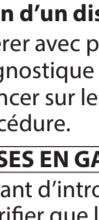
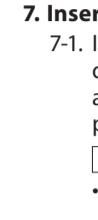
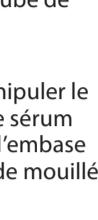
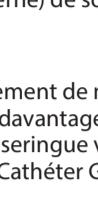
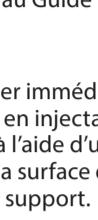
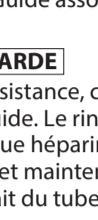
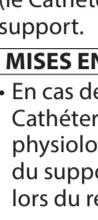
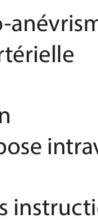
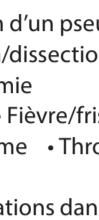
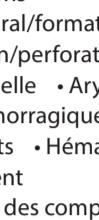
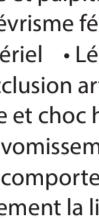
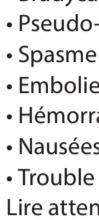
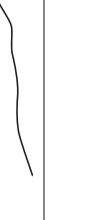
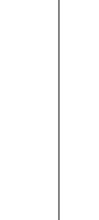
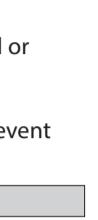
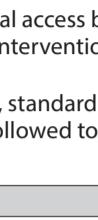
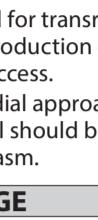
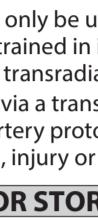
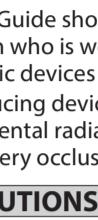
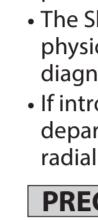
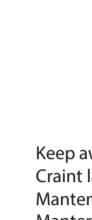




G254XV000-03

RX ONLY

CAUTION: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.
 ATTENTION : Conformément au droit fédéral des Etats-Unis, ce dispositif ne peut être vendu que par ou sur prescription d'un médecin.
 ATENCIÓN: La Ley Federal (EE.UU) restringe la venta de este dispositivo a un médico o bien por orden de éste.
 ATENÇÃO: A Lei Federal dos EUA. restringe a venda deste dispositivo por médicos ou por sua prescrição.

**Guiding Catheter****Inner Guide****Hydrophilic Coating Length****O.D.****I.D.**

Hydrophilic coating length
 Longueur du revêtement
 Longitud del recubrimiento
 Comprimento do revestimento hidrofílico

Outer Diameter
 Diamètre maximal du guide
 Diámetro exterior
 Diametro esterno
 Diametro interno

Inner Diameter
 Diamètre intérieur
 Diametro interno
 Diametro interno

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TERUMO CORPORATION

44-1, 2-CHOME, HATAGAYA, SHIBUYA-KU, TOKYO 151-0072, JAPAN

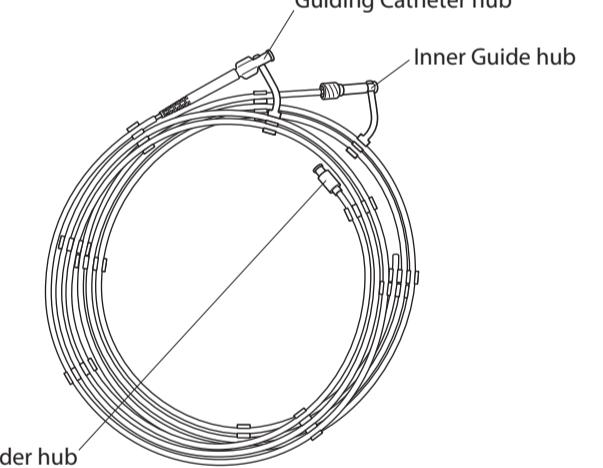
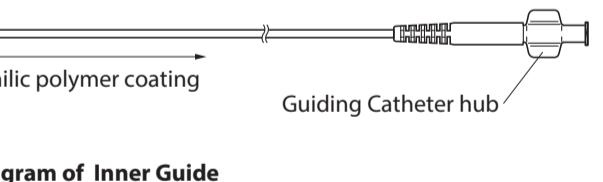
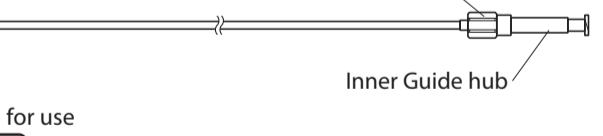
MADE IN JAPAN

TERUMO

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ENGLISH**DESCRIPTION**

The R2P SlenGuide consists of a Guiding Catheter and an Inner Guide, which when combined, are used as a dual catheter system. The distal part of the Guiding Catheter is coated with a hydrophilic polymer, which becomes highly lubricious when wet.

Diagram of R2P SlenGuide**Diagram of Guiding Catheter****Diagram of Inner Guide****Instruction for use**

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Specifications of Guiding Catheter

- Usable length of Guiding Catheter : 150cm, 120cm
- Hydrophilic polymer coating : 300 mm
- Outer diameter of Guiding Catheter : 7Fr. (2.37 mm)
- Inner diameter of Guiding Catheter : 0.087" (2.20 mm)

Specifications of Inner Guide

- Inner diameter of Inner Guide : 0.045" (1.15 mm)
- Inner Guide protruding length : 30 mm

Please read all instructions prior to use

INDICATIONS FOR USE

The R2P (radial to peripheral) SlenGuide is designed for the introduction of interventional and diagnostic devices into the peripheral vasculature of the lower extremities.

CONTRAINDICATIONS

- Patients with a contraindication to antiplatelet and/or anticoagulation therapy.
- Pregnant patients or patients who may be pregnant.
- Patients with known upper extremity vascular disease, extreme tortuosity, anomalous radial artery takeoff, severe subclavian stenosis or severe atherosclerosis.
- Patients with known Buerger's disease or Raynaud's phenomenon.
- Patients with a cario-venous fistula.
- Patients with known anatomical abnormalities of the upper extremity/orta.
- Patients with known dissecting thoracoabdominal aortic aneurysm.
- Do not use within the cerebral vasculature, the carotid arteries and the coronary arteries.
- Do not use via femoral access site.

CAREFUL READ THE LIST OF CONTRAINDICATIONS IN THE INSTRUCTIONS ACCOMPANYING THE OTHER INTERVENTIONAL/DIAGNOSTIC DEVICES TO BE USED WITH THE SLENGUIDE CATHETER**COMPLICATIONS**

- Possible complications associated to catheterization include, but are not limited to, the following.
- Bleeding complications • Allergies to drugs
 - Bradyarrhythmia and palpitation
 - Distal embolization (air, tissue, thrombosis) • Hypotension
 - Infection and pain at puncture site • Arteriovenous fistula
 - Femoral artery spasm • Perforation/tear/dissection
 - Arterial spasm • Arterial injury/perforation/dissection
 - Arterial embolism/occlusion • Arrhythmia
 - Hemorrhage and hemorrhagic shock • Fever/chill
 - Nausea and vomiting • Hematoma • Intra-vessel thrombosis
 - Behavior disorder

Carefully read the list of complications in the instructions accompanying the other interventional/diagnostic devices to be used with the SlenGuide catheter.

WARNINGS

- Carefully handle this product under fluoroscopy. If you feel any resistance while handling this product, immediately stop the manipulation and find out the cause of the resistance, in order to avoid damage to blood vessels and separation or breakage of this product. Ignoring this warning may necessitate retrieval of fragments of the device.

• Before inserting/withdrawing this product over a guidewire, clean the surface of the guidewire with gauze moistened with heparinized physiological saline solution. Advancing/withdrawing this product over a guidewire with residual blood on its surface or over a guidewire, which is not fully wet, may result in separation or breakage of the device.

• To avoid possible complications, such as thrombotic embolism, administer appropriate anti-coagulant and antiplatelet therapy according to the patient's condition.

• Do not torque this product. It may cause damage, which could result in possible separation or breakage of the product.

• Do not attempt to reprocess the catheter tip by heating it with a dryer or other device and/or by making side holes in the catheter tip. This may result in possible separation or breakage of this product and combine one or damage to vessel may result. This may also compromise the sterility, biocompatibility and functional integrity of the device.

• Do not advance a guidewire harshly and/or insert it into the Guiding Catheter by force when the catheter is bent or twisted. Such manipulations may cause the catheter to rupture/break, resulting in damage to the vessels.

• Prior to use, consider the patient's condition and anatomy. Ignoring this may cause severe embolization and/or stroke.

PRECAUTIONS

- Prior to the procedure, carefully examine all devices to verify their proper function and integrity. Confirm that the design and the size of the SlenGuide and of the combined products are suitable for the operation and technique to be used. Please refer to the labels of the product for the size indication.
- The SlenGuide should be used by a physician, who is well trained in fluoroscopy. When using a drug or a device concurrently with the SlenGuide, the operator should have a full understanding of the properties/characteristics of the drug or device, in order to avoid damage to the SlenGuide.
- The SlenGuide is provided sterile, in an unopened and undamaged unit package. Do not use if the unit package or the SlenGuide is broken or soiled. The SlenGuide should be used immediately after opening the package and be disposed of safely properly after use, following local regulations for medical waste management.
- Consider the use of systemic heparinization.
- The entire operation should be carried out aseptically.
- This product has been sterilized by ethylene oxide gas.
- For single use only. Do not reuse. Do not sterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.

Please read all instructions prior to use

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