



AQUABRID® Surgical Sealant

Frequently Asked Questions (FAQ's)

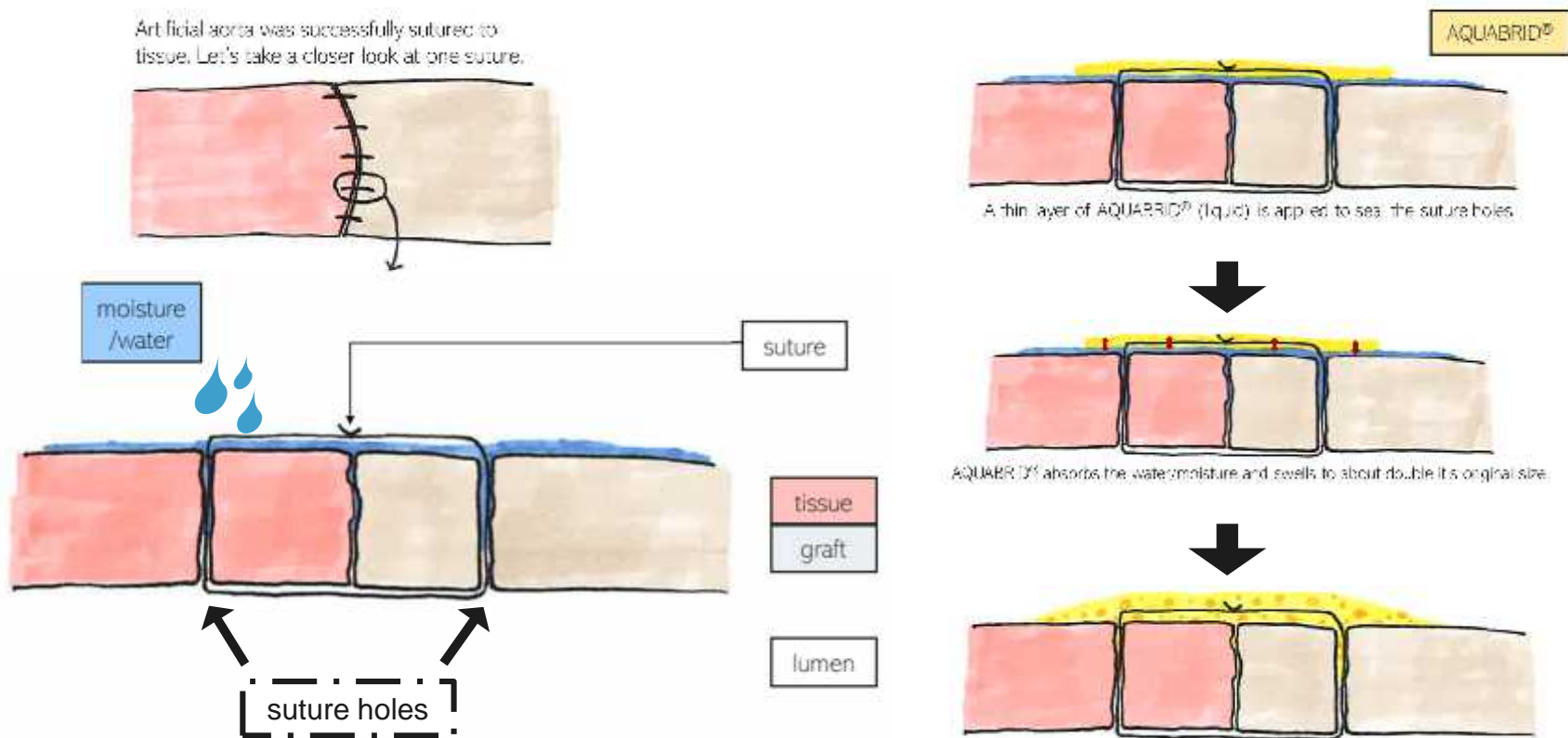
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FAQ regarding AQUABRID® Surgical Sealant

▪ How does AQUABRID® work?

AQUABRID® reacts with water in blood and tissue surfaces and polymerizes gradually becoming a soft gel which adheres to the vascular anastomosis site and hardens to an elastic spongy material.



The surgical site remains moist/wet. For most other sealants this moisture would need to be removed. AQUABRID® uses this moisture for reaction.

FAQ regarding AQUABRID® Surgical Sealant

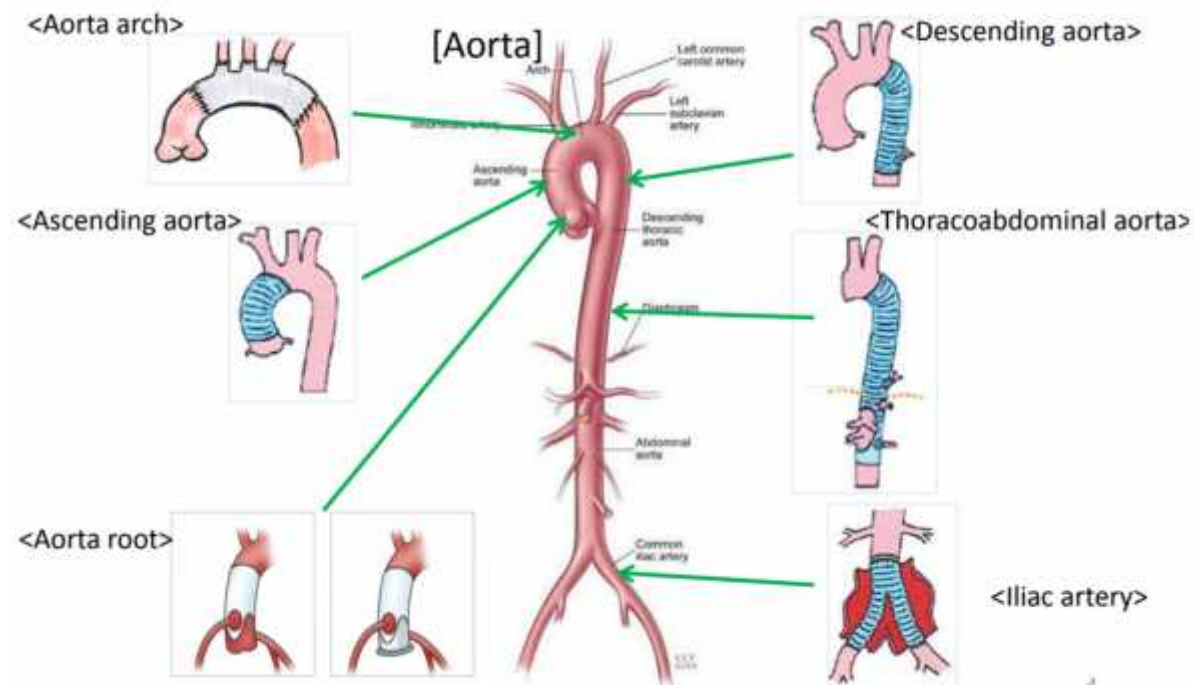
▪ What to consider when applying AQUABRID®?

- Thin layer only → a thick layer takes too long to cure and is **not** needed
- First time the plunger will need to be pushed firmly
- Consider swelling 2-3 times
- Needs direct contact to bleeding spot for best result (e.g., felt between bleeding spot)
- approx. 3-5 minutes curing time
- Remove silicone sheet carefully
 - fast and reckless removal of sheet may lead to sealant removal as well
- No other materials (e.g. gloves) should be used besides the silicone sheet for the direct and transfer method to create a mechanical blocking or so-called sealing layer

FAQ regarding AQUABRID® Surgical Sealant

▪ Where can AQUABRID® be used?

- AQUABRID® is indicated for use as an adjunct to standard methods of cardiovascular surgical repair to seal (such as sutures, staples, electrocautery, and/or patches) related to aorta surgery
- Indicated sites are **sutured sites and anastomosis of aorta** (associated dissection, rupture or aneurysm)



FAQ regarding AQUABRID® Surgical Sealant

- **How is the spatula, the silicone sheets, and the syringe sterilized?**

- All components are sterilized by gamma radiation

- **Do you need to use the spatula?**

- If you can “coat the sealant liquid firmly to the bleeding point”, there is no problem even if you do not use the spatula

- For example, if you wipe the sealant liquid with a sheet, you can apply the sealant liquid thinly and evenly without using a spatula

- **How long does it take to prepare AQUABRID® before using it?**

- AQUABRID® is ready to use. No manual mixing steps, nor preparation required

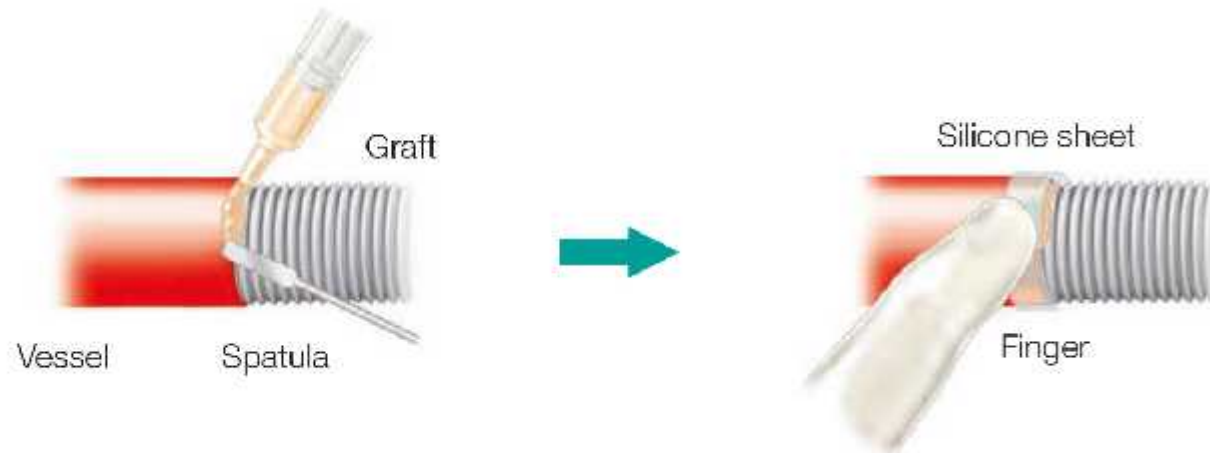
FAQ regarding AQUABRID® Surgical Sealant

▪ Do you need to use the silicone sheets?

- To obtain close fit without unintended contact with the surrounding tissues, cover the application site with the sheet and press the sheet (forceps may be used to secure the fit).
- For small bleeding sites, finger press on the sheet is sufficient.
- For larger bleeding site, apply e.g. sterile gauze on the sheet and press it by finger(s).
- AQUABRID® may stick to the gloves when pressed directly with finger. Never use AQUABRID® without the silicone sheet.
- Be sure to **remove** the silicone sheet after curing

Direct method

- = apply AQUABRID® directly from the syringe to the bleeding spot



FAQ regarding AQUABRID® Surgical Sealant

- **The symbol of single use (see symbol below) is labelled on the pouch but does not appear on the products themselves. It could create some confusion for some nurses if they put it back on the sterilization tray. May it be possible to check it with Regulatory Affairs?**
 - RA of manufacturer and Terumo Europe check all labels and notified body reviewed them. It is correct that the symbol (see below) means single use. We very much hope the nurse understands that labeling the symbol of single use on the spatula is too difficult and accepts treating with it according the label marked on the pouch



FAQ regarding AQUABRID® Surgical Sealant

- **What do you need to consider/ pay attention to, when applying the sealant?**
 - With AQUABRID there is no need to get a dry field for application. Seeing the bleeding and applying on top is ideal for AQUABRID®

- **Should you always wait for three minutes after application?**
 - Please wait more than three minutes to complete film curing, though sometimes curing may be completed within 3 minutes depending on the amount of water and thickness of film.

- **What's the clogging time?**
 - Clogging time of sealant when cap of the syringe is left open was measured. It is found that the tip part was cured completely in 60 minutes, and it was impossible to extrude sealant liquid, also after 30 minutes it was harder to extrude. Therefore, we officially recommend to put the cap on the syringe between multiple applications within a single operation (as indicated in the instructions for use).

FAQ regarding AQUABRID® Surgical Sealant

- **Is 1 syringe of AQUABRID® Surgical Sealant enough for a “proximal/ distal and brachiocephalic trunk/ left common carotid artery/ Left subclavian connection” case?**

- Many Japanese surgeons experienced that 1 syringe of AQUABRID® Surgical Sealant was enough for anastomoses of total arch replacement. But it depends on surgeon’s technique

- **Can AQUABRID® be reused?**

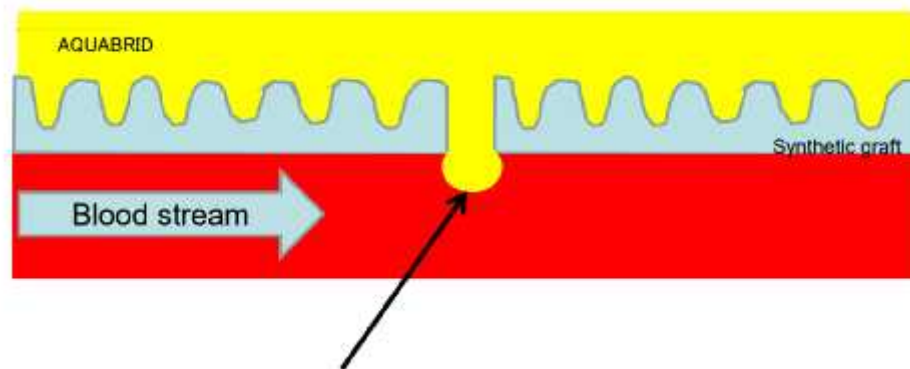
- No. Please see labels/ IFU.

- **How long can it be used?**

- The shelf life of AQUABRID® is 2 years. Once packaging is opened, it should be used immediately.

FAQ regarding AQUABRID® Surgical Sealant

- **Can AQUABRID® be used if stored outside the specified storage temperature (1-30 °C)**
 - Its quality is not guaranteed if AQUABRID® is stored outside the specified storage temperature (1-30 °C)
- **Does AQUABRID® swell in the blood vessels or go to the periphery?**



- When the sealant liquid comes into contact with water, the reaction starts a few seconds later and adheres strongly to the surrounding tissues and grafts. There is little risk of swelling or separate embolization in the blood.

FAQ regarding AQUABRID® Surgical Sealant

■ Is it OK to vacuum by sucker?

- When collecting blood from the surgical field, be careful not to inhale this product before curing is complete to avoid clogging in the reservoir.

■ What will happen in the long period?

- There was no problem in the analysis of the excised specimen 5 years later.
 - Microscopic observation : No noticeable changes such as deterioration
 - Elasticity test: No change
 - Bacterial culture test: negative
 - Moisture content: No change



FAQ regarding AQUABRID® Surgical Sealant

- **Is it possible to put a suture through the cured layer of AQUABRID®?**
 - Yes, You can put a suture through the cured layer, if needed

- **How is the sales situation in Japan?**
 - In Japan, AQUABRID® has been used in a total of more than 40,000 cases since its launch in 2014

- **What kind of comments do Japanese surgeons make?***
 - AQUABRID can be used in dry and wet environment
 - Can suture over the AQUABRID® cured film
 - Vascular tissue is not damaged by AQUABRID®
 - High adhesiveness to tissue and graft at small amounts
 - Reduced transfusion by surely stopping bleeding

* Data on file at Terumo Cardiovascular and Sanyo Chemical Industries Ltd.

FAQ regarding AQUABRID® Surgical Sealant

▪ How about effectiveness and safety?

- At Japanese academic societies, several institutions reported that the amount of blood transfusion decreased in cases using AQUABRID®.
- From the results of about 500 cases in post-marketing surveillance in Japan, no adverse events caused by AQUABRID® were observed.



Please refer to the Instruction of Use for more detailed information on the use of the device.