Progreat

（カテーテル単体　英文）

取扱説明書（A2 サイズ 2 ページ）

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版下管理番号：MC_PC_E,A_50_006

2019-08

Micro Catheter System

Progreat®

Catheter

Please read Instruction For Use for Coaxial type on the reverse side of paper.

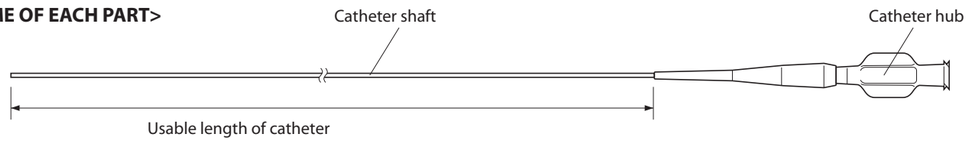
Read all instructions prior to use.
To avoid complications, observe all warnings and precautions throughout these instructions.

DESCRIPTION OF COMPONENTS

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 coating gives it lubricity when it is wet. When infusing a contrast media through the catheter, a power injector can be used.

<APPLICATION>
The PROGREAT is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities and all coronary vessels. The PROGREAT is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. The PROGREAT should not be used in cerebral vessels.
Note: The 2.7Fr./2.9Fr. and 2.8Fr./3.0Fr. PROGREAT are also indicated for Uterine Fibroid Embolization procedures.

<NAME OF EACH PART>



⁎ Please see the package for the available size

SPECIFICATIONS

Catheter O.D.	Catheter I. D.	Recommended guiding catheter	Suitable O.D. of Guide wire
2.0 Fr./2.7 Fr. (0.67/0.90 mm)	0.019" (0.49 mm)	0.038" (0.97mm) or bigger guide wire compatible	0.016" (0.41 mm) or smaller
2.4 Fr./2.9 Fr. (0.80/0.97 mm)	0.022" (0.57 mm)	0.038" (0.97mm) or bigger guide wire compatible	0.018" (0.46 mm) or smaller
2.7 Fr./2.9 Fr. (0.90/0.97 mm)	0.025" (0.65 mm)	0.038" (0.97mm) or bigger guide wire compatible	0.021" (0.53 mm) or smaller
2.8 Fr./3.0 Fr. (0.93/1.00 mm)	0.027" (0.70 mm)	0.038" (0.97mm) or bigger guide wire compatible	0.021" (0.53 mm) or smaller

INDICATIONS FOR USE

1. CONTRAINDICATIONS
Generally, angiography or intravascular therapy is contraindicated for, but not limited to, the patients listed below.
- Patients in the acute phase of myocardial infarction
- Patients with serious arrhythmia
- Patients with serious serum electrolyte imbalance
- Patients who in prior procedures have developed an adverse reaction to the injection of contrast media
- Patients with renal dysfunction
- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability for some reasons
- Patients who cannot lie on their back on the operating table because of congestive heart failure or some respiratory disorder
- Patients with mental disease or those who are not expected to lie quietly during angiography
- Pregnancy patients

2. COMPLICATIONS
Angiography or intravascular therapy may be accompanied by, but not limited to, the following:
· Headache · Nausea and vomiting · Fever and chill · Abnormality in blood sampling tests · Blood pressure drifting · Shock
· Myocardial infarction · Renal failure · Infection and pain at the puncture site
· Haemorrhage, haematoma, arterio-venous fistula and false aneurysm at the puncture site
· Spasm, artery perforation, dissecting aneurysm and false aneurysm with the use of a guide wire or catheter
· Inflammation with embolic material · Cerebral oedema · Bradycardia · Cerebral infarction from peripheral artery occlusion
· Behavior disorder · Death

3. WARNINGS
- **Flush the lumen of the guiding catheter and the catheter continuously with heparinized saline solution. Residual contrast media or blood clots on the catheter surface reduce its lubricity, preventing smooth catheter movement. If flushing fails to restore surface lubricity, discontinue the use of the catheter and remove it slowly and carefully together with the guiding catheter. Excessive force used in pulling the catheter may cause breakage/rupture/separation, which may necessitate retrieval.**
- **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 catheter and damaging to the vessels.**
- **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. If any resistance is felt in the vessel, do not advance or withdraw the catheter until the cause of resistance is determined through a high resolution fluoroscope and a digital subtraction angiography monitor. Manipulating the catheter and/or the guide wire against resistance 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 advance the catheter by force in extremely tortuous vessels. This may result in kink of the catheter or damage to the vessel.**
- **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 hold catheter in place by inserting catheter into stent strut. This may cause the catheter to break/rupture/separate, which may result in damage to the vessel.**

4. PRECAUTIONS
- The catheter should be used by a physician who is familiar to the intended procedures.
- Manipulation of the catheter should be monitored through a high resolution fluoroscope and a digital subtraction angiography monitor.
- The entire procedure should be carried out aseptically.
- The surface of the catheter must be completely wet with heparinized saline solution to maintain a lubricious surface.
- Refer to instructions for use information on any drugs and/or devices you may wish to use with this catheter to determine compatibility and prevent catheter damage.
- Make sure to warm contrast medium to 37 °C before use.
- Before starting a procedure, make sure to check all devices and tools are in proper condition.
- From diagnostic and anatomical point of view, choose proper shape and size for target lesion.

DIRECTIONS FOR USE

1. Carefully remove the catheter in its holder from the package.
2. Immerse the catheter in its holder in a heparinized saline solution bath and fill the holder with heparinized saline solution through the hub of the holder using a syringe, to thoroughly wet the surface of the catheter (Fig.1). For catheter types with shaped end, inject heparinized saline solution into the holder of the Y-shaped holder hub.
   CAUTION The heparinized saline solution should be injected slowly into its holder so that the catheter is not driven out of its holder.
3. Remove the catheter slowly from its holder. If resistant is felt, do not try to remove it against the resistance, but inject heparinized saline solution again into its holder again, and try once more.
   CAUTIONS
   - Do not use if the catheter has been damaged or if any other abnormality is observed.
   - When wet, the shaft of the catheter is very lubricious. Hold the catheter by its hub during handling.
4. When shaping this catheter by steam, insert the enclosed shaping mandrel into the distal tip of the catheter and gently shape it to the desired angle. Then expose the tip to the steam for approximately 10 seconds (Fig.2). Check the resulting shape after removing of the shaping mandrel.
   CAUTIONS
   - Do not rub or bend the catheter tip with too small radius, pinch by forceps or tweezers, which may result in the damage of the surface coating, collapse of the catheter shaft and/or deformation of catheter.
   - Positioning the catheter tip closer than 2 cm from the steam source may result in the damage of the surface coating or the tip of the catheter.
   - Excessively re-shaping the catheter may damage the surface coating or the tip of the catheter.
   - When shaping with steam, take care not to burn yourself.
   - Do not insert the enclosed shaping mandrel into the patient's body.
   - Do not stretch the catheter tip tightly or bend excessively when shaping it not with enclosed shaping mandrel but with your fingers. It may result in collapse of the catheter shaft and/or deformation of the catheter.
5. Using a syringe, prime the catheter lumen with heparinized saline solution through its hub. To reduce the injection resistance, use of a 1 mL or 2.5 mL lure lock syringes is recommended (Fig. 3). Inject slowly more than 2 mL into the catheter until more than 10 drops of the solution appear out of its tip in order to prime the catheter sufficiently. Priming is completed if no air bubble can be seen in drops of solution.
6. Attach a haemostatic valve or rotating haemostatic valve (Tuhoy-Borst type) to the hub of the catheter, if necessary. Insert a guide wire, previously immersed in heparinized saline solution and of a compatible size into the catheter through its hub or the attached valve and advance the guide wire to the distal end of the catheter. When using haemostatic valve, insert the enclosed inserter into the valve and insert the guide wire through the inserter. A Torque Device may be attached to the proximal end of the guide wire to facilitate guide wire manipulation (Fig. 4). To maintain surface lubricity, immerse the catheter and guide wire assembly in a heparinized saline solution bath or put it back into the catheter holder filled with heparinized saline solution.
   CAUTIONS
   - Do not insert the guide wire through the catheter's distal end. This may damage the catheter.
   - When the haemostatic valve is attached, insert the guide wire after priming the haemostatic valve into the catheter and advance to the distal end of the catheter.
7. Insert a guiding catheter into the patient's vessel. Attach a rotating haemostatic valve (Tuhoy-Borst type) to the guiding catheter and irrigate the catheter continuously with hepalinized saline solution. Insert the catheter and the guide wire assembly through the valve into the guiding catheter and advance to the distal end of the guiding catheter (Fig. 5). For smooth insertion through the rotating haemostatic valve and guiding catheter, it is recommended to keep the guide wire tip within the catheter until the catheter reaches the distal end of the guiding catheter.
   WARNINGS
   - **Do not manipulate and/or withdraw the catheter through a metal entry needle or a metal dilator. Manipulation and/or withdrawal through a metal entry needle or a metal dilator may result in abrasion of the surface coating, destruction and/or separation the catheter shaft.**
   - **If the guiding catheter is fitted with a stopcock, do not close the stopcock with the catheter inside the guiding catheter. The catheter may be broken.**
   - **Make sure that the guiding catheter does not slip out of the vessel. If the guiding catheter should leave the vessel when the catheter and/or the guide wire is moved, this may result in the damage of the catheter.**

   CAUTIONS
   - Do not tighten the rotating haemostatic valve excessively on the catheter, or manipulate of the catheter through a tightened valve. Damage to the catheter may occur.
   - If resistance is felt, do not force the catheter into the guiding catheter as this may result in the damage of the catheter.
   - Do not advance the catheter with the guide wire withdrawn in it. Kink in the distal and proximal of the catheter may occur. If the distal part of the catheter is inserted through the hub of the guiding catheter, withdraw the guide wire slowly and carefully advance to the catheter.
8. 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.
   WARNINGS
   - **If any resistance is felt in the vessel, do not advance or withdraw the catheter until the cause of resistance is determined through a high resolution fluoroscope and a digital subtraction angiography monitor. Manipulating the catheter and/or the guide wire against resistance may result in damaging the vessel, the catheter or the guide wire.**
   - **If manipulate the catheter in the vessel without the guide wire, it may result in damaging the vessel. When re-inserting the guide wire into the catheter, carefully advance the guide wire while making sure of the position of the guide wire tip through a high resolution fluoroscope and a digital subtraction angiography monitor. The quick and unreasonable movement may cause the damage of the vessel.**

   CAUTIONS
   - When advancing the catheter into the peripheral vessel, draw it back slightly under fluoroscopy each time it has been advanced, to make sure that the catheter has not been advanced so far that it can not be drawn back.
   - Do not manipulate the catheter by force. The catheter tip, highly flexible, may be stretched or damaged.
   - Before injecting agents into the guiding catheter, take up the slack of the catheter and withdraw it a little in order to avoid damage to the vessel if the catheter is suddenly advanced.
9. When the desired site is reached, remove the guide wire from the catheter.
   CAUTIONS
   - Drawing back the guide wire against resistance may cause the catheter to kink. If any resistance is felt, draw back the catheter to a position where no resistance to the guide wire withdrawal is noticed, then remove the guide wire. Withdraw the guide wire without this manipulation may damage the catheter.
   - Rinse residual blood from the removed guide wire in a heparinized saline solution bath. If the residual stains will not come off, wipe the guide wire once with gauze moistened with heparinized saline solution. Blood remaining on the guide wire could cause resistance when inserted into the catheter.
10. Before introducing an embolic material or other agent, slowly inject a small volume of contrast media into the catheter using a syringe and verify under high resolution fluoroscopy and a digital subtraction angiography monitor that the media come out of the catheter tip. With its small lumen the catheter offers a high resistance to infusion. When infusing contrast media or drug with a syringe, use a 1 mL syringe or smaller. Refer to instructions for use information for any drugs and/or devices you may wish to use with this catheter to determine compatibility and prevent catheter damage. In case of using different kind of embolic material or other agent, it is recommended to change the catheter each time.
    WARNINGS
    - **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 break, resulting in damage to the vessel.**
    - **If no contrast media come out, it indicates possible kinking of the catheter. If drawing back the catheter fails to correct the kink, replace the catheter with a new one. Do not try to correct the kink by inserting guide wire or by pressurized infusion. Starting the introduction of 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/rupture/separate and this may result in damaging the vessel.**
    - **Friction between the catheter wall and the embolic material may work to advance the catheter, resulting in perforation of the vessel wall. To prevent this, take up the slack of the catheter by drawing it back slightly and hold.**

    CAUTIONS
    - **Increased resistance to infusion suggests that the catheter be blocked with the drug or contrast media being infused or with blood clots. Discontinue infusion immediately and replace the catheter with a new one.**
    - When a power injector is to be used, follow the instructions given below under **"Instruction For Using a Power Injector with the catheter"**.
    - In case of using organic solvents, make sure to check its characteristic before use.
    - 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, do not use material or devices exceeding 0.018" (0.46mm) in diameter. Always check the movement of the embolic material and supportive device through a high resolution fluoroscope and a digital subtraction angiography monitor. Do not advance or withdraw the catheter, if any resistance is felt in the vessel especially while using embolic material and supportive device suitable for catheter with 0.016" (0.41mm) inner diameter of smaller. Advance or withdraw the catheter, only after the cause of resistance is determined through a high resolution fluoroscope and a digital subtraction angiography monitor. Any quick and unreasonable movement may cause the catheter to break/rupture/separate, which may result in damage to the vessel.
11. 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 guide wire, discontinue to advance the guide wire and replace with a new one. If there is difficulty in inserting the guide wire into the catheter hub, insert the guide wire tip by turning the guide wire or the catheter hub clockwise and counter-clockwise.
    WARNING **When re-inserting the guide wire into the catheter, verify the location of the guide wire tip through a high resolution fluoroscope and digital subtraction angiography monitor. Any quick and unreasonable movement of the wire may cause the catheter to break/rupture/separate, which may result in damage to the vessel.**
12. When the procedure is completed, carefully remove the catheter together with the guiding catheter.
    WARNING **If any resistance is felt, do not remove the catheter by force. Withdraw the catheter carefully together with the guiding catheter. Removing the catheter by force may result in the catheter breakage/separation, which may necessitate retrieval.**

Instruction For Using a Power Injector with the catheter

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, which varies with the type and temperature of the media, the model and setting of the power injector and how the injector is connected to the catheter. The observed flow rate values indicated below are for reference only.

WARNINGS
- **Do not use a power injector to infuse agents other than contrast media, as the catheter may become blocked.**
- **Setting of injection pressure must not exceed below listed maximum injection pressure that correspond to outer diameter of each catheter tip. Exceeding of injection pressure beyond the maximum injection pressure may cause catheter rupture.**

Catheter O.D.	Maximum injection pressure
2.0Fr., 2.4Fr., 2.7Fr.	5171 kPa (750psi)
2.8Fr.	6205 kPa (900psi)

- **Under high resolution fluoroscopy and DSA monitor, inject small amount of contrast media with syringe and confirm the flow of contrast media out of the catheter tip before using injector.**
- **If expansion of the catheter O.D. is observed during the injection, it may be an excess over the maximum pressure limit. In such case, stop the injection immediately.**
- **When securing the catheter in position, secure it by the hub so that catheter shaft is not damaged. In securing, do not hold the catheter shaft with forceps, or this may result in catheter separation.**

CAUTIONS
- If the catheter has been kinked or bent sharply, replace it with a new one.
- Connect the power injector to the catheter using a pressure-resistant extension tube.
- When re-inserting the guide wire after completion of angiography, flush out the catheter lumen with heparinized saline solution.

Fig. 1

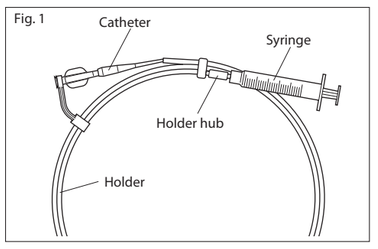


Fig. 2

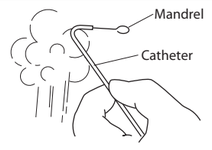


Fig. 3

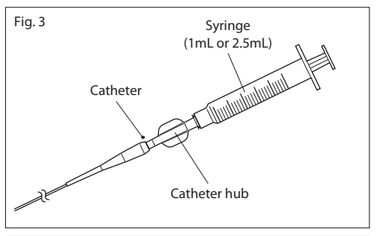


Fig. 4

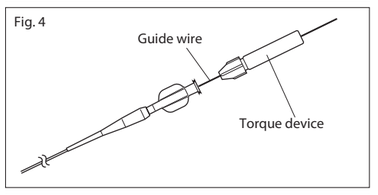
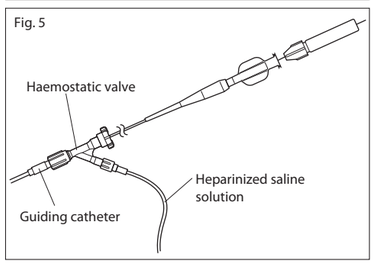


Fig. 5



REFERENCE DATA

1. Injector use — MARK V Provis(MEDRAD)
2. Conditions and injector setting
   - Contrast media temperature ····· 37ºC
   - Injection pressure monitor/limit ····· 4137 kPa (600 psi), 5171 kPa (750 psi), 6205 kPa (900 psi)
   - Flow scale ····· mL/sec
   - Linear rise seconds ····· 0.3 sec
3. Results
   The set injection volume is not attained because of varying conditions, including the viscosity of the contrast media.

Catheter O.D.	Usable length of Catheter (cm)	Contrast media	Iodine content (mg/mL)	Viscosity (cP)	Set Condition		Actual Flow Rate (mL/sec)			Dead Space Volume (mL)
					Flow Rate (mL/sec)	Volume (mL)	4137 kPa (600 psi)	5171 kPa (750 psi)	6205 kPa (900 psi)	
2.0 / 2.7Fr. (0.67/ 0.90mm)	100	Iopamidol	300	4.4	3.0	10	1.2	1.4	–	0.37
			370	9.1	3.0	10	0.7	0.9	–	
	110	Iopamidol	300	4.4	3.0	10	1.1	1.3	–	0.39
			370	9.1	3.0	10	0.6	0.8	–	
	130	Iopamidol	300	4.4	3.0	10	0.9	1.2	–	0.43
			370	9.1	3.0	10	0.5	0.6	–	
	150	Iopamidol	300	4.4	3.0	10	0.7	1.0	–	0.46
			370	9.1	3.0	10	0.4	0.5	–	
2.4 / 2.9Fr. (0.80 / 0.97mm)	100	Iopamidol	300	4.4	3.0	10	2.0	2.4	–	0.45
			370	9.1	3.0	10	1.2	1.5	–	
	110	Iopamidol	300	4.4	3.0	10	1.9	2.3	–	0.48
			370	9.1	3.0	10	1.1	1.4	–	
	130	Iopamidol	300	4.4	3.0	10	1.6	2.0	–	0.53
			370	9.1	3.0	10	0.9	1.1	–	
	150	Iopamidol	300	4.4	3.0	10	1.5	1.8	–	0.58
			370	9.1	3.0	10	0.8	1.0	–	
2.7 / 2.9Fr. (0.90 / 0.97mm)	100	Iopamidol	300	4.4	6.0	10	3.1	3.7	–	0.54
			370	9.1	3.0	10	1.8	2.2	–	
	110	Iopamidol	300	4.4	6.0	10	2.9	3.5	–	0.57
			370	9.1	3.0	10	1.7	2.1	–	
	130	Iopamidol	300	4.4	6.0	10	2.6	3.2	–	0.64
			370	9.1	3.0	10	1.4	1.8	–	
	150	Iopamidol	300	4.4	6.0	10	2.3	2.8	–	0.71
			370	9.1	3.0	10	1.2	1.6	–	
2.8 / 3.0Fr. (0.93 / 1.00mm	100	Iopamidol	300	4.4	6.0	10	3.5	4.4	5.2	0.56
			370	9.1	6.0	10	2.1	2.7	3.3	
	110	Iopamidol	300	4.4	6.0	10	3.4	4.1	4.7	0.61
			370	9.1	6.0	10	2.0	2.6	3.1	
	130	Iopamidol	300	4.4	6.0	10	3.2	3.7	4.3	0.68
			370	9.1	6.0	10	1.9	2.2	2.9	
	150	Iopamidol	300	4.4	6.0	10	2.6	3.1	3.9	0.75
			370	9.1	6.0	10	1.5	2.0	2.4	

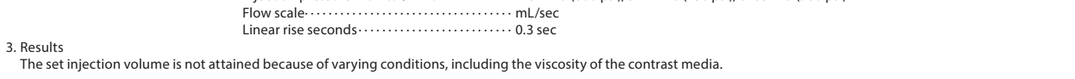
PRECAUTIONS FOR USE

- This device is sterilized with ethylene oxide gas and is intended for single use only. Do not re-sterilize and/or reuse this device.
- Do not use if the unit package or the product has been damaged or soiled.
- Use immediately after opening the package and dispose of safely following your local procedure for the disposable of medical waste.

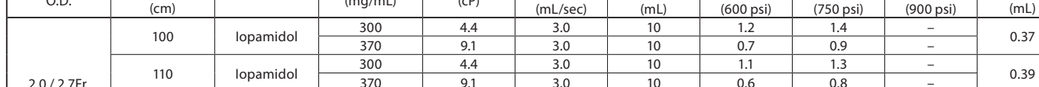
PRECAUTION FOR STORAGE

Avoid exposure to water, direct sunlight, extreme temperature or humidity during storage.

Rx ONLY CAUTION : Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.



Catalogue number · Batch code · Use by date · Sterilized using ethylene oxide · Do not reuse · Consult instructions for use · Contents · Manufacturer



Do not resterilize · Do not use if package is damaged · Inner Diameter · Radiopaque marker · Maximum injection pressure · Max guidewire outer diameter

®: Registered Trademark

TERUMO CORPORATION
44-1, 2-CHOME, HATAGAYA, SHIBUYA-KU, TOKYO 151-0072, JAPAN MADE IN JAPAN

TERUMO

2019-08

PG34E002-03

Micro Catheter System Progreat® Coaxial catheter system

Please read Instruction For Use for Catheter type on the reverse side of paper.

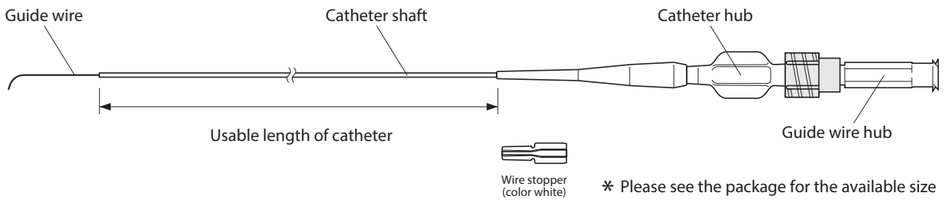
Read all instructions prior to use.
To avoid complications, observe all warnings and precautions throughout these instructions.

DESCRIPTION OF COMPONENTS

The catheter assembled with the guide wire is for angiographic or intravascular therapy. The catheter has a hydrophilic polymer coating on the surface over its entire length except its proximal end. The coating gives it lubricity when it is wet. Furthermore, the guide wire consists of super elastic alloy core, polyurethane jacket, hydrophilic coating on its surface, and a gold coil distal tip marker can help to advance the catheter to target vessels. There are two types of guide wire available, pre-shaped type and shapeable type. Shapeable type guide wire tip can be reshaped. When infusing a contrast media through the catheter, a power injector can be used.

<APPLICATION>
The PROGREAT is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities and all coronary vessels. The PROGREAT is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. The PROGREAT should not be used in cerebral vessels.
Note: The 2.7Fr./2.9Fr. and 2.8Fr./3.0Fr. PROGREAT are also indicated for Uterine Fibroid Embolization procedures.

<NAME OF EACH PART>



* Please see the package for the available size

SPECIFICATIONS

Catheter O.D.	Catheter I. D.	Guide wire O.D.	Recommended guiding catheter	Suitable O.D. of Guide wire
2.4 Fr./2.9 Fr. (0.80/0.97 mm)	0.022″ (0.57 mm)	0.018″ (0.46 mm)	0.038″ (0.97mm) or bigger guide wire compatible	0.018″ (0.46 mm) or smaller
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2.8 Fr./3.0 Fr. (0.93/1.00 mm)	0.027″ (0.70 mm)	0.021″ (0.53 mm)	0.038″ (0.97mm) or bigger guide wire compatible	0.021″ (0.53 mm) or smaller

INDICATIONS FOR USE

1. CONTRAINDICATIONS
Generally, angiography or intervascular therapy is contraindicated for, but not limited to, the patients listed below.
- Patients in the acute phase of myocardial infarction
- Patients with serious arrhythmia
- Patients with serious serum electrolyte imbalance
- Patients who in prior procedures have developed an adverse reaction to the injection of contrast media
- Patients with renal dysfunction
- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability for some reasons
- Patients who cannot lie on their back on the operating table because of congestive heart failure or some respiratory disorder
- Patients with mental disease or those who are not expected to lie quietly during angiography
- Pregnancy patients

2. COMPLICATIONS
Angiography or intravascular therapy may be accompanied by, but not limited to, the following:
· Headache · Nausea and vomiting · Fever and chill · Abnormality in blood sampling tests · Blood pressure drifting
· Shock · Myocardial infarction · Renal failure · Infection and pain at the puncture site
· Haemorrhage, haematoma, arterio-venous fistula and false aneurysm at the puncture site
· Spasm, artery perforation, dissecting aneurysm and false aneurysm with the use of a guide wire or catheter · Inflammation with embolic material
· Cerebral oedema · Bradycardia · Cerebral infarction from peripheral artery occlusion · Behavior disorder · Death

3. WARNINGS
- **Flush the lumen of the guiding catheter and the micro catheter system continuously with heparinized saline solution. Residual contrast media or blood clots on the micro catheter system surface reduce its lubricity, preventing smooth catheter movement. If flushing fails to restore surface lubricity, discontinue the use of the micro catheter system and remove it slowly and carefully together with the guiding catheter. Excessive force used in pulling the catheter may cause breakage/rupture/separation, which may necessitate retrieval.**
- **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 catheter and damaging to the vessels.**
- **Monitor the manipulation of the micro catheter system in the vessel by confirming the position of the catheter tip / guide wire 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 micro catheter system until the cause of resistance is determined through a high resolution fluoroscope and a digital subtraction angiography monitor. Manipulating the catheter and/or the guide wire against resistance 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 or the guide wire with the guiding catheter.**
- **Do not advance the micro catheter system by forcing in extremely tortuous vessels. This may result in kink of the catheter or damage to the vessel.**
- **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 lubricity of the catheter or guide wire.**
- **Do not hold catheter in place by inserting catheter into stent strut. This may cause the catheter to break/rupture/separate, which may result in damage to the vessel.**

4. PRECAUTIONS
- The micro catheter system should be used by a physician who is familiar to the intended procedures.
- Manipulation of the micro catheter system should be monitored through a high resolution fluoroscope and a digital subtraction angiography monitor.
- The entire procedure should be carried out aseptically.
- The surface of the catheter must be completely wet with heparinized saline solution to maintain a lubricious surface.
- Refer to instructions for use information on any drugs and/or devices you may wish to use with this micro catheter system to determine compatibility and prevent the micro catheter system damage.
- Make sure to warm contrast medium to 37 °C before use.
- Before starting a procedure, make sure to check all devices and tools are in proper condition.
- From diagnostic and anatomical point of view, choose proper shape and size for target lesion.

DIRECTIONS FOR USE

1. Carefully remove the micro catheter system in its holder from the package.
2. Fill the holder with heparinized saline solution through the hub of the holder using a syringe, to thoroughly wet the surface of the catheter (Fig. 1).
3. Remove the micro catheter system slowly from its holder. If resistant is felt, do not try to remove it against the resistance , but inject heparinized saline solution into its holder again, and try once more.
   CAUTIONS
   - Do not use if the micro catheter system has been damaged or if any other abnormality is observed.
   - When wet, the shaft of the micro catheter system is very lubricious. Hold the catheter by its hub during handling.
4. Make sure that the lock adapter is not loose. Inject heparinized saline solution into the guide wire hub using the attached 2.5 mL lure lock syringe (Fig. 2). In order to prime the catheter sufficiently, slowly inject at least 1 mL of the solution into the catheter until more than 10 drops of the solution appear out of its tip. To maintain surface lubricity, immerse the catheter and the guide wire assembly in a heparinized saline solution bath or put it into its holder filled with heparinized saline solution.
   CAUTIONS
   - Use immediately after opening the package. Once the catheter pouch is opened, the enclosed syringe package is no longer sterile.
   - Prime the catheter and guide wire sufficiently. Manipulation of an insufficiently primed catheter may cause wrinkling, separation of the catheter, and/or abrasion of the hydrophilic coating on the guide wire.
5. To shape the tip of the re-shapable type guide wire, maintain its surface lubricity and coil it carefully around your fingertip or the attached inserter (Fig. 3).
   CAUTIONS
   - Do not shape the pre-shaped type guide wire. This may cause damaging to the guide wire.
   - Do not shape the guide wire using method other than that described above. Handling the wire when dry, heating, shaping with forceps or fingernails, bend tightly or back and forth may result in the guide wire breakage/separation. Wiping without surface lubricity may result in abrasion of hydrophilic coating.
6. When shaping this catheter by steam, insert the enclosed shaping mandrel into the distal tip of the catheter and gently shape to the desired angle. Then expose the tip to the steam for approximately 10 seconds (Fig. 4). Check the resulting shape after removing of the shaping mandrel.
   CAUTIONS
   - Do not rub or bend the catheter tip with too small radius, pinch by forceps or tweezers, which may result in the damage of the surface coating, collapse of the catheter shaft and/or deformation of catheter.
   - Positioning the catheter tip closer than 2 cm from the steam source may result in the damage of the surface coating or the tip of the catheter.
   - Excessively re-shaping the catheter may damage the surface coating or the tip of the catheter.
   - When shaping with steam, take care not to burn yourself.
   - Do not insert the enclosed shaping mandrel into the patient's body.
   - Do not stretch the catheter tip tightly or bend excessively when shaping it not with enclosed shaping mandrel but with your fingers. It may result in collapse of the catheter shaft and/or deformation of the catheter.
7. Insert the guiding catheter into the patient's vessel. Attach a rotating haemostatic valve (Tuhoy-Borst type) to the guiding catheter and continuously irrigate the catheter with heparinized saline solution. Insert the micro catheter system with guide wire assembly through the valve into the guiding catheter and advance to the distal end of the guiding catheter. In case of difficulty of the micro catheter system insertion, loosen the lock adapter, slowly pull the guide wire back approximately 20mm from the catheter tip in order to straighten the catheter tip, and then carefully insert the catheter, avoiding catheter kinking (Fig. 5-2). After the catheter tip has successfully negotiated the guiding catheter hub, slowly advance the guide wire and re-tighten the lock adapter.
   WARNINGS
   - **Do not manipulate and/or withdraw the micro catheter system through a metal entry needle or a metal dilator. Manipulation and/or withdrawal through a metal entry needle or a metal dilator may result in abrasion of the hydrophilic coating, destruction and/or separation of the micro catheter system.**
   - **If the guiding catheter is fitted with a stopcock, do not close the stopcock with the micro catheter system inside the guiding catheter. The micro catheter system may be broken.**
   - **Make sure that the guiding catheter does not slip out of the vessel. If the guiding catheter should leave the vessel when the catheter and/or the guide wire is moved, this may result in the damage of the micro catheter system.**

   CAUTIONS
   - Do not tighten the rotating haemostatic valve excessively on the micro catheter system, and/or manipulate the micro catheter system through a tightened valve. Damage to the micro catheter system may occur.
   - If resistance is felt, do not force the micro catheter system into the guiding catheter as this may result in the damage of the micro catheter system.
8. Carefully advance the micro catheter system through the guiding catheter until it reaches the desired site. At bifurcation, rotate the guide wire hub so that the angled tip of the guide wire points in the desired direction (Fig. 5-1). If complicated vessels selectivity is observed, slowly pull the guide wire back approximately 20 mm from the catheter's tip to make its tip straight (Fig. 5-2).
   WARNINGS
   - **Monitor the manipulation of the micro catheter system in the vessel, by confirming the position of the catheter tip / guide wire 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. Manipulating the catheter and/or the guide wire against resistance 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 or the guide wire with the guiding catheter.**
   - **When advancing the micro catheter system into the peripheral vessel, draw it back slightly under fluoroscopy each time it has been advanced, to make sure that the micro catheter system has not been advanced so far that it can not be drawn back.**
   - **If manipulate the micro catheter system in the vessel without the guide wire, it may result in damaging the vessel. When re-inserting the guide wire into the catheter, carefully advance the guide wire while making sure of the position of the guide wire tip through the high resolution fluoroscope and a digital subtraction angiography monitor. The quick and unreasonable movement may cause damage to the vessel.**
9. When advancing the micro catheter system to the desired site, the wire protruding from the catheter tip can be adjusted and affixed with the attached wire stopper. Set the slit part of the wire stopper to the guide wire between the catheter hub and the guide wire hub. Remove the guide wire from the catheter hub and adjust the protruding tip length. Slide the wire stopper into the catheter hub to fix the guide wire (Fig. 6).
   CAUTION
   - Do not move the guide wire while the wire stopper is fixed on the catheter hub. If the guide wire is moved in such a situation, the hydrophilic coating and the coating resin on the guide wire may be abraded.

Fig. 1

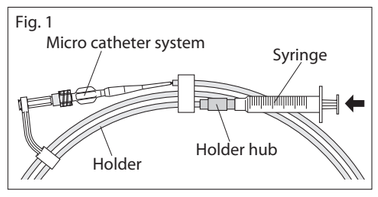


Fig. 2

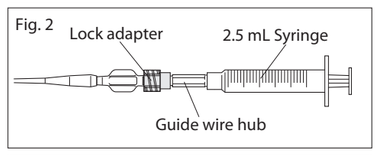


Fig. 3

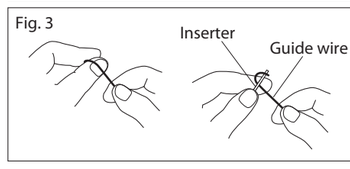


Fig. 4

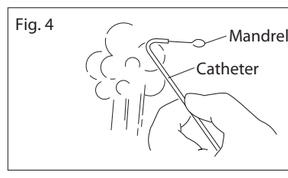


Fig. 5

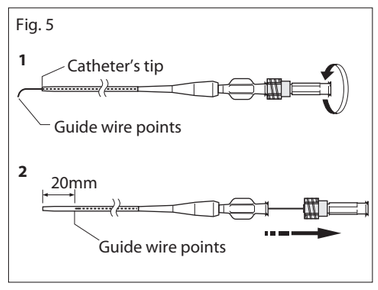
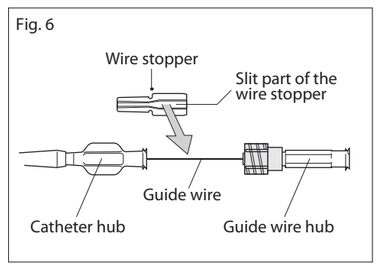


Fig. 6



10. When the desired site is reached, remove the guide wire from the catheter.
    CAUTIONS
    - 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 guide wire. Flush the catheter again with heparinized saline solution.
    - Rinse 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 with gauze moistened with heparinized saline solution. Blood remaining on the guide wire can affect its surface lubricity and could cause resistance when inserted into the catheter.
    - To avoid damage to the surface coating, do not wipe the guide wire with gauze with disinfectant.
11. Before introducing an embolic material or other agent, slowly inject a small volume of contrast media into the catheter using a syringe and verify under a high resolution fluoroscope and a digital subtraction angiography monitor that the media come out of the catheter tip. With its small lumen the catheter offers a high resistance to infusion. When infusing contrast media or drug with a syringe, using 1 mL syringe is recommended. When using embolic materials and drugs, use them following their instruction for use to check their compatibility with the catheter. When using many embolic materials, it is recommended to change the catheter each time.
    WARNINGS
    - **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 break, resulting in damage to the vessel.**
    - **If no contrast media come out, it indicates possible kinking of the catheter. If drawing back the catheter fails to correct the kink, replace the catheter with a new one. Do not try to correct the kink by inserting guide wire or by pressurized infusion. Starting the introduction of 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/rupture/separate and this may result in damage to the vessel.**
    - **Friction between the catheter wall and the embolic material may work to advance the catheter, resulting in perforation of the vessel wall. To prevent this, take up the slack of the catheter by drawing it back slightly and hold.**

    CAUTIONS
    - Increased resistance to infusion suggests that the catheter be blocked with the drug or contrast media being infused or with blood clots. Discontinue infusion immediately and replace the catheter with a new one.
    - Do not use the attached 2.5 mL syringe to inject contrast medium, embolic materials or other medicines. Using the 2.5 mL syringe for high pressure injection of such agents may cause damage of the syringe or dislocation of the syringe from the catheter hub.
    - When introducing an embolic material, do not use the attached guide wire as a supportive device. It may run onto the embolic material inside the lumen.
    - When a power injector is to be used, follow the instructions given below under "Instruction For Using a Power Injector with the catheter".
    - In case of using organic solvents, make sure to check its characteristic before use.
    - 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, do not use material or devices exceeding 0.018" (0.46mm) in diameter. Always check the movement of the embolic material and supportive device through a high resolution fluoroscope and a digital subtraction angiography monitor. Do not advance or withdraw the catheter, if any resistance is felt in the vessel especially while using embolic material and supportive device suitable for catheter with 0.016" (0.41mm) inner diameter of smaller. Advance or withdraw the catheter, only after the cause of resistance is determined through a high resolution fluoroscope and a digital subtraction angiography monitor. Any quick and unreasonable movement may cause the catheter to break/rupture/separate, which may result in damage to the vessel.
12. 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 guide wire, discontinue advancing the guide wire and replace with a new one. If there is difficulty in inserting the guide wire into the catheter hub, insert the guide wire tip by turning the guide wire or the catheter hub clockwise and counter-clockwise.
    WARNING **When re-inserting the guide wire into the catheter, verify the location of the guide wire tip through a high resolution fluoroscope and digital subtraction angiography monitor. Any quick and unreasonable movement of the wire may cause the catheter to break/rupture/separate, which may result in damage to the vessel.**
13. When the procedure is completed, carefully remove the catheter together with the guiding catheter.
    WARNING **If any resistance is felt, do not remove the micro catheter system by force. Withdraw the catheter carefully together with the guiding catheter. Removing the catheter by force may result in the catheter breakage/separation, which may necessitate retrieval.**

Instruction For Using a Power Injector with the catheter

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, which varies with the type and temperature of the media, the model and setting of the power injector and how the injector is connected to the catheter. The observed flow rate values indicated below are for reference only.

WARNINGS
- **Do not use a power injector to infuse agents other than contrast media, as the catheter may become blocked.**
- **Setting of injection pressure must not exceed below listed maximum injection pressure that correspond to outer diameter of each catheter tip. Exceeding of injection pressure beyond the maximum injection pressure may cause catheter rupture.**

Catheter O.D.	Maximum injection pressure
2.4Fr., 2.7Fr.	5171 kPa (750psi)
2.8Fr.	6205 kPa (900psi)

- **Under high resolution fluoroscopy and DSA monitor, inject small amount of contrast media with syringe and confirm the flow of contrast media out of the catheter tip before using injector.**
- **If expansion of the catheter O.D. is observed during the injection, it may be an excess over the maximum pressure limit. In such case, stop injection immediately.**
- **When securing the catheter in position, secure it by the hub so that catheter shaft is not damaged. In securing, do not hold the catheter shaft with forceps, or this may result in catheter separation.**

CAUTIONS
- If the catheter has been kinked or bent sharply, replace it with a new one.
- Connect the power injector to the catheter using a pressure-resistant extension tube.
- When re-inserting the guide wire after completion of angiography, flush out the catheter lumen with heparinized saline solution.

REFERENCE DATA

1. Injector use — MARK V Provis(MEDRAD)
2. Conditions and injector setting
   Contrast media temperature ····· 37ºC
   Injection pressure monitor/limit ····· 4137 kPa (600 psi), 5171 kPa (750 psi), 6205 kPa (900 psi)
   Flow scale ····· mL/sec
   Linear rise seconds ····· 0.3 sec
3. Results
   The set injection volume is not attained because of varying conditions, including the viscosity of the contrast media.

Catheter O.D.	Usable length of Catheter (cm)	Contrast media	Iodine content (mg/mL)	Viscosity (cP)	Set Condition		Actual Flow Rate (mL/sec)			Dead Space Volume (mL)
					Flow Rate (mL/sec)	Volume (mL)	4137 kPa (600 psi)	5171 kPa (750 psi)	6205 kPa (900 psi)	
2.4/2.9Fr. (0.80/ 0.97mm)	100	Iopamidol	300	4.4	3.0	10	2.0	2.4	–	0.45
			370	9.1	3.0	10	1.2	1.5	–	
	110	Iopamidol	300	4.4	3.0	10	1.9	2.3	–	0.48
			370	9.1	3.0	10	1.1	1.4	–	
	130	Iopamidol	300	4.4	3.0	10	1.6	2.0	–	0.53
			370	9.1	3.0	10	0.9	1.1	–	
	150	Iopamidol	300	4.4	3.0	10	1.5	1.8	–	0.58
			370	9.1	3.0	10	0.8	1.0	–	
2.7/2.9Fr. (0.90/ 0.97mm)	100	Iopamidol	300	4.4	6.0	10	3.1	3.7	–	0.54
			370	9.1	3.0	10	1.8	2.2	–	
	110	Iopamidol	300	4.4	6.0	10	2.9	3.5	–	0.57
			370	9.1	3.0	10	1.7	2.1	–	
	130	Iopamidol	300	4.4	6.0	10	2.6	3.2	–	0.64
			370	9.1	3.0	10	1.4	1.8	–	
	150	Iopamidol	300	4.4	6.0	10	2.3	2.8	–	0.71
			370	9.1	3.0	10	1.2	1.6	–	
2.8/3.0Fr. (0.93 / 1.00mm)	100	Iopamidol	300	4.4	6.0	10	3.5	4.4	5.2	0.56
			370	9.1	6.0	10	2.1	2.7	3.3	
	110	Iopamidol	300	4.4	6.0	10	3.4	4.1	4.7	0.61
			370	9.1	6.0	10	2.0	2.6	3.1	
	130	Iopamidol	300	4.4	6.0	10	3.2	3.7	4.3	0.68
			370	9.1	6.0	10	1.9	2.2	2.9	
	150	Iopamidol	300	4.4	6.0	10	2.6	3.1	3.9	0.75
			370	9.1	6.0	10	1.5	2.0	2.4	

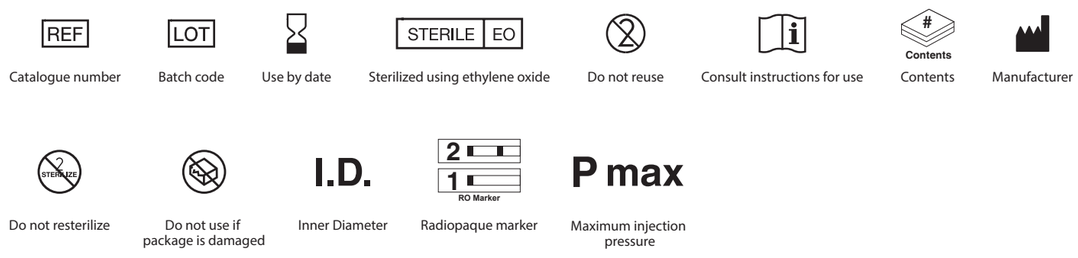
PRECAUTIONS FOR USE

- This device is sterilized with ethylene oxide gas and is intended for single use only. Do not re-sterilize and/or reuse this device.
- Do not use if the unit packaging or the product has been damaged or soiled.
- Use immediately after opening the package and dispose of safely following your local procedure for the disposal of medical waste.

PRECAUTION FOR STORAGE

Avoid exposure to water, direct sunlight, extreme temperature or humidity during storage.

Rx ONLY CAUTION : Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.



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