Instructions for use

aXess Hemodialysis Conduit

INSTRUCTIONS FOR USE
AXESS HEMODIALYSIS CONDUIT

Carefully read all instructions, warnings, precautions and directions prior to use. Only use as indicated. Failure to adhere to the instructions for use may lead to complications. The aXess Hemodialysis Conduit is designed for use by physicians with expertise in vascular graft procedures and dialysis personnel trained in hemodialysis. Training on the actual implantation of the device before first use is highly recommended.
Note: instructions for use are available electronically and in a paper version which can be obtained upon request by contacting ifu.request@xeltis.com.

PRODUCT DESCRIPTION

The aXess Hemodialysis Conduit is intended for use as a vascular implant in patients requiring access for hemodialysis.

aXess is comprised of two porous electrospun bioresorbable polymer layers, and a nitinol microskeleton (also referred to as strain relief system (SRS)) embedded within the polymer (see **Figure 1**). The nitinol component provides kink resistance and extends through most of the conduit, leaving the ends free to facilitate trimming and customization during surgical anastomosis.

aXess is made of a fully synthetic bioresorbable supramolecular polymer, designed to facilitate endogenous tissue restoration (ETR). The resorbable polymer microporous structure is the host for own patients' human cells allowing the transformation of the aXess scaffold to a natural human like vascular access vessel. Post implant, aXess provides rapid vascular access with its unique ''self healing'' properties throughout its entire lifetime.

The proprietary bioresorbable polymer used in aXess is free from intentionally introduced per- and polyfluoroalkyl substances (PFAS).

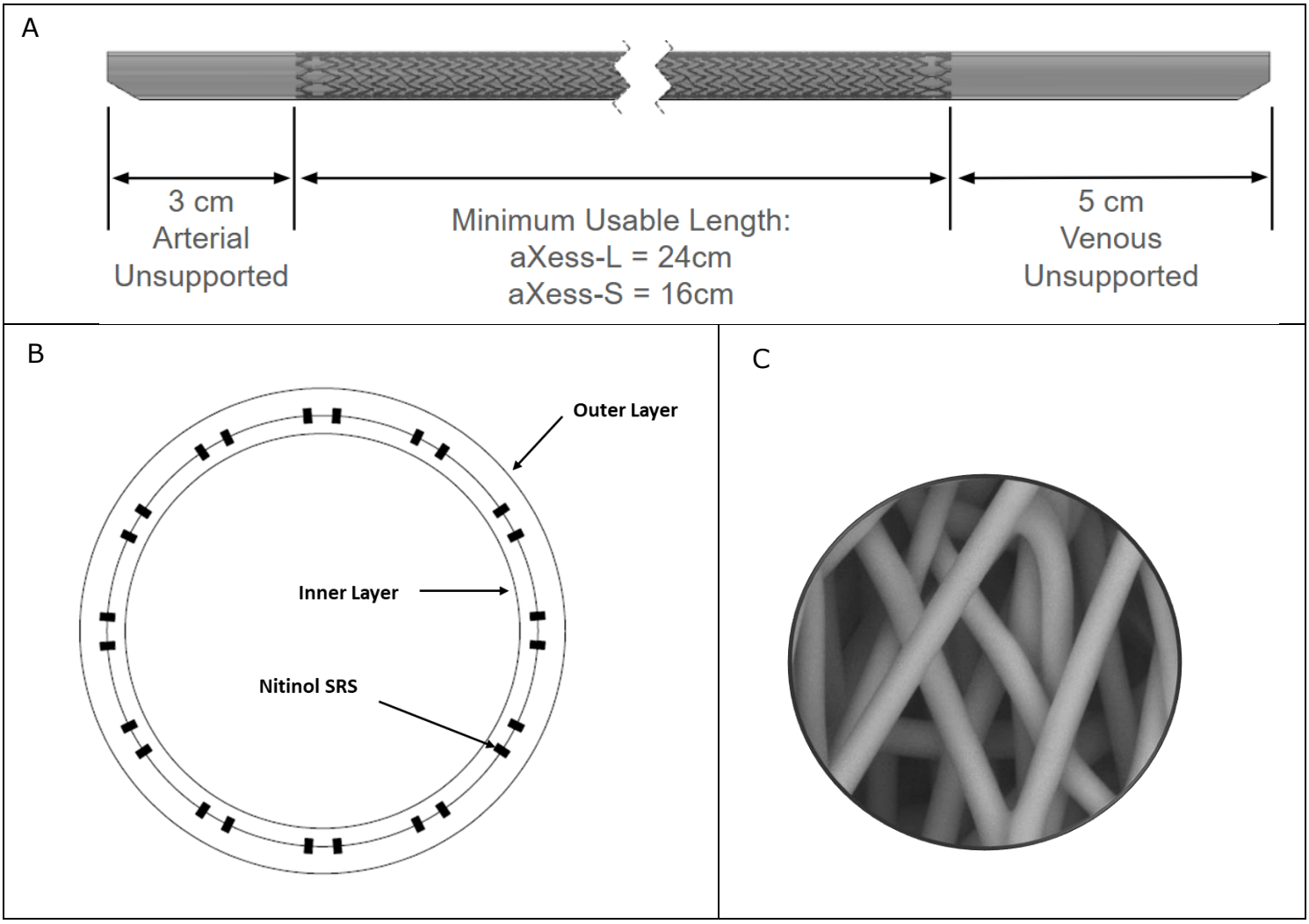


Figure 1: aXess Hemodialysis Conduit (A: axial view, B: cross section, C: scanning electron microscope picture illustrating porosity)

DEVICE VERSIONS

The aXess device is supplied in two sizes, a 24 cm length for a straight configuration (aXess-S) and a 32 cm length for a loop configuration (aXess-L). See **Table 1** for details on the two models. The proximal end (artery) the polymer part is shorter (3 cm). The distal end (vein) is larger (5 cm).

Table 1: Model aXess

Model device	Lumen diameter	Total length	Minimum usable length*
aXess-S	6mm	24 cm	16 cm
aXess-L	6mm	32 cm	24 cm

*presents the heel-to-heel length of the aXess when trimmed. The heel of the anastomoses is ~2mm from the SRS on each end.

DEVICE COMPOSITION

The overall qualitative and quantitative information on the implant materials to which patients can be exposed is listed below in **Table 2**.

Table 2: aXess composition

Material	Level of Patient exposure (g) (size L)
Polycarbonate-based polyurethane	1.5 g
Nitinol	1.1 g

Note: The weight of each material is based on the size L device prior to trimming. The material in the patient's implant may weigh less.

INTENDED PURPOSE

The aXess Hemodialysis Conduit is intended for use as a vascular implant in patients requiring access for hemodialysis.

INDICATION FOR USE

The aXess Hemodialysis Conduit is indicated for patients with end-stage renal disease (ESRD) who require arteriovenous hemodialysis access in the upper extremities.

TARGET PATIENT POPULATION

Adult patients suffering from ESRD, requiring a vascular access for hemodialysis and having a suitable anatomy according to the treating physician (e.g. artery and vein with a lumen diameter of 3mm or greater).

PERFORMANCE CHARACTERISTICS / CLINICAL BENEFIT

The aXess Hemodialysis Conduit provides vascular access for patients requiring hemodialysis. Patients may experience meaningful clinical benefits, including improved long-term patency with fewer interventions needed to maintain or restore it, as well as a reduced risk of infection over the lifetime of the device.

CONTRAINDICATIONS

None known.

WARNINGS

- aXess is for single use only, do not reuse or resterilize.
- Do not use if the packaging has been damaged, opened, or the use by date has passed, as sterility may be compromised.
- Do not use aXess if it has been dropped, shows signs of damage, deterioration, or imperfections.
- Do not implant an aXess-L in a straight configuration.
- Use atraumatic instruments including clamps/forceps (or use protective boots) and non-cutting needles to prevent damage to aXess.
- Use standard tunnelling techniques to implant aXess, ensuring that the tunneler is placed between 3 and 10 mm under the skin. Avoid tunneling without an appropriately sized safety sheath, as this may lead to deformation or damage to the conduit.
- Do not use electrocautery in close proximity of aXess due to the risk of local melting, leading to possible structural damage or altering of the resorption behavior.
- Do not implant aXess in patients with active local or systemic infections, bleeding disorders or thromboembolic disease.
- Warn patients of potential hypersensitivity reactions due to the presence of nitinol, an alloy of nickel and titanium. Individuals with known allergies to these metals may experience an allergic or hypersensitivity response. Counsel patients prior to implantation regarding the device materials and the potential for allergic reactions.
- Always use atraumatic, soft-tipped guidewires for endovascular procedures, do not use mechanical devices (cutting balloons, burrs, cutters, rotablation) that could damage the inner wall or the SRS of aXess.
- When performing angioplasty within aXess, do not use a balloon size larger than 8 mm.

- Avoid the use of balloon-expandable stents in the conduit as per standard of care.

PRECAUTIONS

General

- Perform MRI scans in accordance with the MRI Safety Information label found in IFU on page 9 as aXess contains a non-magnetic metal (Nitinol) structure.
- Do not implant aXess if there is known or suspected central vein obstruction, as this can lead to early patency loss.
- Use in the following population has not been clinically evaluated: patients with history or evidence of severe cardiac condition, patients with uncontrolled or poorly controlled diabetes or patients with significantly reduced liver function.
- Use in pregnant and breastfeeding patients has not been clinically evaluated.

Implantation

- Ensure that selection of aXess size is done according to vessel mapping performed prior to implant.
- Tear open the aluminum pouch at the designated notch, marked “tear here”.
- Do not implant aXess across the elbow.
- Avoid severe kinking, stretching, twisting or any permanent deformation of aXess as early occlusion or stenosis might occur.
- Avoid cutting the SRS when trimming aXess to length for implantation and position the heel of the anastomosis between 1 to 3 mm from the SRS, see **Figure 3**.
- Use only synthetic, non-absorbable monofilament sutures for suturing aXess.
- Place suture bites no more than approximately 1 mm from the free edge of the conduit to prevent conduit material from protruding into the anastomosis, which could obstruct blood flow.
- Do not allow stagnant blood to reside in the conduit for an extended period of time. Flush aXess with saline removing any residual blood before the final anastomosis is completed.

Vascular access cannulation

- Do not use a tourniquet on the arm with aXess.
- Do not use needles with a back-eye.
- Do not use needles larger than 16G to puncture aXess.
- Cannulate with the needle in the bevel-down position.
- Do not puncture in the U-bend region when using a looped configuration or within 10 mm from the end of the SRS (see **Figure 4**).
- Do not puncture within a pseudoaneurysm, in accordance with international guidelines.

Interventions

- Use caution when cutting the SRS during interposition procedures to avoid material embolism.
- In case of a surgical intervention done through aXess, especially in the first 6 months post implantation, consider the use of pledgeted sutures to close the conduit incision.
- If percutaneous intra-conduit access is required, the catheter size should be ≤ 8 Fr.
- Avoid using thrombolytic agents in the first month following implantation as they may dissolve the clot within the conduit during the early healing phase
- When performing endovascular procedures, ensure proper positioning within the lumen using local standard of care procedures to reduce the risk of delamination or false lumen formation.
- When performing percutaneous reinterventions on pseudoaneurysms, make sure the guidewire does not get entangled in the SRS by gently inflating a 6mm balloon in the pseudoaneurysm region.

POTENTIAL ADVERSE EVENTS

Potential device and procedure-related adverse events

General complications reported with the surgical implantation of hemodialysis vascular access grafts include general risks that are related to the surgical procedure and use of aXess. These general risks could also apply to the surgical implantation and use of aXess, including but not limited to:

Very common (More than 10%)

- Non-infectious fluid collections/accumulation: hematoma, seroma, lymphocele, edema
- Pain
- Pseudoaneurysm at the puncture site
- Stenosis
- Thrombosis / Occlusion

Common (between 1 and 10%)

- Abnormal inflammatory/healing response (e.g., non-infective surgical incision site healing disorder, necrosis)

- Anastomotic complications
- Aneurysm, dilatation, or dissection of the aXess conduit
- Bleeding (intraoperative, postoperative, or at the puncture site)
- Mechanical disruption or tearing of the suture line, conduit, and/or host vessel
- Infection
- Remote non-device related complications: steal syndrome, venous hypertension, neuropathy
- Skin ulceration/erosion

Uncommon (between 0.1 and 1%)

- Limb ischemia

Rare (less than 0.1%)

- Allergic-type hypersensitivity reactions may occur after repeated exposure to similar materials as the device.
- Embolism (air, material, thromboembolism)
- Death (Life-threatening bleeding event)

Serious incident reporting

Any serious incident that has occurred in relation to the use of aXess should be reported to the manufacturer and the competent authority of country in which the device was used.
To report an event or incident to Xeltis B.V., email complaints@xeltis.com or call +31407517642.

HOW SUPPLIED

Contents

aXess is packaged in a retainer with a lid, enclosed in a foil pouch (primary sterile barrier) further protected by a Tyvek pouch (secondary sterile barrier).

Sterility

aXess is sterilized via gamma irradiation.
aXess is designed for single use only; do not reuse. Reuse may cause conduit failure or procedural complications including contamination (see WARNINGS).

STORAGE AND HANDLING

Store at room temperature (below 25°C).

DIRECTION FOR USE

Required materials for implantation

- 37°C saline or Lactated Ringer's solution to pre-wet aXess.
- Container long enough to submerge aXess without bending or kinking it.
- Atraumatic instruments.
- Sheath tunneller with inner diameter of 8 mm MINIMUM, and outer diameter of 12 mm MAXIMUM.
- Non-absorbable monofilament suture, such as Prolene (size 6-0/7-0).

Required materials for cannulation

16G or 17G standard sharp needles or plastic cannula needles.

Device Implantation steps

STEP 1: Preparing the aXess Hemodialysis Conduit for use

- Open the outer non-sterile Tyvek pouch and retrieve the sterile aluminum pouch. At the designated tear notch, see "tear here" label, open the aluminum pouch and remove the sterile tray containing aXess.
- Submerge aXess in warm (~37° C) sterile non-heparinized saline or Lactated Ringer's solution (pre-wetting) prior to implantation for at least 10 minutes. Ensure that aXess is submerged in a container or tray, which is long enough to accommodate the conduit without bending or kinking it**.** Gauze may be used to cover aXess to ensure it remains submerged. Pre-wetting softens the conduit, improving kink resistance and ease of positioning during the implant.

STEP 2: Surgery

Use standard surgical techniques for tunneled placement of a hemodialysis conduit.
Take extra care when tunneling, as aXess is initially stiffer than a native vessel.
Use atraumatic instruments, including clamps/forceps (or use protective boots) for the entire procedure.

- Presurgical planning:
  - Perform ultrasound screening and/or angiography to locate a suitable artery and vein, with a lumen diameter of ~3mm or greater.
  - Ensure that the length of the planned trajectory will match the trimmed length of aXess.

        - aXess is trimmable at both ends. Avoid oversizing or undersizing the length of the conduit to prevent deformation of the anastomoses.
    - Ensure a minimum loop diameter of 4 cm for loop configurations to reduce the risk of kinking.
- Identify the proximal (arterial) and distal (venous) ends: the proximal (arterial) end is shorter and both ends feature v-notch orientation marks (see **Figure 2**).
- Use v-notch or surgical markers to orient aXess to avoid torsion at the anastomotic sites.

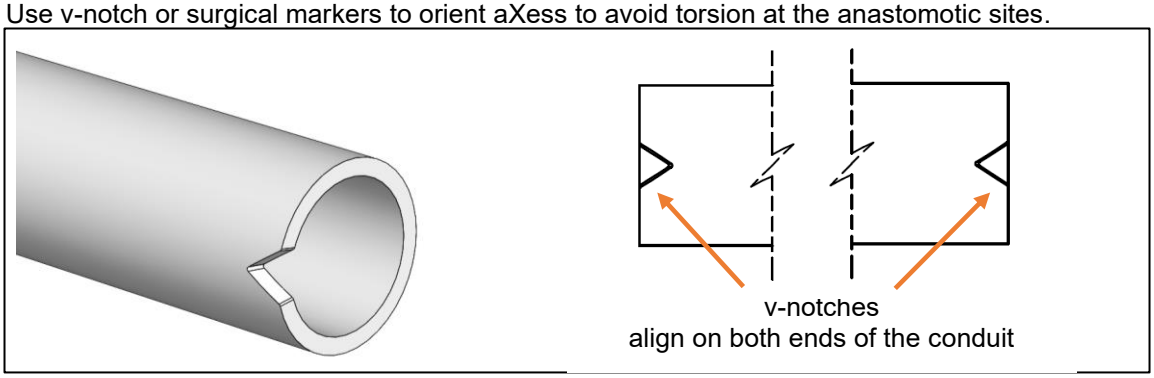


Figure 2: Image and drawing of v-notch marks

- Tunneling:
    - Use an 8mm tunneler with a safety sheath that has an inner diameter of at least 8 mm and an outer diameter of 12 mm maximum.
    - Position the tunneler subcutaneously, between 3 and 10 mm under the skin.
    - Insert the tunneler alone in the desired anatomical position, advance aXess into the tunneler and withdraw tunneler.
- Maintain a heel distance of 1 to 3 mm from the end of the SRS when trimming. Avoid trimming aXess within the nitinol-supported region, see **Figure 3**.
- Trim the device to the appropriate length without deforming aXess, the anastomosis or the native vessel.
- Discard all trimmed-off portions of aXess, do not use them for any other purpose.
- Ensure a toe-to-heel distance of at least 20 mm for the venous anastomosis, see **Figure 3**
- aXess wall is porous. To initiate hemostasis, expose the conduit to blood temporarily:
    - Complete the venous anastomosis first, declamp vein and allow blood through aXess.
    - Flush aXess with saline to remove residual blood, reclamp vein and continue with arterial anastomosis.
- Select the final position of the proximal anastomosis.
- Flush aXess with blood and completely de-air it before closing the anastomoses.
- Inspect each anastomosis for deformations or leakages, revise if necessary.
- Confirm adequate hemostasis of aXess and the anastomoses before closing surgical incisions.
- Ensure proper flow through aXess before skin closure.

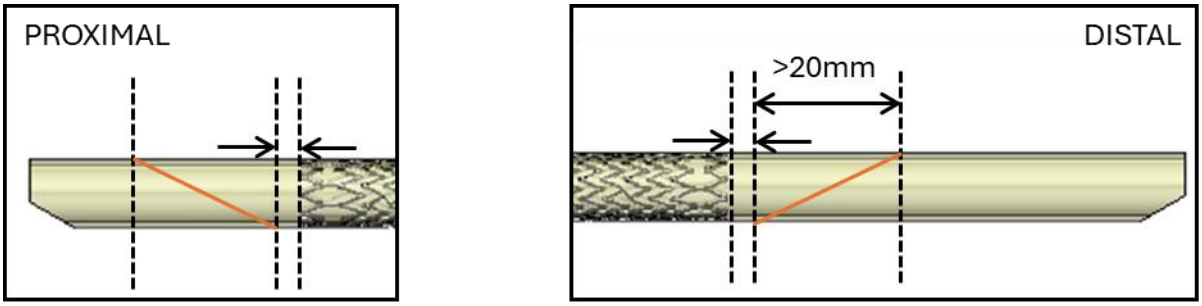


Figure 3: Image with line drawing of suggested trimming of the proximal (arterial) anastomosis as well the distal (venous) anastomosis and the minimal distance (1-3mm) between the SRS and the heel of the trimmed anastomosis

Post implantation medication

Postoperative antiplatelet therapy is recommended at the attending physician's discretion (e.g. Aspirin 75 – 200mg/day).

Cannulation and hemodialysis

- The cannulation can be performed 2 weeks after implantation.
- Cannulation of the device has not been evaluated in the context of home dialysis.
- Only experienced and trained personnel should puncture the device.
- Refer to PRECAUTIONS and **Figure 4** for guidance on needle type and technique.
- Use of rope ladder technique is highly recommended in order to minimize risk of conduit material disruption or formation of a hematoma and/or pseudoaneurysm.
    - Implement a puncturing schedule.
    - Utilize the full length of the conduit.
    - Maintain a 5 cm distance between needles.
    - Establish 3-5 puncturing sites with at least 1 cm between punctures.
- Use 17G needles for the first month of cannulation, then progress to 16G needles in the bevel-down position.

- To prevent damage or fracture of SRS, if resistance is met during needle insertion, avoid pushing, pull the needle back a few millimeters, and attempt to insert the needle at a slightly steeper angle. If resistance is still encountered, re-puncture at a slightly different location (~10mm away).
- Separate cannulation sites adequately when repeated needle punctures of aXess are necessary.
- Insert the needle at approximately a ~ 45° angle.
- Avoid rotating the needle to prevent inner wall damage.
- Use ultrasound guidance when aXess is not visible through the skin or cannot be easily felt through the skin.
- Puncture at least 1 cm away from both ends of the SRS (see **Figure 4**). This can be confirmed using ultrasound.
- If there is no backflow or there are signs of suboptimal flow indicating that the needle has passed through the wall of the conduit, remove the needle, apply local pressure to achieve hemostasis and puncture again at a different location.
- Needle removal:
    - Only compress the puncture site after the needle is removed.
    - After needle removal, apply compression in 5-minute intervals until bleeding stops (typically 5 - 10 minutes).
    - Avoid complete compression/occlusion of the conduit.
    - Apply a bandage for a minimum of 2 hours.
    - Do not use a tourniquet-style bandage.

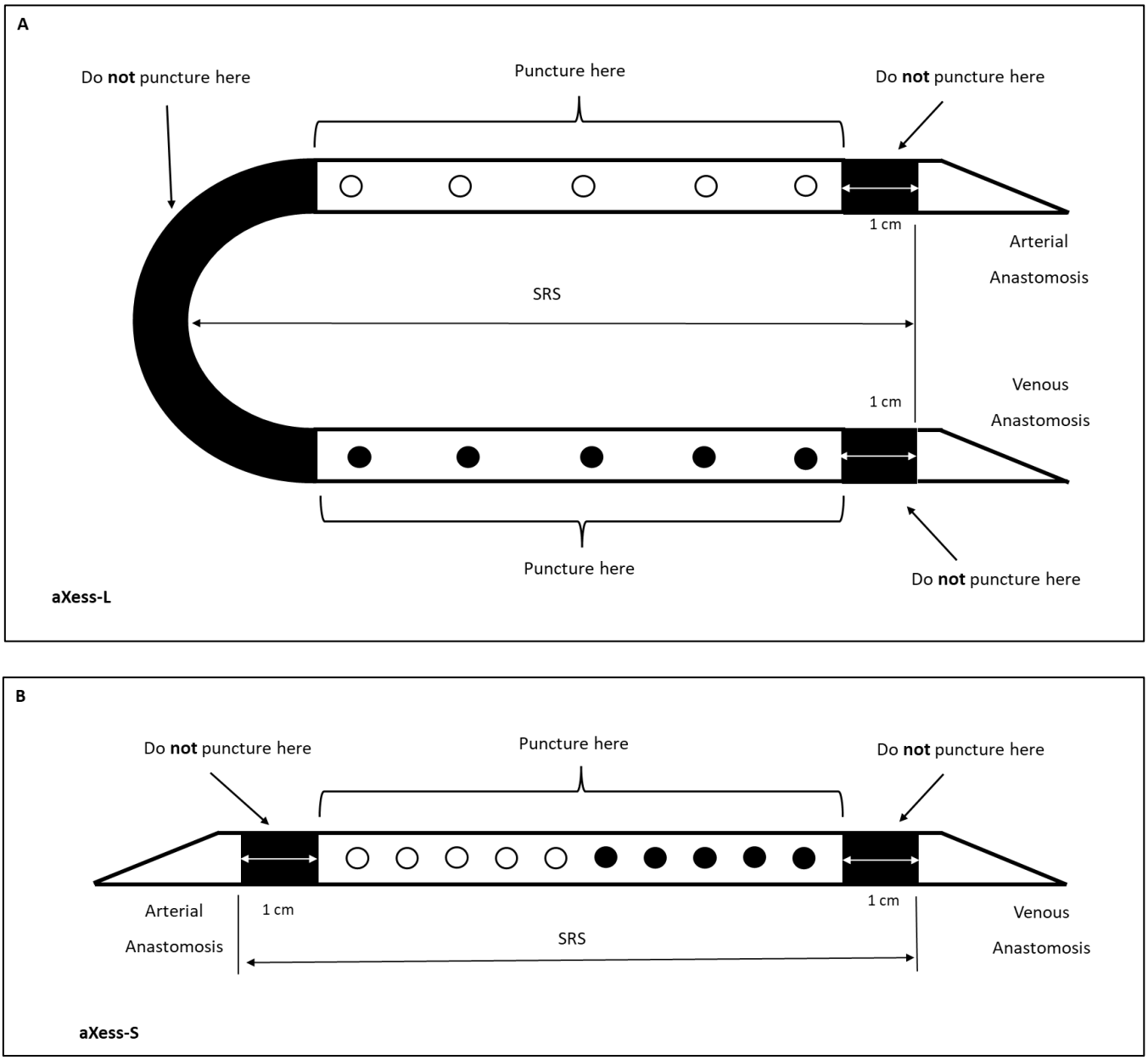


Figure 4: Schematic drawing of the loop (aXess-L) configuration (A) and the straight configuration (B) of the aXess device. Puncture in white region of SRS only annotated as "Puncture Here" zones. White dots indicate locations for arterial needles and black dots locations for venous needles.

Interventions

Interventions can be performed in cases where aXess is not performing adequately. The following recommendations are made to avoid or minimize damage to aXess.

Surgical access

- Open aXess carefully, do not cut the SRS struts.
- Use a scalpel blade (#11 or #15) instead of scissors to reduce the risk of cutting the SRS struts.

- Close aXess with pledgeted sutures if needed.
- Alternatively, use ePTFE sutures to close the incision.
- Graft interpositions can be used. Caution is recommended to avoid embolization of polymer and / or nitinol fragments.

Percutaneous access

- Percutaneous access through aXess can be performed using an 8 Fr or smaller sheath.
- Use atraumatic, soft tipped guidewires during endovascular procedures through or within the conduit to minimize the risk of delamination or false lumen.

Angioplasty

- Use only non-compliant balloons.
- Limit balloon size to 8 mm maximum.
- Perform angioplasty at any aXess locations, including at the anastomoses and the loop region.

Stenting

- Use self-expanding covered stents as the preferred option.
- Follow manufacturer's sizing guidelines (avoid both undersizing and significant oversizing).
- Limit balloon size to 8 mm maximum for post implant dilatation.
- Ensure at least 2 cm of stent overlap with the SRS region of the conduit.
- Perform stenting at any aXess locations, including at the anastomoses and loop region.

Thrombectomy

- Perform thrombectomy within a few days after the onset of thrombosis while the thrombus is still soft, according to local standard practices.
- Perform surgical thrombectomy using a 4 Fr Fogarty catheter over a guidewire as the preferred option. Do not use sizes above 6 Fr.
- Preferred options for percutaneous thrombectomy are suction only devices, size 8 Fr or similar.
- Clamp aXess with an atraumatic clamp, if necessary.
- Use a second Fogarty catheter as an endoclamp, if necessary.

Pseudoaneurysms

- Consider thrombin glue injection to treat pseudoaneurysms, at physician discretion. It is recommended to use a 7 mm standard PTA balloon inside the aXess conduit to occlude the pseudoaneurysm neck prior to the thrombin glue injection.
- Use covered stents for treating larger pseudoaneurysms (e.g. with a size of > 1.5 cm in one dimension or an area of > 4 cm^2). Timely treatment of expanding pseudoaneurysms is important to minimize damage to the SRS.
- Perform surgical repairs when clinically indicated.

Disposal

- Use standard institutional practice and local regulations to dispose of the packaging materials.
- Dispose of aXess in the same manner as hospital waste and biohazardous materials.

PATIENT COUNSELING INFORMATION

- Provide information about the device, procedure, potential advantages, risks, and differences between treatment options.
- Provide information on the materials contained in the device including potential for allergy/hypersensitivity to nitinol.
- Provide safety information about the device including potential adverse events and corresponding symptoms and recommended actions for the patient, if any.
- Provide patients with the Patient Information Leaflet and the Implant Card.
- Patients should be advised on the following information related to aXess care, as per standard of care:
  - Avoid putting any pressure on the aXess arm, such as tourniquets or blood pressure cuffs.
  - Avoid sleeping on the aXess arm.
  - Avoid carrying heavy weight in arm with aXess.
  - Avoid taking blood samples or administering intravenous fluid or medications through aXess.
- Patients should be warned against smoking or any other nicotine usage. Smoking or nicotine are known risk factors for thrombosis and stenosis formation.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP), which includes clinical benefits, can be located on the European Database on Medical Devices (Eudamed): https://ec.europa.eu/tools/eudamed. The aXess conduit Basic UDI-DI can be used to find the corresponding SSCP, Basic UDI-DI: 87208924750AX00139.

EXPECTED DEVICE LIFETIME

Clinical data supports the safety and performance of aXess and provides assurance that the benefits outweigh the risks. Bench testing conducted by Xeltis supports the performance and the safety of the product. While aXess materials are intended to remain safe for the patient's lifetime, the expected device lifetime per regulatory requirements is limited to 2 years due to factors such as duration of clinical use and effects of multiple cannulations.

The expected device lifetime per regulatory requirements is not meant to be a recommendation or indication for intervention or removal of the device. The expected device lifetime is based on normal conditions for use and is not meant to be a warranty or guarantee as the actual duration of clinical use or implantation of the device for a particular patient may be shorter or longer than the expected device lifetime based on the patient's medical conditions, anatomy, or other medical treatment as well as procedure and clinical factors and decisions.

MR INFORMATION

MRI Safety Information

MR Conditional

A patient implanted with an aXess Hemodialysis Conduit may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

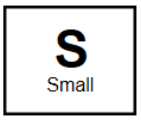
Parameter	***Condition of Use / Information***
Static Magnetic Field Strength	1.5 T, 3 T
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	1.5 T: 79.82 T/m (= 7982 G/cm) 3 T: 39.91 T/m (= 3991 G/cm)
RF Polarization **(Note: formerly called RF Excitation)**	Circularly Polarized (CP)
RF Transmit Coil	Integrated Whole Body Transmit RF Coil
RF Receive Coil	Any receive RF coil may be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Maximum Whole Body SAR	Whole Body Averaged SAR ≤ 2 W/kg Note: Under the scan conditions defined above, the aXess Hemodialysis Conduit is expected to produce a maximum temperature rise in vivo of less than 6 °C at 1.5 T and at 3 T after 60 minutes of continuous scanning.
Scan Duration and Wait Time	Scanning for 1h max without a cooling period, then wait 15 minutes before resuming scanning. Note: Autoscanning / Autoscan Mode is considered continuous scanning. Note: Short pauses between scan sequences are considered part of the scan time.
MR Image Artifact	The presence of the item within the MR image field of view may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 6.2mm from the device edge when imaged with a spin echo pulse sequence and 5.4mm with a gradient echo, both at 1.5 T.

DEFINITIONS

Standardized symbols

	**Manufacturer**		**Do not re-use**
	**Catalog number**		**Consult instructions for use.**
	**Serial number**		**Use by date**
	**Lot number**		**Do not use if package is damaged**
	**Sterilized using irradiation**		**Upper limit of temperature- Avoid exposure beyond 25°C**
	**Double sterile barrier system**		**Minimum Usable Length**
	**Single sterile barrier system with protective packaging inside**		**Inner diameter**
	**Do not re-sterilize**		**Medical Device**
	**MR conditional**		**Conformité européenne**
	**Non-Pyrogenic**		**Date of Manufacture**

Customized symbols

	**Device Size Large**		**Device Size Small**

Manufacturer **Xeltis BV**
De Lismortel 31
5612 AR Eindhoven
The Netherlands
www.xeltis.com
Made in the Netherlands

CE
2797