

## PRESSURE MONITORING LINE

### **1. PRODUCT DESCRIPTION:**

Seguro Pressure Monitoring Line is precisely designed for use during PTCA and any other intravascular therapeutic procedures that need to monitor pressure of any fluid or blood, and is mainly made of the medical grade materials that are commonly used globally such as PVC (Poly Vinyl chloride) and some plasticizer. It is more comfortable and reduces the workload of medical staff. Pressure monitoring line assembly & High Pressure monitoring line assembly is made up of three components PVC tube, Male adaptor (connector), Female adaptor (connector). PVC tube (450/1100 / 1200psi) is having different size according to the requirement.

#### **Pressure monitoring line assembly**

Seguro Pressure monitoring line is made of PVC (Poly Vinyl chloride) and some plasticizer. The Poly Vinyl Chloride (PVC) industry is absolutely comfortable with the choice of PVC for the medical device. PVC compounds produced specifically for the healthcare industry have been used for over 50 years with no validated instance of adverse health effects in children or adults. The manufacturers of medical devices want to use a tested material that is easy and safe to process and so expert the following from a polymer.

- Optical clarity (visual and microscopically inspection);
- sterilization(preferably steam chemicals, ionizing radiation);
- long-term shelf-life stability;
- design latitude
- large processing window;
- compliance with medical regulation and standards
- environmental compatibility; and
- high performance at reasonable cost

PVC fulfils all these requirements. Most of the conditions are also essential to those that actually use the device. However, this does not mean that PVC is the right material for many applications in the medical device area. Male connector and Female connector are made up of Polycarbonate material, It is approved from supplier and related body. Biocompatibility is a general term used to describethe suitability of a material for exposure to the body or bodily fluids. It is the ability of a material to perform with an appropriate response in a specific application and is very dependent on the particular application or circumstances. A material will be considered biocompatible (in a specific application) if it allows the body to function without any complications such as allergic reactions or other adverse side effects. Biocompatibility is not the same as sterility. Sterility is the treatment of a material to remove or destroy all living organisms (including bacterial or fungal spores), and does not concern itself with the actual biocompatibility of the material. Advanced Polymers' revolutionary polyester tubes are seamless, thin walled, ultra-high strength, optically clear or pigmented, and heat

shrinkable. These unique properties are made possible by a unique and proprietary process developed exclusively by Advanced Polymers. The tubes combine these characteristics with a unique combination of properties previously unavailable. Tubing can be used as is or heat-shrunk for a variety of applications. Shrinking can be accomplished at very low temperatures to protect delicate components. Non-shrink tubing can also be fabricated in virtually any size.

**High pressure Braided tubing:**

**Description:** Soft high pressure tubes are reinforced with a high strength fiberbraiding. High Pressure Tubing with Rotating Adapter or Fixed Male Luer

**Material:** Thermoplastic polyurethane (TPU). Reinforcement: nylon fiber.

**High Pressure Non-Braided tubing:**

**Description:** High Pressure Tubing with Rotating Adapter or Fixed Male Luer

**Material:** Poly Vinyl Chloride (PVC).

**Male/Female Connectors/Male Rotator:** Made from Polycarbonate with different ID and OD. Used for connecting the PVC or Braided lines. In Male Rotator, there is rotating Luer lock with silicone locking ring.

**LOCTITE UV bonding solution:** Globally accepted solution from Henkel Adhesives, USA in Medical Device Industries

**2. INTENDED USE:**

Pressure Monitoring Line is precisely designed for use during PTCA and any other intravascular therapeutic procedures that need to monitor pressure of any fluid or blood.

**3. CONTRAINDICATIONS:**

There are NO known contraindications for this device.

**4. WARNING:**

- Do Not Reuse or Re-sterilize.
- Use Pressure Monitoring Line prior to the expiration date specified on the package.
- Do not autoclave.
- Do not use if the package is damaged.
- Keep Away from Sunlight

**5. PRECAUTIONS:**

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your SLS representative. Inspect prior to use to verify that no damage has occurred during shipping.
- For single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the

device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

- Reuse, reprocessing or re sterilization may also create a risk of contamination of The device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

## **6. POTENTIAL COMPLICATIONS/ADVERSE EFFECTS:**

Carefully read all instructions for use. The device shall only be applied for its intended use and in accordance with these instructions.

Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

## **7. INSTRUCTIONS:**

The package of the product should be open in sterile environment. After pulling opaque substance into Control Syringe, fix the pressure monitoring line on the rotating adapter or luer lock to the front end of the syringe Be sure that there are no air bubbles in syringe and pressure monitoring line. Fix the manifold to the other end of the pressure monitoring line and inject the opaque liquid slowly to the vessels. This device for single use only.

## **8. SUPPLIED:**

The Pressure Monitoring Line is supplied sterile and it is intended for single use only. The Pressure Monitoring Line is sterilized with ethylene oxide gas. It will remain sterile as long as the packaging remains unopened and undamaged.

## **9. CAUTION:** Do not use if package is opened or damaged.

## **10. STORAGE:**

- Storage temperature 0-30 °C
- Avoid Exposure to direct Sunlight or Heater.
- Keep the Product in a clean, organized cool and dry place.

## 11. DISPOSAL:

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted hospital medical practice, and applicable local European and international disposal regulation.

### Explanation of symbols as per MDD 93/42/EEC, ISO 15223-1:2021:

Sr. No.	Symbol	Meaning
1.		Symbol for "Reference number"
2.		Symbol for "Batch code"
3.		Symbol for "Date of manufacture"
4.		Symbol for "Use Before"
5.		Symbol for "Do not reuse"
6.		Symbol for "Manufacturer"
7.		Symbol for "Caution"
8.		Symbol for "Do Not use if package is damaged"
9.		Symbol for "Keep away from sunlight"
10.		Symbol for "Keep Dry"
11.		Symbol for Consult Instruction for Use
12.		Symbol for Do not Re-sterilize
13.		Symbol for Quantity
14.		Store at 0-30 °C
15.		Non Pyrogenic

**Warranty / Liability:**

Although this product has been manufactured under carefully controlled quality conditions, Seguro Life Science has no control over the conditions under which this product is used. Seguro Life Science therefore disclaims all warranties both express and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Seguro Life Science shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Seguro Life Science to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular term held to be invalid.



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