HEMOSTASIS Y CONNECTOR WITH BLUNT INTRODUCER, TORQUER

1. PRODUCT DESCRIPTION:

Seguro Hemostasis Y- Connector with blunt introducer and totquer is precisely designed for use during percutaneous Transluminal Coronary Angioplasty (PTCA) and any other intravascular therapeutic procedures that utilize a guiding catheter. Y connector is designed to ease & simplify the procedure undertaken by the cardiologist during angioplasty procedure and Blunt Introducer is to facilitate guide wire and Torque is meant for the tightening of the guide wire. The Y connector is an accessory that can be connected, by a standard male luer-lock, to any standard Angiographic catheter, up to 7 or 9 Fr. Guiding catheters. The device has a septum that prevents blood loss. Common guide-wires in diameter of 0.014" 10 0.038%) can be introduced via the device (through the slit septum) without bleeding due to the intra-catheter human arterial pressure. The septum can be opened to an unsealed position in order to enable introduction of various angioplasty devices (such as; balloons and stents).

Product Types:

1. Seguro Hemostasis Y Connector Push Click Type
   Clear Polycarbonate Y shape body, "Push click" knob hemostasis valve at the proximal end &distal end have rotating male luer lock. Y-Connector should be without any visual defects.
2. Seguro Hemostasis Y Connector Push Pull Type
   Clear Polycarbonate Y shape body, "Push Pull" knob hemostasis valve at the proximal end & distal end have rotating male luer lock. The side access lumen with a side arm clear, smooth outer and inner surface, for tubing assembling with end by a standard three-way stopcock. Y-Connector should be without any visual defects.
3. Seguro Hemostasis Y Connector Screw Type
   Clear Polycarbonate Y shape body, "Screw type" knob hemostasis valve at the proximal end & distal end have rotating male luer lock. The side access lumen with a side arm clear, smooth outer & inner surface tubing ending by a standard three-way stopcock. Y-Connector should be without any visual defects.

2. INTENDED USE:

Seguro Y-Connector: (Push Click Type, Push Pull Type, Screw Type)

- Seguro Y Connector intends to provide two tunnels into the blood vessel; this can introduce the contrast medium and guide wire or catheters during the interventional surgery. Y Connector valve intends to prevent blood lost.
- It provides a mean for inserting guide wires or catheters deep into the vasculature, and positioning and locking them into a desired place. Y-connector includes a straight and a side access lumen. The hemostasis valve located at the proximal end of the straight lumen can be opened or closed by operation of the

Push-click button. The distal end has a rotating male luer lock. The side access lumen allows pressure monitoring and perfusion.

Blunt Introducer (Insertion Tool):

- It is an accessory design to facilitate the introduction of guide wires (up to 0.018") used in conjunction with interventional devices during vascular interventional procedures. Blunt introducer inserts the valve of Y connector, making a tunnel for guide wire to get through and protecting guide wire tip

Torquer:

- Torquer holds guide wire and makes torque guide wire move easily. It is design to facilitate steering of 0.010" to 0.014" guide wires inside the vasculature.

3. CONTRAINDICATIONS:

There are NO known contraindications for this device.

4. WARNING:

- Do Not Reuse OR Re-sterilize,
- Use H- Y Connector Kit 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:

- Hemostasis Y- Connector kit is supplied sterile.
- Inspect the Hemostasis Y- Connector kit prior to use.
- Use prior to the Expiration Date that appears on the packaging label.
- Do not use the device if package is found to be open or damaged.
- Ensure that Hemostasis Y- Connector kit is flushed correctly and all air removed before use. (see instruction for use)
- Always open the hemostasis Y-connector using the Push-click, Push Pull and Screw type button opener before inserting any device with a fragile distal portion, in order to avoid damage of the product when passing through the valve.
- Always retrieve the metallic insertion tool before retrieval of the guide wires, to avoid any damage of the guide wire.
- The metallic insertion tool should be inserted carefully through the valve in order not to damage or dislodge it.
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- Always retrieve the metallic insertion tool before retrieval of the guide wires, to avoid any damage of the guide wire.
- The metallic insertion tool should be inserted carefully through the valve in order not to damage or dislodge it.
- Hemostasis Y- Connector kit should exclusively use by physicians trained in Interventional procedures.

6. POTENTIAL COMPLICATIONS I ADVERSE EFFECTS:

Carefully read all instructions for use. The device shall only be applied for its intended use and inaccordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

7. INSTRUCTION:

- Connect Hemostasis Y- Connector side access to the perfusion (manifold) device using a stopcock if needed. Setup the continuous flush with a normal saline solution to remove trapped air from all channels.
- Connect the male rotating Luer lock of the Hemostasis Y- Connector to the guiding catheter or any other device chosen by the operator.
- Aspirate any air that may have been entered the system before the introduction of the devices, to make sure that no air bubble has been captured.
- Introduce the guiding catheter or any device chosen by physician following the recommendations of respective device manufacturers. Insert the guide wire or the guide wire and dilation catheter together, or any chosen device in to Hemostasis Y- Connector straight lumen.
- The metallic insertion tool supplied with the Hemostasis Y- Connector kit (with or without Torquer) must be used when the guide is alone is inserted through the valve, in order to protect the guide wire distal tip.
- Perform the rest of the procedure following the recommendations of respective device manufacturers.
- The maneuverability of the guide wires when introduced through the inner lumen of Hemostasis Y- Connector can be improved by the use of the Torquer supplied as an accessory.
- Positioning/moving procedure: Unscrew the cap of the Torquer. Insert the proximal end of the guide wire in to the funnel shaped hole on the distal end of the Torquer. Once the Torquer is positioned at the desired location, tighten the Torquer to secure to the guide wire. To move the guide wire to the
- New positions, loosen the proximal end of the Torquer, slide the device along the guide wire to the desired location and tighten the Torquer.

8. SUPPLIED:

The Hemostasis Y- Connector kit is supplied sterile and it is intended for single use only.

The Hemostasis Y- Connector kit 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:

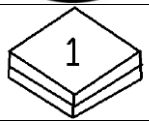
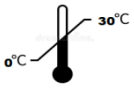
- Storage temperature (0 - 30 °C)
- Avoid Exposure to direct Sunlight or Heater.
- Keep the Product in a clean, organized cool and dry place.

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℃
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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