<table>
<thead>
<tr>
<th>Progreat</th>
<th>(カテーテル単体 英文)</th>
</tr>
</thead>
<tbody>
<tr>
<td>取扱説明書 (A2 サイズ 2 ページ)</td>
<td></td>
</tr>
<tr>
<td>色指定:1C</td>
<td>スミ</td>
</tr>
<tr>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>版下管理番号:MC_PC_EA_50_006</td>
<td></td>
</tr>
</tbody>
</table>
The heparinized saline solution should be injected slowly into its holder so that the catheter is not pulled out of the holder by force. If any resistance is felt, do not remove the catheter by force. Withdraw the catheter carefully together with the guiding catheter. Removing the catheter forcefully may damage the catheter.

- If any increase of resistance is felt during infusion, replace the catheter with a new one. Injection against increased resistance may cause the catheter to break.
- Do not rub or bend the catheter tip with too small radius, pinch by forceps or tweezers, which may result in damage of catheter.
- Maximum injection pressure should be limited to 4137 kPa (600 psi), 5171 kPa (750 psi), 6205 kPa (900 psi).
- Do not inject any volume greater than the maximum injection volume of this catheter.
- Before use, check the size of the coiled embolic material and supportive device to determine if the combination is suitable. When introducing an embolic material or the agent without correcting the kink or attempts to correct the kink by inserting guide wire or by infusion may cause the catheter to break.
- Do not stretch the catheter tip tightly or bend excessively when shaping it not with enclosed shaping mandrel.
- Do not insert the enclosed shaping mandrel into the patient's body.
- Do not inject the embolic material or the agent with the guide wire or by infusion if the situation is not solved. Do not inject the embolic material or the agent without correcting the kink or attempts to correct the kink by inserting guide wire or by infusion may cause the catheter to break.
- Do not inject the embolic material or the agent with the guide wire or by infusion if the situation is not solved. Do not inject the embolic material or the agent without correcting the kink or attempts to correct the kink by inserting guide wire or by infusion may cause the catheter to break.
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Inflammation with embolic material
- Cerebral oedema
- Bradycardia
- Cerebral infarction from peripheral artery occlusion

Angiography or intravascular therapy may be accompanied by, but not limited to, the following:
- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability for some reasons

Generally, angiography or intravascular therapy is contraindicated for, but not limited to, the patients listed below.

- Do not soak or wipe this product with agents containing organic solvents, like antiseptic alcohol. It may damage this product or it may decrease the lubricity of this product.
- Do not advance the catheter by force in extremely tortuous vessels. This may result in kink of the catheter or damage to the vessel.
- Monitor the manipulation of the catheter in the vessel, by confirming the position of the catheter tip through a high resolution fluoroscope and a digital subtraction angiography monitor. Any quick and unreasonable movement of the wire may cause the catheter to break/cut/separate, which may result in damaging the vessel, the catheter or the guide wire. If the situation is not solved, withdraw the entire system of the catheter with the guiding catheter.
- Do not drive the guide wire from the catheter through the holder into the sheath. This may damage the catheter.
- Do not pressurize the catheter or advance the guide wire through the catheter when the catheter is kinked or blocked. This may result in breakage of the vessel.
- Do not shape this catheter by steam, insert the enclosed shaping mandrel into the distal tip of the catheter or pull the catheter into a tightened valve. Damage to the catheter may occur.
- Do not drive the guide wire from the catheter through the holder into the sheath. This may damage the catheter.
- Do not advance the catheter to the target vessel. If a catheter is inserted beyond the selected target vessel without any visualization and catheter damage may occur.
- Do not insert the guide wire beyond the selected target vessel without any visualization and catheter damage may occur.
- Do not inject any volume greater than the maximum injection volume of this catheter.
- Do not inject the embolic material or the agent with the guide wire or by infusion if the situation is not solved. Do not inject the embolic material or the agent without correcting the kink or attempts to correct the kink by inserting guide wire or by infusion may cause the catheter to break.
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The following table shows the in vitro testing result which was conducted using this catheter.

<table>
<thead>
<tr>
<th>Catheter</th>
<th>Injection pressure monitor/limit</th>
<th>Max. injection volume</th>
<th>Max. injection pressure</th>
<th>Injection volume</th>
<th>Injection pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.8 Fr.</td>
<td>4137 kPa (600 psi)</td>
<td>5 mL</td>
<td>750 psi</td>
<td>3 mL</td>
<td>500 psi</td>
</tr>
<tr>
<td>3.0 Fr.</td>
<td>5171 kPa (750 psi)</td>
<td>7 mL</td>
<td>900 psi</td>
<td>5 mL</td>
<td>600 psi</td>
</tr>
<tr>
<td>3.5 Fr.</td>
<td>6205 kPa (900 psi)</td>
<td>10 mL</td>
<td>1000 psi</td>
<td>7 mL</td>
<td>800 psi</td>
</tr>
</tbody>
</table>

Read all instructions prior to use.

Please read Instruction For Use for Coaxial Catheter

Micro Catheter System

Progreat

Catheter

Manufacturer

TERUMO CORPORATION

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1. Please see the package for the available size.

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

3. Do not reuse.

**Inner Diameter**
- Increased resistance to infusion suggests that the catheter be blocked with the drug or contrast media being infused or with blood clots. Discontinue.

**Mandrel**
- Monitor the manipulation of the micro catheter system in the vessel, by confirming.

4. If any resistance to the guide wire being removed is felt, do not remove the guide wire by force. The resistance may indicate insufficient lubricity of the catheter and damaging to the vessel.

5. When a power injector is to be used, follow the instructions given below under “Instruction For Using a Power Injector with the catheter”.

**WARNINGS**

- The introducer system should be used by physicians who are familiar with the procedure.

- The procedure should be done by a person who is experienced in the actual use of the micro catheter system.

6. The radiopaque marker of the guide wire should leave the vessel when the catheter and/or the guide wire is moved, which may result in the damage of the surface coating, collapse of the catheter shaft and/or deformation of catheter.

7. When advancing the micro catheter system into the peripheral vessels, do not advance the guide wire into the catheter, carefully advance the guide wire until it reaches the desired site.

8. Before starting a procedure, make sure to check all devices and tools are in proper condition.

- Do not soak or wipe this product with agents containing organic solvents, like antiseptic alcohol. It may damage the catheter or guide wire, or it may decrease the friction between the guide wire and catheter hub.

9. Do not move the guide wire while the micro catheter system is being inserted into the vessel. This may cause the catheter to break and become trapped, which may result in damage to the vessel.

**PRECAUTIONS**

- Observe the warnings and cautions given below. The flow rate depends upon such factors as the viscosity of the contrast media, Iodine content.

- Patients who cannot lie on their back on the operating table because of congestive heart failure or some respiratory disorder

- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability for some reasons

- Patients with serious arrhythmia

- Before starting a procedure, make sure to check all devices and tools are in proper condition.

- Make sure to warm contrast medium to 37 °C before use.

10. Do not move the guide wire while the micro catheter system is being inserted into the vessel. This may cause the catheter to break and become trapped, which may result in damage to the vessel.

**CONNECTIONS**

- Do not move the guide wire while the micro catheter system is being inserted into the vessel. This may cause the catheter to break and become trapped, which may result in damage to the vessel.

**INSTRUCTION FOR USING A POWER INJECTOR WITH THE CATHETER**

- To avoid damage to the surface coating, do not wipe the guide wire with gauze with disinfectant.

- An angiography or intravascular therapy may be accompanied by, but not limited to, the following:

- Patients who cannot lie on their back on the operating table because of congestive heart failure or some respiratory disorder

- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability for some reasons

- Patients with serious arrhythmia

- Before starting a procedure, make sure to check all devices and tools are in proper condition.

- Make sure to warm contrast medium to 37 °C before use.

- Do not move the guide wire while the micro catheter system is being inserted into the vessel. This may cause the catheter to break and become trapped, which may result in damage to the vessel.

**PREFERENCES**

- 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 viscosity of the contrast media, Iodine content.

- Patients who cannot lie on their back on the operating table because of congestive heart failure or some respiratory disorder

- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability for some reasons

- Patients with serious arrhythmia

- Before starting a procedure, make sure to check all devices and tools are in proper condition.

- Make sure to warm contrast medium to 37 °C before use.

- Do not move the guide wire while the micro catheter system is being inserted into the vessel. This may cause the catheter to break and become trapped, which may result in damage to the vessel.

**NUMBER OF PARTS**

- Guide wire
- Guide wire hub
- Catheter hub
- Catheter
- Guide wire sheath

**USEFUL LENGTH OF CATHETER**

- Catheter: 100 mm
- Guide wire: 4.0 mm

**DIAPHRAGMATIC INPUTS**

- Do not move the guide wire while the micro catheter system is being inserted into the vessel. This may cause the catheter to break and become trapped, which may result in damage to the vessel.

**DIAGRAM**

- Diagrams and additional information at points of view, proper shape and size used for better design.