**DESCRIPTION**

Plateltex® is a modular device system including:
- Plateltex®-PREP - device for the preparation of platelet-rich plasma (PRP, or platelet concentrate PC)
- Plateltex®-Act 0/0 - activation device for the preparation of the gel
- Plateltex® 35/70 or 70/100 - activation device for the preparation of the gel providing specific containers for gel preparation

These models can be used singularly or combined.

**INTENDED USE**

Plateltex® is designed to make the preparation of topically applied blood components (platelet gel, fibrin gel, bone marrow-derived cells) easy, quick, and safe. Plateltex® is intended for handling autologous blood products. The principles of sing Plateltex® for wound healing and tissue repair is to deliver locally concentrated tissue repairing and healing factors, such as those contained in platelet-rich plasma, also providing tissue repairing cells, and a provisional fibrin scaffold to support cell migration.

Plateltex® is to be used by medical doctors and by trained nurses under medical responsibility. One must be aware the therapeutic efficacy depends from the intrinsic quality of the blood component preparation. Plateltex® supports the preparation and the activation (gelation) of the blood component; Plateltex® is not therapeutic by itself.

The major indications for Plateltex® include the treatment of acute wounds and chronic ulcers involving either skin and mucocutaneous tissue and bony lesions. Some applications are listed below.

**Oral Surgery:** dental implants; alveolar repair; sinus lifts; mandibular reconstruction; bone graft; oral nasal fistula;

**Ears, Nose and Throat:** cleft lip repair; septrhinoplasty and rhinoplasty; head and neck surgery; facial fractures;

**Plastic, Reconstructive, Aesthetic Surgery:** face and neck lifts; musculocutaneous flaps and reconstruction; chronic ulcers; breast reconstruction and mammoplasty; cranio-facial reconstruction; facial laser treatments;

**Orthopedic Surgery:** pseudarthrosis; osteosynthesis; fractures; bone grafts; prosthesis implants;

**Neurosurgery:** cranioplasty: Burr holes and craniectomy; cerebrospinal fluid leak;

**Vascular and Cardiothoracic Surgery:** sternal repair; artery bypass grafting, reconstructive arterial surgery; broncopleural fistula;

**Ophthalmology:** corneal wounds and ulcers; macular hole repair (hyperconcentrated platelets)

**INSTRUCTION FOR USE**

See attached sheets:
- Instruction sheet - Plateltex® PREP
- Instruction sheet - Plateltex®-Act 0/0
- Instruction sheet - Plateltex®-Act 35/70/100

**Bone-marrow derived cells gel.**

Plateltex® model Act 0/0, 35/70, and 70/100 can be used to induce gelation of plasma-resuspended bone-marrow derived cells. Plateltex® does not provide disposable material for harvesting and concentrating bone-marrow cells. Once harvested with dedicated disposable materials, plasma-resuspended bone marrow-derived cells are to be manipulated like PRP or PPP for gelation to be induced as shortly described below:

- take 1 mL of calcium gluconate and put it into the batroxobin vial
- take the calcium-batroxobin solution with a 3.0 mL syringe
- in a sterile container, mix the calcium-batroxobin solution (1 mL) and the bone-marrow derived cells (5-8 mL)
- mix gently and let the mixture stand without stirring for 2.8 minutes, until gelation occurs
WARNINGS

- **Plateletex®** provides sterile components. Care must be used to avoid any source of environmental contamination of the biologic product. On demand, **Plateletex®** provides a laminar-flow cabinet for the ex-vivo manipulation of biologic products.

- A great deal of literature indicates that topical treatment with platelet-derived components is achieved with a platelet concentration of at least 0.8-1.0 x 10^6 platelets per microliter (optimal 1-2 x 10^6 platelets per microliter). In Plateletex®-PREP instruction for use are provided for such platelet concentration to be obtained. If platelets are obtained through other means or provider, these should provide quality assurance about the platelet concentrate.

- The gel consistency depends upon the fibrinogen concentration of the plasma moiety of the product. When fibrinogen is less than < 100 mg/dL low density gel may occur. If the fibrinogen plasma concentration is within the physiologic range, the gelation time is not affected by variation of the fibrinogen level. In Table 1 the mean gelation-time which is obtained under physiologic circumstances is reported. After complete have occurred (4-12 minutes) the gel is stable for 20-40 minutes if not stirred. Gelation time is somewhat affected by the area of the surface/liquid contact; the higher the surface, the higher the gelation rate Approximately after 40 minutes or after detachment of the gel from the container's well, the clot retraction starts.

<table>
<thead>
<tr>
<th>minutes</th>
<th>Starting</th>
<th>Consolidation</th>
<th>Retraction</th>
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<tr>
<td></td>
<td>3±1</td>
<td>8±4</td>
<td>&gt; 40</td>
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* Experimental conditions: Temperature 25±2°C; plasma ACD or citrate 10±2%; plasma fibrinogen 140-630 mg/dL; calcium 132-330 mM; batroxobin (0.8-1.0 BU/mL or 0.14-0.18 NIH units).

PRECAUTIONS

**Drug interactions.** No interaction with other drug for local use is described. For bone regeneration, the association of the platelet gel with the autologous bone chips or with deantigenized morcelised bone chips is described.

The release of the growth and healing factors from platelets may be active (through platelet activation) or passive (after platelet lysis). Hence, a delayed factors release should be expected in patients taking cyclooxygenase inhibitors (aspirin, FANS) or platelet aggregation inhibitors. Nevertheless, no contraindication exist to platelet gel therapy in patients treated with cyclooxygenase inhibitors, platelet aggregation inhibitors, heparin, calcium heparin, oral anticoagulants.

Congenital or acquired platelet defects. Patients with congenital or acquired platelet defects are likely to release poor amount of growth and healing factors.

**Thrombocytopenia.** In patients with low platelet count (< 80-100.000/L) the platelet enrichment procedure is likely to fail reaching the optimal platelet concentration (> 1 x 10^6 platelets per microliter).

**Malignancy.** Platelet-derived factors accelerate the cell proliferation rate. Hence, the platelet gel treatment is contraindicated if there is evidence of local tissue malignancy. Caution is highly recommended in high risk of malignancy conditions.

**Informed consent.** Likewise any other medical treatment, it is advisable to obtain a signed informed consent form.

CONTRAINDICATIONS

Tissue toxicity has never been described.

Major contraindications to the topical use of the platelet gel have never been described with the relevant exception of infection and malignancy. Local infection must be rule out and, if present, it must be eradicated with appropriate antibacterial therapy prior treatment with platelet gel.

Malignancy. Platelet-derived factors accelerate the cell proliferation rate. Hence, the platelet gel treatment is contraindicated if there is evidence of local tissue malignancy or if hidden local malignancy is suspected.

Platelet gel therapy might be not applicable to thrombocytopenic patients therapy since it is highly improbable to achieve satisfactory platelet enrichment processing their own blood.

RECOMMENDATIONS

Do not use beyond the expiry date.

Do not reuse.

Dispose the kits if they show signs of deterioration.

Store in fresh dry place.

Do not expose do direct sun rays.

Disposal of used materials: dispose of according to local and state regulations.

TABLE OF SYMBOLS

- Do not reuse
- Manufacturer
- Use by
- Cautions, consult accompanying documents
- LOT Batch code
- REF Catalogue number

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