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System for temporary gingival retraction

### PRESENTATION

Box containing:

- Manual applicator,
- Capsules of Expasyl in a bag which can be closed. Usually 2 to 3 retractions per capsule, up to 8 retractions depending on technique,
- Single-use cannulas which may be bent for application.

Note: Capsules, cannulas and manual and powered applicators are also sold separately.

### COMPOSITION

- Aluminium chloride ( $\approx 15\%$ ). • Kaolin. • Excipients.

### PROPERTIES

Expasyl is a paste for temporary gingival retraction that ensures separation of the marginal gingiva and drying of the sulcus.

The main characteristics of Expasyl are as follows:

- **Respect of the periodontium:** the consistency of Expasyl is especially formulated not to damage the healthy periodontium; the phenomena of gingival recession or bone resorption are thus avoided.
- **Optimal ergonomics and appreciable saving of time:** gingival retraction is obtained by a single application of Expasyl in the sulcus. After one to two minutes, Expasyl, easily visible owing to its colour, is simply eliminated by an air and water spray, and a dry and widely opened sulcus is then obtained.
- **Painless method** when Expasyl is used on a healthy periodontium.
- **Expasyl has astringent and hemostatic surface properties by compression:** absence of bleeding or oozing allows a perfectly dry sulcus to be achieved.
- **Mean duration of retraction:** 1 to 2 minutes according to operative conditions.

### INDICATIONS

Expasyl may be used in all the indications of sulcular opening, such as:

- dental impression with or without prior gingival removal,
- sealing of prosthesis,
- in conservative dentistry when restoring class II and V cavities,
- placement of rubber-dam,
- parodontology (surfacing, etc),
- orthodontia (orthodontic bands bonding).

### CONTRA-INDICATIONS

- Presence of periodontal pockets or furcations. • Known allergy to aluminium chloride.

### PRECAUTIONS FOR USE

- In the case of intra-sulcular preparation, if the preparation reaches the epithelial attachment, it is required to perform a surgical or orthodontic coronal elongation allowing to re-create the biological space.
- Verify there is no periodontal pocket and/or furcation.
- Do not introduce the cannula into the sulcus, always stay in contact with the tooth.
- Introduce the paste slowly into the sulcus (2mm/s).
- As the paste is particularly hydrophilic, avoid contact of Expasyl with saliva during the time of pause.
- Verify that Expasyl is totally removed from the sulcus.
- Residual chemicals from haemostatic agents can lower bond strength to dentin: before bonding, rinse the area for at least 10 seconds with water.
- In case of contact with the eyes, rinse thoroughly with water.
- Do not swallow.
- Keep out of the reach of children.
- Single-use cannulas. DISPOSE OF the used cannulas after use.
- Do not store cannulas in contact with capsules. Store new cannulas in their original packaging, away from capsules (risk of corrosion).
- In case of use of polyether materials, silicones or hydrocolloids (reversible or not) for impression-taking, rinse abundantly the sulcus in order to avoid any interaction (risk of alteration and/or tearing the impression).



### System for temporary gingival retraction

#### INSTRUCTIONS FOR USE

• **Preparation:** Remove the cap from the capsule, and introduce the short tip of a cannula into it (fig 1). Insert the capsule fitted with its cannula into the capsule-holder. Bend the cannula if necessary.

• **Setting in place:** Rinse and slightly dry the prepared tooth. Inject slowly the paste into the sulcus resting on the tooth (2mm/s). The point of the cannula must create a closed space between the tooth and the marginal edge of the gingiva. Do not apply any pressure with the cannula on the gingiva. Straighten gradually the axis of the cannula (fig 2). Do not tilt the cannula away from the axis of the tooth (fig 3). NB: when a tooth is not cut (Class II or V conservative care for example), incline the cannula to a nearly horizontal position to create a closed space between the gingiva and the tooth, then put it back in the upright position while injecting the paste. The cord of paste placed must have a dry and compact appearance; if not, perform a second injection. Place a sufficient quantity of product to totally fill the sulcus in order to obtain an adequate retraction (fig 4).

• **Time of pause:** Expasyl must be left in place for 1 to 2 minutes on average; this time depending on two factors:

- **the tonicity of the marginal gingiva:** 1 minute for a thin one, 2 minutes for a thick and fibrous one.
- **the integrity of the marginal gingiva:** in the case of disepithelialization or of epithelial attachment rupture (after rotary curettage or removal with electro surgery for example), the action of the paste is much quicker and more efficient, the time of pause must then be reduced (30 seconds are enough).

• **Removal:** Remove Expasyl, by an air and water spray with simultaneous surgical aspiration. In case of use of polyether materials, silicones or hydrocolloids for the impression, rinse abundantly. Verify that Expasyl is completely removed, all around the tooth. Do not use any instrument that may damage the tissues.

#### TOXICITY

- Hamster studies (ISO / DIS 10993.10 protocol) reveal neither the lack of any local irritant effect of Expasyl (cheek pouch) nor any systemic toxic reaction.
- Expasyl is free of any skin sensitization effect in the guinea pig (ISO / DIS 10993.10 protocol and 406 OCDE guidelines).
- Expasyl has a good antimicrobial efficacy (Eur. Phar. 3<sup>rd</sup> ed.), which explains why only the extract of Expasyl diluted to 1/10 is not cytotoxic (EN 30993-5 standard).
- Moreover, according to its application time on gingival mucous (between 30 seconds to 2 minutes), Expasyl can be considered to be biocompatible.

#### STORAGE

- After use, remove imperatively the capsule from the dispenser gun and re-close it with its original stopper after having taken away and thrown the used cannula.
- Store all the capsules in the provided bag at a temperature < 25 °C.
- Do not use past the expiry date indicated on the outer package.

#### DISPOSAL OF EMPTY CAPSULES AND USED CANNULAS

Do not discard into sewers or streams. Do not discard with household waste.

Professional dental product.

Classification according to European Directive EEC 93/42  
Medical device Class I

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fig. 1

Step 1 Step 2 Step 3 Step 4

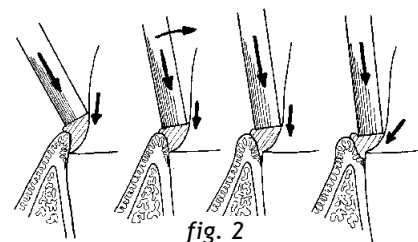


fig. 2

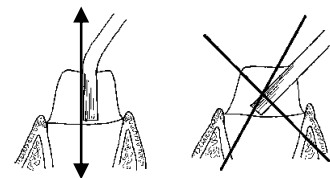


fig. 3

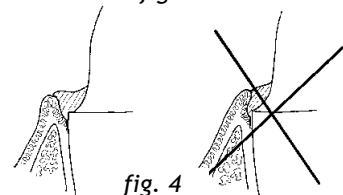


fig. 4

