AVflo™ Vascular Access Graft

Instructions for use

www.nicast.com

ENGLISH

Sterile (EO) – For Single Use Only

Y	***Caution***
	Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

1. GENERAL

Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.

2. DESCRIPTION

The AVflo™ Vascular Access Graft is made of medical grade polycarbonate urethane nanofibers supplied in both straight and coiled factory pre-sterilized configurations. The straight configuration has a length of 300 mm (see figure 1a), and the coiled configuration has a length of 350 mm (see figure 1b).

Both configurations' inner diameter is 6.0 mm. The wall thickness is approximately 0.8 mm The coiled configuration is manufactured with an additional polyethylene terephthalate (PET) reinforcement segment for kink resistance improvement. It may be found in two versions: centered coil and off-centered coil segments. The coiled graft has a 80 mm segment to prevent kinking.

Figure 1a. AVflo™ straight configuration

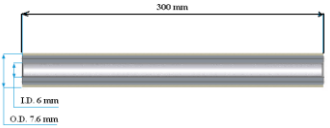
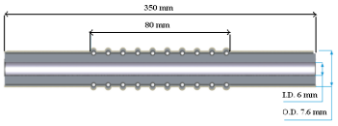
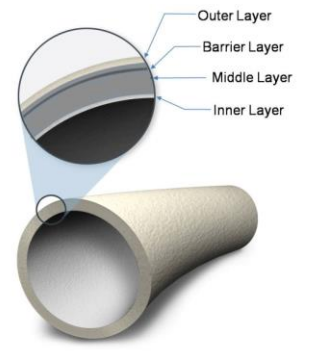
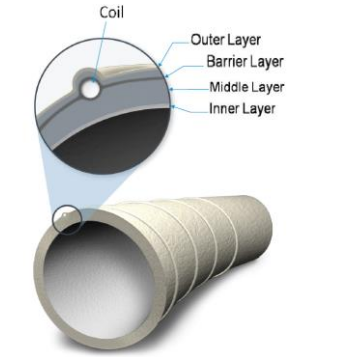


Figure 1b. AVflo™ coiled configuration







The graft features a self-bonded, four-layer design:

The nanofiber microporous blood-contacting **inner** layer is designed to minimize platelet adhesion.

The microporous self sealing **middle** layer, contains a 40µm thick **barrier** layer which prevents the diffusion of large molecules and provides strength and elasticity to the graft's structure. In the coiled AVflo™ vascular access graft configuration the barrier layer also secures the anti-kinking coiled segment in place.

The nanofiber's **outer** layer is designed to enhance graft anchoring via tissue ingrowth.

3. PROPOSED INDICATIONS FOR USE

The AVflo™ vascular access graft's proposed indication for use is as a subcutaneous, arteriovenous conduit for blood access.

4. CONTRAINDICATIONS

Do not use on patients with a known sensitivity / allergy to polycarbonate urethanes and PET.

5. POTENTIAL COMPLICATIONS

Potential complications that may occur with any surgical procedure involving a vascular prosthesis include (but not limited to): aneurysm; anastomotic disruption or tearing of the suture line and/or host vessel; embolic events; infection; bleeding; occlusion; stenosis; thrombosis; kinking or compression;

swelling of the implanted limb; formation of hematomas or pseudoaneurysms; steal syndrome and/or skin erosion.

6. WARNINGS Y

AVOID CONTACT OF THE AVflo™ WITH ORGANIC SOLVENTS.

AVOID EXCESSIVE AXIAL ELONGATION OR STRETCHING OF THE AVflo™ (>15%) DURING HANDLING AT IMPLANTATION.

Cut the graft long enough to prevent excessive stress on the anastomoses sites and/or to allow for a full range of body movements. Excessive elongation or stretching of the graft may result in damage to the graft's microporous layers, or anastomotic disruption that could lead to hematoma, bleeding, pseudoaneurysm, or ischemia.

DO NOT USE AN UNSTERILIZED GRAFT.

Do NOT use the product if its package has been damaged or opened, as sterility may be compromised.

Do NOT resterilize the graft.

DO NOT REUSE GRAFT.

The AVflo™ is in intimate contact with the patient's blood and surrounding tissue; reuse of an explanted graft on another patient may result in dissemination of blood and skin transmitted pathogens, and in induction of immune response. Therefore transferring of graft between different patients is forbidden.

7. PRECAUTIONS

7.1. When using a balloon angioplasty or an embolectomy catheter within the lumen of the AVflo™, match the inflated balloon size to the inner diameter size of the graft (see figures 1a, 1b). Over-inflation of the balloon or use of an inappropriately sized balloon catheter may damage the graft. Care must be exercised to avoid causing excessive axial elongation of the graft during retraction.

7.2. Preclotting this graft is not necessary.

7.3. Hydrate the graft in a sterile physiologic saline solution prior to implantation. The inner and outer luminal walls of the graft are microporous and the voids in these surfaces contain air that must be displaced (see Operative Techniques #8 for more information).

7.4. Use of a tunneler sheath is mandatory to minimize subcutaneous trauma and to minimize the force required to position the graft during implant. Pulling the graft without the use of a tunneler might result in damage to the graft.

7.5. If clamping of the AVflo™ is necessary, use only atraumatic, or appropriate vascular smooth-jawed, or shod clamps to avoid damage to the graft wall during implantation.

7.6. Guideline 17 of the Clinical Practice Guidelines from the Final Report of the Vascular Access Work Group of the National Kidney Foundation (US) - Dialysis Outcomes Quality Initiative, recommends the following for infected arteriovenous grafts:

"When infected, a dialysis graft should be treated surgically. An untreated access infection may lead to bacteremia, sepsis, hemorrhage, and death. Surgical exploration and removal of any infected graft or graft segment is necessary for resolution of the infection because the graft material acts as a foreign body unless eliminated."

Y	***Caution***
	Some tunneler sheaths are reusable. If reused, make sure that they are clean and sterilized prior to re-using.

8. OPERATIVE TECHNIQUES

8.1. *Opening the Package*

Open the sterile package using and maintaining sterile technique only. Carefully remove the graft using sterile atraumatic instruments or gloves.

8.2. *Hydrating the Graft*

Prior to implantation, hydrate or soak the graft in a sterile solution of normal physiologic saline. While soaking, gently compress the submerged graft to displace the air from the voids in the porous structure. When the bubbling stops, the air has been displaced and you may proceed with the graft implantation.

Y	***Warning***
	For coiled configuration: Compression of the coiled segment may damage the graft.

8.3. *Implantation Tips and Technique*

The AVflo™ may expand longitudinally by up to 5 mm once exposed to normal arterial pressure.

The following implantation procedure tips and techniques are recommended in order to allow for graft expansion and to reduce any chance of kinking.

When performing the anastomoses, trim the graft to a length approximately 0.5 to 1 cm shorter than the length measured. Pull each end slightly tensed when performing anastomosis to the vessel. The end of the graft should be beveled to accommodate a smooth positioning of the graft.

Y	***Caution***
	For straight configuration: Trim to allow proper sizing of the graft. Avoid bending when positioning and trimming the graft, especially near or at the anastomotic ends.

Y	***Caution***
	For coiled configuration: The non-reinforced segment must be trimmed to allow for proper sizing of the graft. Trim the graft at least 10mm from the coil's edges to avoid exposure of the coil segment which could lead to laceration of the adjacent tissue and anastomotic bleeding. Avoid bending when positioning and trimming the graft, especially near or at the anastomotic ends.

8.4. *Tunneling*

Because the graft may be damaged if pulled excessively, use of a sheath tunneler is mandatory. The tunneler is designed to permit graft placement by gently pushing the graft through the tunneler sheath rather than pulling. Refer to the Tunneler's Instructions for Use.

Irrigate the inside of the tunneler sheath liberally as well as all surfaces of the graft with a sterile solution of normal physiologic saline, to facilitate easier slipping of the graft through the tunneler sheath.

Y	***Caution***
	Care should be taken to push rather than pull the graft through the tunneler sheath. Use tunneler sheath having an external diameter not exceeding 11 mm.

8.4.1. Tunneling and implantation of STRAIGHT configuration

8.4.1.1. Create the tunnel at a suitable depth that will allow easy visualization and palpation of the AVflo^{TM} graft.
8.4.1.2. Place the tunneler sheath over the rod and thread the tunneler's tip onto the end of the tunneler's rod to hold the sheath in place (see figure 3).
8.4.1.3. Make incisions for distal and proximal entries of the implant site.
8.4.1.4. Insert the fully assembled tunneler into one of the incisions to create a subcutaneous tunnel between the distal and proximal incisions.
8.4.1.5. With the tip of the tunneler exposed, the tip is removed and the rod is pulled away, leaving the sheath in place subcutaneously.

8.4.1.6. Insert the graft into the subcutaneously placed sheath and gently push the graft through, using a gentle rotating motion if necessary, while irrigating liberally with sterile saline.

8.4.1.7. In order to prevent graft rotation and twisting it is recommended that prior to the insertion of the AVflo™ into the tunneler sheath, the surgeon will make a mark on both graft's edges with a sterile surgical marker.

Y	***Caution***
	Do NOT pull the graft through the tunneler sheath. Do NOT twist the graft. Do NOT attempt to reposition the graft after sheath removal.

8.4.1.8. When positioning of the graft is complete, carefully remove the sheath leaving the graft in place subcutaneously (see figure 4).

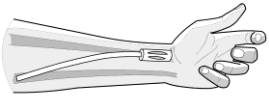


Figure 3. Placement of Tunneler Sheath for straight configuration implantation

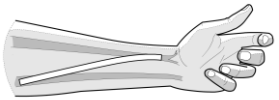


Figure 4. Completed straight graft positioning

8.4.2. Tunneling and implantation of COILED configuration

Create the tunnels at suitable depths that will allow easy visualization and palpation of the AVflo™ graft. To minimize trauma, it is recommended to allow for a minimal distance of 1" (2-3cm) between the 2 branches of the graft during tunneling.

8.5. *Implantation*

8.5.1. Make incisions for the distal and proximal ports of the implanted device.

8.5.2. Make sure the bullet tip of the tunneler sheath can be separated easily from the sheath tube.

8.5.3. Insert the fully assembled tunneler sheath into one of the incisions to create a subcutaneous tunnel between the distal and proximal incisions (see figure 5).

8.5.4. With the tip of the tunneler sheath exposed, the tip is removed.

8.5.5. Insert the graft into the subcutaneously placed sheath and gently push the graft through, using a gentle rotating motion if necessary, while irrigating

liberally with sterile saline. The use of tunneler grasping forceps is recommended.

8.5.6. When implanting a coiled graft, insert the other side of the graft repeating stages 8.5.2, 8.5.3, 8.5.4, 8.5.5. Make sure to position the coil segment in a sufficient radius to prevent kinking (see figure 6).

8.5.7. In order to prevent graft twisting it is recommended that the surgeon make a mark on both graft's edges with a sterile surgical marker, prior to the insertion of the AVflo™ into the tunneler sheath.

Y	***Caution***
	Do NOT pull the graft through the tunneler sheath. Do NOT twist the graft. Do NOT attempt to reposition the graft after sheath removal. Ensure a maximal radius at the distal part.

8.5.8. When positioning of the graft is complete, carefully remove the sheath leaving the graft in place subcutaneously**.**

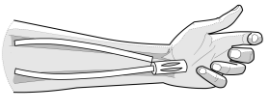


Figure 5. Placement of tunneler sheath for coiled configuration implantation

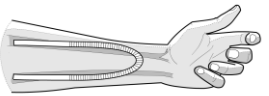


Figure 6. Completed coiled graft positioning

8.6. *Anastomotic Preparation*

Once the graft is properly positioned, an anastomosis should be made between the vessel and the graft. The end of the graft should be beveled to accommodate a smooth lie of the graft. The anastomosis may be performed using a one- or two-suture technique. The other end of the graft should be trimmed and anastomosed in the same manner.

8.7. *Graft Suturing*

Best results are achieved using a tapered, non-cutting needle with Prolene 6-0 suture. Care must be taken to follow the curve of the needle and pull the suture at a 90° angle, assuring that the needle penetrates all layers of the graft to minimize suture hole elongation and bleeding. Use systemic or local heparinization unless contraindicated.

8.8. *Final Suturing*

Surgeon should consider the necessity of installing a draining catheter at the site of implantation to avoid fluid collecting.

Y	***Caution***
	Suturing should be positioned about 1mm from the edge of the graft at the anastomoses sites. Greater distance may induce tension force on the vein wall with subsequent bleeding. Elongation of suture holes or gaps between the graft and host vessel could lead to anastomotic bleeding Thus, avoid: (1) Excessive tension that may cause suture holes to elongate or tear. (2) Undue tension on the suture line. (3) Gaps between the graft and host vessel, and (4) inappropriate suture placement and bites.

Please refer to "The 7 Important Principles for Implanting Nicast's AVflo™ Graft" brochure for additional information.

9. THROMBECTOMY

The AVflo™ may be declotted with an embolectomy balloon catheter using standard arterial embolectomy / thrombectomy procedures and precautions. The balloon diameter should not exceed 6mm. (Note: the F number of 6mm thrombectomy balloon catheters differs among various suppliers).

Care must be taken not to over-inflate the balloon catheter. The wall of the AVflo™ is more flexible than the wall of an ePTFE graft, and over inflation may dilate or damage the graft.

Do not place use excessive pulling force on the anastomosis or incision when placing or removing the embolectomy balloon catheter.

Y	***Caution***
	If performing the thrombectomy on a vascular graft containing a coiled section (center coiled or off-center coiled AVflo™), care must be taken not to access the graft lumen through the coiled section. This may lead to irreparable damage to the graft

10. SURGICAL REVISION

If it becomes necessary to repair the graft with a surgical interposition bypass graft, the use of the AVflo™ should be considered.

Y	***Caution***
	Only end-to-side anastomosis of the revision graft to the implanted graft is recommended.

11. CANNULATION

	Note
	Puncturing of the AVflo™ may be considered for vascular access within 24-48 hours after implant, provided that no contraindications are present (see # 11.4 below).

Insert the blood access (dialysis) needle at a 45° angle with the bevel facing up until the graft is penetrated. If the blood access needle is inserted such that the angle between the needle axis and the graft is too small, tears in the wall of the graft may occur. If the needle is inserted at a 90° angle, it increases the possibility of puncturing the far wall of the graft, which may lead to hematoma formation.

Y	***Caution***
	For coiled configuration: Do NOT insert the blood access needle through the coiled segment of the graft.

For best results follow the established cannulation practices listed below:

11.1. Rotate cannulation sites: repeated cannulation in the same area may lead to damage of the graft wall and/or formation of hematomas or pseudoaneurysms. Needle puncture sites should be equally spaced along the subcutaneous length of the graft.

11.2. Do not cannulate within the dialysis needle's length of the proximal or distal anastomoses.

11.3. Strict adherence to aseptic technique is required to minimize infection.

11.4. As with all dialysis, do not cannulate if there are any signs of infection, bleeding, swelling, edema, hematoma, or in the absence of a strong "thrill".

After needle withdrawal, **use gentle, non-occlusive digital pressure** to compress the cannulation site to aid in hemostasis; the AVflo™ graft is expected to seal quicker and with less applied pressure compared to most commercially available ePTFE grafts.

Y	***Caution***
	Prolonged compression or use of stasis clamps or pressure cuffs may lead to clot formation, restricting flow through the graft.

Please refer to "The 5 Important Principles for Dialysis" brochure for additional information.

12. STORAGE

To provide maximum protection, store the grafts in their original, unopened packages at room temperature. Avoid excessive heat or cold (>-10°C to <50°C).

The grafts must be used before the expiration date printed on the package's label.

Y	***Caution***
	The AVflo™ should be removed from its package only in a sterile environment.

13. LABEL GRAPHICAL SYMBOLS

SYMBOL	
H	Use by
f	Serial number
D	Single use only
B	Do not resterilize
h	Catalog number
i	Consult instructions for use
L	Do not use if package is damaged
IQ	Method of sterilization using ethylene oxide
p	Keep dry
w	Keep away from sunlight
s	Temperature limitation
P	Authorized representative in the european community
M	Manufacturer