Plateltex®

CE 1936

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

Plateltex® Line

Plateltex-Prep® is a medical device which allows the preparation of Platelet Rich Plasma (PRP) starting from the patient's blood. It 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.

Plateltex-Act® consists of common disposable devices (syringes with needles, pipettes) and two 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-Dish®

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 (Ø 35mm), Plateltex-Dish®70 (Ø 70mm), Plateltex-Dish®100 (Ø 100mm).

Plateltex- Act®

Purpose of use

Growth factors and the components of fibrin in platelet gel are known as accelerators and inducers of cell proliferation and cooperate to the regenerative and reparative processes of tissue lesions.

Plateltex-Act ® allows the activation in gel of blood components for topical use (platelet concentrate) and concentrate bone marrow. The device and the biological products prepared with it (platelet gel and concentrated bone marrow), 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.

Platelet gel produced with **Plateltex-Act®** is used for 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**: vertebral reconstructions. **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 gel. Platelet-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 gel.

The peculiar factor of the set is batroxobin, which is used to transform fibrinogen into fibrin in combination with Ca^{++} ions supplied by calcium gluconate. The fibrin reticulum which forms in few minutes after the addition of batroxobin and Ca^{++}, causes the gelification of the product.

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 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. The action of batroxobin is not affected by the presence of heparin. 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

The whole procedure has to be carried out in a clean (preferably sterile) environment. All items **not included in the kit** must be sterile and single use.

Supplied batroxobin is reconstructed with 1 mL of calcium gluconate.

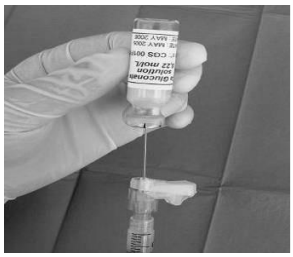
- 1 mL of reconstructed batroxobin activates 6-10 mL max of platelet concentrate.
- Maximum tolerate range for reconstruction of batroxobin: +0.5mL of calcium gluconate (1.5 mL final total volume)
- Reconstructed batroxobin must be used within one hour.

Sterilized container for gel preparation is not supplied.

- 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, gently shake to obtain a homogeneous transparent mixture (Figure A-1).
- Aspirate the mixture of batroxobin/calcium gluconate (Figure A-2) and mix it with the platelet concentrate (Figure B-1).
- Shake gently the container with a rotating movement and wait for gel formation. (7- 10 min).
- Take and apply the gel on the area or in the site to be treated (Figure B-2).

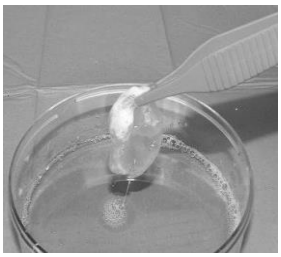
Caution: If platelet gel is not manipulated, a spontaneous retraction of fibrin net (clot) may occur; gel surface reduces and plasma is released. Therefore, an immediate application after gelation is recommended. However, the released plasma is rich in platelet grow factors, and it can be used as it is (liquid) or re-activated with calcium gluconate (fibrin gel) (Figure B-2).

A1



A2

B1



B2

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, detersion and cleansing usually established by the Good Clinical Practice for the point-of-care.

Drug interactions: cyclo-oxygenase inhibitors (Aspirin and NSAID's), platelet anti-aggregants, heparin, calciheparin, 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, calciheparin, 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 platelet gel. 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.

Thrombocytopenia: It is unlikely to achieve a platelet concentrate enriched enough for clinical use.

Platelet 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.

Contraindications

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.**

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.

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
25°C 4°C TEMPERATURE LIMITATION	NON PYROGENIC	MANUFACTURER	KEEP DRY	LOT BATCH CODE	DO NOT USE IF PACKAGE IS DAMAGED	USE BY

Manufacturer:

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