SP-GRIPFLOW

Selective Cerebral Perfusion Catheter

Fuji Systems

Device Description :
- This product is a silicone catheter equipped with a silicone balloon to be used during surgery for aortic aneurysm.
- During surgery for aortic arch aneurysm and dissecting aortic aneurysm, antegrade blood flow (perfusion) can be demonstrated for cerebroprotection through these catheters inserted into three branches of the aorta.
- The balloon allows for an improved grip on/reduction of pulls from the target artery because of the rib on the balloon surface.
- A catheter allows for adequate/optimizes perfusion flow rates.
- There are two types of forms depending on the connector.
- Type I has a Luer Connector and Type II has a Taper connector.
- Balloon compliance is referred to the Table 1.

Figure 1:

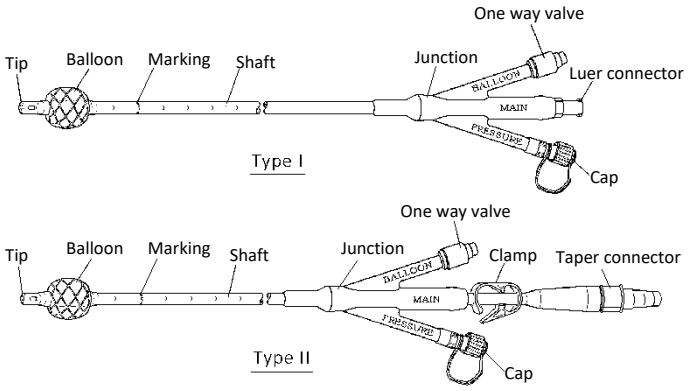

Table 1: Balloon Compliance

Injection Volume (mL)	Balloon Diameter (mm)		
Size	12F	14F	16F
0.0	6	7	8
1.0	13	13	14
2.0	16	17	17
3.0	19	19	20
3.5	20	20	21

*Maximum capacity of the balloon : 3.5 mL

Indications for Use :

This product is intended to be placed in the branches of the aortic arch for the cerebral perfusion during surgery of aorta.

Complications :

Possible complications include, but are not limited to, the following:
cerebral ischemia, vessel damage.

Warnings :
- Do not reuse. Discard after one procedure. Structural integrity and / or function may be impaired through reuse or cleaning.
- Determine whether this product is appropriate for your patient by preoperative testing. [If the diameter of blood vessels is large, this product may not seal.]
- Make sure to inflate the balloon with the sterile saline solution for balloon priming. [If the balloon bursts, it could cause air embolism and hemorrhage.]
- The infusion amount into a balloon must be less than its maximum capacity based on clinical judgment.
- If the balloon bursts, immediately stop perfusion (blood transmission), after no damage in the blood vessel is confirmed, perform hemostasis and deaeration, etc. exchange the catheter with a new one. [Heavy hemorrhage, air embolism, etc. could occur in the damaged blood vascular site.]
- Determine the balloon placement site after undertaking diagnostic before and during surgery.
- When placing the catheter in arteries such as the brachiocephalic artery, place it in such a way that its tip does not over the vessel bifurcation. [If placing it over the vessel bifurcation, it may cause cerebral ischemia.]
- Pay attention to the potential damage to vessels caused by overinflation of the balloon when placing this product.
- The connector of each blood transmission line (MAIN) of this product can be connected to a blood circuit in a heart-lung machine equipped with a male luer-lock connector (Type I) or blood circuit tube (Type II) shown in the following table.

Appropriate connector or tube	
Type I	A 6/100 tapered male luer-lock connector ISO80369-7
Type II	Blood circuit tube ID : 6.3mm (1/4 inch)

Precautions :
- Do not use this catheter if the sterile package is damaged, wet or opened prior to use.
- Do not use this catheter that has been damaged. [Damaged silicone products are significantly weakened.]
- Do not grasp the balloon with forceps and the like.
- Do not clamp the Type I catheter. [It may cause damage to the catheter.]
- When clamping the Type II catheter, do not use a clamp other than the one that came with this product.
- Connect each blood transmission line (MAIN) properly and secure it with adhesive tape or plastic belts. Check the connection status regularly. [Improper connection may increase the risk of loose connection.]
- Always confirm that there are no decreased volume of perfusion and/or abnormalities such as kinking, etc. during use.]
- Do not use the product if air leakage and / or odd expansion is observed on the balloon during the inflation test.
- Do not pull the shaft with a tension more than 15 N (1.5 kgf).
- Remove the sterile saline solution in the balloon completely before performing intubation, extubation, and placement adjustment. [Incomplete deflation of the balloon may cause the burst and the damage to blood vessels.]
- Place (secure) the balloon properly. [Improper placement of the balloon may cause blood leakage during perfusion.]
- Care must be taken to avoid physical damage to the catheter when securing it using Vessel Loop after placement.
- Put the connector cap on the pressure measuring line (PRESSURE) properly after priming with the sterile heparinized saline solution if using the catheter without monitoring perfusion pressure based on clinical judgment. [Improper tightening of the connector cap may cause blood leakage.]
- After use, dispose of this product and packaging based on the hospital, administrative and /or local government policy.
- If user and/or patient notice any serious incident that has occurred in relation to the catheter, please report to the manufacturer and the competent authority.

Recommended Procedure :
1. Carefully remove the product from the sterile package, and check that the catheter is not damaged.
2. Prior to balloon inspection, inject and aspirate the sterile saline solution that is less than the maximum capacity for the purpose of removing air from the balloon and the balloon lumen (BALLOON). Repeat this procedure several times.
3. Inject the maximum volume of the sterile saline solution into the balloon, and check that there is no abnormality such as leakage or uneven inflation (balloon inspection)
4. Before inserting the catheter, the pressure measuring line (PRESSURE) and the blood transmission line (MAIN) must be adequately primed with the sterile heparinized saline solution.
5. After inserting the catheter into targeted blood vessels, inject the sterile saline solution into the balloon and place (secure) it.
6. Secure the catheter using Vessel Loop if needed.
7. If necessary, connect the pressure measuring device to the pressure measuring line, and monitor the perfusion pressure at the catheter tip during perfusion.

Storage Conditions :

Keep the product dry and store in clean conditions, avoiding high temperature, humidity and direct sunlight.

Symbols Used on Product Labels :

MD	Medical Device
	Consult instructions for use
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged and consult instructions for use
	Caution
	Do not re-use
Rx.Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Do not resterilize
	Single sterile barrier system
STERILE EO	Sterilized using Ethylene Oxide
REF	Catalogue number

LOT	Lot number
CONT	Contents
	Date of manufacture
	Use-by date
	Manufacturer
UDI	Unique Device Identifier

Manufacturer

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