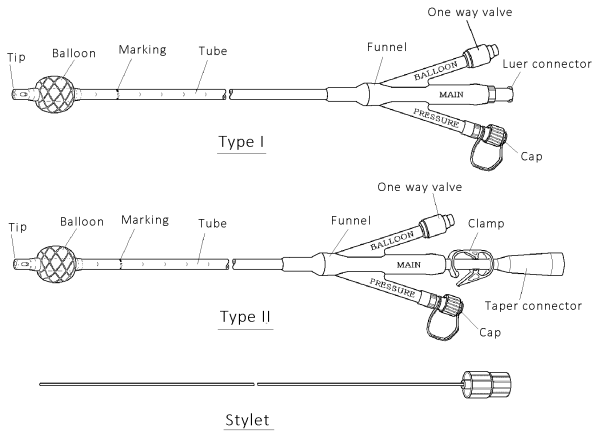
SP-GRIPFLOW

CIRCULATION PERFUSION CATHETER

Fuji Systems

Device Description :
- This product is a silicone catheter equipped with a balloon to be used during surgery for aortic aneurysm.
- There are two types of forms depending on funnels.
- The Type I catheter comes with a stylet.
- Maximum capacity of the balloon
  Fr-8, Fr-10 : 1.0 mL
  Fr-12, Fr-14, Fr-16 : 3.5 mL

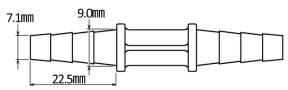
Figure 1:



Indications for Use :

This product is intended to be placed in arteries including three branches of the aorta, the celiac artery, the superior mesenteric artery, and the renal artery, for the purpose of obstructing blood flow to the operative field (hemostatic techniques during surgery) and protecting the brain and various organs (perfusion) during surgery for aortic aneurysm.

Warnings :
- 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 and the celiac 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 or abdominal organ ischemia.]
- Pay attention to the potential damage to vessels caused by overinflation of the balloon when placing this product.
- Do not use this catheter to the patients with significant arteriosclerosis and those whose vascular walls have been calcified.
- The connector of each blood transmission line (MAIN) of this product (Type I and II) can be connected to a blood circuit in a heart-lung machine equipped with a male connector shown in the figure below or other connector.

Appropriate connector	
Type I	A 6/100 tapered male luer-lock connector ISO594-2
Type II	1/4 inch Connector（7.1mm-9.0mm） 

Precautions :
- Do not grasp the balloon with forceps and the like.
- Do not use a device that has been damaged. [Damaged silicone products are significantly weakened.]
- 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.
- When the stylet is not used, remove and discard it before inserting the catheter.
- Do not use the product if air leakage and / or odd expansion is observed on the cuff during the inflation test.
- Do not pull the tube 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 strings 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.]

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 strings if needed.
7. 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 :

⚠	Caution
	Do not re-use
LOT	Lot number
REF	Catalogue number
STERILE EO	Sterilized using Ethylene Oxide
	Use-by date
	Manufacturer

Manufacturer :

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