Instructions for Use – Set for Applying Beriplast P (Tradename Pantaject®)

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Instructions for Use

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Pantaject®

CE 0297

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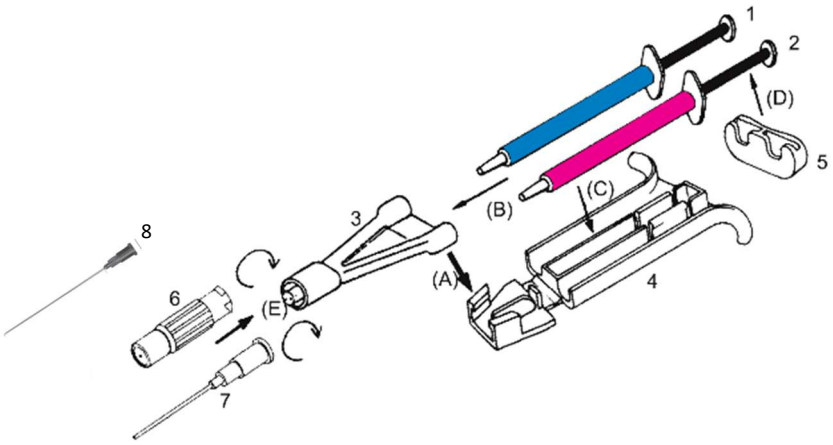


Figure 1 Pantaject®

ThPantaject® consist of the following components:

1. Blue marked syringe (for fibrinogen solution)
2. Red marked syringe (for thrombin solution)
3. Y-piece
4. Syringe holder
5. Grip plate
6. Spray-tip
7. Cannula (for Application)
8. Withdrawal Cannula

The User Steps A- E in Figure 1 are described in Section “Handling of the Set”.

Pantaject® 0,5 ml + 1 ml and 3 ml

Pantaject® fulfills the requirements of Regulation (EU) 2017/745 on medical devices (MDR).

Before using Pantaject® read these instructions for use. Follow the instructions at all times. This document is intended for experienced healthcare professionals using the Beriplast® P Combi-Set.

The Pantaject® device (henceforth "set") is supplied as part of the Combi-Set for joint application of the fibrinogen solution and thrombin solution. This document contains instructions for use and safety relevant information for Pantaject®. It does not contain information relevant to the medicinal product Beriplast P. Refer to the leaflet included in the Beriplast P Combi-Set for information concerning the medicinal product Beriplast P.

Intended Purpose

Pantaject® is intended to facilitate the administration of the ready-to-use two-component fibrin sealant Beriplast P directly into the operating area. The device is intended for transient and surgically invasive use. It must not be used for monitoring, diagnosis, treatment, or correction of defects of the heart or of the central nervous system.

Device description

Pantaject® is intended for single-use only and delivered in a sterile state. The set components are supplied together in a hard blister which is packaged in a sterile bag. This allows extraction of the hard blister and subsequent assembly and application of Pantaject® under sterile conditions in the operating room. The device is ethylene oxide sterilized.

Pantaject® contains two disposable syringes and two disposable cannulas for drawing up the reconstituted adhesive components from the respective vials. After removing the needles, the two syringes are placed into the syringe holder after the latter has been connected to a Y-piece. This Y-piece facilitates simultaneous application of both adhesive components, either through a (blunt) application cannula or, for larger wound surfaces, through a spray tip. In order to ensure smooth forward movement of both syringe plungers, a grip plate is connected to the plungers.

Intended User

The set is intended for professional use only by experienced physicians and/or surgeons.

The following information on the indications, contraindications and patient population is provided based on the Beriplast P Combi-Set for the medicinal product Beriplast P.

Indications (coincide with those of the medicinal product)

Supportive treatment where standard surgical techniques are insufficient to achieve tissue adhesion/sealing, suture support and haemostasis. It can further be used for haemostasis in endoscopic treatment of bleeding gastroduodenal ulcer.

Contraindications (coincide with those of the medicinal product)

- Intravascular use.
- Arterial and strong venous bleeding.
- Hypersensitivity to active substances or to any of the excipients of the Beriplast P Combi-Set.

Patient Population (coincides with that of the medicinal product)

The safety and efficacy of the medicinal product Beriplast P in children and adolescents has not yet been established in controlled clinical studies.

Only limited experience regarding the administration of Beriplast P in pregnant or breastfeeding women is available. Therefore, the product should be administered to pregnant and lactating women only if clearly indicated.

Performance characteristics and clinical benefits

Performance Characteristics:

Pantaject® allows simultaneous application of both adhesive components of Beriplast P, surpassing conventional methods. This can be achieved through a (blunt) cannula or spray tip, ensuring precise delivery of fibrin sealant Pantaject® for enhanced efficacy.

Clinical Benefits:

Tailored for transient and surgical procedures, Pantaject® facilitates direct administration of fibrin Beriplast P into the operating area, prioritizing safety. It ensures uniform mixing of both components, minimizing risks and optimizing therapeutic outcomes.

Residual risks associated with the use of Pantaject®

Despite advancements in healthcare practices and safety measures, the use of Pantaject® poses the residual risk of needlestick injuries. While efforts have been made to minimize such incidents, it is crucial to acknowledge and address the potential risks associated with syringe usage.

⚠ If a needle stick injury occurs, please follow local medical attention, wound care, and incident report instructions.

Despite stringent infection control measures and the application of a sterilized Pantaject® device, there is a residual risk of contamination for healthcare professionals and patients. Contamination can occur through direct contact with bodily fluids, contaminated surfaces, or medical devices. The risk is particularly relevant when handling sharps, such as needles and other medical instruments.

⚠ It is mandatory to follow local environmental cleaning procedures, use personal protective equipment follow hygienic restrictions, needle stick preventing actions and reporting and monitoring procedures in the surgical environment.

General Warnings and Precautions

⚠ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is located. Manufacturer address:

Effectum Medical AG
Kirchgasse 11
CH-4600 Olten

⚠ Do not use if (sterile) packaging is damaged or (unintentionally) opened before use. Only use products from intact packaging and dispose of products from damaged or opened packaging (infection risk).

⚠ Do not apply the device intravascular. Life threatening thromboembolic complications may occur if the medicinal product is applied intravascularly: intravascular injection could lead to alterations of coagulation, e.g. clotting of vessels or excessive coagulation resulting in severe bleeding; there is also a risk of anaphylactic reaction.

⚠ Before administration of Beriplast P, ensure that parts of the body outside the desired application area are sufficiently protected (covered) to prevent tissue adhesion at undesired sites.

⚠ Do not re-use. The set is intended for use on one patient during a single procedure (single-use device). The set is not intended to be reprocessed (cleaned, disinfected / sterilized) and used on another patient (infection risk).

⚠ Do not push the syringe plungers against a resistance. Before use in the wound region the system must be checked for blockages.

Handling of Pantaject® (see figure on the packaging)

Open the bag in the sterile area. Retrieve and open the sealed hard blister under sterile conditions using aseptic technique. Only the inside of the blister pack and the enclosed components of the Pantaject® device are sterile.

Connect the needles to the syringes.

Incline the vial containing fibrinogen solution (blue marking) and draw up the contents into the blue marked syringe. Completely draw up the contents of the vial containing thrombin solution (red marking) into the red/pink marked syringe.

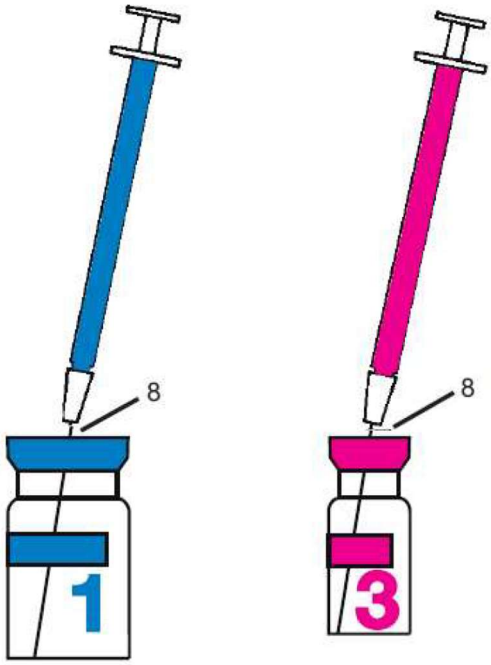


Figure 2 Vial No. 1 Fibrinogen Solution (Blue) Vial No. 3 Thrombin Solution (Red)

Remove the needles from the syringes filled with the fibrinogen solution (blue marking) and thrombin solution (red/pink marking).

(A) Insert the Y-piece (3) in the conical recess of the syringe holder (4).

(B) Firmly connect to the Y-piece (3) the syringes filled with the fibrinogen solution (blue marking) and thrombin solution (red/pink marking) through a screwing movement while taking care that the syringe plungers and finger flanges do not get entangled.

(C) Snap both syringes into the syringe holder (4).

(D) Connect the grip plate (5) to the syringe plungers to prevent jamming of the syringe plungers and to ensure smooth forward movement. While attaching the grip plate, care should be taken to not push the plungers in order to avoid premature mixing of the solutions and blockage of the device.

(E) Finally, firmly screw on the spray tip (6) or the application cannula (7) (both equipped with a Luer-Lock connector) to the end of the Y-piece to apply Beriplast P.

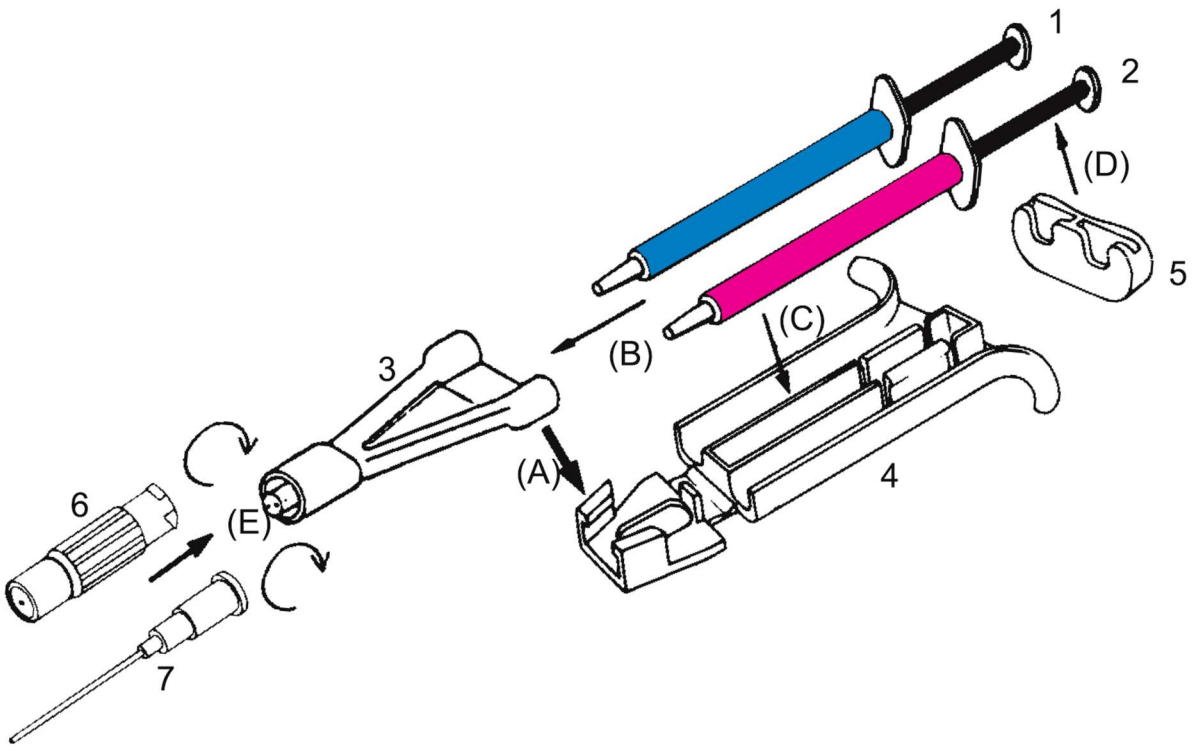


Figure 3 Step A - E

By applying an even pressure to the grip plate – like for an injection – the fibrin sealant is applied directly into the operating area through the application cannula.

Alternatively, for covering large wound surfaces the fibrin sealant can be sprayed as a fine, even aerosol using the enclosed spray tips – also by applying an even pressure to the grip plate – or used in combination with fleece consisting of e.g. polyglycolic acid or collagen. The spray tips are best applied at a distance of about 10 cm. A fine film of fibrin sealant forms on the tissue to be coated.

⚠ During assembly, as well as before and in between uses, care should be taken to hold the syringes tilted backward, to avoid premature mixing of the solutions and blockage of the device.

⚠ Any interruption in the application, even of short duration, may result in blockage of the spray tip or application cannula. In such cases the spray tip or application cannula is unsuitable for further use and must be replaced. For this purpose, the Pantaject® device contains two spray tips (1ml pack) / three spray tips (3ml pack) and four blunt application cannulas.

⚠ It is recommended to use Pantaject® immediately after opening the bag.

The used set including any unused medicinal product should be disposed of in accordance with local requirements.

Transport and Storage Conditions

⚠Keep away from sunlight  .

⚠Keep dry  .

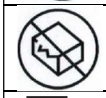
⚠Keep in its intact original packaging until use  .

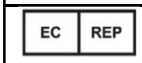
⚠ Do not use after the indicated “Use by Date”  on the peel off label.

⚠ If any of such conditions are compromised, please use a new Pantaject® device.

Safety instructions

The following symbols are used in these instructions for use and on the labels of Pantaject®:

	Catalogue Number
	Batch number
	Unique device identifier
	Medical Device
	Date of Manufacture
	Indicates the Medical Device Manufacturer
	Indicates the entity importing the medical device into the local
	Consult instructions for use or consults electronic instructions for use
	Single sterile barrier system with protective packaging inside
	Do not resterilize
	Do not use if package is damaged and consult *instructions for use*
	Use-by date
	Sterilized using ethylene oxide
	Do not re-use
	Authorized representative in the European Union
	Keep away from sunlight
	Keep dry

	Effectum Medical AG Kirchgasse 11 CH-4600 Olten https://www.effectummedical.com info@effectummedical.com
	EMERGO EUROPE Westervoortsedijk 60 NL-6827 AT Arnhem
	CSL Behring GmbH Emil-von-Behring-Straße 76 DE-35041 Marburg