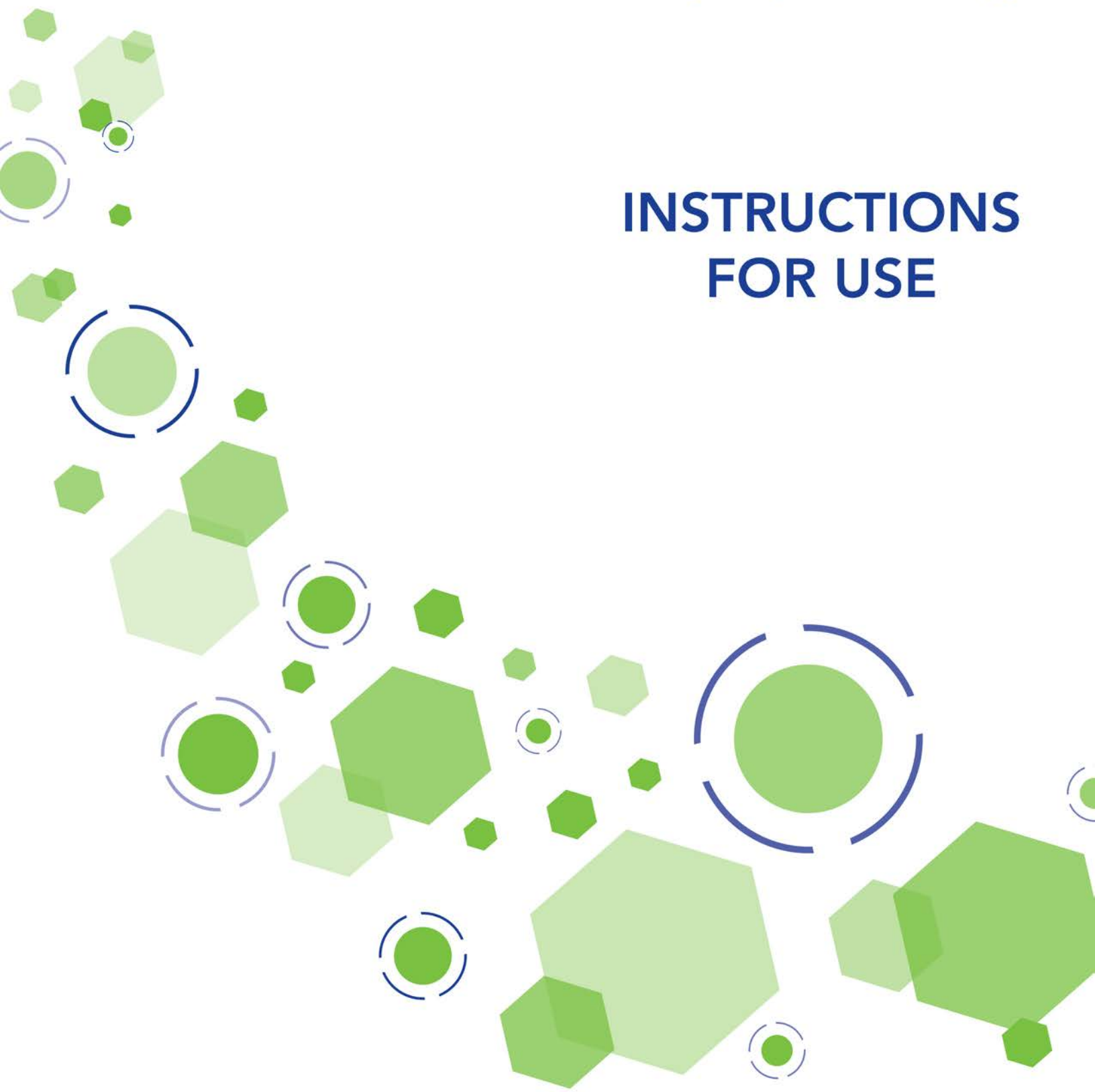




INSTRUCTIONS FOR USE





Phocal Apf - NDC 55918-001-20
Phocal pHn - NDC 55918-002-20

INSTRUCTIONS FOR USE

Purpose and Indications

- **Phocal** disks are topical delivery vehicles designed to fluoridate interproximal tooth surfaces. This action aids in the prevention of dental caries on intact surfaces, arrests progress on surfaces with incipient carious lesions and enhances remineralization. Phocal disks are also effective at tooth restoration margins and furcations.
- **Phocal** disks are to be applied only by dental professionals at selected sites to achieve the desired benefits.

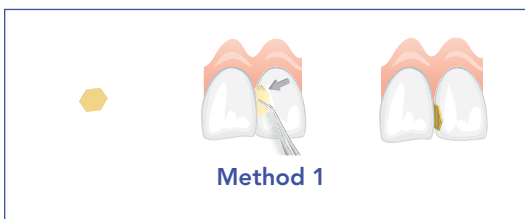
Description

- The patented **Phocal** topical fluoride disks are provided in two forms:
 - pink acidulated phosphate fluoride Apf disks
 - yellow non-acidic sodium fluoride pHn disks
- These thin, round disks contain 1.02% fluoride ions. Once positioned interproximally they rapidly expand, soften into a gel and release fluoride for approximately 10 minutes before biodegrading. This release period can be increased as explained in the Directions for Use.
- Each **Phocal Apf** disk contains 0.1135mg of sodium fluoride in a matrix of FD&C red 3, gum arabic, gelatin (of marine origin), propolis wax, phosphoric acid, sodium benzoate and water. These disks induce an optimized low pH environment that cleans and etches tooth surfaces and facilitates fluoride penetration and stimulates remineralization.
- Each **Phocal pHn** disk contains 0.1135mg of sodium fluoride in a matrix of gum arabic, gelatin (of marine origin), propolis wax, sodium benzoate and water. These disks are less acidic than the Phocal Apf disks and will not etch ceramic crowns or tooth-colored restorations while inducing fluoridation and remineralization.

Directions for Use

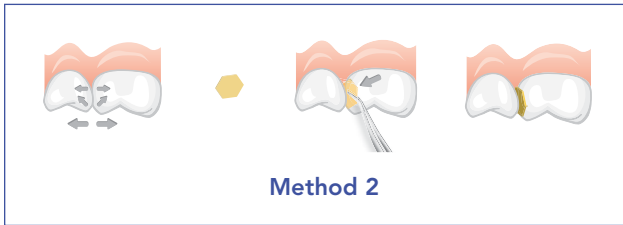
- There are different methods for the placement of Phocal fluoride disks.
- The choice of placement method and Phocal type is subject to the discretion of the dental professional and is usually dependent upon the nature of the site being treated, interproximal tightness and the strength and type of adjacent restorations and teeth.
- Prior to treatment using either of the placement methods below, all debris and calculus should be removed from the selected site(s) and the site(s) should remain **dry** during placement. Premature wetting softens the disks and can compromise correct interproximal placement.

Method 1 – Insertion of flat Phocal disks; recommended for anterior teeth and where spacing allows.



- o When spacing allows, insert the flat Phocal disk interproximally with forceps and/or by hand directly between the contact points of the two adjacent teeth.

Method 2 – Insertion of flat Phocal disks with separation; recommended for posterior teeth and where spacing is restrictive.



- o In some cases, separation with wedges or rings may be necessary prior to insertion.
- o After separating the teeth by your chosen method of separation, insert the flat Phocal disk interproximally with forceps and/or by hand directly between the contact points of the two adjacent teeth.

- In rare cases nickel titanium springs, elastic O-rings or Maxian strips can be used to separate teeth but this is usually a slower process which requires two visits: one for separation and then one for disk placement.
- To accelerate the initial reactions of Phocal disks a curing light can be applied for 3-10 seconds.
- To extend the fluoride release time period, a varnish can be applied to partially cover the interproximal site or disk occlusally, buccally or/and lingually. However the disk should not be completely coated with varnish.
- To shorten the release time the disks can be removed using an appropriate instrument, dental floss and/or aspiration.
- If Phocal Apf is used, in order to guard against possible etching of porcelain crowns or tooth-colored restorations, a protective matrix should be used. With Phocal pHn there is no risk of etching.
- Advise the patient not to eat, drink or rinse for at least 30 minutes after treatment.
- If multiple applications are necessary, treat no more than 8 sites at a time and delay subsequent Phocal applications for at least a day.
- If deemed necessary, patients may be recalled at intervals of 2 to 12 months for repeated treatments.
- Phocal disks are versatile, and with specific gentle moisturization they can be trimmed, rolled, or folded to fit other inaccessible areas such as furcations.

Warnings

- In rare cases, sensitivity or adverse reactions may be experienced. In such cases immediately remove the disks while preventing swallowing and refer the patient to a physician.
- Patients less than 12 years old and patients with special needs should remain under professional supervision until the Phocal disks have biodegraded or have been removed.
- The disks are not intended for systemic ingestion and should be kept out of children's reach. If more than 20 disks are accidentally swallowed, seek immediate medical assistance.
- Phocal should not be applied in sites with: gingival inflammation, immediately prior to or after oral soft tissue surgery and in cases of known allergies to any of the Phocal ingredients.
- Phocal is to be sold as unbroken boxes with all disks sealed within the blister packs and is to be used for application in the dental office by professionals only.
- When Phocal treatment is utilized, routine systemic and topical administrations of fluoride should be suspended during the day of application.
- Recommended storage temperatures are 42°F-78°F (5°C-25°C).

Responsibility of the Professional

- Phocal disks have been developed for use only by licensed professionals in the dental care setting. Phocal Therapy, Inc. warrants the quality of the products for the uses described and when used in the manners outlined here and in our sales and delivery documents. It is the responsibility of the professional to use the products.