

CONTROL DEVICE

1. PRODUCT DESCRIPTION:

The Seguro Life Sciences Control Device Consists of the following components. These components may be packaged in a single pouch.

12 cc Palm and Finger Control

Control syringe Raw material: Poly Carbonate (PC), Acrylonitrile Butadiene styrene (ABS), &Silicone

2. INTENDED USE:

Seguro Control Device is precisely designed for use during PTCA and other intravascular therapeutic procedures that need to inject die or any other fluid material.

3. PRODUCT SPECIFICATIONS:

Seguro Control Syringe 2 ml, 3 ml, 5 ml, 10 ml, 12 ml, 20 ml, 25 ml capacity. Device Design Stable Ergonomic, Device Body Clear fluid barrel, and Self – lick Mechanism.

4. WARNING:

- This product is ETO Sterilized and Disposable for use.
- Do not re-sterilize or reuse.
- Do not use this device if the unit package or the product has been damaged or soiled.
- The device should be used immediately after opening the package and disposed of safely and properly after use.
- Do not more than 12 ml. There is a possibility the device if this volume is exceeded

5. PRECAUTIONS:

- Control Device is used in Invasive Cardiology in order to inject opaque substance into vessel in order to examine under fluoroscopy.
- Before starting the procedure, check all the materials and equipment's. Also check if Control Device is damaged or not and compatible with all other equipment's and materials.
- Seguro Control Device should be used by as physician trained on the technique of using this device.
- Do not use too much power on Device.

6. SIDE EFFECT & CONTRAINDICATIONS:

- There is no side effect for this product.

- There are NO known contraindications for this device.

7. MAIN PERFORMANCE INDICES

Appearance: Transparent and smooth.

Airproof: There should be no air leakage.

Sterility: The Product is sterilized by EO.

8. INDICATIONS:

Seguro Control Device (12 ml/20 ml) is an accessory design to facilitate the injection of die or any other fluid material used in conjunction with interventional devices during vascular interventional procedures.

9. DIRECTION FOR USE:

- The package of the product should be open in sterile environment.
- Pull opaque substance into Control Device. You can determine the amount of opaque Liquid by the markers on Device. Fix the high pressure line on the rotating adapter or luer lock to the front end of the Device.
- Be sure that there are no air bubbles in Device and high pressure line.
- Fix the manifold to the other end of the high pressure line and inject the opaque liquid slowly to the vessels.
- For single use only

10. CONTRAINDICATIONS:

None Known

11. STORAGE:

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

12. 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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