Progreat
（カテーテル単体 英文）
取扱説明書 (A2 サイズ 2 ページ)
色指定:1C スミ20%
版下管理番号:MC_PC_E_A_50_005
**Micro Catheter System**

**Progreat**

For use in the treatment of vascular access difficulties.

**Catheter Hub**

**Catheter**

For use in the treatment of vascular access difficulties.

To avoid complications, observe all warnings and precautions throughout these instructions.

### CONTENTS OF CONTAINMENT

- **Components:**
  - Catheter Hub = 1
  - Catheter = 1
  - Guide wire = 1
  - Shaping mandrel = 1
  - Inserter & inserter sheath = 1
  - Irrigation sheath = 1
  - Wrist rest = 1
  - Catheter insert = 1

### CONTENTS OF CONTINUOUS

- **Precautions:**
  - Use by date = 2016-10
  - Sterilized using ethylene oxide

### SPECIFICATIONS

- **Inner Diameter:**
  - 2.8Fr. 6205 kPa (900psi)
  - 2.9Fr. 6205 psi

### CONTRAINdications

- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability for some reasons.
- From diagnostic and anatomical point of view, choose proper shape and size for target lesion.
- The catheter should be used by a physician who is familiar to the intended procedures.

### APPLICATION

- This catheter is for angiography and intravascular therapy. The catheter has a hydrophilic polymer coating on the surface over its entire length except its proximal end. The observed flow rate values indicated below are for reference only.

### RESULTS

<table>
<thead>
<tr>
<th>Contents</th>
<th>100 Iopamidol 300</th>
<th>110 Iopamidol 300</th>
<th>150 Iopamidol 300</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iopamidol (mg/mL)</td>
<td>4.4</td>
<td>4.4</td>
<td>4.4</td>
</tr>
<tr>
<td>Concentration (mg/mL)</td>
<td>2.6</td>
<td>2.9</td>
<td>3.5</td>
</tr>
<tr>
<td>Viscosity (cP)</td>
<td>2.9</td>
<td>3.5</td>
<td>2.1</td>
</tr>
<tr>
<td>Viscosity (cP) at 37°C</td>
<td>0.8</td>
<td>0.8</td>
<td>0.7</td>
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<tr>
<td>Result</td>
<td>1.2</td>
<td>1.4</td>
<td>0.9</td>
</tr>
<tr>
<td>Temperature (°C)</td>
<td>37</td>
<td>37</td>
<td>37</td>
</tr>
<tr>
<td>Linear rise (seconds)</td>
<td>0.3</td>
<td>0.3</td>
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<tr>
<td>Linear rise (seconds) at 37°C</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

### WARNING

- Do not resterilize

### CAUTIONS

- Use immediately after opening the package and dispose of safely following your local procedure for the disposal of medical waste.
- Do not advance the catheter with the guide wire withdrawn in it. Kink in the distal and proximal end of the catheter may result in damage of the catheter.

### INSTRUCTIONS FOR FALSE ENTRY INTO THE SUBCLAVIAN AND SYMPATHETIC VESSELS

- When a catheter is inserted into the subclavian or sympatetic vessels, it must be done in the appropriate medical environment, containing an appropriate resuscitation team and necessary medical equipment for resuscitation. The Progreat device should be inserted only by persons who are well-trained and have adequate experience in medical intervention.

### SECTION II. WARNING

- Do not advance the catheter through a metal entry needle or a guide wire. The catheter or the guide wire should not be manipulated while inside the vessel. Penetration of the catheter has to be made through a non-porous wall of the vessel. This can be achieved through the following steps:
  1. Oscillate the catheter with a non-stiff metal tip, by applying torque of 20 to 30N. This will cause the catheter to break, resulting in damage to the vessel.
  2. Manipulation of the catheter should be monitored through a high resolution fluoroscope and a digital subtraction angiography monitor. If any resistance is felt in the vessel, do not advance or withdraw the catheter until the cause of resistance is determined. This may result in damage to the catheter.

### SECTION III. SPECIFICATIONS

- The catheter is compatible with a 0.018" (0.46 mm) or smaller guide wire and a 0.022" (0.57 mm) or larger guide wire. A 0.018" (0.46 mm) guide wire should be inserted into the catheter hub through the inserter. A Torque Device may be attached to the proximal end of the guide wire to facilitate manipulation of the catheter.

### SECTION IV. CONTRAINDICATIONS

- Use by date

- Do not advance the catheter with the guide wire withdrawn in it. Kink in the distal and proximal end of the catheter may result in damage of the catheter.

### SECTION V. COMPLICATIONS

- Manipulation of the catheter should be monitored through a high resolution fluoroscope and a digital subtraction angiography monitor. If any resistance is felt in the vessel, do not advance or withdraw the catheter until the cause of resistance is determined. This may result in damage to the catheter.

### SECTION VI. RESULTS

- Linear rise seconds...
Please see the package for the available sizes.

- If any increase of resistance is felt when infusion, replace the catheter with a new one. Injection against increased resistance may cause the catheter to rupture.

Do not manipulate and/or withdraw the micro catheter system through a metal entry needle or a metal dilator. Needle or a metal dilator may result in abrasion of the hydrophilic coating, destruction of coating on the guide wire.

- Do not use a power injector to infuse agents other than contrast media, as the catheter may become blocked.

- A power injector can be used to infuse a contrast media through the catheter. Observe the warnings and cautions given below. The flow rate depends upon such factors as the type of contrast media, concentration, viscosity, viscosity at the temperature of the surrounding medium, speed of flow, temperature of the contrast media, and the amount of residual blood from the removed guide wire in a heparinized saline solution bath. If the residual stains do not come off, wipe the guide wire once and the catheter using a pressurized water jet.

- Before inserting the catheter into additional vessels, sufficiently inject the heparinized saline solution into the catheter. If any resistance is felt during the insertion of the catheter, make sure that the micro catheter system has not been advanced so far that it cannot be drawn back. Advance or withdraw the catheter until the cause of resistance is determined.

- After the catheter is fully inserted into the patient's vessel, attach a rotating haemostatic valve (Tuhoy-Borst type) to the catheter hub. After making sure that the tip of the catheter's needle has successfully negotiated the guiding catheter hub, slowly advance the guide wire and re-tighten the lock on the catheter hub. After positioning the catheter tip closer than 2 cm from the steam source may result in the damage and/or breakage of the catheter's tip.

- Do not use if the unit packaging or the product has been damaged or soiled.

- Do not use if it is over the date specified on the reverse side of the paper.

- Do not use if the guide wire or the catheter has kinked, bent or broken.

- Do not use if the guide wire stopper is not attached to the catheter tip. The guide wire stopper prevents the guide wire from being pulled into the catheter which may result in the guide wire breakage/separation. Wiping without surface lubricity may result in the breakage of the guide wire stopper.

- Do not use if the guide wire stopper is accidentally cloned or otherwise removed.

- Do not use if the guide wire stopper is missing.

- Do not use if the packaging is damaged or soiled, or if the product is over the date specified on the label.

- Do not use if the hub of catheter is accidentally damaged.

- Do not use if the catheter insulation coating is damaged.

- Do not use if the catheter insulation coating has not adhered to the hub.

- Do not use if the catheter and the micro catheter system are not ready to use.

- Do not use if the catheter hub and the micro catheter system are not securely connected.

- Do not use if the guide wire is not compatible with the micro catheter system.

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- Do not use if the product is not assembled in the recommended configuration.

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