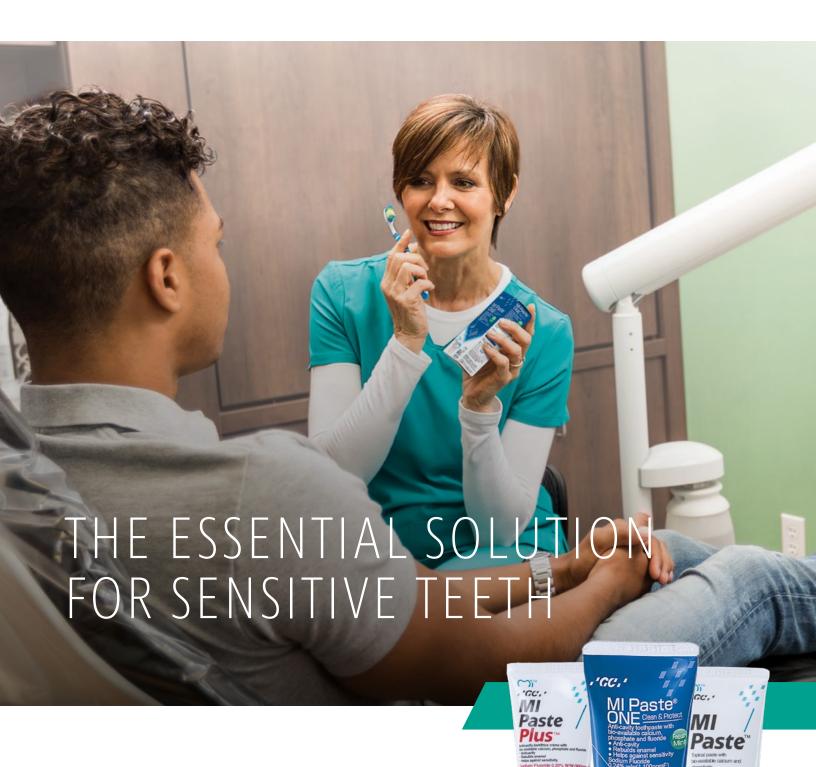
.'GC.'





The MI Paste® Family



# THE MI PASTE® FAMILY



# MI Paste® ONE with RECALDENT" (CPP-ACP)

Anti-cavity Toothpaste with Milk Casein & Bio-available Calcium, Phosphate & Fluoride



## MI Paste Plus®

with RECALDENT™ (CPP-ACP)\*

Topical Tooth Crème with Milk Casein & Bio-available Calcium, Phosphate & Fluoride



## MI Paste®

with RECALDENT™ (CPP-ACP)\*

Topical Tooth Crème with Milk Casein & Bio-available Calcium & Phosphate

## Choose the right MI Paste® product for your patients.

Whether you are establishing a preventive care program for your patient, or they are dealing with significant caries, sensitivity or white spots, start the conversation about a family of products that dental professionals around the world trust.

#### \*RECALDENT™ (CPP-ACP) is derived from milk casein.

(See Clinical Guidelines on page 4 for a full list of indications and usage notes.)



#### Use MI Paste Plus® & MI Paste® ONE for:

- Tooth sensitivity:
  - Due to general tooth hypersensitivity
  - Due to tooth whitening
  - Before and after professional cleaning
- For adults and children 12 years of age or older
- Remineralization
- Anti-cavity
- Dry mouth syndrome sufferers (as they are at a greater risk for caries)
- White spot lesions
- pH buffering to help neutralize pH levels in the mouth
- Preventive care

#### Use MI Paste® for:

- Pregnant or nursing women
- Children under six
- Tooth sensitivity:
  - Due to general tooth hypersensitivity
  - Due to tooth whitening
  - Before and after professional cleaning
- Preventive care



## HOW TO APPLY



## At the Dental Office:

#### **CUSTOM TRAY APPLICATION:**



- Fill a custom tray with MI Paste® or MI Paste Plus®
- Place it in the patient's mouth. Leave undisturbed for a minimum of 3 minutes.
- Remove tray and spread remaining MI Paste® or MI Paste Plus® over tooth surfaces with a gloved finger.
- Have your patient expectorate but not rinse; leave the excess to slowly dissolve.

#### **NON-TRAY APPLICATION:**



- Apply a pea-sized amount of MI Paste® or MI Paste Plus® to your patient's tooth surface using a cotton swab or gloved finger.
- Leave undisturbed for a minimum of 3 minutes.
- Have your patient expectorate but not rinse; leave the excess to slowly dissolve.

## At Home:

#### MI Paste® & MI Paste Plus®

(After regular brushing and flossing)



on a cotton swab or fingertip.



Squeeze a pea-sized amount Apply to all teeth and use tongue to spread evenly.



Leave undisturbed for a minimum of 3 minutes, then expectorate, but do not rinse. Let the excess slowly dissolve. Refrain from eating for 30 minutes.

#### MI Paste® ONE



Brush teeth with MI Paste® ONE for 2 minutes.



Expectorate, but do not rinse.



Refrain from eating for 30 minutes.



# CLINICAL GUIDELINES FOR USE OF MI PASTE® PRODUCTS

INDICATION	MI Paste <sup>®</sup>	MI Paste Plus <sup>®</sup>	MI Paste <sup>®</sup> ONE	FREQUENCY	DURATION	ADDITIONAL COMMENTS
General prevention	<b>✓</b>	>	<b>&gt;</b>	Minimum once a day	Ongoing as part of a general prevention program	Regular use of MI Paste® products will help maintain a healthy oral environment.
Caries risk		>	>	Twice a day	Until risk of future caries has been reduced	Assessment to determine the potential source(s) of risk should be undertaken and suggestions made on how the patient can reduce their caries risk.
Orthodontic treatment		>	>	Twice a day	During entire orthodontic treatment	Complete treatment 12 weeks after the finish of orthodontic debanding or thereafter as required to reverse any white spot lesions with MI Paste Plus®/MI Paste® ONE.
Clear aligner treatment		>	<b>✓</b>	Twice a day	During entire clear aligner treatment	Complete treatment 12 weeks after the finish of clear aligner treatment as required to reverse any white spot lesions.
Whitening Sensitivity (prior to starting treatment)	<b>✓</b>	>	<b>&gt;</b>	Twice a day	Start 1-2 weeks before whitening procedure	Pre-whitening applications of MI Paste® products will help reduce the degree of whitening sensitivity.
Whitening Sensitivity (during treatment)	<b>✓</b>	<b>&gt;</b>	<b>&gt;</b>	Following removal of the whitening tray	Use for 2 weeks after the final whitening application	The whitening tray can also be used to apply MI Paste Plus <sup>®</sup> . MI Paste <sup>®</sup> can be used for desensitizing during whitening treatment.
White spot lesions		>	>	Twice a day	8-12 weeks and thereafter as required	There are different types of white spots and pre-treatment of the white spot surface prior to application of MI Paste Plus®/MI Paste® ONE may be required.
Sensitive teeth	<b>✓</b>	<b>✓</b>	<b>✓</b>	Twice a day during acute phase, followed by once a day application	4-6 weeks or until resolved	If sensitivity persists additional diagnostic testing could be required.
Exposed root surfaces	<b>✓</b>	>	>	Minimum twice a day, and as required for sensitivity	Continuous treatment as required	Additional protection can be achieved by sealing exposed root surfaces with GC Fuji Glass lonomers.
Developmental defects in enamel		>	>	Minimum twice a day	Continuous treatment as required	Depending on severity, additional protection can be achieved by sealing hypomineralized surfaces with GC Fuji Glass Ionomers.
Tooth erosion and wear		<b>&gt;</b>	<b>&gt;</b>	Minimum twice a day, before and after exposure to acid challenges	Until risk of acid exposure is reduced	Identify source of acid and where possible reduce or encourage a reduction in exposure and increase saliva stimulation.
During and after periodontal care	<b>✓</b>	<b>✓</b>	<b>✓</b>	Twice a day	During entire period of care and for 4 weeks after completion	Acts as a tooth desensitizer.

Robertson MA, Kau CH, English JD, Lee RP, Powers J, Nguyen JT. MI Paste Plus® to prevent demineralization in orthodontic patients: a prospective randomized control trial. Am J Orthod Dentofacial Orthop 2011;140:660-8. MI Paste® and MI Paste Plus® can be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment.

RECALDENT and RECALDENT Device are trademarks used under license.

Caution: RECALDENT™ (CPP-ACP) is derived from milk casein. Do not use on patients with a milk protein or hydroxybenzoates allergy. In case of allergic reaction, stop use, rinse mouth with water, and seek medical advice.



# WHO CAN BENEFIT FROM MI PASTE® PRODUCTS?

Easy to use and safe for all children and adults not allergic to milk protein or hydroxybenzoates – even those who are lactose-intolerant – MI Paste® products are highly effective when used as part of preventive care.



Children 3-6 Years

MI Paste® helps new teeth in infants and young children mature and become more resistant to decay.



Pregnant or
Breastfeeding Women
Regular use of MI Paste®
during pregnancy helps
maintain elevated levels of
calcium and phosphate in

the saliva.



Aligner Patients

MI Paste Plus® and

MI Paste® ONE can help
prevent demineralization,
caries, and erosion in
patients wearing clear
aligners for extended
periods each day.

Clear Orthodontic



Orthodontic Patients

MI Paste Plus® and

MI Paste® ONE can help
prevent plaque buildup and
white spot development.



## **Active Sportsmen**

The consumption of acidic energy drinks and dehydration both affect saliva quality, causing the mouth itself to become acidic. MI Paste Plus® and MI Paste® ONE help neutralize the mouth's pH (guarding against caries and erosion) and help prevent demineralization.



**Adults** 

For adults, MI Paste Plus® and MI Paste® ONE should be part of their ongoing dental health program as it helps protect against hypersensitivity, sensitivity from whitening, caries and white spot lesions.

MI Paste Plus® and MI Paste® ONE promote remineralization and help prevent tooth erosion.



**Seniors** 

Today's seniors keep their teeth longer. Meanwhile, their oral health often diminishes from adverse general health conditions and resulting medications.

MI Paste Plus® and

MI Paste® ONE help fight caries and erosion. Dry mouth syndrome sufferers are at a greater risk for caries; MI Paste Plus® and MI Paste® ONE can help these patients.



# WHAT IS RECALDENT™ (CPP-ACP)\*?

# The only natural solution of its kind, RECALDENT™ (CPP-ACP):

- Is a naturally occurring milk protein
- Protects the ACP component
- Is very sticky
- Acts as an effective delivery vehicle for ACP to the tooth

#### Only RECALDENT™ (CPP-ACP):

- Uses naturally occurring molecules (CPP) that bind calcium and phosphate ions and stabilize ACP
- Delivers the essential building blocks of teeth in a noncrystalline state to your patients' teeth

# RECALDENT™ (CPP-ACP) technology has proven its effectiveness time and again as the most researched, evidenced-based calcium phosphate delivery:

- First developed and tested in Australia
- Extensively researched by the University of Melbourne Dental School beginning in the 1980's
- Dozens of clinical trials and laboratory studies worldwide

# The power of RECALDENT™ (CPP-ACP) and fluoride together.

When fluoride meets RECALDENT™ (CPP-ACP), the peptide preferentially combines with, and stabilizes, fluoride to create an excellent source for building fluorapatite. Using bio-available calcium, phosphate, and fluoride, the full potential of fluoride to help protect and repair teeth can be achieved.

In other words, MI Paste Plus® and MI Paste® ONE, both containing RECALDENT $^{\text{\tiny M}}$  (CPP-ACP) and fluoride, are excellent remineralization delivery vehicles for fluoride.



#### Synergizes with Fluoridea-i

CPP-ACP promotes the incorporation of fluoride into plaque and sub-surface enamel, producing effects superior to those that can be achieved by using fluoride alone.



# MI Paste Plus® & MI Paste® ONE Inhibit Demineralization and Promote Subsurface Enamel Remineralization®

Fluoride with CPP-ACP is a proven technology that promotes sub-surface enamel remineralization.



# pH Buffer<sup>m-r</sup> (Helps neutralize pH levels in the mouth)

In a recent clinical study, application of MI Paste® elevated plaque pH levels for 48 hours, while application of MI Paste Plus® elevated plaque pH levels for 96 hours.

\*CPP-ACP = Casein phosphopeptide Amorphous calcium phosphate.

a) Garry et al. (2015). ORCA abstract 133 Caries Res 49:297-369. b) Hicks, Flaitz (2013). J Dent Res 92 (Spec Iss A): 773. c) Katsura et al. (2010). Niigata Dent. J. 40(1):53-57. d) Duraisamy et al. (2015). J Pharm Bioallied Sci. 7(Suppl 2):S513-517. e) Akin M, Basciftci FA. (2012). Angle Orthock 82:770-775. f) Cochrane et al. (2010) J Dent Res 89(11):1187-1197. g) Shen et al. (2011) J Dent 39:518-525. h) Robertson et al. (2011) Am J Orthocd Dentofacial Orthop 140(5):660-668. i) Scrivivasan et al. (2010) Arch Oral Biol 55:541-544. j) Sakaguchi et al. (2006) J Dent Res 85(Spec Iss B):0191. k) Bailey et al. (2009) JDent Res 88:1148-1153. l) Cochrane et al. (2009) ORCA abstract 42. Caries Res 43:179-244. m) Emamieh et al. (2015) Novelty in Biomedicine 3((1)33-37. n) Pukallus et al. (2013) Pediatr Dent 35(7):550-555. o) Cochrane NJ, Reynolds EC (2012) Adv Dent Res 24(2):41-47. p) Sato et al. (2011) J Dent Res 93 (Spec Iss B): 4174. o) Heshmat et al. (2013) J Dent Res 92 (Spec Iss B): 82902. r) Connor et al. (2014) J Dent Res 93 (Spec Iss A): 270.

Caution: RECALDENT™ (CPP-ACP) is derived from milk casein. Do not use on patients with a milk protein or hydroxybenzoates allergy. In case of allergic reaction, stop use, rinse mouth with water, and seek medical advice.



# HOW MI PASTE PLUS® & MI PASTE® ONE CONTAINING FLUORIDE & RECALDENT™ (CPP-ACP) WORK

MI Paste® products release RECALDENT™ (CPP-ACP) - a natural milk protein peptide that adheres to soft tissue, plaque, pellicle, and enamel's hydroxyapatite delivering amorphous calcium and phosphate (ACP) into the saliva. The mechanism of action is similar to that of the salivary protein statherin and the supply of bio-available calcium and phosphate is able to drive remineralization by Fluoride (MI Paste Plus® and MI Paste® ONE), buffer acid, and reduce the plaque acid effect on tooth structure.

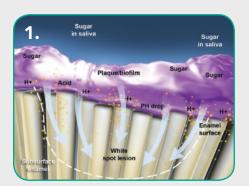
An analysis of the chemistry of demineralization and remineralization indicates that a major source of mineral loss in the caries process is the destruction of apatite with the creation of water as a by-product, and the leakage of a neutral species calcium hydrogen phosphate across a porous enamel surface.

When placed on the surface of a tooth, RECALDENT™ (CPP-ACP) interacts with hydrogen ions and forms the same species calcium hydrogen phosphate which, under a diffusion gradient, can enter the tooth, react with and consume the water to produce enamel mineral, thereby removing subsurface mineral defects.

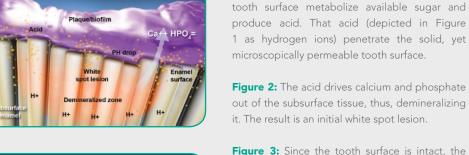
MI Paste Plus® and MI Paste® ONE treatments of enamel subsurface caries have been shown to cause rapid remineralization, which causes a change in the appearance of the lesions.

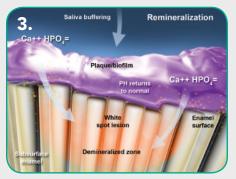
Any incipient white spot lesions which are developing because of cariogenic plaque can be treated locally with RECALDENT™ (CPP-ACP) to achieve subsurface remineralization by Fluoride (MI Paste Plus® and MI Paste® ONE). This may occur in fairly short periods of time - in the order of two to four weeks.

A key principle with RECALDENT™ (CPP-ACP) is that the longer the material is maintained in the mouth, the more effective the result. The MI Paste® family of products contain 10% of the RECALDENT™ (CPP-ACP) molecule by weight.









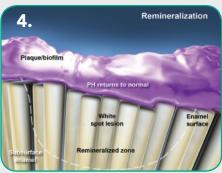


Figure 4: Remineralization of the tooth. The key is the integrity of the tooth surface; if it remains intact, uncavitated, remineralization is possible.

are delivered back into the tooth.

reverse biochemical process can occur. Saliva buffering can reverse the low pH in the plague and with the raised pH, calcium and phosphate

Figure 1: Bacteria in the plaque on the attacked

Figures and text courtesy of Dr. Steven Steinberg.



# UNIQUE CHARACTERISTICS OF CPP-ACP AND FLUORIDE

#### **Ensuring Fluoride Efficacy**

Saliva is the main source of free calcium that will ensure fluoride's effectiveness. The salivary protein Statherin can bind and stabilize calcium and phosphate to maintain a state of saturation with respect to the tooth mineral under normal oral conditions.

However, if saliva quantity or quality is compromised, or if acid producing biofilms exist on smooth surfaces, or if the tooth is constantly challenged by acid (e.g. erosion), then significantly more calcium and phosphate is required to enhance fluoride's effectiveness.  $RECALDENT^{TM}$  (CPP-ACP) is the ideal source of such additional calcium and phosphate. When fluoride ions come into contact with  $RECALDENT^{TM}$  (CPP-ACP), the peptide preferentially combines with and stabilizes fluoride, to create the ideal source of ions for building fluorapatite.



#### **Amorphous state**

The casein phosphopeptide will bind calcium, phosphate, and fluoride in an amorphous state, (i.e. not crystallized). This is essential to its function of delivering bio-available minerals.



#### **Adhesive**

The casein phosphopeptide will bind to tooth surfaces to localize bio-available calcium, phosphate, and fluoride where it is most needed.



#### Ideal size

CPP-ACP and Fluoride (CPP-ACPF complex) is less than 2 nanometers in size and can penetrate biofilms and enamel. CPP-ACPF complex has a neutral charge, so is not hindered in its diffusion characteristics.



#### Release of ions

CPP-ACP and Fluoride (CPP-ACPF complex) is a significant source of calcium, phosphate, and fluoride ions, with an increasing level of release as the oral pH lowers.



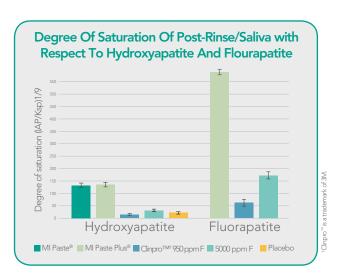
#### pH buffer

Via several mechanisms, CPP-ACP and Fluoride (CPP-ACPF complex) is an excellent buffer to counter acid challenges. Helps neutralize pH levels in the mouth.

# Measuring Effectiveness - Changes In Salivary Mineral Content

A group of patients with normal salivary parameters applied various topical remineralization agents. After 3 minutes, the salivary contents were spit out and chemical analysis undertaken to determine the mineral forming potential of the saliva.

These results show the limiting factor for the effectiveness of a mineral formation is calcium and phosphate availability. MI Paste Plus® has a far higher potential to create fluorapatite based on its availability of calcium and phosphate, despite having a lower level of fluoride than many other fluoride containing products.



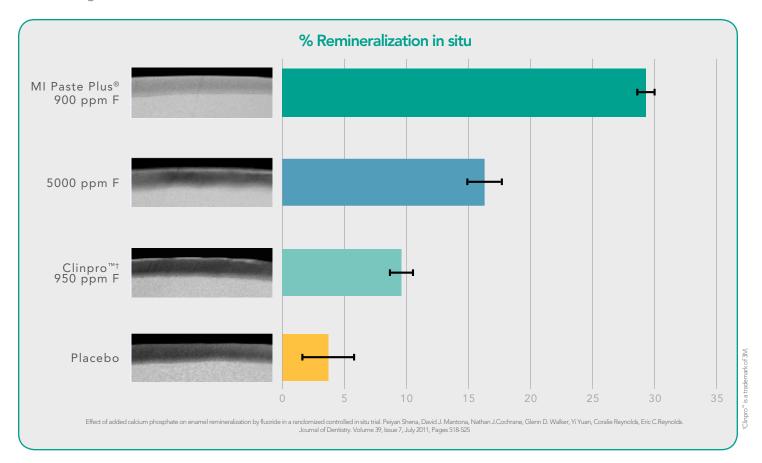
Effect of added calcium phosphate on enamel remineralization by fluoride in a randomized controlled in situ trial. Shena P, Mantona D, Cochrane N, WalkerG, Yuan Y, Reynolds C, Reynolds E. Journal of Dentistry. Volume 39, Issue 7, July 2011, Pages 518-525



# CHANGES IN MINERAL CONTENT OF WHITE SPOT LESIONS

#### **Ensuring Fluoride Efficacy**

Creating a highly controlled, proven method of measuring remineralization provides a mechanism for comparing different technologies and gives guidance for clinical recommendations. The use of an in situ model, where enamel slabs are demineralized, embedded in a palatal appliance and worn by volunteers who have healthy saliva, gives a good understanding of the effectiveness of different products. Results are imaged and measured using highly accurate microradiography as per the following research:







## CASE STUDIES

#### **During and After Orthodontic Treatment**





Fixed or removable orthodontic appliances (and clear aligners) are plaque traps because cariogenic bacteria prefer growing on hard, non-shedding surfaces. With increased levels of cariogenic bacteria in the mouth, caries risk increases during orthodontic treatment as seen above.

#### How MI Paste Plus® & MI Paste® ONE Work:

MI Paste Plus® and MI Paste® ONE can help maintain healthy tooth structure around brackets, archwires, springs, and other appliances. RECALDENT™ (CPP-ACP) can assist the saliva in buffering acids produced by dental plaque. MI Paste Plus® and MI Paste® ONE also help decalcification from developing, and arrests and reverses white spot lesions.

#### **Treatment Protocol:**

- Use MI Paste Plus® or MI Paste® ONE routinely throughout the full course of orthodontic treatment.
- Apply MI Paste Plus® or MI Paste® ONE twice daily for the entire period of orthodontic or clear aligner treatment.

#### **Treatment Of White Spot Lesions**





In cases of incipient carious lesions, the subsurface water can be converted back into enamel because of the neutral ions species moving by diffusion through the porous surface. When it reacts with the water, the hydroxyapatite formed will regenerate in the subsurface space. Once 80-85% regeneration has occurred, the enamel will appear optically normal. This means that the appearance of the white spot lesion also disappears.

#### **Treatment Protocol:**

For existing active white spot lesions:

 No need to etch prior to applying MI Paste Plus® or MI Paste® ONE. For arrested lesions:

• Etch for no more than 15 seconds with low concentration phosphoric acid to make the surface permeable.\*

Considerable work has been undertaken confirming that MI Paste Plus® and MI Paste® ONE can reverse the visible appearance of white spot lesions. Moreover, it can rebuild other areas that are water-rich, demineralized or otherwise defective, such as orthodontic decalcification, fluorosis and excessively bleached teeth. As a part of orthodontic treatment, MI Paste Plus® and MI Paste® ONE is highly recommended since it protects teeth by remineralizing areas of decalcification which may have occurred during treatment, even in patients with meticulous oral hygiene.

\*Excessive etching may lead to irreversible tooth damage.



## CASE STUDIES

#### Severe Sensitive Teeth





Patient presents with low resting salivary pH, the enamel is dissolved into the oral fluids and as a result the exposed dentin then lacks a protective smear layer, and is extremely sensitive with open tubules.

#### **How MI Paste® Works:**

Apply MI Paste® onto the surface of this dentin, the protein component bonds strongly and subsequently mineral plugs form, which begin to occlude the tubules.

#### Scientific Evidence:

Several clinical studies have shown that MI Paste® has a potent long acting desensitizing effect when used in patients with cervical sensitive dentin.

Three clinical studies conducted at the University of Queensland, Australia in 2006 followed the symptom pattern in groups of patients with long standing cervical dentinal hypersensitivity (CDH). As part of the first study, 18 patients applied MI Paste® each night before retiring. Compared with the baseline values, CDH scores were reduced significantly at four weeks on average by 47%, and at six weeks by 57%.

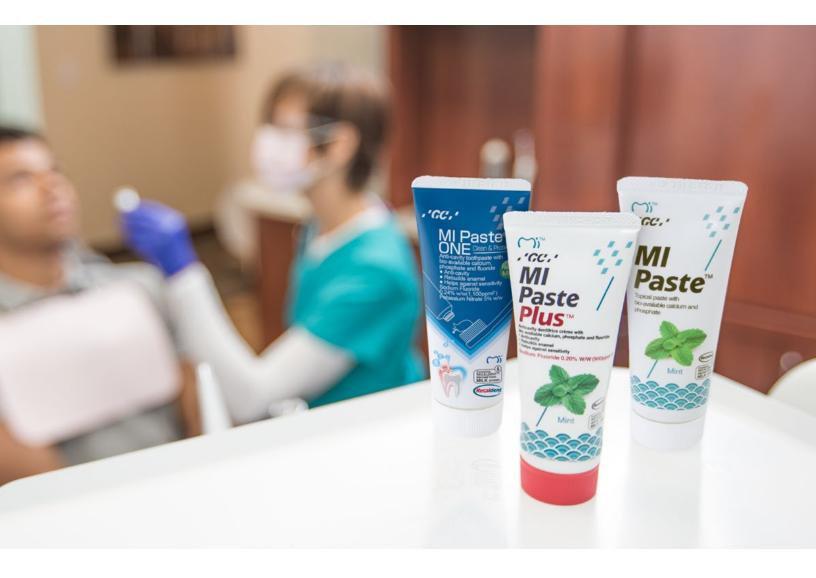
In a second study, 31 patients used the same home treatment protocol, as in the first study, for six weeks, and then stopped treatment with MI Paste® completely. Importantly, this wash-out study showed that the reduction of sensitivity achieved (on average 31%) was maintained during the next four weeks, indicating an effect on the cause of CDH as well as the symptoms.<sup>2</sup>

In the third study, a group of ten patients with long standing salivary dysfunction and associated symptoms of CDH were followed over 12 months. There was a dramatic reduction in symptoms after one month, and this effect was maintained over the ensuing months up to one year, with a sustained reduction on average of 38%. There was evidence of an accumulating effect over time, from the first month onwards.<sup>3</sup>

MI Paste® with RECALDENT™ (CPP-ACP) applied at least once daily provides both immediate and long-term solutions to the common problem of dentinal hypersensitivity. It can arrest the process of dental erosion which is a common underlying cause of chronic tooth sensitivity.

- 1. Walsh LJ et al. Effect of CPP-ACP versus potassium nitrate on cervical dentinal hypersensitivity. J Dent Res 2006; 85 (Spec Iss A): 0947.
- 2. Bird K, et al. Comparative efficacy of two dentinal sensitivity treatment modalities: A 10-week study. Unpublished research report, University of Queensland, 2006.
- 3. Vlacic J. In vivo and in vitro investigations of laser and non-laser therapies in treatment of root surface erosion and root surface caries. PhD thesis, University of Queensland, 2006.

# ,'GC,'



#### Talk to your patients about the MI Paste® Family

If your patients are coming to you with sensitive teeth, the whole MI Paste® Family of products can help. If your patients have caries or white spots, talk to them about using the innovative professional products: MI Paste Plus® and MI Paste® ONE, only from GC America.

MI Paste Plus® and MI Paste® ONE are the essential solutions to deliver calcium, phosphate, and fluoride to your patient's teeth, which provides powerful pain relief within 3-5 minutes. It's a quick and easy conversation that could have significant benefits for your patient's overall oral health and sensitivity management.

#### MI Paste® ONE

Contains: 10 tubes (46g each). 437000 Fresh Mint

#### MI Paste®

Contains: 10 tubes (40g each). 424505 Strawberry 423679 Mint

422265 Assorted (2 each: Vanilla, Strawberry, Mint, Melon and Tutti-Frutti)

#### MI Paste Plus®

Contains: 10 tubes (40g each).

422888 Vanilla 422621 (US) / 428295 (CA) Mint

422886 Strawberry

422614 Assorted (2 each: Vanilla, Strawberry, Mint, Melon and Tutti-Frutti)