

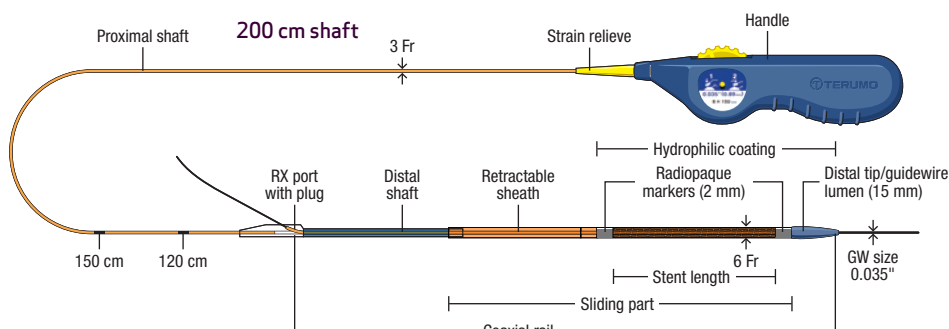
Diagram of R2P™ MISAGO® RX Self-expanding Peripheral Stent



This In-Service Guide is an abridged overview of steps for successful use and deployment of the R2P™ MISAGO® RX Self-expanding Peripheral Stent.

This device should only be used by a physician who is familiar with, and well trained in, Percutaneous Transluminal Angioplasty (PTA) techniques, stent implantations, and transradial access.

Always refer to the labels and package insert for complete warnings, precautions, potential complications, and instructions prior to use.



Stent length (mm)	40	60	80	100	120	150
Sliding part (cm)	25.5	27.5	29.5	31.5	38.5	41.5
Coaxial rail (cm)	45	47	49	52	64	67

Directions for Use¹

Step 1: Preparation Prior to Stent Implantation—Prepare the Lesion

1-1 Pre-dilate the lesion site according to standard practice.

PRECAUTION: Confirm that the guidewire outer diameter does not exceed 0.89 mm (0.035").

Step 2: Selection and Preparation of the Stent System

2-1 Choose a stent size according to the **stent size** selection table.

Reference vessel diameter (mm)	Unconstrained stent diameter (mm)
4.0 - 5.0	6
5.0 - 6.0	7
6.0 - 7.0	8

2-2 Carefully remove the stent system from its holder.

PRECAUTION: Do not remove the green plugging tube at this stage.



2-3 Confirm that the thumbwheel on the deployment handle is in the "Lock" position.

2-4 Fill the enclosed syringe with heparinized saline solution; then, connect the syringe to the **catheter tip** and flush.



2-5 CONFIRM the solution comes out of the proximal and distal ends of the sheath.

2-6 Wet surface of distal tip and sheath.



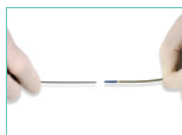
Step 3: Insertion of the Stent System

3-1 Unplug the **plugging tube** from the delivery catheter.



3-2 Pass the proximal end of the guidewire through the catheter tip and advance the stent system in line with the guidewire to target.

3-3 For 200 cm usable length, the depth marker on the shaft will help confirm how far the stent system has been advanced.



3-4 At this point, eliminate any slack in the delivery catheter and fix in position. The stent can become compressed or elongated during deployment.

PRECAUTIONS: Do **not** deploy the stent until it is properly positioned. (If the stent is deployed in an incorrect position, it may **not** expand fully.)

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Step 4: Stent Deployment

- 4-1** Grasp the deployment handle firmly and depress the thumbwheel until it clicks.



- 4-2** While observing the stent under high-resolution fluoroscopy, slowly roll back the thumbwheel using the thumb (with successive click sounds). The stent will start to deploy gradually from the distal end.



PRECAUTIONS: Do not pull the delivery system tight during stent deployment. (The stent can become elongated during deployment.)

Do not hold the sliding part of the delivery catheter. (The stent can become compressed during deployment.)

- 4-3** Continue rolling back the thumbwheel until the stent deployment is completed.

PRECAUTIONS: Ensure that the radiopaque markers for the delivery catheter do not move during stent deployment.

As a guide, stent deployment commences on rolling back the thumbwheel 5-10 clicks for stents up to 100 mm long and 10-15 clicks for stents at least 120 mm long. Carefully roll back the thumbwheel one click at a time and adjust the position of the stent just prior to deployment if necessary.

Deploy the stent completely, even if the delivery catheter bends or corrugates.

If the stent does not deploy when the thumbwheel is rolled back, if no corrugations can be seen in the delivery catheter, stop rolling the thumbwheel, observe using high-resolution fluoroscopy, and then carefully remove the stent system.

A partially deployed stent cannot be retracted into the sliding part or repositioned.

Where multiple stents are deployed in one patient, deploy the stent within the distal lesion first and ensure that there is more than 5 mm but less than 10 mm overlap between the stents by observing the position of the radiopaque markers fluoroscopically.

Stop rotating the thumbwheel when stent deployment is complete.

Do not rotate the thumbwheel in a forward direction.

Ensure that the introducer sheath, guiding sheath, or guiding catheter does not move while the stent is deploying.

- 4-4** Observe that the deployed stent has expanded sufficiently under high-resolution fluoroscopy.

Step 5: Removal of the Delivery Catheter

- 5-1** Confirm under fluoroscopy that the stent expands sufficiently so that the delivery catheter tip can pass through it.

- 5-2** Remove the delivery catheter slowly while allowing the guidewire to maintain the position within the lesion site.

- 5-3** Post-dilate in accordance to standard practice.

Indications

The R2P™ MISAGO® RX Self-expanding Peripheral Stent is indicated to improve luminal diameter in symptomatic patients with *de novo* or restenotic native lesions or occlusions of the Superficial Femoral Artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4 mm to 7 mm and lesion length up to 150 mm.

Important Safety Information

Do not use this device in patients who exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty (PTA) procedure, patients with contraindication to antiplatelet and/or anticoagulation therapy, patients who are judged to have a lesion that prevents proper placement or deployment of the stent, a lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion, or a lesion through which a guidewire cannot pass. This device should only be used by a physician who is familiar with, and well trained in, Percutaneous Transluminal Angioplasty (PTA) techniques, stent implantation, and transradial access.

RX ONLY. Refer to the product labels and package insert for complete warnings, precautions, potential complications, and instructions for use.

Reference: 1. MISAGO® RX Self-expanding Peripheral Stent [Instructions for Use.] Tokyo, Japan: Terumo Corporation; 2020-02.

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