

Endopaste [Instruction for Use]

INTENDED USE:

1. For use as root canal lubricant during mechanical instrumentation in endodontic treatment of teeth.
2. For use as chelating agent during cleaning and shaping of canals in endodontic treatment of teeth.
3. For use as root canal conditioner during chemico-mechanical preparation of root canal and shaping the canal, aiding in the removal of debris from the prepared tooth.

COMPOSITION:

Ethylenediaminetetraacetic Acid (EDTA), carbamide peroxide, water soluble base.

PRODUCT DESCRIPTION:

1. Endopaste is a ready to use Ethylenediaminetetraacetic Acid (EDTA) and carbamide peroxide paste, packed in Multi-dose, Plastic dispensing syringe. It is both lubricating and chelating material in paste form, to be used during cleaning and shaping of the root canals during endodontic treatment. This is non sterile device & does not require sterilization while being used.
2. Endopaste is a combination of EDTA and carbamide peroxide specifically formulated to provide cleansing of the root canal preparation. Endopaste facilitates the shaping of the root canal while rotary and hand instrumentation as it adheres to the endodontic files / reamers.
3. Endopaste is designed to be used with endodontic irrigation solutions such as sodium hypochlorite. Oxygen bubbling occurs through the release of oxygen from carbamide peroxide. This action allows for pulp tissue, dentinal shavings and debris to be easily removed from the root canal.
4. Endopaste aids in achieving an appropriate internal canal surface for penetration of other medicaments used in endodontic therapy by cleaning and conditioning the root canal.

PROCEDURE & PRODUCT HANDLING:

1. Open the pulp chamber in the usual manner and obtain adequate access to the root canal or canals.
2. Extripate the pulp and flush canal with sodium hypochlorite solution.
3. Dispense endopaste either directly from the multi dose, plastic dispensing syringes, using the pre bent cannula / applicator in and around the canal orifice, OR dispense endopaste from the multi dose plastic dispensing syringes, into a dappen dish and carry it to the canal by coating the endodontic files or reamers as desired.
4. The lubricant action is achieved on mechanical instrumentation, allowing the files and reamers to act smoothly. EDTA acts by chelating the calcium in the dentinal tubules there by aiding in the removal of the hard tissue. Carbamide peroxide acts by releasing the oxygen thereby aiding in the removal of soft tissue debris.
5. Using a small hand file, explore the canal, mixing the endopaste and sodium hypochlorite.
6. Gently irrigate and evacuate with sodium hypochlorite.
7. The sodium hypochlorite will react with the endopaste and begin to effervesce or release the oxygen.

8. Coat the file or reamer in the hand / rotary file technique with endopaste and use to desired depth. Repeat the instrumentation to achieve the desired canal shape and complete debridement.
9. Once shaping is completed, thoroughly flush and evacuate the canal using EDTA liquid to remove all irrigants and smear layer.
10. Dry the canal and obturate.

CAUTION / WARNING:

1. Device to be used by a qualified dentist or dental technician only.
2. Do not inject material under pressure into the canal.

PRECAUTIONS:

1. Avoid contact of the device with skin and mucosa, avoid contact with eyes. Avoid inhalation of fumes. Do not take internally.
2. Eye contact: if the product comes in contact with eye, it may cause irritation. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
3. Skin Contact: Avoid contact with skin, it may cause skin sensitization. If contact with skin occurs immediately wipe off thoroughly with cotton and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.

CONTRAINDICATIONS:

1. Do not use the product if the patient is allergic to any of the ingredients.
2. Do not use the product on mucosa or skin.
3. Not Intended for use beyond the confinement of root canals of teeth.

INTERACTIONS WITH OTHER DENTAL MATERIALS:

No such Reactions Noted . Kindly communicate and inform manufacturer in details of any instance.

ADVERSE REACTIONS:

No such Reactions Noted. Kindly communicate and inform manufacturer in details of any instance.

PACKAGING:

Multi dose, Plastic dispensing syringe, with applicator tips.

STORAGE CONDITIONS:

Keep Away from Direct Sunlight. Keep locked up and out of the reach of children. Store at a temperature between 10°C to 30°C. Shelf life (2 years from the date of manufacturing) not affected after opening if stored in a cool dry place.

DISPOSAL CONDITIONS:

Dispose in accordance with local, state and federal environmental regulations.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel.

Shiva Products

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These instructions for use should be kept for the duration of product use.



Symbol for "BATCH CODE"



Symbol for "USE BY"



Symbol for "NON STERILE"



Symbol for "KEEP DRY"



Symbol for "CAUTION"



Symbol for "CONSULT INSTRUCTION FOR USE"



Symbol for "CATALOGUE NUMBER"



Symbol for "EUROPEAN COMMUNITY AUTHORIZED REPRESENTATIVE"



Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"



Symbol for "KEEP OUT OF THE REACH OF CHILDREN"



Symbol for "MANUFACTURER NAME & ADDRESS"



Symbol for "TEMPERATURE LIMITATION"



Symbol for "KEEP AWAY FROM SUNLIGHT"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.