Issued 2023-12-1

Progreat λ™ Lambda

Micro Catheter System

TERUMO

Contents

Order No.
Order number

REF
Catalogue number

LOT
Batch code

STERILE EO
Sterilized using ethylene oxide

Use-By-Date

Manufacturer

Do not reuse

Consult instructions for use

Marker configuration

Do not resterilize

Max Guide Wire O.D.
Max guide wire outer diameter

Catheter inner diameter

Inserter

Non-pyrogenic

Rx ONLY
Indicates that the device requires a prescription to use

Do not use if package is damaged

Keep away from sunlight

Keep dry

Please read all instructions prior to use.

DESCRIPTION

<INDICATION>

Progreat Lambda is intended for the infusion of contrast media, or embolic materials for hemostasis, into the peripheral vasculature, excluding the blood vessels belonging to the central circulatory system. Progreat Lambda is also indicated for drug infusion in intra-arterial therapy in the peripheral vasculature. Progreat Lambda should not be used in cerebral or coronary vessels.

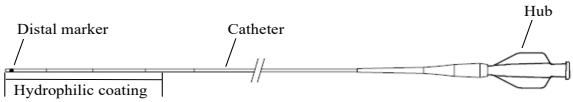
<DESCRIPTION>

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.

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

NAME OF EACH PART



The Progreat Lambda include:

・ Inserter

Other materials required but not provided are:

・ Syringe
・ Haemostatic valve
・ *Guiding catheter
・ *Rotating haemostatic valve (Tuohy-Borst type)
・ *Guide wire
・ *Sterile heparinized saline (for system flushing)

* Please see the information on the package label for the accessories and size.

SPECIFICATIONS

The Progreat Lambda is able to be used with guidewires and guiding catheters with the following dimensions:

Size (Fr.)	Catheter O.D. (Distal/Proximal)	Catheter I.D.	Recommended guiding catheter	Max. Guidewire Diameter
1.7Fr.	0.57mm/0.94 mm (1.7 Fr./2.8 Fr.)	0.43mm (0.017”)	0.97mm (0.038”) or bigger guidewire compatible	0.41mm (0.016”)
1.9Fr.	0.64mm/0.94 mm (1.9 Fr./2.8 Fr.)	0.48mm (0.019”)	0.97mm (0.038”) or bigger guidewire compatible	0.41mm (0.016”)

CAUTION 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 who are pregnant or are supposed to be pregnant.

2. COMPLICATIONS

Angiography or intravascular therapy may be accompanied by, but not limited to, the following:

- Headache
- Fever and chill
- Blood pressure drifting
- Myocardial infarction
- Nausea and vomiting
- Abnormality in blood sampling tests
- Shock
- 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
- Bradycardia
- Behavior disorder
- Cerebral oedema
- Cerebral infarction from peripheral artery occlusion
- 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 of the fragments.**
- **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 damage to the vessels.**
- **Monitor the manipulation of the catheter in the vessel, by confirming the position of the catheter tip under high resolution fluoroscopy and a digital subtraction angiography monitor (DSA). If any resistance is felt in the vessel, do not advance or withdraw the**

catheter until the cause of resistance is determined under high resolution fluoroscopy and DSA. 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.

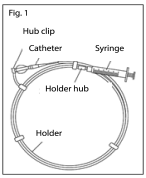
- **Do not advance the catheter by force in extremely tortuous vessels. This may result in kink of the catheter or damage to the vessel.**
- **Do not pass the catheter through a stent strut.**

4. PRECAUTIONS

- The catheter should be used by a physician who is familiar with the intended procedures.
- Manipulation of the catheter should be monitored under high resolution fluoroscopy and DSA.
- This product has been sterilized by ethylene oxide gas. For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
- Do not use if the unit package or the product has been damaged or soiled.
- The product should be used immediately after opening the package and be disposed of safely and properly after use.
- The entire operation should be carried out aseptically.
- The surface of the catheter must be completely wet with heparinized saline solution to maintain a lubricious surface.
- Before use, consult the instructions for use of the drugs and devices to be used along with this catheter to determine compatibility and to prevent catheter damage.
- The Progreat Lambda should be used only by physicians trained in percutaneous, intravascular techniques and well trained in the use of the device.
- Do not use the 175cm catheter length to deploy detachable embolic coils since it has not been tested for compatibility with detachable embolic coils.

DIRECTIONS FOR USE

1. Take the catheter in its holder out of the package.



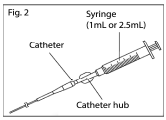
2. Immerse the catheter in its holder in saline. Fill the holder with heparinized saline through the holder hub by using a syringe. (Fig. 1) For the preshaped type catheter, inject the heparinized saline from Y shape holder.

CAUTION
The heparinized saline solution should be injected slowly into its holder so that the catheter is not driven out of its holder.

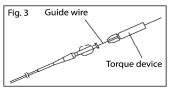
3. Remove the catheter slowly from its holder. If resistance is felt, do not try to remove it against the resistance, but inject heparinized saline solution again into its holder, and try once more.

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. 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 luer lock syringes is recommended (Fig. 2). 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.



5. Attach the 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. A torque device may be attached to the proximal end of the guide wire to facilitate guide wire manipulation (Fig. 3). 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.

6. 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 heparinized 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. 4). 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.

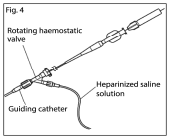


Fig. 4

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 of 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 part 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 the catheter.

7. Monitor the manipulation of the catheter in the vessel, by confirming the position of the catheter tip through a high resolution fluoroscope and DSA.

WARNINGS

- If any resistance is felt in the vessel, do not advance or withdraw the catheter until the cause of resistance is determined under high resolution fluoroscopy and DSA. Manipulating the catheter and/or the guide wire against resistance may result in damaging the vessel, the catheter or the guide wire.
- If the catheter is manipulated in the vessel without the guide wire, it may result in damage to 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 under high resolution fluoroscopy and DSA. The quick and unreasonable movement may cause damage to 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.
- Injecting agent through the guiding catheter may result in perforation of the vessel wall. To prevent this, take up the slack of the catheter by drawing it back slightly and hold.

8. When the desired site is reached, remove the guide wire from the catheter.

CAUTIONS

- If any resistance is felt while removing the guide wire, do not remove the guide wire by force. Drawing back the guide wire against resistance may cause the catheter to kink. Carefully remove the guide wire together with 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.

9. 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 DSA that the media come out of the catheter tip. When infusing contrast media or drug with a syringe, using a 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 during 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 comes 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 a 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 is 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”.
- Using organic solvents may cause damage to the catheter.
- Be careful of cracking of the three-way stopcock of heamostatic valve when administering pharmaceuticals containing fat emulsion the oily components such as castor oil, surfactant or solubilizing agent such as alcohol etc, [when the three-way stopcock is cracked due to the above chemical solutions, there is a possibility of leakage of blood, chemical solution, or aeration. In particular, administration of a general anesthetic, a vasopressor, an antineoplastic agent, an immunosuppressant or the like cannot secure the necessary dosage and may cause severe effects on the patient. Excessive re-tightening of the Syringe to the three-way stopcock may occur the cracks.]
- When introducing an embolic material, use material and loading devices not exceeding 0.016" (0.41 mm) in diameter.
- When using embolic material and accessory devices suitable for catheter with 0.016" (0.41 mm) or smaller inner diameter, the accessory devices may run on to the embolic material inside the lumen because of wide clearance between their outer diameter and the catheter inner diameter.

Size (Fr.)	Max. Guidewire Diameter	Embolic coil	Microsphere	Dimethyl sulfoxide (DMSO)
1.7Fr.	0.016” (0.41 mm)	When using an embolic coil, use it according to the IFU of the embolic coil.	≤500μm	Applicable
1.9Fr.	0.016” (0.41 mm)	When using an embolic coil, use it according to the IFU of the embolic coil.	≤500μm	Applicable

10. When inserting the catheter further more to the other vessel, inject a sufficient amount of the heparinized saline solution into the catheter. If any resistance is felt during the insertion of the guide wire, stop advancing the guide wire and replace with a new one. In case the guide wire is difficult to be inserted into the catheter hub, insert the guide wire tip by turning the guide wire or the catheter hub right and left.

WARNING

- 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 under high resolution fluoroscopy and a DSA.

Any quick and sudden movements may cause the catheter to break/rupture/separate and may result in damage to the vessel.

CAUTION

- Do not flush heparinized saline or saline water from the three-way stopcock of the hemostasis valve with the catheter inserted. [Leakage of liquid or breakage may occur.]

11. When the procedure is completed, remove the catheter together with the guiding catheter carefully.

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 of the fragments.

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 corresponds to outer diameter of each catheter tip. Exceeding of injection pressure beyond the maximum injection pressure may cause catheter rupture.

Size (Fr.)	Maximum Injection Pressure	Maximum Flow Rate*
1.7Fr.	6,205kPa(900psi)	4.3 mL/sec.
1.9Fr.		4.8 mL/sec.

*catheter effective length: 110cm

- Under high resolution fluoroscopy and DSA monitor, inject a 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 the catheter shaft is not damaged. In securing, do not hold the catheter shaft with forceps, or this may result in catheter separation.

- Do not use a power injector to infuse any solution. through the heamostatic valve or three-way stopcock. [Leakage or breakage may occur].

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

……4,137 kPa (600 psi), 5,171 kPa (750 psi), 6,205 kPa (900 psi)

Flow scale……mL/sec

Linear rise seconds……0.3 sec

3. METHODS AND RESULTS

The value of injection volume was selected to be three times the set flow rate value. The set injection volume is not attained because of varying conditions, including the viscosity of the contrast media.

Size (Fr.) (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)	4,137kPa (600psi)	5,171kPa (750psi)	6,205kPa (900psi)	
1.7Fr. (0.57/0.94mm)	110	Iopamidol	300	4.4	5.0	15	1.9	2.3	2.6	0.50
			370	9.1			1.1	1.3	1.6	
	130		300	4.4			1.6	2.0	2.4	0.55
			370	9.1			0.9	1.1	1.4	
	150		300	4.4			1.6	1.9	2.2	0.60
			370	9.1			0.8	1.0	1.2	
	165		300	4.4			1.5	1.8	2.0	0.64
			370	9.1			0.8	0.9	1.1	
	175		300	4.4			1.2	1.4	1.7	0.67
			370	9.1			0.6	0.7	0.9	
1.9Fr. (0.64/0.94mm)	110		300	4.4			2.2	2.7	3.2	0.52
			370	9.1			1.4	1.7	2.1	
	130		300	4.4			2.0	2.5	2.9	0.58
			370	9.1			1.1	1.4	1.8	
	150		300	4.4			1.8	2.2	2.6	0.63
			370	9.1			0.9	1.2	1.5	
	165		300	4.4			1.6	1.9	2.3	0.67
			370	9.1			0.7	0.9	1.2	
	175		300	4.4			1.4	1.7	2.1	0.70
			370	9.1			0.6	0.8	0.9	

PRECAUTION FOR STORAGE

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

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