

Beriplast® P/Combi-Set

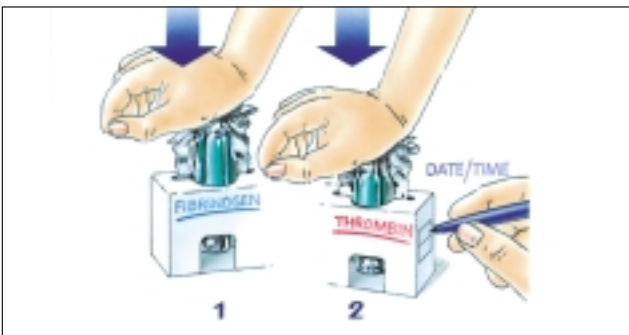
Fibrin Sealant Set

Reconstitution procedure

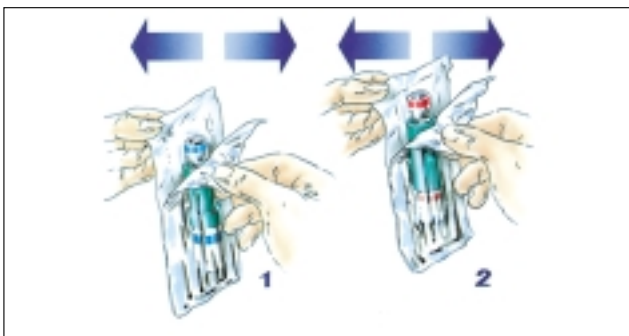
Circulator



1 Remove Combi-Set from storage (+2 °C to +8 °C) and bring to room temperature.



2 Press down on both parts of Combi-Sets together. Leave the Combi-Set in the sterile package. Write the date and time on the side of the package. Let stand for a few minutes. The solution is stable for 24 hours in the sterile package and up to 8 hours outside the sterile package at +15 °C to +25 °C.

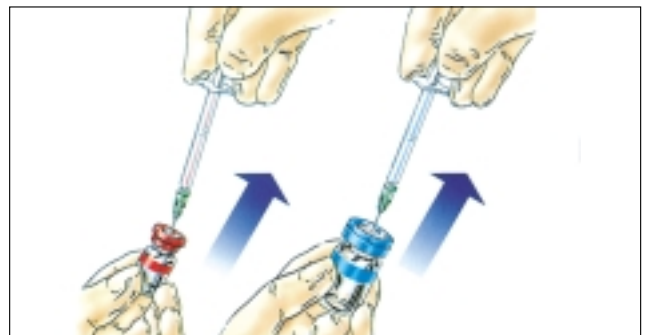


3 Remove the plastic wrapping.

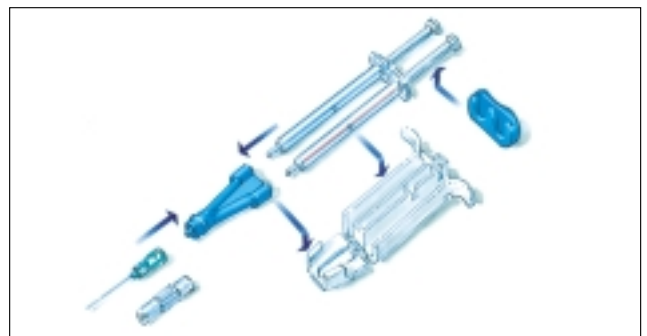
Scrub



4 Remove the plastic transfer piece (green plastic part) together with the top bottle. The fibrinogen solution and the thrombin solution are ready.



5 Draw up the fibrinogen solution (blue vial) into the application syringe (blue scale). Draw up the thrombin solution (red vial) into the application syringe (red scale).



6 Place filled application syringes into Y-piece. Snap on syringe holder and thumb piece, and insert an application cannula, or a spray tip.

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Basic Information

Beriplast® P Combi-Set

is a two-component adhesive containing human fibrinogen concentrate and human thrombin concentrate. The two components are first reconstituted and then sequentially applied to the target surface area. Simultaneous application can be achieved by using the Pantaject® ("dual-syringe") system, in combination with application cannulas, spray-tips, catheters for endoscopic use or other methods.

For covering large wound surfaces Beriplast® P can be sprayed using the enclosed spray-tips, or used in combination with collagen fleece. The tissues requiring adhesion should be fixed in place for several minutes until provisional adhesion is achieved.

Beriplast® P Combi-Set

1/3 ml

Fibrin Adhesive Set

– prescription only –

Composition:

Beriplast® P 1 ml contains:

Combi-Set I consisting of

Vial 1: fibrinogen concentrate (lyophilized) containing 90 mg fibrinogen (human plasma fraction), and 60 U coagulation factor XIII (human plasma fraction), human albumin, L-arginine hydrochloride, L-isoleucine, sodium chloride, sodium citrate dihydrate, sodium L-glutamate monohydrate connected via transfer device to

Vial 2: aprotinin solution 1 ml, containing 1000 KIU of bovine lung aprotinin corresponding to 0.56 PEU, sodium chloride, water for injections.

Combi-Set II consisting of

Vial 3: thrombin (human plasma fraction) with an activity of 500 I.U., sodium chloride, sodium citrate dihydrate connected via a transfer device to

Vial 4: calcium chloride solution for Beriplast® P 1 ml; solution containing 5.9 mg calcium chloride, water for injections.

Beriplast® P 3 ml contains three times the amount of the above mentioned quantities, respectively.

Indications:

Beriplast® P can be used locally as supportive treatment in all surgical disciplines, including endoscopic specialities to achieve tissue adhesion/sealing, suture support and haemostasis. It can further be used for haemostasis in endoscopic treatment of bleeding gastroduodenal ulcers.

Contraindications:

Arterial and heavy venous bleeding.

Known hypersensitivity to bovine proteins or other constituents of the product.

Special warnings and special precautions for use:

Beriplast® P may only be used for local administration. Beriplast® P must not be applied intravascularly. Thromboembolic complications may occur if the preparation is unintentionally applied intravascularly.

If allergic or anaphylactic reactions occur, the administration has to be discontinued immediately and an appropriate treatment has to be initiated. Therapeutic measures depend on the nature and severity of the side effect.

Care is to be taken that parts of the body outside of the desired application area are sufficiently protected (covered) to prevent tissue adhesion at undesired sites.

Special note on local injection

As with each injection, tissue damage is possible independent of the product. On local injection by endoscopic treatment of gastrointestinal bleedings such tissue damage can lead to formation of intramural haematoma. Abdominal pain, nausea, or vomiting within 1 to 3 days after such endoscopic treatment with injection can constitute symptoms of intramural haematoma. In patients with intramural haematoma of the duodenal wall, pancreatitis has been reported in single literature cases. Nevertheless, differential diagnosis for pancreatitis should be carefully evaluated.

Virus safety

When medicinal products prepared from human blood or plasma are administered, infectious diseases due to the transmission of infective agents cannot be totally excluded. This also applies to pathogens of hitherto unknown nature.

Some viruses, such as parvovirus B19 or hepatitis A, are particularly difficult to remove or inactivate at this time. Parvovirus B19 may most seriously affect seronegative pregnant women, or immune-compromised individuals.

To reduce the risk of transmission of infective agents, stringent controls are applied to the selection of donors and donations. In addition, virus removal and/or inactivation procedures are included in the production process of Beriplast® P. Beriplast® P is prepared exclusively from plasma donations which have been tested negative for antibodies to HIV-1, HIV-2, HCV and for HBs antigen. The levels of ALT (GPT) in the plasma are also determined and must not exceed twice the normal value specified in the test. In addition, the plasma pool is tested for antibodies to HIV-1, HIV-2, HCV and for HBs antigen. The plasma pool is used for further processing only if the results are negative. The production process of Beriplast® P contains various steps which contribute towards the elimination/inactivation of viruses. The heat treatment of the preparation in aqueous solution at 60 °C for 10 hours was introduced for virus inactivation.

Undesirable effects:

In rare cases, hypersensitivity or allergic reactions (e.g. dyspnoea, flush/rash, urticaria, hypotension) may occur, extending in isolated cases as far as shock. Such reactions may especially be seen, if the preparation is applied repeatedly, or administered to patients known to be hypersensitive to bovine proteins or other constituents of the product.

If allergic or anaphylactic reactions occur, the administration has to be discontinued immediately and an appropriate treatment has to be initiated. The current medical standards for shock treatment are to be observed.

Drug interactions:

No formal interaction studies have been performed. Similar to comparable products or thrombin solution, Beriplast® P may be denatured after exposure with solutions containing alcohol, iodine or heavy metal (e.g. antiseptic solutions). Such substances should be removed to the greatest possible extent before applying Beriplast® P.

Dosage:

The volume of Beriplast® P to be administered and the frequency of application should always be oriented towards the underlying clinical needs of the patient. The dose of Beriplast® P to be applied is governed by variables including, but not limited to, the type of surgical intervention, the size of the area of intended application, and the number of applications.

Application of Beriplast® P must be individualised by the treating physician. The initial volume of Beriplast® P to be applied at a chosen anatomic site or target surface should be sufficient to entirely cover the intended application area.

Administration:

Prepare the solutions as described in the package leaflet. The reconstituted solutions (of vial 1 and 3) are to be administered locally to the tissue (sequentially or in combination). Before Beriplast® P is applied, the surface of the wound should be as dry as possible.

The application can be repeated, if necessary.

Storage and stability:

Beriplast® P is to be stored and protected from light at a refrigerated temperature of +2 to +8 °C. Do not use after expiration date given on the package and containers.

Once reconstituted the thrombin and fibrinogen solutions remain stable in the vials at +15 to +25 °C for 24 hours if stored in the unopened sterile blister packaging or for 8 hours if stored outside the sterile blister packaging.

Use the reconstituted solutions immediately after withdrawal into the syringes. The storage conditions for the finished product and the reconstituted solutions should be observed strictly.

Additional information:

The safety of Beriplast® P for use in human pregnancy or breastfeeding has not been established in controlled clinical trials. Experimental animal studies are insufficient to assess the safety with respect to reproduction, development of the embryo or fetus, the course of gestation and peri- and postnatal development.

Only limited experience regarding the administration of Beriplast® P in pregnant women is available.

Presentation:

Beriplast® P Combi-Set is available in packages of 1 ml and 3 ml.

This is basic information only.
For national prescribing information please see your country's specific package insert that comes with the product.