing. (See Figure 12) or sutures. You may also secure the Y-fitting to the skin using a STATLOCK® Securement Device (See Figure 14)

2. Do not remove the 3-way stopcock and syringe to the IAB catheter.

3. When using a chest X-ray to identify the location of the IAB Catheter, it is best to place the IABP in stand-by to improve visualization while the X-ray is taken and then immediately resume pumping.

4. Secure the Y-fitting to the skin line using a STATLOCK® Securement Device (See Figure 14)

5. Either during advancing or once the catheter is correctly positioned; note the position of the IAB catheter in the femoral artery. (See Figure 13) or sutures. You may also secure the Y-fitting to the skin using a STATLOCK® Securement Device (See Figure 14)

6. If after a few cycles of counterpulsation, it appears that the balloon membrane is not fully open, perform the following procedure:

7. Ensure that the balloon membrane is inflating and deflating in an unrestricted manner and not restrained as a result of lodging beneath a plaque, within a subintimal space, within the subclavian artery, aortic arch, abdominal aorta, or if the balloon membrane volume is too large for the specific patient’s aorta.

WARNING
- If you note any restraint, unusual folding patterns of the balloon membrane or flaring of the inner lumen, immediately reposition the IAB catheter. The life of a balloon membrane may be unpredictably shortened as a result of restraint, which could lead to a balloon failure.

8. If you observe unusual bleeding or subcutaneous hematoma at the insertion site, treat appropriately.

9. Evaluate peripheral pulses. If the distal pulse is not satisfactory or signs of limb ischemia are present, exercise discretion concerning the continuation of IAB pumping.

10. Restrain movement of the IAB catheter by securing the suture pads and the Y-fitting to the skin using a STATLOCK® Securement Device (See Figure 13) or sutures. You may also secure the Y-fitting to the patient with tape. (See Figure 14)

11. Apply a dressing to the insertion site using sterile technique according to hospital policy.
3. Apply only gentle force to the syringe when aspirating the inner lumen.

4. Prior to fast flushing, stop IAB pumping to reduce the risk of an embolus entering the aortic arch should an embolus be ejected from the inner lumen and then immediately perform a manual flush using the transducer and syringe to the IAB catheter’s male luer fitting.

**PRECAUTION**

- If you must initiate IAB pumping after the removal of the IAB catheter, any securement device or suture that may have been applied over the sheath seal or STAT-GARD sleeve and reposition the IAB catheter.
- If the IAB catheter tip is appropriately positioned within the aorta, the radiopaque cloud will wash away with the next two or three heartbeats.
- If the IAB catheter tip is positioned in a false lumen, the radiopaque cloud will remain surrounding the IAB catheter.
- If the IAB catheter is found to lie within a false lumen, remove the IAB catheter from the patient. Consider insertion of a new IAB catheter into the contralateral femoral artery.

In addition to the above, physiological conditions can contribute to poor augmentation. Among them are:

- Patient’s mean arterial blood pressure is low.
- Patient’s systemic vascular resistance is low.
- Patient’s heart rate is rapid enough to compromise venous filling and ejection.

**WARNING**

- Do not use IAB pumping if there is any undue resistance during withdrawal.
- Do not use scissors or other objects to remove the dressing.
- Do not attempt to withdraw the balloon membrane through the inner lumen of the IAB catheter.

**REMOVAL OF THE IAB CATHETER**

1. Consider tapering or discontinuing anti-coagulation therapy prior to removal.
2. Stop IAB pumping.
3. Disconnect the IAB catheter from the IABP pump permitting the IAB catheter to vent to atmosphere. Patient blood pressure will collapse from the inner lumen of the IAB catheter.
4. Remove all securement devices and/or sutures and dressings.

**PRECAUTION**

- To avoid cutting the IAB catheter or the introducer, do not use scissors to remove the dressing.
- Do not attempt to withdraw the balloon membrane through the inner lumen of the IAB catheter.

**WARNING**

- Do not perform manual inflation of the IAB catheter without the catheter extender tubing attached to the IAB catheter.
- Do not aspirate blood to the extracorporeal tubing.
- Aspirate to assure blood is not returned through the extracorporeal tubing.

**WARNING**

- Never inject air into the inner lumen (female luer hub).
- Aspire to assure blood is not returned through the extracorporeal tubing.

**WARNING**

- Do not use a R.O.S.E. (Resonance Over Shoot Eliminator) or other damping device.
- Do not use the same insertion site.

- Ensure that all air bubbles are removed from the inner lumen and flushing apparatus.
- Do not over-flush the inner lumen by placing a luer cap on the female luer hub.

**RECOMMENDATIONS FOR ACHIEVING OPTIMAL PRESSURE SIGNAL QUALITY**

1. Use no more than 8 ft (2.5 meters) of a low compliance pressure tubing such as that supplied by MAQUET in the IAB Insertion Kit between the transducer and Y-fitting of the catheter.
2. Once the catheter is in place, aspirate and discard 3cc of blood from the inner lumen and then immediately perform a manual flush using the transducer and Y-fitting of the catheter.
3. Do not use room temperature flush solution.
4. Do not use the inner lumen of the IAB catheter for blood sampling.
5. Do not aspirate blood to the extracorporeal tubing.

**WARNING**

- The IAB is designed and validated for single use only. There is no product validation evidence to support a second use of the product be it sterile or non-sterile and product failure may occur (e.g. balloon membrane perforation, inability to obtain arterial pressure signal). If the IAB is not inserted and removed in accordance with the IFU, patient injury may result (e.g. prone to infection).

**APPENDIX A: FACTORS AFFECTING AUGMENTATION**

If after pumping has commenced, augmentation is not within the desired range, one of the following may be indicated:

1. Balloon membrane has not fully exited from the introducer sheath. Pull the introducer sheath back until the balloon membrane fully exits the introducer sheath.
2. Balloon membrane has not fully opened. See Section B, Initiating IAB Pumping (IABP), Item 6.
3. IAB augmentation/volume control on the IAB pump is set too low.
4. Adjust the IAB augmentation/volume control on the IAB pump.
5. IAB catheter is positioned in the aortic arch, subclavian artery, or otherwise malpositioned in the aorta. Inspect the entire introducer sheath and IAB catheter to be certain the inner lumen is patent.

If the IAB catheter tip is not appropriately positioned within the aorta, do not attempt to withdraw the balloon membrane through the inner lumen of the IAB catheter.

**WARNING**

- Do not remove excess pressure when injecting contrast media through the inner lumen. Do not use an angiographic catheter or the IAB catheter extender to introduce contrast. The high pressure generated by the contrast media may damage the inner lumen. Do not use a syringe smaller than 20cc to inject through the inner lumen. If resistance is met, consider the inner lumen obstructed and permanently seal it off.

- If the IAB catheter tip is appropriately positioned within the aorta, the radiopaque cloud will wash away with the next two or three heartbeats.
- If the IAB catheter tip is positioned in a false lumen, the radiopaque cloud will remain surrounding the IAB catheter.
- If the IAB catheter is found to lie within a false lumen, remove the IAB catheter from the patient. Consider insertion of a new IAB catheter into the contralateral femoral artery.