

INSTRUCTIONS FOR USE

# Knit-Pak<sup>™</sup>+

Impregnated Knitted Cord







Manufacturer:

Premier® Dental Products Company 1710 Romano Drive, Plymouth Meeting, PA 19462 U.S.A. 888-670-6100 • 610-239-6000 premierdentalco.com

Made in Korea





#### Intended Use:

Knit-Pak+ is a prescription-only, Aluminum Chloride Hexahydrate impregnated cord is used for temporary chemo-mechanical retraction of gingival tissues and hemostasis of the gingival margin around the tooth. It is intended for accurate and enhanced results when acquiring dental impressions, for cavity preparation or wherever hemostasis and retraction is required.

# **Device Description:**

Premier\* Knit-Pak+ is an aluminum chloride impregnated gingival retraction cord created from knitted microfibers for temporary chemo-mechanical retraction of gingival tissues and hemostasis of the gingival margin around the tooth.

#### **Contents:**

Item no.	Product Specifications
9007560	Knit-Pak+ Impregnated Knitted cord – Standard Pack • Color – Dark Green • Size – 000.0 • Length – 100inch (254cm)
9007561	Knit-Pak+ Impregnated Knitted cord – Standard Pack • Color – Green • Size – 000 • Length – 100inch (254cm)
9007562	Knit-Pak+ Impregnated Knitted cord – Standard Pack • Color – Brown • Size – 00 • Length – 100inch (254cm)
9007563	Knit-Pak+ Impregnated Knitted cord – Standard Pack • Color – Purple • Size – 0 • Length – 100inch (254cm)
9007564	Knit-Pak+ Impregnated Knitted cord – Standard Pack • Color – Blue • Size – 1 • Length – 100inch (254cm)
9007565	Knit-Pak+ Impregnated Knitted cord – Standard Pack • Color – Orange • Size – 2 • Length – 100inch (254cm)

#### Contraindications:

## Do not use Knit-Pak+ in the following conditions:

- Patients with significant periodontal disease or furcation involvement.
- Infection within the gums from re-use of cords.
- An intraoral site that has active infection or inflammation

# **PRECAUTIONS:**

- Be sure to rinse treated area before taking impression to avoid inhibition of polymerization of impression material.
- The reuse of a single-use device can expose patients and staff to cross-contamination.
- Rx, for dental use only.

#### **WARNINGS:**

- Do not apply excessive force and violate the biological width when packing the retraction cord into sulcus.
- Do not leave the cord in the gum for more than 20 minutes as this may cause a lasting recession of the gum.
- Ensure all aluminum chloride is removed by rinsing prior to dental impression to avoid inhibition of polymerization of impression material.
- Do not reuse cord. Cords are single-use only.
- Do not use in patients with known allergies to Aluminum Chloride.
- Aluminum Chloride is Irritating to skin and eyes.

## **Adverse Reactions:**

Adverse reactions may include but are not limited to:

- Recession of the gums from prolonged use or excessive force in sulcus
- Additional procedures may be necessary if impression material was inhibited due to residual Aluminum chloride.
- Allergic type of reactions such as swelling, inflammation, irritation, and pain could occur in persons with known allergy to Aluminum chloride.

#### Materials:

NP Conjugated Yarn (Nylon-6, PET) Impregnated with Aluminum Chloride.

## **Directions for Use:**

- 1. Evaluate the health of the gingiva and the depth of the sulcus.
- Select the impregnated cord of appropriate-size and cut the cord to required length by closing the cap (ceramic blade in cap will sever the cord)
- 3. Apply the cord tightly to the cervix of the tooth and carefully insert into sulcus by means of a cord packer hand instrument.
- 4. Leave the cords in the place and wait one (1) to three (3) minutes.

- 5. Before removing the cord, it should be wetted/rinsed with water so it won't grab and tear gingival tissue when removed creating more bleeding.
- 6. Remove cord; rinse the area with a firm air/water spray to complete removal of Aluminum Chloride and dry preparation.
- 7. Examine the treatment site to verify hemostasis.
- 8. If the bleeding is persistent when the cord is removed, repeat the procedure from step 2 to step 7 until hemostasis is achieved.

# Storage:

- Always store the device in original protective packaging, prior to first and subsequent usage.
- Store in a dry place at temperatures between 10°C/50°F to 28°C/82.4°F.

# **Shelf Life:**

- Knit-Pak+ has a shelf life of 3 years (36 months) from the date of manufacturing.
- Do not use after device has expired. See expiry date on the device label.

## For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbols	Symbol Meaning
	Expiry date
	Manufacturer
LOT	Batch number
<b>(!</b> >	Irritant
	The upper and lower limits of temperature of use, storage and transportation
<b>(2)</b>	Do Not Reuse
$\triangle$	Caution: See instructions for use
R <sub>X</sub> ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
[]i	See IFU on premierdentalco.com