Retroplast - Resin composite for retrograde sealing of roots

Retroplast is intended to be used for retrograde endodontic sealing of tooth roots and to prevent outflow of bacteria from an infected root canal. The product shall only be used by qualified dentists.

Instructions for use

Preparation

- The root is resected with a large round bur exposing the main root canals and any apical leaks from the canals. The whole resected root-end is made slightly hollow. No regular cavity in the root-end must be made.

Hemostasis

- Use (if possible) local anaesthesia containing adrenaline (epinephrine).
- Moisten a haemostatic sponge (e.g., Spongostan Dental 1 x 1 x 1cm, Ethicon) with not more than 2 drops of a solution of 1% adrenaline (epinephrine).
- Place the sponge in the periapical bone cavity for about 2 min. Cover the surface of the sponge in the cavity with gauze to prevent absorption of adrenaline by the surrounding soft tissue.
- Residual bleeding is controlled with a needle-suction and eventually by electrocoagulation.

Adrenaline should not be administered to patients with untreated hypertension, thyrotoxicosis or patients medicated with tricyclic antidepressants or MAO-inhibitors, unless the responsible physician has given permission.

Etching and dentin bonding

- Retroplast is bonded to the dentin using adhesive technique in combination with a light or dual/chemical curing dentin adhesive, that must be compatible with dual/chemical curing composites. Use the current products instructions for use to ensure the correct etching and preparation procedure is used.

Note: If the root end throughout the procedure with dentine adhesive is contaminated with blood or saliva, the procedure must be repeated, starting with a new slight hollowing of the root end followed by retreatment with dentin adhesive.

Application of Retroplast

- Apply a small portion of Retroplast A and B on a sterile glass plate/mixing pad. In order to have a controlled application the stamp must be pressed carefully, with a rotating movement.
- Mix equal portions of Retroplast-A and Retroplast-B on a mixing pad until homogenous (10 seconds).
- Cover the resected surface with the mixture within 1-1½ minutes after mixing by applying small amounts, one at a time, with a small excavator. A "painting" technique is applied at this step. Cover the entire resected root-end with Retroplast but leave the periodontal membrane space free.
- When the mixed Retroplast starts to set on the mixing plate, set a timer for 2 minutes. Hereafter, remove the unpolymerized surface layer of the Retroplast with a miniature brush soaked in 96-99% ethanol. Repeat this two times. Finally rinse the whole operating field thoroughly with physiologically sterile saline. Remove any surplus of Retroplast overhanging the periodontal ligament with a suitable scalpel blade, without pulling in the filling.

Retroplast should be stored in refrigerator, but not used until it has reached ambient temperature. If the material has been out of use in a couple of months, then discard the first delivered portion from each syringe.

Be aware not to mix up the two small tips(black/white) covering the syringes, since this could cause polymerization of Retroplast in the superficial parts of the tips.

Disposal

Retroplast and the syringes must not be disposed together with household rubbish, but in accordance with local regulations. Retroplast must not be allowed to reach the sewage system.

Serious incident

In the event that any serious incident that has occurred in relation to using Retroplast, this should be reported to Endoplast ApS, whose contact details are shown below, and the competent authority of the Member State in which the user and/or patient is established.

Precautions

Unpolymerized composite material can cause sensitization at susceptible persons. Always wear protective clinical gloves when handling composite materials. In case of skin contact wash thoroughly with water and soap.

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The Summary of Safety and Clinical Performance is available on the websites www.endoplast.dk, www.retroplast.com now that the draft summary has been validated by the Notified Body, Intertek Medical Notified Body AB. It will be placed on the EUDAMED website by the Notified Body, when the required module is available.

Warranty. Endoplast ApS recognizes its responsibility to replace products if proven defective. Endoplast ApS does not accept liability for any damages or loss, either direct or consequential, stemming from the use of or inability to use the products as described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

Turn page

Symbols used on the packaging and in the Instructions for Use:

Symbols	Description
REF	**Catalogue number**: Indicates the medical device manufacturer's catalogue number (RP01) so that the medical device can be identified
LOT	**Batch code**: To signify the current LOT number
	**Use by date**: To signify the date by which the product must be used, expressed as YYYY-MM-DD, where YYYY = Year, MM = Month, DD = Day
	**Manufacturer**: Indicates the medical device manufacturer as defined in applicable medical device regulations
	**Warning symbol**: Read warnings
MD	**Medical Device**: Indicates the product meets the definition of a medical device in accordance with Regulation (EU) 2017/745
CE 2862	**CE Mark:** To denote that the product meets the requirements of Regulation (EU) 2017/745 with Notified Body no. 2862, Intertek Medical Notified Body AB
UDI	**Unique Device Identifier (UDI) symbol**: A unique numeric or alphanumeric code related to a medical device.
	**See instructions for use**: Indicates the need for the user to consult the instructions for use
	**Temperature limit** Recommended that the product should be stored between use in a refrigerator between 2 – 8 °C