



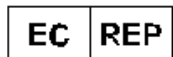
2292 CE

Disposable Microcatheter

Instructions for Use



Beijing Taijiweiye Technology Co., Ltd.
No.1 Plant, Maohua Industrial, Nancal Industrial Park, Shunyi,
Beijing, P.R.China
Tel.: +86-010-89471461 Fax: +86-010-89471460



Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, the Netherlands
Tel: +31-515-573399 Fax: +31-515-760020

Issue Date: 2018.7.1 Rev.: 3/2

Beijing Taijiweiye Technology Co., Ltd.

1. DEVICE DESCRIPTION

The Disposable Microcatheters are variable stiffness, single lumen catheters designed to access small, tortuous vasculature. They are available in a variety of outer and inner diameters (see table 1). The inner lumen is lined with lubricious PTFE to facilitate movement of guidewires and other devices. The distal sections of the catheter bodies are radiopaque to aid visualization under fluoroscopy, and the distal tips are clearly distinguished by one or two radiopaque markers.

Table 1 Product Features of Disposable Microcatheter

Spec	Effective Length	Soft Length	Proximal O.D.	Distal O.D.	Inner Diameter	Shape of distal tip	Marker
TJMC10	150cm	50cm	2.2F/ 0.73mm	1.8F/ 0.60mm	0.015"	straight/ 45°/90°/J	2Markers 3cm
TJMC14	150cm	50cm	2.3F/ 0.76mm	1.9F/ 0.63mm	0.0165"	straight/ 45°/90°/J	2Markers 3cm
TJMC16	150cm	50cm	2.8F/ 0.93mm	2.3F/ 0.76mm	0.021"	straight/ 45°/90°/J	2Markers 3cm
TJMC18	140cm	30cm	2.8F/ 0.93mm	2.5F/ 0.83mm	0.027"	straight	Single Marker

The pressure resistance is 600PSI (4137kPa).

2. INDICATIONS FOR USE

The Disposable Microcatheter is intended to be used as a mechanism for superselective angiography of the brain, spinal cord vascular, and for the infusion of various diagnostic, embolic agents (such as embolic coil) and vascular stents into the artery vessel.

The suitable guiding catheter and guidewire should be selected when use the microcatheter.

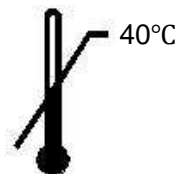
3. POTENTIAL COMPLICATIONS

The complications irrelevant with the device may occur during or after the procedure:

- Complications related with Puncture
- Hematoma at the puncture site



No secondary sterilization



Upper limit of temperature is 40°C



Do not re-use



Do not use if package is damaged



Attention, see Instruction for Use



Keep away from sunlight and keep dry



Sterilized by ethylene oxide

- (6) Consistently follow the general technical requirements of the use of the Microcatheter, including the systematic heparinization, and flushing all the Microcatheters which need to be inserted into blood vessel with aseptic heparinized saline solution or similar isotonic solution.
- (7) Choose the technical method according to different conditions of patients and the experience of physicians, as the Microcatheter has different applications.
- (8) Don't insert the Microcatheter through the guiding catheter which is smaller than the minimum dimension.
- (9) The Microcatheter is intended for one use only and don't re-sterilize or reuse this device; otherwise the device may be damaged and the risk of cross infection may be increased.
- (10) The Microcatheter should be used under X-ray condition.
- (11) The Microcatheter position should only be changed by capture wire. Any moving of the device during the intervention procedures is prohibited.
- (12) Never withdraw or move the Microcatheter against any resistance unless the cause is confirmed.
- (13) Use the Microcatheter before the expiry date.

6. INSTRUCTIONS FOR USE

- (1) The Microcatheter is packaged in a protective protection dispenser. Before removing the catheter from the protection dispenser, flush the dispenser with heparinized saline through the end of the protection dispenser.
Remove catheter and inspect to verify that it is undamaged.
- (2) Microcatheter is packaged with a shaping mandrel. In order to maintain catheter burst integrity and dimensional stability, it is strongly recommended that the user follow these instructions when shaping a catheter.
 - a) Remove shaping mandrel from mounting card and insert into distal tip of catheter.

- b) Bend catheter tip and shaping mandrel into desired shape. Over exaggeration of the desired shape is recommended to accommodate for slight catheter relaxation.
- c) Hold shaping mandrel/ catheter assembly directly over the steam source for approximately 30 seconds to set shape.
- d) Remove shaped catheter assembly from heat source and allow to cool in either air or liquid prior to removing the mandrel.
- e) Remove shaping mandrel from catheter and discard.
- (3) Prior to use, flush the catheter lumen with heparinized saline solution by attaching a saline filled syringe to the catheter hub.
- (4) Remove the appropriate steerable guidewire from its package and inspect for damage.
- (5) Carefully insert guidewire into the funneled hub of the catheter and advance into the catheter lumen.
- (6) Place the appropriate guiding catheter using a percutaneous entry technique of choice. Connect a hemostatic sidearm adapter to the guiding catheter hub and maintain a continuous heparinized saline flush.

Note: Microcatheters require a continuous flush during the procedure.

- (7) Introduce the guidewire and microcatheter as a unit through the hemostatic sidearm adapter into the lumen of the guiding catheter. Advance guidewire/catheter assembly to the distal tip of the guiding catheter.
- (8) Alternatively advance the guidewire and microcatheter until the desired site has been accessed.

Caution: If strong resistance is met during manipulation, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, withdraw the catheter and guidewire as a system.

- (9) When ready to infuse, withdraw the guidewire completely from the microcatheter. Connect a syringe containing infuse to the

microcatheter hub and infuse according to the manufacturer's instructions and precautions.

Warning: If flow through the catheter becomes restricted, do not attempt to clear the catheter lumen by infusion. Determine and remedy the cause of blockage or replace the blocked catheter with a new catheter before resuming infusion.

(10) After completing the procedure, withdraw the microcatheter and discard.

7. STORAGE

The Disposable Microcatheter should be stored in a cool, dry, clean and well ventilated place with the relative humidity no more than 80%, temperature below 40 °C, no toxic and corrosive gas.

8. STERILIZATION VALID PERIOD

The Disposable Microcatheter is aseptic and pyrogen-free, and the sterilization validity is three years.

- Hemorrhage at the puncture site
- Local or distal thromboembolism
- Thrombosis
- Arteriovenous fistula
- Pseudo aneurysm
- Puncture site infection

Complications related with Operation

- Artery dissection
- Vessel wall perforation or aneurysm rupture
- Long time vasospasm
- Acute occlusion required for surgical intervention

Complications related with Device

The anticipated adverse reactions related with the device are minimal (pyrogen reaction, infection, etc.), but it can't completely exclude the possibility of occurrence of adverse reactions.

4. CONTRAINDICATION

No special contraindications are known with the Disposable Microcatheter, and its clinical contraindications are the same with the general endovascular interventional operation.

- (1) Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated.
- (2) Do not use in vessels with excessive tortuosity and serious calcification.
- (3) Do not use in patients with renal impairment, who are allergic to contrast medium.

5. WARNINGS

- (1) Confirm whether the patients have allergic reaction to contrast agent before operation.
- (2) Only the experienced physicians should use the Disposable Microcatheter.
- (3) The Microcatheter is sterile and make sure the package is intact before use.
- (4) Prohibition of the use of the Microcatheter if the inner package is open or damaged.
- (5) Check the Microcatheter before use in order to make sure the size or spec meet the requirements of operation.