AQUABRID™

Surgical Sealant

English

English

[Product description]

This sealant liquid is a viscous liquid consisting of fluorinated urethane polyether prepolymer with reactive isocyanate groups (-NCO) at both ends. It reacts with water in blood and tissue surfaces and polymerizes gradually while releasing carbon dioxide gas. The product becomes a soft polymer gel that adheres tightly to the vascular and tissue surfaces and stops bleeding from the anastomosis and sutured site. The polymer possesses appropriate elasticity and strength, thus it endures blood pressure and follows pulsation in the blood vessel and tissue surfaces. After surgery, it is permanently implanted in human body.

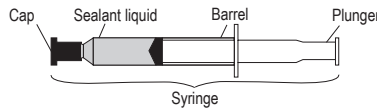
Effective use of AQUABRID requires;

- Apply sealant liquid as thin as possible to facilitate evaporation of carbon dioxide gas, in order to avoid formation of continuous voids.
- Compress the applied sealant until it is cured to obtain increased adhesion.
- Consider swelling of the sealant (two to three times of the initial size) when using on narrower site.

Components

1. Surgical sealant (main unit):

The main unit is a syringe filled with sealant liquid. The sealant liquid consists of viscous fluorinated urethane polyether prepolymer. The device has no components made of natural rubber latex. Ready to use – no mixing required.

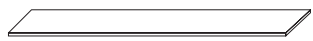


Content : 2 g (1.7 ml)

2. Sheet (accessory): Silicone rubber wrapped with paper

Purpose of use:

- To press the applied sealant
- To shield the sealant liquid from unnecessary attachment to unintended sites



Content : 2 sheets
Length 190 mm × Width 25 mm

3. Spatula (accessory): Stainless steel

Purpose of use:

- To spread the sealant liquid thinly

Content : 1 spatula
Length 160 mm

[Intended purpose]

To stop bleeding from the anastomosis and sutured site.

[Indications]

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).

Intended users are Physicians. (more specifically, cardiovascular surgeon)

[Contraindications]

- Do not use the product inside a blood vessel.
- Do not use the product when inside of the aorta is exposed to negative pressure caused by vacuum-assisted drainage in cardiopulmonary bypass, that is, aortic root vent or left ventricular vent.
- Do not connect or anastomose blood vessels with the product.

[Warnings]

- Do not terminate the operation leaving the accessory sheet, used for application, inside the body.
- Do not use the product on contaminated or infected vascular anastomosis.
- Surgical sealant should only be used in combination with sutures.
- Safety and effectiveness of AQUABRID have not been established in children and pregnant women.

[Precautions]

- For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
- Contents sterile if package not opened or damaged.
- Product has been sterilized by gamma radiation.
- Use the minimum required amount of product. (According to the biological safety study, the upper limit is 5 g in a patient weighing about 50 kg, taking a safety factor of 10 into consideration.)
- Extend the product to form the thin layer, considering swelling of the cured film to 2 or 3 fold by absorption of water.
- Avoid careless contact with unintended site, because this product tightly adheres to tissues.
- In case that removal is needed after curing, carefully remove the product without damaging the vessel and tissue.
- Confirm carefully absence of re-bleeding from the sutured site before closing the operation field.

[Procedure]

1. Apply to bleeding blood vessels or tissues treated by standard methods of cardiovascular surgical repair (such as sutures, staples, electrocautery, and/or patches) to seal. Spatula and sheet can be used to apply the product. Cover part of or the entire suture site depending on width or length of the bleeding site.

[NOTE]

(1) Do not use if packages have been damaged or unintentionally opened.

(2) Prior to use, sealant liquid shall not be exposed to liquids or excessive humidity as moisture accelerates the curing process. Do not use if by any chance the tip was occluded.

(3) Wipe the target site to remove excess blood and water.
(4) Apply appropriate amount of the product thinly and uniformly. (Example of appropriate amount: approximately 0.13 ml/cm of suture line)
(5) Application methods include (A) direct method and (B) transfer method. See <Basic methods>.
(6) Application to flat surface, partial or entire circumference are shown (a and b). See <Recommended technique>.
(7) Use full-length of the sheet. Do not use cut sheet unless the use of full-length sheet is not adequate.
2. Before complete curing, remove the excessive amount of the applied product and product applied to unintended site. Then wait 3 to 5 minutes until desirable cured film (intended strength and perfect fit to the surface) is obtained. When a sheet is used, remove the sheet without peeling off the cured film.

[NOTE]
(1) Curing process may generate bubble gas of carbon dioxide.
(2) The sealant liquid cures generally within 3 to 5 minutes after application.
(3) If curing is insufficient even after reasonable time, moisten the sealant with saline.
(4) When the sheet adheres to the sealant too tightly to remove, moisten the sheet with physiologic saline solution to keep it wet during peeling. Spatula can also be used to remove the sheet.
(5) When multiple use of the sheet in single operation is required, the sheet should before every use be flushed with physiologic saline solution and cleaned with sterile gauze until no residues are present.

3. Confirm bleeding is completely stopped. Remove unnecessary cured sealant by using e.g. scissors, if needed, without damaging tissue.
4. If bleeding cannot be completely stopped, perform additional hemostasis procedures (re-application of AQUABRID or other surgical procedures).

[NOTE]
(1) Complete adherence of the sealant to the bleeding point is important to stop bleeding. For continued bleeding due to incomplete adherence, a part of the film covering the bleeding point should be removed to apply additional hemostatic procedure.
(2) If the film covering the bleeding point cannot be removed completely after the procedure described above, suture the bleeding site through the film and/or re-apply the sealant as close as possible to the bleeding point.

5. For multiple applications within a single operation, capping the syringe after each use is necessary to avoid curing of the sealant by moisture from the air.

[NOTE]
(1) Wipe out water from the tip of syringe with clean gauze.
(2) Do not use once the tip is occluded and the plunger is not moved.
(3) Dispose any component of product after the procedure following local regulations and rules of your facility.

6. Retrieve all sheets and the spatula. Do not leave sheet or spatula in the body. Dispose of sheets and spatula as medical waste following local regulations and rules of your facility.

[NOTE]
(1) If sheet is inevitably cut to use, all cutout pieces should be collected after the procedure to make sure no piece is left in the body. Sheet-shape print on the wrapping paper can be used to check complete collection of all pieces.

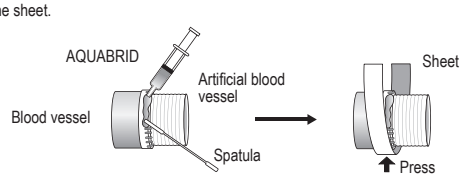
7. After use, dispose of remainder of surgical sealant, sheets and spatula as medical waste following local regulations and rules of your facility. These products are biohazardous.

<Basic methods>

(A) Direct method

This is to apply the sealant liquid to the target site directly from the syringe.

1. Apply appropriate amount of the sealant liquid to the target site for hemostasis directly from the syringe.
2. Spread the sealant thinly using the attached spatula.
3. To obtain close fit without unintended contact with the surrounding tissues, cover the application site with the sheet and press the sheet.



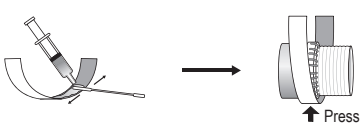
Apply the sealant directly to the bleeding point and spread it thinly using the spatula.

Sheet can be used to cover the suture site, if necessary.
<REMOVE THE SHEET after curing>

(B) Transfer method

This is a method for transferring the sealant spread on the sheet to the target site. This method is used when direct application is difficult, such as application to invisible parts of the blood vessel.

1. Apply an appropriate amount of the sealant liquid on the sheet and spread it thinly using the spatula.
2. Wrap the target site for hemostasis with the sheet covered with the sealant liquid and press it to obtain close fit.



Apply a suitable amount of the sealant liquid on the sheet and spread it thinly using the spatula.

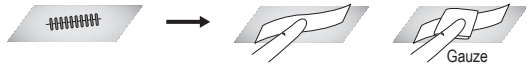
Cover the suture site with the sheet.
<REMOVE THE SHEET after curing>

English

<Recommended technique>

(a) Application to flat surface or partial circumference

Apply the sealant throughout the suture line to cover entire suture site. For small bleeding sites, finger press on the sheet is sufficient. For larger bleeding sites, apply e.g. sterile gauze on the sheet and press it by finger(s).



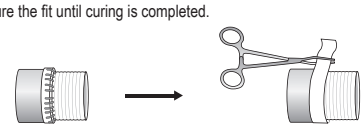
Before application, confirm completion of the suture.	For small bleeding site: Press with finger(s).	For larger bleeding site : Press with e.g. gauze and finger(s). <REMOVE THE SHEET after curing>

(b) Application to the entire circumference

Apply the sealant throughout the suture line to cover entire suture site. Preserve the natural architecture of the vessel by filling the vessel with blood or inserting a dilator, sponge, or catheter etc.

(b1) Curing in end-to-end anastomosis

Forceps may be used to secure the fit until curing is completed.



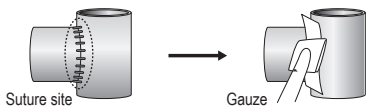
Before application, confirm completion of the suture.	Application to circumference. <REMOVE THE SHEET after curing>

(b2) Curing in end-to-side anastomosis

Whole circumferential pressing at once may not provide entire close fit. Multiple applications are recommended. Example: First, cover the half arc of the cured film with a sheet and press it with finger(s) and then do the same for the other half to obtain close fit.

[NOTE]

(1) Do not apply the product outside the suture site (indicated by the circle), especially for narrow vessel.



Before application, confirm completion of the suture.	Application to circumference half by half. <REMOVE THE SHEET after curing>

[Adverse events]

During the Japanese clinical test[1)] and post market surveillance[2)], no increase in frequency of adverse events has been noted with the use of AQUABRID compared with surgery alone. However, there may be the potential for adverse reactions including infection, foreign body reaction, and allergic reaction as with any surgically implanted biomaterials.

1) Morita S, Matsuda T, Tashiro T, Komiya T, Ogino H, Mukohara N, Tominaga R.: Randomized clinical trial of an elastomeric sealant for hemostasis in thoracic aortic surgery. Gen Thorac Cardiovasc Surg. 2020, 68:112-121.

2) Morita S, Yaku H.:A sealant with a hemostatic mechanism independent of the blood coagulation function was effective in both elective and emergency surgery for thoracic aorta. Gen Thorac Cardiovasc Surg. 2023, 71:505-514.

[Storage conditions]

Store the product at 1 °C to 30 °C avoiding exposure to water and direct sunlight.

[Incidence reporting]

If during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

[Summary of safety and clinical performance (SSCP)]

For the summary of safety and clinical performance (SSCP), please visit https://ec.europa.eu/tools/EUDAMED (BASIC UDI-DI: 458051418000000000000001GH)

[Safety and performance information]

For safety and performance information, please visit https://www.sanyo-chemical.co.jp/eng/medical_device/