FIBRIN SEALANT
TWO-COMPONENT FIBRIN SEALANT, VAPOR HEATED, KIT
TISSEEL® VH KIT

DESCRIPTION

Two-Component Fibrin Sealant, Vapor Heated (TISSEEL® VH KIT) contains the following substances in four separate vials:

1. Sealer Protein Concentrate (Human), dried powder;
2. Fibrinolysis Inhibitor Solution (Bovine);
3. Thrombin (Human), dried powder;
4. Calcium Chloride Solution

Fibrinolysis Inhibitor Solution (Bovine) is formulated as a sterile, non-pyrogenic solution containing 3,000 kallidinogenase inactivator units (KIU)/mL of Aprotinin, an inhibitor of proteases including plasmin.

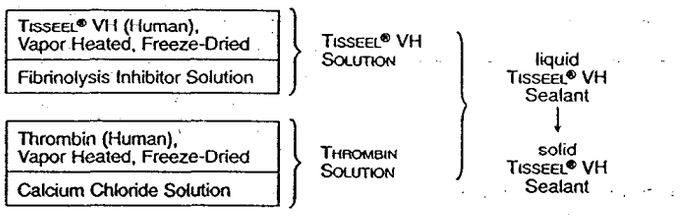
Sealer Protein Concentrate (Human) is formulated as a sterile, non-pyrogenic, freeze-dried, vapor-heated powder preparation made from pooled human plasma. After reconstitution of the lyophilized Sealer Protein Concentrate in Fibrinolysis Inhibitor Solution, the resulting Sealer Protein Solution (TISSEEL® VH SOLUTION) contains:

Total protein:	100–130 mg/mL
Fibrinogen:	75–115 mg/mL
Fibrinolysis Inhibitor:	3,000 KIU /mL
Excipients:	see table below

Thrombin (Human) is formulated as a sterile, non-pyrogenic, freeze-dried, vapor-heated powder preparation made from pooled human plasma. Calcium Chloride Solution is formulated as a sterile, non-pyrogenic solution containing 40 µmol/mL $CaCl_2$. After reconstitution of the lyophilized Thrombin in Calcium Chloride Solution, the resulting Thrombin Solution contains:

Thrombin (Human):	500 I.U./mL
Calcium Chloride:	40 µmol/mL
Excipients:	see table below

The Sealer Protein and Thrombin Solutions are then combined (e.g., by delivering with a Duploject® syringe) to form the Fibrin Sealant:



The TISSEEL® VH KIT is supplied in four different package sizes of 0.5, 1.0, 2.0 and 5.0 mL, containing the following components:

		Package Sizes			
		0.5 mL	1 mL	2 mL	5 mL
Sealer Protein Concentrate	Fibrinogen (mg):	37.5–57.5	75–115	150–230	375–575
	Total Protein (mg):	50–65	100–130	200–260	500–650
	Polysorbate 80 (mg):	0.1–0.2	0.2–0.4	0.4–0.8	1–2
	Sodium Chloride (mg):	1–2	2–4	4–8	10–20
	Trisodium Citrate (mg):	2–4	4–8	8–16	20–40
	Glycine (mg):	7.5–17.5	15–35	30–70	75–175
Fibrinolysis Inhibitor Solution	Aprotinin (KIU):	1500	3000	6000	15000
	Volume (mL):	0.5	1	2	5
Thrombin	Thrombin (IU):	250	500	1000	2500
	Total Protein (mg):	22.5–27.5	45–55	90–110	225–275
	Sodium Chloride (mg):	4–6	8–12	16–24	40–60
	Glycine (mg):	1.2–1.8	2.4–3.6	4.8–7.2	12–18
Calcium Chloride Solution	$CaCl_2$ (µmol):	20	40	80	200
	Volume (mL):	0.5	1	2	5
	Total Combined Volume (mL):	1	2	4	10

Source Plasma obtained from US licensed plasma collection centers is used to produce **Sealer Protein Concentrate** and FEIBA* bulk powder, the starting material of **Thrombin.** To obtain **Sealer Protein Concentrate,** the cryoprecipitate derived from Source Plasma is washed, dissolved in buffer solution, filtered, and freeze-dried. **Fibrinolysis Inhibitor Solution** is produced from Aprotinin Solution obtained from BAYER being identical to the one used by BAYER to manufacture their US licensed final product TRASYLOL®. **Thrombin** is prepared by dissolving FEIBA bulk powder and incubating the solution with calcium chloride in order to activate prothrombin to thrombin. After several filtration steps, the final bulk solution is freeze-dried. The **Calcium Chloride Solution** is prepared from calcium chloride complying with USP23.

Two components of the TISSEEL® VH KIT, i.e., Sealer Protein Concentrate and Thrombin, are made from pooled human plasma. The two-step vapor heat treatment used in their manufacture has been shown to be capable of significant viral reduction. However, no procedure has been shown to be completely effective in removing viral infectivity from derivatives of human plasma (see **Clinical Pharmacology and Warnings**).

TISSEEL® is intended only for topical administration.

CLINICAL PHARMACOLOGY

TISSEEL® contains Fibrinogen (Sealer Protein) as the main active ingredient. It also contains Thrombin, Calcium Chloride, and Fibinolysis Inhibitor (Aprotinin) which is a substance of bovine origin. The two reconstituted components, the Sealer Protein and Thrombin Solutions, are mixed and applied topically as described in the Dosage and Administration Section. Mixing the Sealer Protein and Thrombin Solutions produces a viscous solution that quickly sets into an elastic coagulum.

* Final product, FEIBA® VH IMMUNO, which is manufactured by ÖSTERREICHISCHES INSTITUT FÜR HAEMODERIVATE GES.M.B.H. from the same bulk, is licensed and distributed in the U.S.A. for the control of spontaneous bleeding episodes or to cover surgical interventions in hemophilia A and B patients with inhibitors.

Thrombin is a highly specific protease that transforms the fibrinogen contained in Sealer Protein Concentrate into fibrin. The thrombin is partly adsorbed by the fibrin so formed. Excess thrombin, if any, is inactivated by protease inhibitors in the blood.

Fibrinolysis Inhibitor (Aprotinin) is a polyvalent protease inhibitor which prevents premature degradation of fibrin. Released aprotinin and its metabolites are eliminated by the kidney. (Its half-life in blood is known to average between 30 to 60 minutes.[1]) Preclinical studies with different Fibrin Sealant preparations simulating the fibrinolytic activity generated by extracorporeal circulation in patients during cardiovascular surgery have shown that incorporation of Aprotinin in the product formulation increases resistance of the fibrin sealant clot to degradation in a fibrinolytic environment.[2,3,4,5]

To examine the risk of bovine sensitization, Fibrinolysis Inhibitor was injected intravenously into sensitized guinea pigs.[6] None showed shock symptoms. No case of clinically manifest bovine sensitization was observed in any of the clinical studies conducted and no reports of sensitization have been made with respect to a similar product marketed outside the U.S. Nonetheless the physician should be aware of the possibility of sensitization to bovine-derived protein.

The manufacturing procedure for TISSEEL® includes processing steps designed to reduce the risk of viral transmission. In particular, a two-step vapor heating process is included in the manufacturing of Sealer Protein Concentrate and Thrombin. Validation studies were conducted using samples drawn from manufacturing intermediates for each of the two human plasma derived components, Sealer Protein Concentrate and Thrombin. These samples were spiked with stock virus suspensions of known titers followed by further processing under conditions analogous to those in the respective manufacturing steps.

The virus reduction factors (expressed as $\log_{10}$) of independent manufacturing steps were as follows for each of the viruses tested:[7,8]

Reduction Factors for Virus Removal and/or Inactivation during the Manufacture of Sealer Protein Concentrate

Manufacturing Step	Virus Reduction Factor of Virus Tested				
	HIV-1	TBEV	PRV	ERV-1	HAV
Cryoprecipitation and Washing of Precipitate	2.6	1.3	1.5	1.8	n. d.
Freeze-Drying	1.2	1.3	2.1	3.2	3.0
Vapor Heating	>4.7	>5.6	>4.8	>4.0	>3.0

n. d. = not determined

Reduction Factors for Virus Removal and/or Inactivation during the Manufacture of Thrombin (Human)

Manufacturing Step	Virus Reduction Factor of Virus Tested				
	HIV-1	TBEV	PRV	ERV-1	HAV
Cryoprecipitation	1.4	≤1.0	1.1	≤1.0	n. d.
Adsorption on DEAE-Sephadex	2.0	3.0	3.1	≤1.0	n. d.
Freeze-Drying	2.0	≤1.0	2.6	1.9	2.7
Vapor Heating	>4.6	>7.0	>4.8	>4.7	>3.9

n. d. = not determined

In a study of 30 patients treated with an earlier version of TISSEEL®, processed by a single-step heating method, there were no transmissions by the product of HIV or hepatitis.[9] In post-marketing surveillance in Europe, no cases of viral hepatitis or HIV infection were reported after administration of a product similar to TISSEEL®.

TISSEEL® was evaluated in an open-label crossover study against control topical hemostatic agents in 489 patients undergoing cardiovascular reoperation or resternotomy at 11 institutions.[9,10,11] Patients were randomized to TISSEEL® or control hemostatic agents when a topical hemostatic was needed at the conclusion of surgery and after all attempts at surgical hemostasis. Patients were crossed to the alternative therapy if bleeding continued after the 5 minute endpoint. At 10 centers, TISSEEL® was used after administration of protamine sulfate. At one site, TISSEEL® could be used before administration of protamine sulfate. For the primary endpoint, successful hemostasis at 5 minutes, TISSEEL® was statistically significantly superior to control topical hemostatic agents:

Hemostasis within 5 minutes	
TISSEEL®	Control Topical Hemostatic Agent
159/246 (65%)	76/243 (31%)
Pearson χ^2, two sided; $p < 0.0001$; intent-to-treat analysis	

Similarly, absolute time to cessation of bleeding was statistically significantly shorter for TISSEEL® than for control topical hemostatic agents ($p<0.0001$, Wilcoxon-Gehan test, two sided, Monte Carlo option).

In a single center, prospective open label study of 120 patients randomized to standard of care (59 patients) or standard of care plus Fibrin Sealant (61 patients) for elective colostomy closure after temporary colostomy placement for treatment of traumatic injury to the colon, TISSEEL® plus standard of care was shown to be statistically significantly superior to standard of care alone ($p = 0.0406$, Jonckheere-Terpstra test for ordinal data, two sided) with regard to anastomotic complications (leakage, intra-abdominal abscess formation, re-operation, septic shock, and death).[12]

In a single center, open label trial, TISSEEL® was compared to historical controls in patients undergoing laparotomy for blunt or penetrating traumatic injury to the spleen and/or liver.[13] Use of TISSEEL® resulted in the need for statistically significantly fewer splenectomies than control hemostatic maneuvers:

	Splenectomy Rate		
Injury to:	TISSEEL®	Historic Controls	
Spleen	0/19	14/22	$p < 0.001$
Spleen and liver	1/26	19/34	$p < 0.001$

TISSEEL® did not result in statistically significantly reduced mortality in patients with blunt or penetrating trauma to the liver alone or to the liver and spleen ($p = 0.067$, χ^2, one sided).

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

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TISSEEL® VH KIT

INDICATIONS AND USAGE

TISSEEL® is indicated for use as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass and treatment of splenic injuries due to blunt or penetrating trauma to the abdomen, when control of bleeding by conventional surgical techniques, including suture, ligature, and cautery, is ineffective or impractical.[9,13,14,15,16] TISSEEL® is not indicated for the treatment of massive and brisk arterial bleeding.

TISSEEL® has been shown to be an effective sealant as an adjunct in the closure of colostomies.[12]

TISSEEL® is a satisfactory hemostatic agent in fully heparinized patients undergoing cardiopulmonary bypass.[9]

CONTRAINDICATIONS

TISSEEL® is contraindicated in individuals who are known to be hypersensitive to bovine protein.

To avoid a risk of allergic-anaphylactoid reaction and/or thromboembolic events, which may be life-threatening, do not inject TISSEEL® into a vessel or tissue.

WARNINGS

TISSEEL® VH KIT is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and removing certain viruses (see **Clinical Pharmacology**). Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to the U.S. distributor Baxter Healthcare Corporation, Phone # 1 800 423 2862. The physician should discuss the risks and benefits of this product with the patient.

TISSEEL® contains Fibrinolysis Inhibitor (Aprotinin) of bovine source. U.S.D.A. restrictions preclude the use of this product in domestic livestock, such as poultry, cattle, sheep, swine, horses, etc.

PRECAUTIONS

General

Since the Sealer Protein and Thrombin Solutions can be denatured by contact with solutions containing alcohol, iodine, or heavy metal ions, they should not be applied before the wound surface is cleaned to remove any antiseptics which may contain such substances.

Because of their low pH, oxycellulose containing preparations may reduce the efficacy of TISSEEL® and should not be used as carrier materials. The safety and efficacy of the combined use of TISSEEL® with other biocompatible carrier materials has not been evaluated in controlled clinical trials.

If a water bath is used for reconstitution instead of the Fibrinotherm®, a combined heating and stirring device, special precautions have to be taken against submersing the vial, particularly the septum, to avoid possible contamination.

Information for Patients

Some viruses, such as parvovirus B19 or hepatitis A, are particularly difficult to remove or inactivate at this time. Parvovirus B19 most seriously affects pregnant women, or immune-compromised individuals. Symptoms of parvovirus B19 infection include fever, drowsiness, chills, and runny nose followed about two weeks later by a rash, and joint pain. Evidence of hepatitis A may include several days to weeks of poor appetite, tiredness, and low-grade fever followed by nausea, vomiting, and abdominal pain. Dark urine and a yellowed complexion are also common symptoms. Patients should be encouraged to consult their physician if such symptoms appear.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies to evaluate the carcinogenic potential of TISSEEL® or studies to determine the effect of TISSEEL® on fertility have not been performed.

Pregnancy Category C

Animal reproduction studies have not been conducted with TISSEEL®. It is also not known whether TISSEEL® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. TISSEEL® should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

As with any other plasma derivatives, anaphylactoid or anaphylactic reactions may occur in rare cases. No adverse events of this type were reported during the course of the clinical trials.

Mild reactions can be managed with antihistamines; severe hypotensive reactions require immediate intervention using current principles of shock therapy.

In cases of hypersensitivity to bovine proteins or after repeated administration, allergic or anaphylactic reactions can occur on rare occasions.

INTERACTIONS

None known.

DOSAGE, ADMINISTRATION, PREPARATION, AND APPLICATION OF THE COMPONENTS

TISSEEL® is to be administered only topically. The required dose of TISSEEL® depends on the size of the surface to be covered, as in the following table:

Maximum size of the area to be sealed	Required package sizes of TISSEEL® VH KIT
4 cm²	0.5 mL
8 cm²	1.0 mL
16 cm²	2.0 mL
40 cm²	5.0 mL

TISSEEL® VH KIT contains the following substances in four separate vials:

1. Sealer Protein Concentrate (Human), dried powder;
2. Fibrinolysis Inhibitor Solution (Bovine);
3. Thrombin (Human), dried powder;
4. Calcium Chloride Solution

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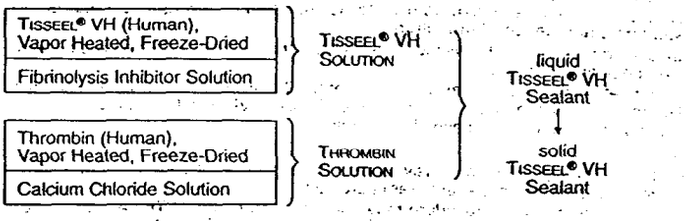
TISSEEL® VH KIT

Freeze-dried Sealer Protein Concentrate and Thrombin are reconstituted in Fibrinolysis Inhibitor Solution and Calcium Chloride Solution respectively. The resulting TISSEEL® VH, Sealer Protein Solution and the Thrombin Solution are then combined (e.g., by delivering with a Duploject® syringe) to form the Fibrin Sealant:



Use separate syringes for reconstituting TISSEEL® VH and Thrombin Solutions and for applying the two solutions to prevent premature clotting.

Preparation of TISSEEL® VH, Sealer Protein Solution

- Freeze-dried Sealer Protein Concentrate is reconstituted in the Fibrinolysis Inhibitor Solution of 3,000 KIU/mL.
- Remove the flip-off caps from the vial containing the Sealer Protein Concentrate and the vial containing the Fibrinolysis Inhibitor Solution, disinfect the rubber stoppers of both vials with a germicidal solution and allow to dry. **Do not use iodine containing preparations such as betadine for disinfection.**
- Reconstitute the freeze-dried Sealer Protein Concentrate in the Fibrinolysis Inhibitor Solution either using the Fibrinotherm® heating and stirring device or a standard incubator, or a water bath.

Reconstitution of Freeze-Dried Sealer Protein Concentrate Using the Fibrinotherm®:
(Preferred mode of reconstitution)

For ease of handling, a combined heating and stirring device, the Fibrinotherm®, has been developed (the vials for freeze-dried Sealer Protein Concentrate contain a magnetic stirrer). Heating and stirring can be operated independently. The Fibrinotherm® maintains a constant temperature of 37°C and has been designed to hold the various vial sizes of freeze-dried Sealer Protein Concentrate and Fibrinolysis Inhibitor Solution.

- Insure that the stirrer is initially switched off (green switch).
- Place the vials containing the freeze-dried Sealer Protein Concentrate and the Fibrinolysis Inhibitor Solution into the appropriate openings of the Fibrinotherm® and turn the heater on (amber switch). Wait until the signal lamp goes out indicating that the Fibrinotherm® has reached 37°C. Preheat the vials for ten minutes after this point.
- Transfer the Fibrinolysis Inhibitor Solution into the vial containing the freeze-dried Sealer Protein Concentrate.
- Place the vial into the largest opening of the Fibrinotherm® using the appropriate adaptor. Turn on the stirrer (green switch) and stir the contents for 8–10 minutes.
- Reconstitution of the freeze-dried Sealer Protein Concentrate is complete as soon as no undissolved particles are visible. Otherwise, return the vial to the Fibrinotherm® and agitate for a few more minutes until the solution appears homogeneous.

Note:

- Do not use the Sealer Protein Concentrate until it has fully dissolved. If the Sealer Protein Concentrate has not dissolved within 20 minutes using the Fibrinotherm®, discard the vial and prepare a fresh kit.
- If not used promptly, keep the TISSEEL® VH Solution at 37°C without stirring. To ensure homogeneity, switch on the stirrer of the Fibrinotherm® shortly before drawing up the solution.

Reconstitution of Freeze-Dried Sealer Protein Concentrate Using a Water-Bath:

- Preheat the vial with the freeze-dried Sealer Protein Concentrate and the vial with the Fibrinolysis Inhibitor Solution to about 37°C (but not beyond 40°C).
- Transfer the Fibrinolysis Inhibitor Solution into the vial containing the freeze-dried Sealer Protein Concentrate.
- Allow the vial to stand at 37°C for one minute.
- Swirl briefly and vigorously with a circular motion (avoid excessive frothing) and place the vial into a water-bath for another 10–15 minutes.
- Reconstitution of the freeze-dried Sealer Protein Concentrate is complete as soon as no undissolved particles are visible. Otherwise, swirl again briefly and keep the vial at 37°C for a few more minutes.
- Draw up the reconstituted TISSEEL® VH Solution into a sterile syringe using aseptic precautions.

Note:

- If a water bath is used for reconstitution instead of the Fibrinotherm®, special precautions have to be taken against submersing the vial, particularly the septum, to avoid possible contamination.
- Do not use the Sealer Protein Concentrate until it has fully dissolved.
- If not used promptly, keep the TISSEEL® VH Solution at 37°C. To ensure homogeneity, swirl with a circular motion (avoiding frothing) before drawing up the solution.

Reconstitution of Freeze-Dried Sealer Protein Concentrate Using an Incubator:

- Preheat all preparations included in the TISSEEL® VH Kit in an incubator to a temperature of 37°C (but not beyond 40°C) and keep them at this temperature for 10 minutes.
- Transfer the Fibrinolysis Inhibitor Solution into the vial containing the freeze-dried Sealer Protein Concentrate.
- Return the vial with the Sealer Protein Concentrate to the incubator and keep it at 37°C for one minute.

  Swirl briefly but avoid excessive frothing. Then return the vial into the incubator for another 10–15 minutes.
- Reconstitution is complete as soon as no undissolved particles are visible. Otherwise swirl again and return into the incubator for another 3–5 minutes.

Note:

- Do not use the Sealer Protein Concentrate until it has fully dissolved.
- If not used promptly, keep the TISSEEL® VH Solution at 37°C. To ensure homogeneity, swirl with a circular motion (avoiding frothing) before drawing up the solution.

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Preparation of Thrombin Solution

Freeze-dried Thrombin is reconstituted in the Calcium Chloride Solution.

- Remove the flip-off caps from the vial containing Thrombin and the vial containing Calcium Chloride Solution, disinfect the rubber stoppers of both vials with a germicidal solution and allow to dry. **Do not use iodine containing preparations such as betadine for disinfection.**
- Transfer the contents of the vial with Calcium Chloride Solution into the vial containing the freeze-dried Thrombin.
- Swirl briefly. Keep the Thrombin Solution at 37°C until used. Draw up an amount of Thrombin Solution equal to the amount of TISSEEL® VH Solution that will be used into a sterile syringe using aseptic precautions.

Note:

- Do not use the syringes previously used for reconstitution of the freeze-dried Sealer Protein Concentrate to prevent premature setting.
- The entire preparation procedure may take up to 40 minutes. Therefore, TISSEEL® must be prepared well in advance of its intended use. Do not use the TISSEEL® components more than 4 hours after reconstitution.

Transferring to the Sterile Field

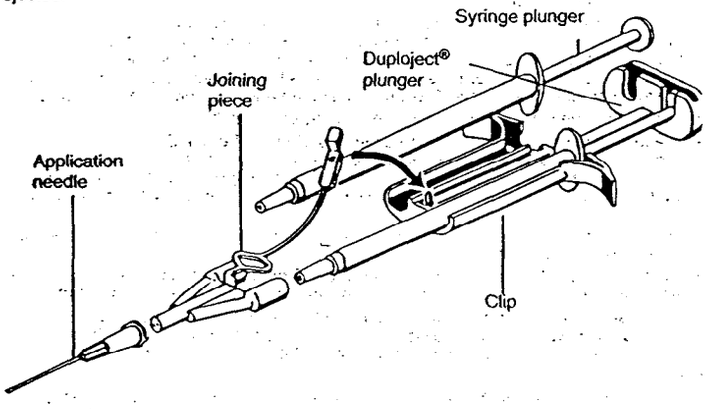
For transfer of the TISSEEL® VH Solution and the Thrombin Solution to the sterile field, the scrub nurse should withdraw the solutions while the circulating nurse holds the unsterile vials.

Note:

- The solutions should be withdrawn slowly by firm constant aspiration to reduce the risk of large air bubbles.

Method of Application Using the Duploject® System

The sterile Duploject® consists of a clip for two identical disposable syringes and a common plunger which ensures that equal volumes of the two components are fed through a common joining piece before being mixed in the application needle and ejected.



Operating Instructions

- Place the syringes filled with the TISSEEL® VH and Thrombin Solutions into the clip. Both syringes should be filled with equal volumes and should not contain any air bubbles.
- Connect the nozzles of the two syringes to the joining piece ensuring that they are firmly fixed. Secure the joining piece by fastening the strap to the clip.
- Fit the application needle onto the joining piece.
  Do not expel any air remaining inside the joining piece or application needle as the aperture of the needle may clog before application of the Sealant.
- Apply the Sealant onto the recipient surface or surfaces of the parts to be sealed.

Note:

- To ensure that the syringes fit perfectly into the Duploject® System, use only the syringes provided in the Kit.
  If application of the two components with the Duploject® and application needle is interrupted, replace the needle with a new one when sealing is resumed (3 spare needles come with the Kit).
  Only replace the application needle immediately before sealing is resumed, otherwise the apertures of the joining piece will clog. (In this case use the spare joining piece provided in the Kit.)

Application

After the two components have been applied fix or hold the sealed parts in the desired position for at least three to five minutes to ensure that the setting Sealant adheres firmly to the surrounding tissue. Solidified Sealant reaches its ultimate strength after about two hours (70% after about ten minutes).

Note:

- In order to avoid excess formation of granulation tissue and slow absorption of the Sealant, only apply thin layers of the two components.
- To prevent the Sealant from adhering to gloves and instruments, wet these with saline before contact with the Sealant.
- Application of TISSEEL® must be completed within 4 hours following reconstitution.
- Partially used vials should be discarded.

HOW SUPPLIED

TISSEEL® VH Kit is supplied in 4 pack sizes:

- Fibrin Sealant, Two-Component Fibrin Sealant, Vapor Heated, Kit, Tisseel® VH Kit 0.5 mL
- Fibrin Sealant, Two-Component Fibrin Sealant, Vapor Heated, Kit, Tisseel® VH Kit 1.0 mL
- Fibrin Sealant, Two-Component Fibrin Sealant, Vapor Heated, Kit, Tisseel® VH Kit 2.0 mL
- Fibrin Sealant, Two-Component Fibrin Sealant, Vapor Heated, Kit, Tisseel® VH Kit 5.0 mL

Each pack size contains:

- 1 vial of Sealer Protein Concentrate (Human), Vapor Heated, freeze-dried, sterile
- 1 vial of Fibrinolysis Inhibitor Solution (Bovine), sterile, 3000 KIU of Aprotinin/mL
- 1 vial of Thrombin (Human), Vapor Heated, freeze-dried, sterile, 500 I.U./mL
- 1 vial of Calcium Chloride Solution, sterile, 40 µmol/mL
- 1 Kit for Reconstitution and Application

Caution: Federal law prohibits dispensing without prescription.

STORAGE

Store at refrigerator temperature (2°C to 8°C, 35°F to 46°F). Avoid freezing.
Do not use after the expiration date.

ACCESSORIES

Fibrinotherm®, a combined warming and stirring device for reconstitution of freeze-dried Sealer Protein Concentrate can be obtained from IMMUNO's US distributors.

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May
Issued ~~April~~ 1998

Manufactured by
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U.S. Pat. No. 4,640,834
U.S. Pat. No. 4,395,396
U.S. Pat. No. 4,359,049
Other U.S. patents pending

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