Bioptimal™

ADDENDUM to INSTRUCTION SHEET

This copy only serves as an addendum to the enclosed Instruction Sheet in the same package for THERMODILUTION CATHETER and PRESSURE MONITORING CATHETER, denoted by suffix “D”.

SAFETYWEDGE™ DEVICE

DEVICE DESCRIPTION

The Safetywedge™ device has a Safetywedge™ balloon that is made with a slightly higher durometer than the regular catheter balloon, only the catheter-tip balloon will inflate when place in a large vessel. Should the catheter-tip balloon be inserted in a small vessel, the expansion of the regular catheter balloon will be restricted and the Safetywedge™ balloon will then sense this obstruction and begin to inflate to absorb the excess volume from the syringe as illustrated in figure 1. This limits the catheter balloon pressure, thus providing some measure of protection for the vessel and its possible rupture.

The Safetywedge™ balloon will also indicate to the user by its inflation that an obstruction exists and repositioning is required to properly inflate the catheter balloon.

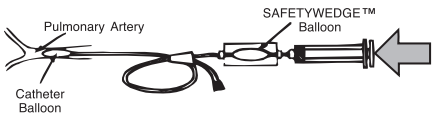

Figure 1.

INTENDED USE

The Safetywedge™ device is intended to be used with Thermodilution Catheter or Pressure Monitoring Catheter to protect the pulmonary artery from rupture being caused by the catheter’s tip balloon during insertion.

Figure 2 is a graph depicting the inflation pressure (solid line) and corresponding diameter (dotted line) of a standard 1.5ml catheter balloon as it is inflated in a 0.14 inch diameter latex tube which simulate a small PA vessel.

Standard PA Catheter without Safetywedge™

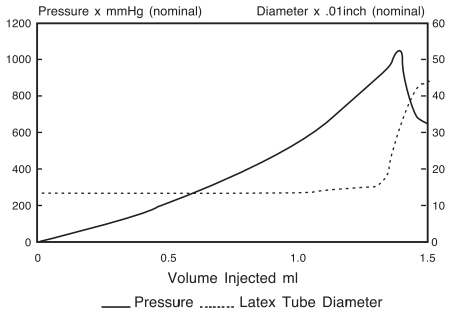

Figure 2.

Figure 3 is a graph depicting the inflation pressure (solid line) and corresponding diameter (dotted line) of a standard 1.5ml catheter balloon as it is inflated in a 0.14 inch diameter latex tube (simulating small PA vessel) using the Safetywedge™ device.

Standard PA Catheter with Safetywedge™

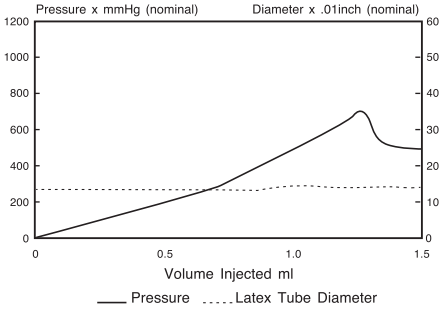

Figure 3.

PREPARATION

Functionality and Leakage Test

Check for normal Safetywedge™ balloon inflation by using the white cap supplied with the packaging to cover the balloon and create an obstruction. Hold the inflation for a while to ensure that there is no leak (see figure 4)

Figure 4.

Detached the syringe and remove the white cap as illustrated in figure 5. Reconnect the syringe and check for proper inflation of the catheter balloon and also for leakage by gradual inflation. Observe that the Safetywedge™ remains deflated.

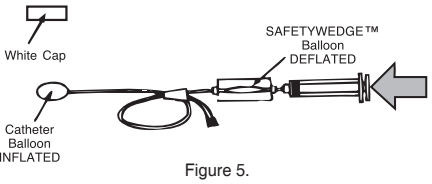

Figure 5.

INSTRUCTION FOR USE

Follow the correct procedure by inflating the catheter-tip balloon gradually. Should the inflation be incorrectly done where a quick rush of inflation gas is inserted, then the Safetywedge™ balloon will inflate first, followed by a gradual inflation of the catheter balloon and deflation of the device balloon.

PRECAUTION

1. This product is to be used only with BIOPTIMAL catheter.
2. This product is designed for single use only. Do not reuse or resterilize.
3. This product contains natural rubber latex which may cause allergic reactions.
4. This device is intended for single patient use only.
5. DO NOT resterilize and/ or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and resterilisation bear the risk of cross contamination and patient infection and may also cause transmission of infectious diseases from patient to patient.

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