

# A NEW DIMENSION OF **VARNISH GEL**



SOOOO PROTECTED  
WITH **PROFISIL®** FLUORIDE VARNISH

TREATMENT OF DENTINAL HYPERSENSITIVITY

  
**KETTENBACHDENTAL**  
Simply intelligent

# PROFISIL® FLUORIDE VARNISH

## A new dimension of Varnish Gel

**Profisil® Fluoride Varnish** contains **5% sodium fluoride** in a mucosa-friendly, pleasantly flavored dimethicone gel. This formula **is not made with ethyl alcohol\* or colophony (rosin)**, thus reducing the potential of soft tissue irritation or rosin-based allergies.

The varnish is available in following versions:

MINT

BERRY

UNFLAVORED

0%  
ETHYL  
ALCOHOL\*



### PRODUCT PROPERTIES

- This formula is designed to securely adhere to the tooth surface for several hours while releasing fluoride ions up to 24 hours
- Transparent and colorless after applying for optimal aesthetics
- Constant viscosity and easy to spread
- Available as single dose unit incl. a brush



### BENEFITS FOR THE DENTAL PROFESSIONAL

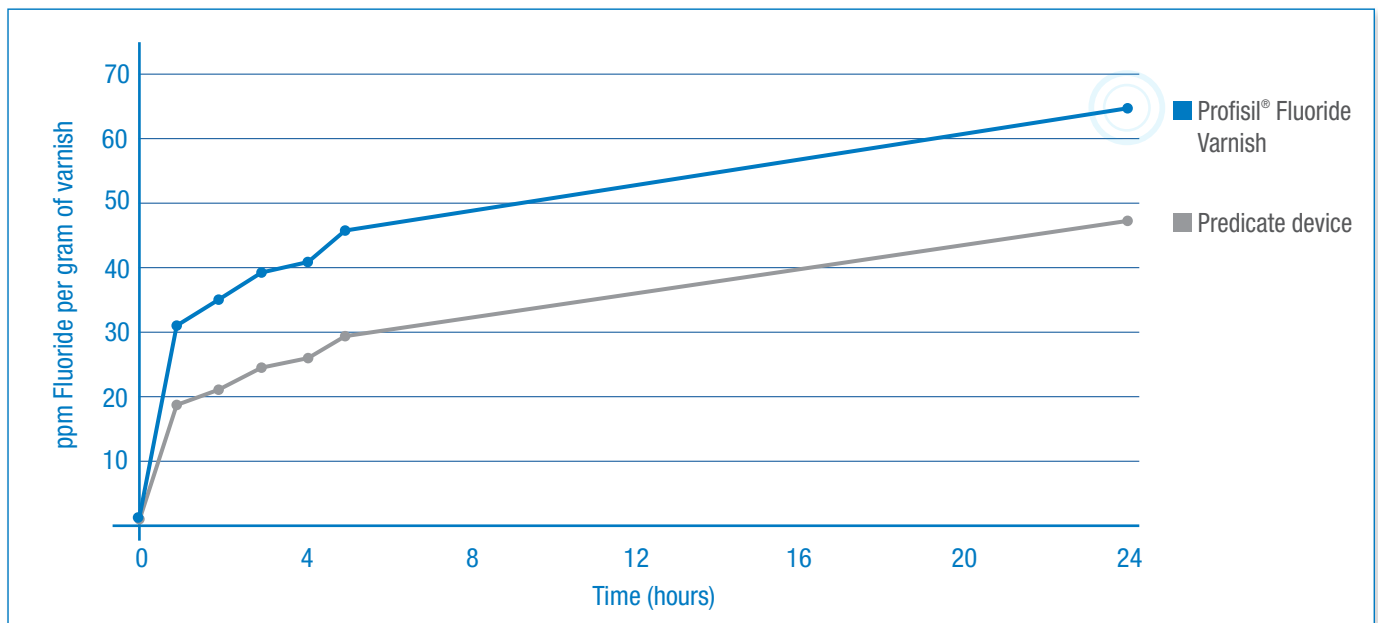
- The single dose blister contains sufficient varnish to cover all affected teeth of both arches
- **Profisil® Fluoride Varnish** can be applied in any direction to all affected tooth surfaces, migrating even to difficult to access areas
- A prophylactic cleaning is not required prior to use
- Unnecessary to dry teeth prior to application of the varnish gel
- Lubricious, non-clumping formula
  - » No need to replace gummy brushes

### BENEFITS FOR THE PATIENT

- Patients appreciate the smooth mouth feel and refreshing lubricating properties
- Protective coating to tooth surfaces by occluding tubules with calcium fluoride crystals
- No bitter taste or burning
  - » not made with ethyl alcohol\*
- Non-allergenic dimethicone formula
- Suitable for all ages and for children with primary teeth

# FLUORIDE ION RELEASE

## Dental Fluoride Varnish / Fluoride Release<sup>1)</sup>



<sup>1)</sup> Data on file – Stephen Gross PhD, Professor of Chemistry

## Conclusion of Study 1 – Stephen Gross, PhD, Professor of Chemistry

The aim of this study was to determine the fluoride release within 24 hours

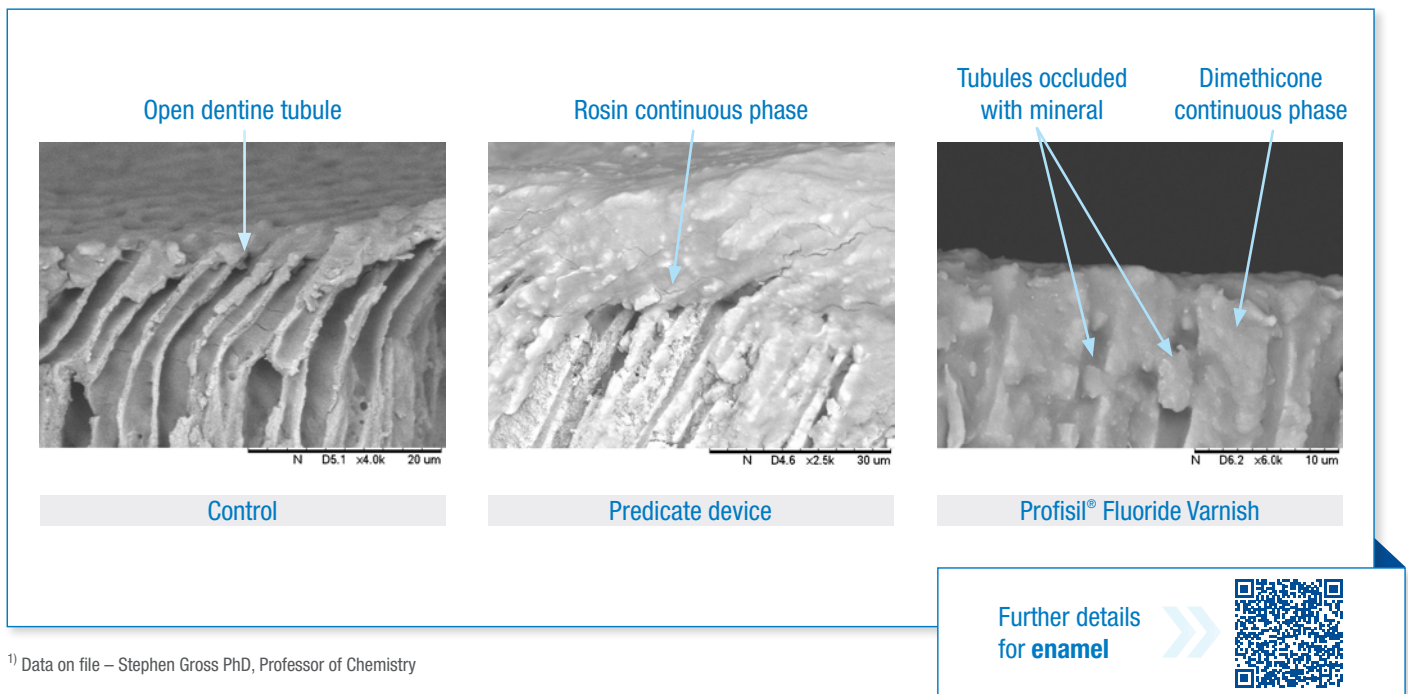


After 24 hours of soaking, 28 % of the fluoride was released from **Profisil®**.

In the case of the competitor, 21 % of the fluoride was released under identical conditions. The release of fluoride was faster from **Profisil®** than the competitive product.

# FLUORIDE UPTAKE

## Fluoride Varnish – dentin tubule occlusion<sup>1)</sup>



<sup>1)</sup> Data on file – Stephen Gross PhD, Professor of Chemistry

## Conclusion of Study 2 – Stephen Gross, PhD, Professor of Chemistry

**The aim of this in vitro study was to determine the effect (fluoride uptake) of various fluoride varnishes at the beginning of enamel lesions.**

Scanning Electron Microscope (SEM) studies show the **Profisil®** Fluoride Varnish from Kettenbach Dental effectively penetrates the exposed dentin surface and occludes the open porosity. These studies were conducted using the predicate device as a positive control. When compared to the predicate device, the **Profisil®** Fluoride Varnish performed in an equivalent manner.

SEM observation of the enamel treated by both the predicate device and **Profisil®** Fluoride Varnish show a similar deposition of calcium fluoride crystals throughout the exposed enamel surface.

Additional fluoride release studies were conducted upon both the predicate device as well as the **Profisil®** Fluoride Varnish. The results of these studies show that both varnishes release fluoride at an equivalent rate.

A study was also conducted on both predicate device as well as the **Profisil®** Fluoride Varnish to show the uptake of fluoride into the tooth enamel surface (Enamel fluoride uptake). This study is a modified version of the FDA

Method 40 protocol for enamel fluoride uptake. The results of the studies show that both the predicate device and the **Profisil®** Fluoride Varnish performed in an equivalent manner.

Based upon these observations, it is proposed that that the **Profisil®** Fluoride Varnish is as effective as the previously cleared predicate device for the reduction of tooth sensitivity.

Biocompatibility data demonstrate that the material is safe for its intended use and equivalent in to safely marketed materials for dentinal use. All substances used in the manufacturing of the product are Generally Regarded As Safe (GRAS) by the USFDA and are commonly used in food and other cleared medical products.

In summary, both the predicate device as well as the **Profisil®** Fluoride Varnish achieve their respective efficacy utilizing the same mechanism of action.

# HOW TO USE PROFISIL® FLUORIDE VARNISH

STEP  
BY STEP

## Step-by-Step instruction



Assure that the seal of the package foil is intact prior to use. The components are intended for single use only.



Peel off the single dose blister foil carefully.



Lift the foil near the brush and remove the brush.



Peel back the remaining foil to expose the varnish.



Mix contents briefly to homogenize the contents.



Apply a thin, even layer to all affected surfaces of the dentition.



The single dose blister contains sufficient varnish to cover all affected teeth of both the upper and lower arch.



Do not rinse or suction immediately after use.



Do not brush or floss for at least four hours.

## GENERAL NOTES



Profisil® Fluoride Varnish can be applied to **all tooth affected surfaces**. A **prophylactic cleaning is not required prior to use**. If a prophylactic cleaning is performed, apply the varnish following scaling and polishing. Unnecessary to dry teeth prior to application of the varnish gel.

# THE RANGE

Profisil® Fluoride Varnish			
Normal pack	Mint		14802
	Berry	50 x 0.5 ml each	14804
	Unflavored		14806
Combi pack		10 x 0.5 ml Mint	
		10 x 0.5 ml Berry	14801
		10 x 0.5 ml Unflavored	



Composition: Polydimethylsiloxanes, 5 % sodium fluoride equivalent to 22.6 mg / g fluoride ion, sucralose\*\*, film forming organic polymer, flavor\*\*. This formular is not made with products containing gluten, peanuts, tree nuts, soy, sesame, corn, shellfish, egg or dairy.

\* “Mint” and “Unflavored” are not made with ethyl alcohol, “Berry” may contain traces of ethyl alcohol.

\*\*not included in the “unflavored” version

## NOTES

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