

ANGIOGRAPHY AND ANGIOPLASTY GUIDE WIRE

1. PRODUCT DESCRIPTION:

The Seguro Corography guide wire is designed for percutaneous vessel entry using Seldinger Technique to facilitate the subsequent introduction of an intravascular device during Invasive Cardiology process. The corography guide wire is manufactured from stainless steel which could be coated with PTFE silicone or not.

The Seguro Corography guide wire is constructed of a solid 304 stainless steel / Nitinol body, terminating in a spring coil. The outer diameter (O.D.) is 0.021" to 0.038", with lengths available of 145cm to 260cm in J/ST tip shape and angioplasty guide wire outer diameter (O.D.) is 0.0014", with lengths available of 175cm to 300cm in J/ST tip shape.

2. INTENDED USE:

The Seguro Corography guide wire is designed for percutaneous vessel entry using Seldinger Technique to facilitate the subsequent introduction of an intravascular device during Invasive Cardiology process. The corography guide wire is manufactured from stainless steel which could be coated with PTFE silicone or not.

3. CONTRAINDICATIONS:

There are NO known contraindications for this device. The device is contraindicated when:

- The presence of other device related infection, bacteremia, or septicemia is known or suspected;
- Severe chronic obstructive lung disease exists;
- Past irradiation of prospective insertion site has occurred,
- Previous episodes of venous thrombosis of vascular surgical procedures at the prospective placement site have occurred;
- Local tissue factors will prevent proper device stabilization and/or access.

4. WARNING:

- Do NOT reuse or re-sterilize.
- Use Seguro Guide Wire prior to the expiration date specified on the package.
- Do Not Autoclave
- Do not use if the package is damaged
- Keep Away from Sunlight
- Only experienced doctors who have been trained in invasive techniques and the use of Guide Wires must apply CARRE the Guide Wire. Do not withdraw through a metal needle.

5. PRECAUTIONS:

Seguro Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged guide wires. Using a damaged guide wire may result in vessel damage and / or inaccurate torque response. Confirm the compatibility of the guide wire diameter with the interventional device before actual use. Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system, because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement. Never attach the torque device to the modified portion of the proximal end of the extendible guide wire; otherwise, guide wire damage may occur, preventing the ability to attach the DOC Guide Wire Extension. Guide Wires with Hydrophilic Coating: Avoid abrasion of the hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire through a metal cannula or sharp-edged object.

6. SIDE EFFECT:

There is no side effect for this product.

7. PRODUCT INSTRUCTION:

The Seguro Corography guide wire is constructed using stainless steel / Nitinol alloy. The Seguro guide wire is packed in a spiral hoop fitted with a J straightener, where applicable, to aid in insertion of the guide wire in to the introducer needle.

OPERATION PROCEDURES:

- Remove the guide wire and the spiral hoop fitted together from the pouch.
- Fill the spiral hoop with heparinized physiological saline solution though the hub of the spiral hoop holder using a syringe.
- Remove guide wire from the spiral hoop holder and inspect the guide wire prior to use, to verify that it is lubricated. If the guide wire cannot be easily removed from the spiral, inject more heparinized physiological saline solution again
- Prior to use, prime the catheter with heparinized physiological saline solution to ensure smooth movement of the guide wire within it.
- The guide wire may slide entirely into the catheter or slip out of the catheter because of its low sliding friction.
- Keep at least 5cm, of the wire extended out of the hub of the catheter during introduction.
- Obtain vascular access.
- Insert guide wire into selected catheter.
- Advance guide wire to desired location under fluoroscopic guidance.

- 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 Guide Wire is used for all ages of group.

8. MAIN PERFORMANCE INDICES:

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

9. INDICATIONS:

The Seguro Guide Wire is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedure.

10. STORAGE:

- Storage temperature (0 - 30 °C)
- Avoid Exposure to direct Sunlight or Heater.
- Keep the Product is 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.



Seguro Life Sciences

Plot No:2IA Epip Phase 1

Jharmajri,

Baddi. Dist.: Solan (HP) -173205

Mob No:09816011985