

INTRODUCER NEEDLE

1. PRODUCT DESCRIPTION:

The Seguro Introducer Needle is consisting of Medical Grade Stainless steel AISI 304 tubing with sharp edge (Back cut & Bevel Cut) and poly carbonate transparent hub is an accessory to puncture the femoral artery for introducing the Guide wire within the body during Angioplasty

2. INTENDED USE:

The Seguro Introducer Needle is an accessory to puncture the femoral artery for introducing the Guide wire within the body during Angioplasty.

The Seguro Introducer Needle is precisely designed for use during Percutaneous Trans luminal Coronary Angioplasty (PTCA) and any other intravascular therapeutic procedures that utilize a guiding catheter.

3. CONTRAINDICATIONS:

There are NO known contraindications for this device.

4. WARNING:

- Do NOT reuse or re-sterilize.
- Use Seguro Introducer Needle 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:

- Seguro Introducer Needle is supplied sterile. Do not use if the product package or a part of the product is damaged during handling.
- The product is for single Use only.
- I must be used by doctors.

6. SIDE EFFCET & CONTRAINDICATIONS:

- There is no side effect for this product.
- There are NO known contraindications for this device.

7. PRODUCT INSTRUCTION:

The Seguro Introducer Needle is consisting of Medical Grade Stainless steel AISI 304 tubing with sharp edge (Back cut & Bevel Cut) and poly carbonate transparent hub is an accessory to puncture the femoral artery for introducing the Guide wire within the body during Angioplasty.

8. OPERATION PROCEDURES:

Operation and Preparation & Use

- Place a sterile drape on a flat surface
- Prior to insertion, flush the needle with saline or heparinized/saline
- Remove protective sheath and introducer from the pouch
- Gain percutaneous access with the Needle Introducer by grasping Main Body
- Advance the Tapered Guide wire through the Needle Introducer to the depth indication mark
- The guide wire should not be withdrawn through the needle. If the guide wire must be withdrawn while still inside the needle, simultaneously remove both the needle and the wire as a unit to prevent the needle from damaging the guide wire.
- Grasp Main Body of the Needle Introducer with one hand and twist the Proximal Hub with other hand until audible click is heard. Audible click indicates the blunting mechanism is activated
- Continue advancing the Tapered Guide wire to desired placement.
- Do not advance or withdraw the guide wire against resistance.
- Fix the cause of resistance before continuing.
- Withdraw the Needle Introducer, leaving the Tapered Guide wire in place.
- 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 regulations.

Use in Special Patient Population: The Seguro Introducer Needle is used for all ages of group.

9. MAIN PERFORMANCE INDICES:

Appearance: Transparent and smooth. Airproof: There should be no air leakage. Sterility: The product is sterilized by EO.

10. INDICATIONS:

The Seguro Introducer Needle is an accessory to puncture the femoral artery for introducing the Guide wire within the body during Angioplasty.













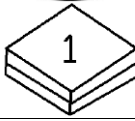
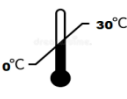

11. STORAGE:

- Storage temperature 0 - 30 °C
- Avoid Exposure to direct Sunlight or Haler.
- 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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