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*Device for the activation (gelification) of blood components destined to the topical non-transfusional use.*

## Plateltex® Act

**Plateltex-Act®** consists of common disposable devices (syringes, needles, tweezers) and two separate components (batroxobin and calcium gluconate). After addition to platelet concentrate and platelet-poor plasma by the modes described in section "**Instructions for use**", these two components convert the blood component from liquid state to the semi-solid gelatinous state such as to be handled and locally applied, according to the Good Clinical Practice, in order to facilitate tissue repair or regeneration.

Plateltex® produces also a kit for collection of platelet concentrate. It consists solely of common devices needed for autologous blood collection and subsequent preparation of platelet concentrate:

**Plateltex-Prep®** contains 1 butterfly needle 21G with extension line and holder, 6 ACD blood collection tubes, 8.5 mL), 2 syringes 20 ml with plastic needle, 1 syringe 10 ml with plastic needle, 2 graduated tubes 15 mL.; 2 luer lock caps.

Preparation of platelet concentrate is performed on sterile containers. Plateltex® produces three types of sterile containers which can be used in platelet gel production together with Plateltex-Act®. These containers are individually sealed in sterile bags and are sold in 20 units boxes. They are available in three different diameters and capacities:

### **Plateltex® Dish 35 ; Plateltex® Dish 70 ; Plateltex® Dish 100.**

### **Purpose of use**

**Plateltex-Act®** is planned and prepared to make the preparation of blood components for topical use (platelet and/or fibrin gel) simple, fast and safe. **Plateltex-Act®** is destined primarily to the application of blood components for topical use of autologous nature (products of the process of patient's blood). Whenever clinical or technical reasons do not enable to produce the autologous blood component, **Plateltex-Act®** may be employed using homologous blood components biologically qualified by the reference transfusional service and after the patient has signed the informed consent form (see Warnings). Fibrin present in platelet and fibrin gels and the tissue growth factors present in the platelet gel are known to be capable of accelerating and inducing the cell proliferation contributing to processes of repair and regeneration of tissue injuries. **Plateltex-Act®** facilitates the gelification of blood components for non-infusional topical use in the laboratory of production of blood components (credited Transfusion Centers) and in the point-of-care, namely: a) operating theaters, b) medical-surgical out-patient services, c) patient's home.

**Plateltex-Act®** should be used exclusively by a medical staff or specialized nurses under the physician's immediate monitoring and responsibility. The device and the biological products prepared with its use (platelet and fibrin gels), should be employed in the range of a complete and accurate clinical-therapeutic approach, possibly following the criteria of evidence-based medicine (EBM). In no instance self-medication is allowed using the device and the biological derivatives prepared with the device itself.

Physicians who use **Plateltex-Act®** should recognize that the therapeutic qualities of the component produced with this set depend on the quality of the original blood component (platelet concentrate and/or platelet-poor plasma). The intrinsic qualities of the original blood component depend exclusively on the center which produces, stores, qualifies and distributes the blood component (see Warnings).

The main destinations of use of platelet and/or fibrin gels produced with **Plateltex-Act®** concern therapy of wounds, ulcers, acute and chronic injuries of the hard and soft tissues. We mention here below some examples of its fields of application: **Maxillo-facial surgery**: mandibular reconstructions, dental implants, oronasal and oropharyngeal fissures; **Otorhinolaryngoiatry**: neck and head surgery, facial or nasal fractures; **Plastic, Reconstructive, Esthetic surgery**: skin flaps, musculo-cutaneous reconstructions, mammoplasty; **Orthopedics**: pseudoarthrosis, osteosynthesis, bone implants, implantations of titanium prostheses; **Neurosurgery**: post-operative loss of cephalorachidian fluid. **General Medicine, Geriatrics, Diabetology, Hematology, Vascular Surgery, Cardiosurgery, General Surgery, Thoracic Surgery, Dermatology, Radiotherapy** are all specialized areas where acute or chronic, primary or secondary ulcers and fissures could find a therapeutic support in the use of platelet or fibrin gel. **Plateltex-Act®** may be used in combination with **Plateltex® Dish 35, Dish 70 and Dish 100** (sold separately) which are sterile devices of a size adequate to the most various clinical requirements.

### **Features of the device**

**Plateltex-Act®** consists of two components, calcium gluconate and batroxobin. Supplied calcium gluconate is in a sterile liquid form at a concentration suitable to saturate the anticoagulant present in the blood components to be transformed into the gel.

The peculiar factor of the set is batroxobin, which is used to transform fibrinogen into fibrin in combination with Ca<sup>++</sup> ions supplied by calcium gluconate. The fibrin reticulum which forms in few minutes after the addition of batroxobin and Ca<sup>++</sup>, causes the gelification of the product which may be easily detached with tweezers and adjusted to the injury to be treated.

**Plateltex-Act®** contains freeze-dried batroxobin (white crystalline) pre-titrated at 5 BU (Batroxobin Units), equivalent to about 0.9 NIH (National Institute of Health) thrombin units: 1BU ~ 0.18 NIH units. This amount of batroxobin is sufficient to induce the gelification of platelet concentrate and/or of platelet-poor plasma in the amounts established in paragraph "**Instructions for use**". Exceeding amounts of anticoagulant versus blood plasma or pathologically low fibrinogen concentrations could delay or prevent the gelification even with optimal amounts of calcium and batroxobin (see Chapter "Warnings"). The use of batroxobin as pro-activator to obtain the platelet gel is protected by an international patent (Patent No. W001/843787)

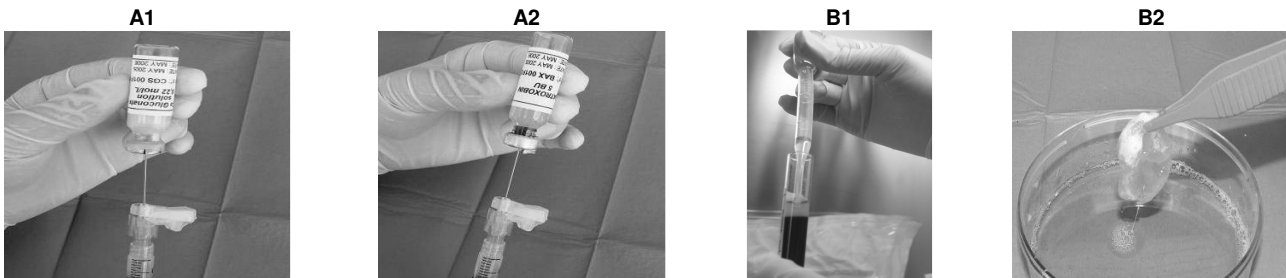
### **Instructions for use**

It's recommended that the whole procedure is carried out in a clean (preferably sterile) environment. All items not included in the kit must be sterile and single use.

- Aspirate, with the aid of a 3 mL syringe, 1 mL of calcium gluconate from the vial, transfer it into the vial containing freeze-dried batroxobin, shake to obtain a homogeneous mixture (Figure A-1).
- Aspirate, with the aid of a 3 mL syringe, the mixture of batroxobin/calcium gluconate (Figure A-2).
- Aspirate, with the aid of a 10 mL syringe, 5-6 mL of platelet concentrate (or 6-10 mL of platelet-poor plasma to prepare the fibrin gel) (Figure B-1).
- Choose the container most suitable to the size of the gel to be prepared.
- Mix the blood component with the solution of batroxobin/calcium gluconate.
- Shake gently the container with a rotating movement and wait for gel formation. (7- 10 min).
- Once the gel is formed, it tends to shrink. If the gel is not manipulated the spontaneous clot retraction occurs after about 30 minutes from the formation of the gel. If the gel is manipulated or detached from the walls of the container, the retraction of the clot is accelerated. The retraction of the gel is accompanied by the release by the latter, a plasma transudate
- The plasma transudate possibly remaining in the container may be taken with one of the two Pasteur pipettes supplied with the package. The transudate may be used as a pre-treatment of the injury or as a pro-activator for the preparation of the fibrin gel (see below).
- Take and apply the gel on the area or in the site to be treated (Figure B-2).

**Fibrin gel may be prepared according to the above mentioned indications. As an alternate, if both fibrin and platelet gels should be prepared, fibrin gel may be also obtained as follows..**

- Take with the aid of one of the two Pasteur pipettes supplied with the package the platelet transudate and introduce it into the most suitable container for the quantity of gel to be prepared.
- Aspirate with the 2.5-mL syringe 2 mL of calcium gluconate from its vial and introduce it into the most suitable container for the quantity of gel to be prepared.
- Aspirate the PPP (platelet-poor plasma) with the 10-mL syringe and introduce it into the most suitable container for the quantity of gel to be prepared.
- Shake gently the container with a rotating movement and wait for gel formation.
- Detach and take the gel.
- Apply the gel on the area or site to be treated.



## Warnings

**Conditions of use.** **Plateltex-Act®** is an activation set. The components are supplied sterile. In the activation steps, be careful to prevent the bacterial contamination of the blood component. Therefore, it is recommended that **Plateltex-Act®** is used in a sterile environment or complying with the criteria of hygiene, deteration and cleansing usually established by the Good Clinical Practice for the point-of-care.

**Base blood components.** The starting blood components for the preparation of platelet or fibrin gels should be prepared only by authorized centers and operators.

**Drug interactions:** cyclo-oxygenase inhibitors (Aspirin and NSAID's), platelet anti-aggregants, heparin, calicheparin, oral anticoagulants (coumadin, Sintrom and similar agents). Growth factors and chemotactic mediators of platelet origin are released mainly passively (i.e. without platelet activation). Therefore, the platelet gel may be prepared from the blood of patients who take oral anticoagulant agents, heparin, calicheparin, platelet anti-aggregants, cyclo-oxygenase inhibitors. However, since a part of the release of growth factors could depend on the state of activability of platelets, it is rational to wait for a delay of the release of growth factors in the event the patient takes cyclo-oxygenase inhibitors or platelet anti-aggregants.

No interactions are known with systemic or topical agents. The expected use does not include the addition of drugs to the platelet or fibrin gels. In case of employ of platelet gel for bone regeneration, gel can be associated with human bone, animal bone certified for human use, other biocompatible materials certified for human use.

**Congenital or acquired platelet defects.** Patients with congenital or acquired functional platelet defects could release a lower amount of growth factors in relationship with the platelet defect.

**Neoplasm.** Growth factors of platelet origin induce a cell proliferation. The use of platelet gel is contraindicated on injuries which are suspected to be of malignant degeneration

**Precautional documentation.** The user, because he/she is treating blood components, should keep a documentation of the features and source of the blood component employed. As a precaution, it is appropriate to keep also one copy of the informed consent form signed by the patient for the treatment with blood components.

## Contraindications

The contraindications described here below refer to the use of the gel.

There are no known contraindications. The gel is reabsorbed within few days. No toxicity phenomena are described in the tissues treated with the gel. The usual procedures of surveillance or prophylaxis against infectious complications should be applied.

Care should be applied in case of tissues suspected or at risk of neoplastic degeneration. In case of piastrinopenia, it is improbable that a platelet concentrate enough enriched for the clinical use, may be obtained. The amount of blood taken from the patient for the preparation of the base blood components should view the patient's hemodynamic conditions. The competent Service of Transfusional Medicine plays the role of reference and consulting center.

## Recommendations for a correct use of the set

**Plateltex-Act®** set is supplied in a sealed and labeled package. The set contains sterile materials. Never use the product after the expiry date. Store the device in a cool and dry place far from the direct sunlight. Never use the device whenever, during the visual inspection, packaging anomalies were found. Store the calcium vial at room temperature. Store the batroxobin vial far from direct light.

## Procedure of waste disposal

Wastes should be disposed in compliance with National and local regulations for the Disposal of Health Wastes.

## TABLE OF SYMBOLS

	CAUTION		DO NOT REUSE		STERILE EO		KEEP AWAY FROM SUNLIGHT		DATE OF MANUFACTURE		DO NOT RESTERILIZE		CONSULT INSTRUCTIONS FOR USE
	15 °C -30 °C	TEMPERATURE LIMITATION		MANUFACTURER		KEEP DRY		LOT	BATCH CODE		DO NOT USE IF PACKAGE IS DAMAGED		USE BY

Manufacturer

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*Ver. 2.1– Mar 2011*