

Retroplast™ - a 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 suction through a wide needle 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

- Apply with a miniature brush (e.g., Quick Stick or Microbrush) the EDTA 18 % gel onto the resected surface for 20 s.
- Rinse the surface with saline followed by moderate drying with compressed bacteria free air.
- Apply with a miniature brush the dentin bonding agent on the resected surface for 20 s and dry for a few seconds with compressed bacteria free air.

Note. In case of contamination of the resected root-end with blood or saliva during the application of a dentin bonding agent, the procedures must be repeated, starting with a new grinding of the root-end and pre-treatment with EDTA and a dentin bonding agent.

Application of Retroplast

- Apply a small portion of Retroplast A and B on the mixing pad. 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 s).
- Cover the resected surface with the mixture within 1-1½ min 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.
- After curing, remove the unpolymerized surface layer on the sealing with a miniature brush soaked in 96% ethanol. Repeat this two times. Finally rinse the whole operating field twice with saline. Remove surplus of material (overhang) with a sharp scalpel blade (e.g., Swann-Morton nr. 11) not earlier than 2 mins after curing.



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 resins may cause skin sensitization in susceptible persons. In case of skin contact wash thoroughly with soap and water.













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

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.

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

Symbols	Description
	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
	Medical Device: Indicates the product meets the definition of a medical device in accordance with Regulation (EU) 2017/745
	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
	GHS 07 Warning: Irritant
	GHS 06 Danger: Acute Toxicity