

# Directions for Use

## Glyde File Prep - Root Canal Conditioner

### Classification

Glyde File Prep is a device in the form of a medicament gel for use in the chemical and mechanical cleansing of the root canal preparation during endodontic therapy.

Caution: U.S. Federal Law Restricts This Device To Sale By or on the Order of a Dentist. For Dental Use Only

### Composition

Glyde File Prep is a combination of ethylenediaminetetraacetic acid (EDTA) and carbamide peroxide in a water soluble base. The EDTA chelates calcium salts for calcified areas within the root canal to facilitate the use of reamers and files.

### Indications for Use

Glyde File Prep is a combination of EDTA and carbamide peroxide specifically formulated to provide cleansing of the root canal preparation and facilitate shaping the root canal.

Glyde File Prep allows for cleansing action that facilitates easy removal of vital pulp tissue and necrotic pulp tissue. The gel is designed to be used with endodontic irrigation with sodium hypochlorite solutions. Oxygen bubbling occurs through the release of oxygen from the carbamide peroxide. This action allows for pulp tissue, dentinal shavings and debris to float out.

Glyde File Prep encourages lightening of the tooth if discoloration exists from non vitality. The use of sodium hypochlorite with the gel promotes internal bleaching of the tooth. This process is enhanced by the release of oxygen from the carbamide peroxide.

Also, Glyde File Prep leaves an appropriate internal canal surface for penetration of other medicaments used in endodontic therapy by more completely cleaning the canal and opening dentinal tubules.

### Contraindications

Do not use Glyde File Prep outside of the root canal system or on soft tissues. Immediately wash skin with soap and water after contact or flush eyes if contact occurs.

### Warnings

1. The syringe package includes a pre-bent applicator tip. This pre-bent applicator tip delivery is for depositing, at working site/orifice only, not injecting material under pressure into the canal.
2. Carbamide peroxide and EDTA should not be applied to tissue outside of the root canal such as mucosa or skin. Wash skin with soap and water after contact.
3. Do not take internally

## **Precautions**

The viscosity of Glyde File Prep is effected by storage conditions. If a more viscous or thicker consistency is desired, store in a refrigerator.

## **Step By Step Instructions**

1. Open the pulp chamber in the usual manner and obtain adequate access to the root canal or canals.
2. Remove the pulp and flush canal with sodium hypochlorite solution.
3. Dispense Glyde File Prep directly from the syringe with a pre-bent canal tip in place.
4. The sodium hypochlorite will react with the root canal preparation gel and begin to effervesce or bubble.

PLEASE TAKE NOTE OF THE BUBBLING REACTION

5. Enhance this reaction by mixing the gel and sodium hypochlorite solution with a fine file.
6. The first instrument should not be worked more than half way down the root canal.
7. Follow the first instrument with a gentle irrigation with sodium hypochlorite solution.
8. Repeat the procedure and carry the second instrument to 3/4 of the way down the canal.

TAKE NOTE OF THE LUBRICATION OR EMULSIFYING EFFECT OF THE CONDITIONER WHEN INSTRUMENTING.

9. Irrigate and instrument to 1 mm short of the radiographic apex.
10. Take an X-ray to confirm measurement of the working length.
11. Glyde File Prep is used in the canal with only the first two or three sizes of instruments.
12. The canals should be further prepared using only sodium hypochlorite.
13. Sodium hypochlorite solution should be used in the canals and repeatedly instrumented into the canals until all evidence of bubbling has ceased.
14. Then dry the canal and obturate.

## **Storage and Shelf Life**

Glyde File Prep should be refrigerated before opening. Once opened, the gel can be stored at room temperature. However, refrigeration is also acceptable between uses.