[Warnings]
1. If any unexpected resistance is felt during use of Product, any abnormality is observed in its movement, and/or Steerable Tip is inserted into branches other than the target branches, stop the procedure immediately. Identify the position of Steerable Tip and the cause of the wrong insertion under high-resolution X-ray or with Digital Subtraction Angiography, and take appropriate measures. Should the abnormality still remain, stop insertion and carefully remove all the devices including Product from the vessels after relieving the tension of Steerable Tip by controlling Steering Dial (after straightening Steerable Tip under X-ray fluoroscopy, and release the hands from Steering Dial). Otherwise, it may cause injury to the vessels and/or damage to Product.
2. Product should only be used by physicians and/or surgeons thoroughly trained in microcatheter operation, and angiography and its complication. Operators should be well trained for general microcatheter procedure before using Product.
3. Insert Product with a guidewire for the sake of safety until gaining confidence in the use of Product. In the case of meeting difficulty while inserting Product without a guidewire, stop the insertion and use a guidewire. Otherwise, it may increase the risk of vessel damage and/or Product breakage.
4. While injecting medication and/or contrast media into Product by injector make sure that the injection pressure should be within the specified maximum injection pressure. Otherwise, it may cause damage to Product.
5. Before injecting medication and/or contrast media into Product by injector, confirm that medication and/or contrast media pass through Steerable Tip without blockage. Do not try to clear the blocked Catheter by pressurization or with the guidewire. Exchange Product with another one. Otherwise, it may cause injury to the vessels and/or damage to Product even within the specified maximum injection pressure, in case where the lumen of Product is blocked.
6. If any unexpected resistance is felt during administration or insertion of embolic materials, medication, and contrast media etc., do not forcibly continue the procedure. Exchange Product with another one. Otherwise, it may cause injury to the vessels and/or damage to Product.
7. Pull back Catheter Shaft, after relieving the tension of Steerable Tip by controlling Steering Dial (after straightening Steerable Tip under X-ray fluoroscopy and releasing the hands from Steering Dial). Otherwise, it may cause injury to the vessels and/or damage to Product.

[Contraindications and Prohibitions]
1. Do not use Product for cardiac and cerebral (intracranial) vessels.
Product is not designed for use in cardiac and cerebral (intracranial) vessels.
2. Do not use Product to patients with following symptoms:
   a) Serious allergy against contrast media or medication same used during the procedure and it leads to difficulty of angiography.
   b) Bleeding tendency
   c) Acute myocardial infarction
   d) Serious refractory arrhythmia failure
   e) Serious renal dysfunction
   f) Serious infection or fever
   g) Serious pulmonary disease
   h) Serious serum electrolyte disturbance
   i) Pregnancy or possibility of pregnancy.
3. Do not immerse Product in any medication containing an organic solvent such as alcohol for disinfection. Do not wipe Product with the medication. Do not apply it to Product. Otherwise, it may cause damage to Product and/or loss of its lubricity.
4. In the case where a guiding catheter with a stopcock is used, do not operate the stopcock during insertion of Product. Otherwise, it may cause breakage and/or cutoff of Product.
5. Do not pinch, bend and crash Steerable Tip. Otherwise, it may cause breakage of Steerable Tip and/or decline in operability of Steerable Tip.
6. Do not reuse and re-sterilize. Product is supplied sterile and intended for single use only.
7. Do not use Product outside the intended purpose.
8. Do not pre-shape Catheter Tip by heat and/or with a metal wire etc. Otherwise, it may cause damage to Tip and/or deterioration in its bending performance.
9. Do not operate Steerable Tip while a guidewire is inserted through into Steerable Tip. Otherwise, it may cause damage to the vessels and/or breakage of Product and/or the guidewire.
10. Administer or insert embolic materials, medication, and contrast media etc. with pressure, and/or insert a guidewire after confirming that Steerable Tip is not directed toward the vessel wall under high-resolution X-ray. Otherwise, it may cause damage or rupture of the vessel wall.

### 1. Model

<table>
<thead>
<tr>
<th>REF</th>
<th>Inner Diameter (mm)</th>
<th>Outer Diameter (mm)</th>
<th>Effective Length (cm)</th>
<th>Guidewire Suitable for Use</th>
<th>Maximum Injection Pressure (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIV-20500</td>
<td>0.54</td>
<td>0.80 (2.4Fr)</td>
<td>0.97 (2.9Fr)</td>
<td>125</td>
<td>Less than 0.018 Inch</td>
</tr>
</tbody>
</table>

STERILE
2. Description

This Product is a microcatheter with Steering Dial at Operating Portion which provides the operator with optimal control of the direction of Steerable Tip. Steering Dial and Steerable Tip are connected by two Operating Wires.

The two Operating Wires are inserted through the two lumens, one each, on the wall of Catheter Shaft. Steering Dial is used to apply tension to either one of Operating Wires for manipulation of Steerable Tip.

Once the direction of Steerable Tip is determined, Steering Dial Lock may be used for maintaining the intended direction.

3. Indications

This Product is a microcatheter designed to be inserted into peripheral vessels except cardiac and cerebral (intracranial) vessels, for the purpose of administration and/or injection of embolic material, medication and/or contrast media.

4. Precautions

1) Selection of the patient and procedure must be done under the responsibility of medical professionals. Outcome may vary depending on, among others, the anatomy and pathology of the patient, and the technique of the surgeon and/or physicians.

2) Storage Conditions:

   - Store Product in the original carton box at a cool, dry and dark place. Keep Product placed in the packaging box when stored.

3) Check the expiration date on the label of Product. Do not use it after expiration.

5. Directions

   - The directions for use are furnished for information purposes only.

   [Before Use]

   1. Prepare following items as necessary at the use of Product.
      - Steerable Microcatheter (Product)
      - Sheath Introducer
      - Syringe with Luer Lock
      - Guiding Catheter
      - Heparinised Saline
      - Embolic Material
      - Disinfectant
      - Contrast Media

   2. Take out Product and Case Pipe from Sterile Pack.

   3. Inject heparinised saline into Case Pipe from T-shaped Connector as described in the following figure. After fully moistening the surface of Catheter Shaft with it, pull out Product slowly from Case Pipe.

   4. Steering Dial of Product is locked at the time of shipment. Hold Handgrip and move Steering Dial toward Connector to release Steering Dial until a clicking sound is heard.

   5. Inject heparinised saline from Connector of Product, and perfuse the lumen of Product.

   [How to use]

   1. Introduce a guiding catheter into the target vessel according to its manual and instruction for use prior to insertion of Product, and then insert Product into the target vessel through the guiding catheter.

   2. Inject the contrast media (more than once if needed) before Steerable Tip reaches the target site and observe vessel morphology (vessel branches).

   3. Manipulate Steering Dial of Operating Portion according to the vessel morphology and guide Steerable Tip toward the target site. Monitor the procedure under X-ray fluoroscopy.

   4. Tension Limiter is built in Steering Dial to prevent Operation Wire from being cut. Application of torque larger than specified activates Tension Limiter, which makes Steering Dial spin freely and generates a clicking sound. In that case, do not apply torque anymore because Steerable Tip does not bend any further than specified.

   5. In the case where there is difficulty in reaching the target site, it is recommended to use a guidewire in combination with Product. It may enhance the vessel selectivity.

   6. After reaching the target site, administer and/or inject an embolic material, medication and/or contrast media from Connector.

   7. To complete the procedure, take the following steps:

      - 1) Manipulate Steering Dial to free Steerable Tip from any tension and straighten its curve. Do not keep holding Dial by hand.

      - 2) Carefully remove Product under X-ray fluoroscopy. Otherwise, it may cause breakage of Product and/or damage to vessels.

6. Essential Precautions

   [Before Use]

   1) Do not use Product outside the intended purpose.

   2) Product should only be used by physicians and/or surgeons thoroughly trained in angiography and versed in its complications. It should be used under X-ray fluoroscopy.

   3) Contact the distributor for any enquiry concerning Product.

   4) Check Product model number and expiration date on the label. Do not use after expiration.

   5) Specifications of Product are subject to change without prior notice. Refer to Instructions For Use attached to every Product in order to avoid any malfunction attributable to the specification changes.

   6) Do not reuse. Product is supplied sterile and intended for single use only.

   7) Check Product dimension and compatibility with other devices to be used in combination before use.

   8) Product shall be used only under aseptic conditions.

   9) Be cautious about accidental contamination and potential risk of infection all the time during use of Product.

   10) Do not use Product, if the sterile pack of Product is damaged or wet before opening. It may be contaminated.

   11) Use Product promptly after the sterile pack is opened and dispose of it as medical waste appropriately after use.

   12) Refer to the manual and instructions for use of medications and medical devices to be used in combination with Product, and use them properly.

   13) Check that all the devices and equipment function properly prior to use.

   14) Confirm that Outer Diameter of Catheter Shaft is suitable for the vessel morphology of the target site prior to use.
15) Manipulate Steering Dial of Operating Portion, prior to insertion, to check that Steerable Tip moves appropriately and that there is no abnormality in its steering function.

16) Take appropriate antithrombotic measures prior to use.

17) While injecting medication and/or contrast media into Product by injector make sure that the injection pressure should be within the specified maximum injection pressure. Otherwise, it may cause damage to Product.

18) In the case of using Product to a child, check the diameter of the target blood vessel and decide whether Product can be used or not.

19) In the case of administrating medications and/or embolic materials to a nursing woman through Product, check instruction for use of the medications and/or the embolic materials and decide whether such medications and/or embolic materials can be used or not.

[During Use]

1) Perfuse the inner lumen and outer surface of Product and the inner lumen of the guiding catheter with physiological saline etc., do not forcibly pull back Product to prevent its damage.

2) Do not pre-shape Steerable Tip by heating and/or with metal wire, etc. Otherwise, it may cause breakage of Steerable Tip and/or decline in operability of Steerable Tip.

3) Straighten Steerable Tip by manipulating Steering Dial of Operating Portion, prior to insertion, to check that Steerable Tip moves appropriately and that there is no abnormality in its steering function. Otherwise, it may cause damage to the vessels.

4) If any unexpected resistance is felt during use of Product, any abnormality is observed in its movement, and/or Steerable Tip is inserted into branches other than the target branches, stop the procedure immediately. Identify the position of Steerable Tip by manipulating Steering Dial and the cause of the wrong insertion.

5) Do not administer or insert embolic materials, medication, and contrast media etc. with pressure, or insert a guidewire into Product while Catheter Shaft is kinked or twisted. Otherwise, it may cause damage to Product.

6) Administer or insert embolic materials, medication, and contrast media etc. with pressure, and/or insert a guidewire after confirming that Steerable Tip is not broken and saline as necessary. Otherwise, it may cause damage or rupture of the vessel wall.

7) If any unexpected resistance is felt during administration or insertion of embolic materials, medication, and contrast media etc., do not forcibly pull back Product to prevent its damage.

8) Connect Product to the injector with a high pressure extension line, which can withstand the maximum injection pressure.

9) Before injecting medication and/or contrast media into Product by injector, confirm that medication and/or contrast media pass through Steerable Tip without blockage. Do not try to clear the blocked Catheter by pressurization or with the guidewire. Exchange Product with another one. Otherwise, it may cause injury to the vessels and/or damage to Product even within the specified maximum injection pressure, in case where the lumen of Product is blocked.

10) Before injecting medication and/or contrast media into Product by syringe or injector, make sure that its connector and Connector of Product are securely attached each other. Otherwise, it may cause leakage of medication and/or contrast media, and/or damage to the syringe, injector and/or Product.

11) Do not immerse Product in any medication containing an organic solvent such as alcohol for disinfection. Do not wipe Product with the medication. Do not apply it. Otherwise, it may cause damage to Product and/or loss of its lubricity.

12) In the case where expansion of Product is observed while injecting medication and/or contrast media into Product by syringe or injector, stop the procedure immediately. Otherwise, it may cause breakage of Product.

13) Remove all air bubbles with a syringe etc. if any air bubbles are observed in Connector of Product. Otherwise, they may lead to risk of air embolism in the vessels.

14) In the case where Product is broken and separated in the vessels, stop the procedure immediately and remove all the catheters, including the guiding catheter, carefully and surely. Then confirm that there is no residue in the vessels under X-ray fluoroscopy. In some cases, residue of Catheter Shaft remains in the stopcock of the guiding catheter because of operation of the stopcock during insertion of Product.

15) Control Steerable Tip by manipulating Steering Dial carefully and push forward Catheter Shaft in the vessels gradually while checking the vessel morphology under X-ray fluoroscopy.

16) If unexpected resistance is felt during removal of Product, carefully remove all devices including the guiding catheter. Otherwise, it may cause breakage, separation and retention of Product and/or injury to the vessels.

17) Do not use a guidewire to help to insert embolic material(s). Otherwise, it may cause entrapment of the guidewire between the lumen of Product and the embolic material(s) and lead to failure of embolization.

18) Pull back Catheter Shaft, after relieving the tension of Steerable Tip by controlling Steering Dial (after straightening Steerable Tip under X-ray fluoroscopy and release the hands from Steering Dial). Otherwise, it may cause injury to the vessels and/or damage to Product.

19) In the case where a guiding catheter with a stopcock is used, do not operate the stopcock during insertion of this Product. Otherwise, it may cause breakage and/or cutoff of Product.

20) Make sure that the guiding catheter obtains access to the vessel nearest to the target site. In the case where the guiding catheter is deviated from the target vessel during operation, it may cause damage to Product and/or injury to vessels. In such a case, stop the procedure and carefully remove all the devices including the guiding catheter. Check if there is no abnormality in Product and the guiding catheter. Reinsert them to obtain access to the vessel nearest to the target site.

21) In the case where Product should be passed through the lumen of a metal such as stent, pay attention so that Product should not contact with the metal which may damage the coating and/or decline the lubricity of Product.
[After Use]
1) Put Product after use in a plastic bag in order to prevent direct contact with the skin, and dispose of it as medical waste.

7. Interactions

[Contraindications/Prohibitions of Concomitant Use]
Do not use in combination with following products.

<table>
<thead>
<tr>
<th>Name of Medical Device</th>
<th>Clinical Symptoms/Countermeasures</th>
<th>Mechanism/Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wiping with and/or immersion in medication containing organic solvent such as alcohol for disinfection etc.</td>
<td>Potential of Product damage and loss of lubricity of Catheter Shaft</td>
<td>Elution of lubricious coating to medication</td>
</tr>
<tr>
<td>Injection of high-viscosity medication such as contrast media and embolic materials with a syringe not designed for high-pressure injection</td>
<td>Potential of breakage of syringe and separation of the syringe and Connector of Product</td>
<td>Insufficient pressure resistance of the syringe</td>
</tr>
<tr>
<td>Injection of cyanoacrylate adhesive</td>
<td>Potential of Product occlusion</td>
<td>Solidification of adhesive</td>
</tr>
<tr>
<td>A guidewire larger than 0.018 inch in diameter</td>
<td>Impossible to insert, possibility of Product damage</td>
<td>This guidewire is not suitable for Product</td>
</tr>
</tbody>
</table>

8. Adverse Events
Use of Product may cause following adverse events.

[Serious Adverse Events]
- Perforation of vessel, intimal dissection
- Dissecting aneurysm
- Pseudoaneurysm
- Ischemic complication
- Aneuroembolism
- Arterial embolism, thrombosis, vessel occlusion
- Shock

[Other Adverse Events]
- Spasm of vessels
- Peripheral vessel occlusion
- Bleeding, infection, and pain at the insertion site
- Fever/chill, nausea, vomiting
- Blood pressure fluctuation
- Tachycardia, bradycardia, palpitation

WARRANTY
THE STEERABLE MICROCATHETER™ MODEL MIV-20500 (HEREAFTER REFERRED TO AS “PRODUCT”) HAS BEEN DESIGNED AND MANUFACTURED CAREFULLY AND EXAMINED BEFORE SALE.
THE WARRANTY IS CONTINGENT UPON PROPER USE OF THE PRODUCT IN THE APPLICATION FOR WHICH IT WAS INTENDED AS INDICATED IN THIS INSTRUCTION. HOWEVER, THE PRODUCT MAY FAIL TO PERFORM ITS INTENDED FUNCTION BECAUSE OF VARIOUS REASONS.
SUMITOMO BAKELITE CO., LTD. MAKES NO WARRANTY EXCEPT FOR LIMITED WARRANTY PROVIDED ABOVE, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT.
SUMITOMO BAKELITE CO., LTD., SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES BY ANY USE, DEFECT OR FAILURE OF THE PRODUCT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

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