



aXess Hemodialysis Conduit

PATIENT INFORMATION LEAFLET



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This leaflet is for people who have, or will soon get, the aXess Hemodialysis Conduit (called aXess for short). It gives you important facts about your aXess implant and how to take care of it. This leaflet explains:

- What aXess is and who it is for
- What aXess is made of
- How to care for your aXess and what to expect at your checkups
- Safety tips and who to call if you have problems
- What your implant card is for and what the symbols on it mean

Please read this leaflet carefully. If you have any questions, talk to your doctor or care team. They are there to help you.

AXESS HEMODIALYSIS CONDUIT

Who needs aXess?

aXess is for people with serious kidney disease who need hemodialysis. Healthy kidneys clean the blood by removing waste and keeping the right balance of fluids and minerals. When kidneys stop working well, hemodialysis does this job by cleaning the blood outside the body.

What is aXess?

aXess is a soft, flexible tube made from a special material. It is placed under the skin in your arm to connect an artery to a vein. This gives strong blood flow, which is needed for hemodialysis.

A few weeks after surgery, once your skin has healed, the aXess can be used for dialysis.

aXess is made from a synthetic material that your body slowly absorbs over time. As it fades, your own body cells grow in its place to form a natural blood vessel. This can improve healing and lower the risk of infection and other problems.

There are two sizes of aXess: 24 cm (aXess-S) and 32 cm (aXess-L). Your doctor will discuss the best option with you.

Materials in aXess

aXess is made of a bioabsorbable polymer (polyurethane urea polycarbonate-based) (1.5g) which means it will slowly disappear inside your body. It also contains nitinol (1.1g), a metal made from nickel and titanium that helps the device keep its shape. These materials are tested to be safe for your body. If you have allergies to any of these materials, tell your doctor.

How long will your aXess last?

aXess is meant to stay in your body for a long time. It has been tested for safety and works well for most people.

The expected lifetime of the device is 2 years but it can stay in your body longer unless there is a medical reason to remove it.

Ask your doctor about the risks and benefits of using aXess.

Follow-up visits with your doctor

After surgery, you may need regular checkups to make sure your aXess is working well. Your doctor will tell you how often to come in.

It is very important to go to all your follow-up visits and follow your care team's advice. If you notice anything new or unusual, tell your doctor or nurse right away.

HOW TO CARE FOR YOUR AXESS

It is important that you help take care of your aXess and work closely with your dialysis care team (your nurses and doctors). This will help you get the best results from your treatment.

General care

- Follow the care instructions given by your nurse or doctor;
- Rest after surgery. Let your aXess arm heal for at least two weeks. Avoid lifting heavy objects, carrying bags, or using the arm for strenuous activity;
- Keep the aXess area clean and dry. Do not scrub or soak the area until your doctor says it is safe to do so;
- Wear loose sleeves to protect your arm. Avoid tight sleeves or anything that could rub or press on the aXess;
- Avoid lying on your aXess arm, especially while sleeping;
- Check your aXess every day. Look for redness, swelling, numbness, warmth, or pain. Call your doctor right away if you see anything unusual;
- Feel for the “thrill” - a soft vibration where your aXess is placed. This means it’s working. Use your fingertips to check this at least once a day. If it changes or stops, tell your doctor or nurse right away;
- Do not allow anyone to use your aXess arm for blood pressure checks, blood draws, or injections;
- As a general recommendation, avoid smoking or other nicotine usage.

Care during hemodialysis

- Remind your care team that you have an aXess – a new type of hemodialysis access. Show them your implant card and ask them to scan the QR code for product info;
- Before using your dialysis access, your care team should always check it carefully to make sure it's safe to use and working properly. This includes:
 - LOOK: check the skin for redness, swelling, bruising, or signs of infection
 - LISTEN: use a stethoscope to listen for the "whooshing" sound, or “bruit”, of blood flow
 - FEEL: gently place fingers over the aXess to feel for the “thrill”
- Try not to move too much when the dialysis needles are in place. Moving could cause pain or damage your aXess;
- After the needles are removed, press gently on the spot as your nurse instructs. Hold pressure until the bleeding stops (usually 5–10 minutes).

SAFETY INFORMATION

aXess is made to help people who need dialysis. But like all medical devices and surgeries, it comes with risks. Some are common, and others are rare.

Very common (occurs in more than 10% of patients)

- Bruising (hematoma), fluid build-up (seroma or edema), or lymph fluid collection
- Pain
- Swelling or bulging near the needle site (pseudoaneurysm)
- Narrowing of the blood vessel (stenosis)
- Blood clots or blocked flow (thrombosis or occlusion)

Common (occurs in between 1 and 10% of patients)

- Wound healing problems or swelling
- Problems where the device connects to your blood vessels
- Swelling or damage to the aXess
- Bleeding during or after surgery
- Damage to the stitches, the aXess, or blood vessel

- Infection
- Other complications, like poor blood flow to the hand, high pressure in veins, or nerve damage
- Skin problems or sores

Uncommon (occurs in between 0.1 and 1% of patients)

- Poor blood flow to part of your arm

Rare (occurs in less than 0.1% of patients)

- Allergic reactions
- Blocked vessels caused by air or blood clots (embolism)
- Death due to heavy bleeding

In case of serious incident

Call your doctor or nurse right away if you think something is wrong with your aXess.

You can also report problems directly to Xeltis B.V.:

Email: complaints@xeltis.com

Phone: +31407517642


MAGNETIC RESONANCE (MR) IMAGING INFORMATION

An MRI is a scan that uses magnets and radio waves to see inside your body.

Your aXess is MR Conditional. This means you can have an MRI, but special steps must be followed to keep you safe. Tell your doctor that you have an aXess implant. Your doctor or MRI technician will need to follow safety rules.

You or your doctor can also find the MRI safety instructions on the Xeltis website and through the QR code on your Implant Card. You may also share the instructions below:

MR INFORMATION FOR YOUR DOCTOR

<p>Non-clinical testing demonstrated that aXess is MR Conditional. MRI is safe under these conditions:</p> <ul style="list-style-type: none"> • Static magnetic field of 1.5 tesla and 3 tesla, only <ul style="list-style-type: none"> ○ For fields of 1.5 tesla, a maximum spatial gradient magnetic field of 7982 gauss/cm (79.82-T/m) or less ○ For fields of 3 tesla, a maximum spatial gradient magnetic field of 3991 gauss/cm (39.91-T/m) or less • Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg (Normal Operating Mode) <p>Under the scan conditions defined above, aXess is expected to produce a maximum temperature rise of less than 6 °C at 1.5 tesla and at 3 tesla after 60 minutes of continuous scanning.</p> <p>The presence of aXess 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 tesla.</p>	
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IMPLANT CARD

When you get your aXess implant, the doctor or nurse will give you an Implant Card. The Implant Card has important information about your device, your doctor, the healthcare institution (hospital) and manufacturer. The QR code on the implant card can be scanned to access this Patient Information Leaflet and other important information. Keep this implant card with you whenever possible, like in your wallet, so you can show it to any doctor or other healthcare professional if you need medical attention.

Explanation of symbols on the Implant Card



Manufacturer



Date of implantation



Catalog number



Patient name or patient ID



Serial number



Name and Address of the implanting healthcare Institution/provider



Medical Device



Information website for patients



Unique Device Identification



Use-by date



MR conditional



Consult instructions for use

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

Made in the Netherlands

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