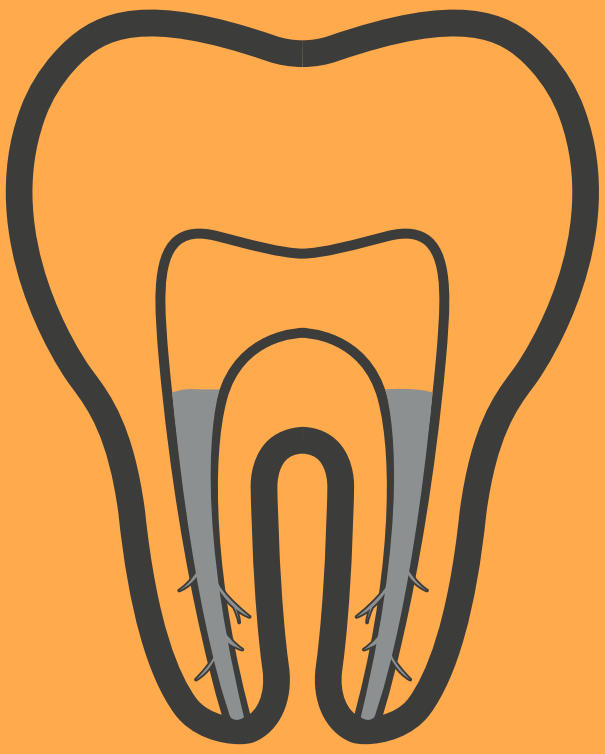
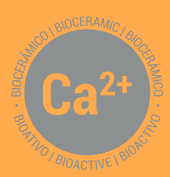
BIO-C® SEALER

Bioceramic root canal sealer ready to use



angelus®



History

Since the foundation of the company in 1994, the business focus has always been the innovation. The company makes continuous investments in the area of Research and Development of new technologies and maintains close relationship with the Universities and National and International Research Centers of several areas of knowledge.

ANGELUS is present in 86 countries and 6 continents on the planet. It holds ISO 13.485:2016 certification, CE marking (as required by the European community), FDA (commercialization approval in the US market), as well as achievements such as UKAS (Canadian market) and JPAL-QMS (Japanese market) and has been making efforts to transform challenges into new projects.

Angelus was the second company to introduce Bioceramic material on the worldwide market, back in 2001 (MTA ANGELUS) and the first company to launch a paste and paste bioceramic sealer in 2010 (MTA-Fillapex).

Since them, Angelus R&D developed a specific research line to increase the Bioceramic portfolio and has a large number of projects developed and in progress for different dental specialties.

Contents

INTRODUCTION

BIO-C® SEALER is a ready-to-use bioceramic endodontic cement.

In addition to the benefits of its bioceramic formulation such as stimulating tissue regeneration, bactericidal action and inhibiting bacterial infiltration, it presents a great advantage over traditional filling cements, **not requiring mixing**. Its ready-to-use presentation makes it easy to apply to the canal, simplifying the procedure with great time saving..

PRESENTATION

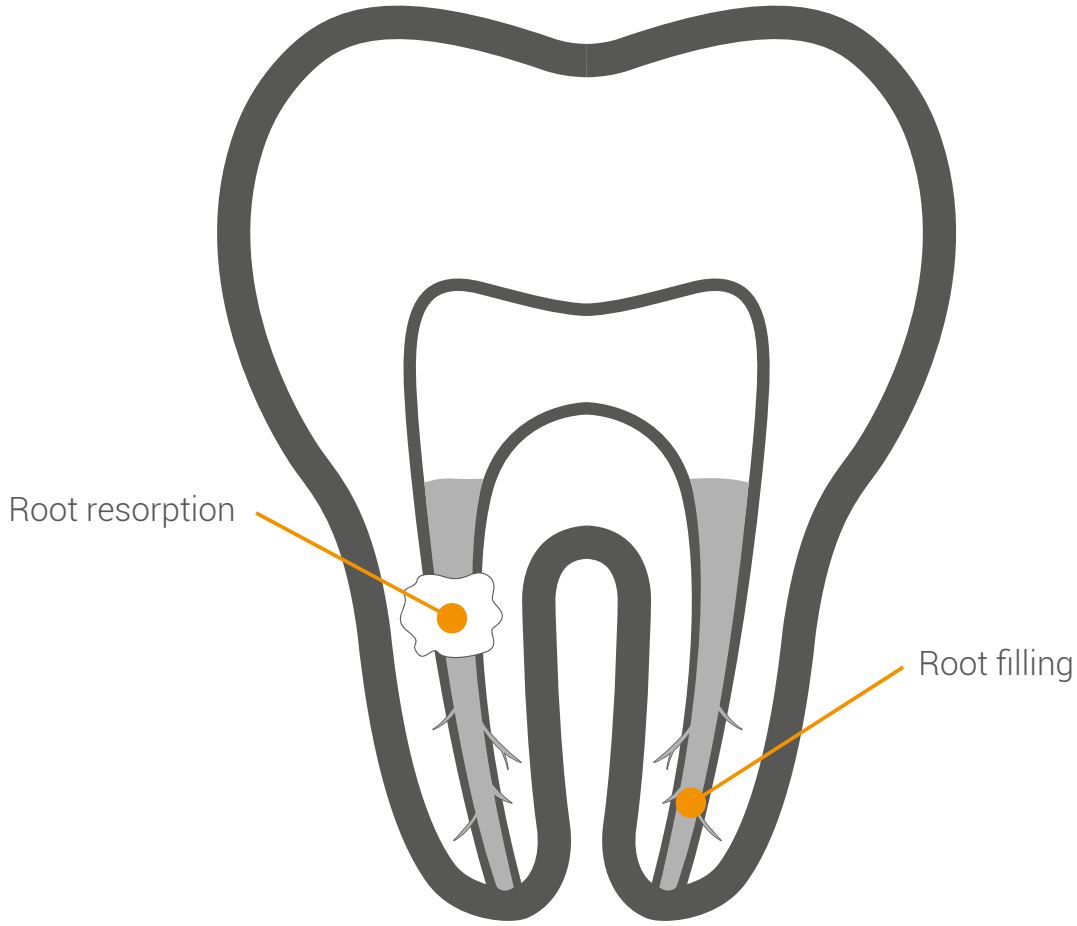
BIO-C® SEALER syringe has been specially developed to properly store materials with bioceramic characteristics, not allowing the material to come in contact with environment's humidity. The amount in each syringe is also an important characteristic, minimizing the risk of hardening the material in the syringe during subsequent uses.

Applicator tips allow taking the material to the most apical region of the canal, and they can be autoclaved before use.

INDICATION

The use of BIO-C® SEALER in filling procedures has shown excellent results. In addition to the physical seal provided by the expansion of the cement, it promotes a biological seal by the formation of an intermediate layer of mineralization.

In cases of non-communicating internal resorptions, the high pH of BIO-C® SEALER neutralizes the acidity of the medium, preventing the resorption to progress.



TECHNIQUES OF USE

A. Root canal filling of permanent teeth

Traditional Technique - Lateral Compression

1. Anesthetize, install rubber dam insulation and do biomechanical preparation of the canal;
2. Dry the canal with paper tips only without causing excessive drying;
3. Position the applicator tip and fill the canal with BIO-C® SEALER;
4. Insert the main gutta percha cone covered with BIO-C® SEALER and later the accessory gutta percha cones;
5. X-ray to verify the correct filling of the canal;
6. Cut the cone at the desired height with heated instruments followed by vertical compaction;
7. Remove excess material from the canal walls with water, perform coronary sealing and restoration.

Single Cone Technique or Hydraulic Compression

1. Anesthetize, install rubber dam insulation and do biomechanical preparation of the canal;
2. Dry the canal with paper tips only without causing excessive drying;
3. Position the applicator tip and fill the canal with BIO-C® SEALER;
4. Insert the selected gutta percha cone covered with BIO-C® SEALER;
5. X-ray to verify the correct filling of the canal;
6. Cut the cone at the desired height with heated instruments followed by vertical compaction;
7. Remove excess material from the canal walls with water, perform coronary sealing and restoration.

B. Internal resorption treatment

1. Anesthetize and install rubber dam insulation;
2. Remove granulation tissue from the resorption area with sharp curettes;
3. Neutralize the medium with calcium hydroxide paste;
4. Remove the calcium hydroxide in the next session;
5. Dry the canal with paper tips only without causing excessive drying;
6. Insert BIO-C® SEALER with the applicator tip into the entire canal, prioritizing the resorption site;
7. Fill the canal according to the selected technique;
8. Cut the cones on top of the resorption with heated instruments. Perform vertical compaction for better cement flow at the resorption site;
9. X-ray to verify the correct filling of the resorption site and the canal;
10. Fill the rest of the canal with gutta percha;
11. Perform coronary sealing with glass ionomer or other material of your choice
12. X-ray and follow for at least two years.

COMPOSITION/FORMULATION

COMPONENT	FUNCTION
Tricalcium Silicate (C_3S)	Mechanical resistance over time Calcium ions release
Dicalcium Silicate (C_2S)	Mechanical resistance over time Calcium ions release
Tricalcium Aluminate	Initial setting
Calcium Oxide	Calcium ions release
Zirconium Oxide	Radiopacity
Silicon Oxide	Rheology agent
Polyethylene Glycol	Dispersing agent
Iron Oxide	Pigmentation

TECHNICAL DATA

Setting Time	≤ 240 minutes
Radiopacity	≥ 7.0 mm Al
pH	≅12
Flow	23.46 mm
Particle Size	< 2 µm
Film Thickness	21 µm
Solubility	2.86%

PHYSICAL-CHEMICAL CHARACTERISTICS

Setting reaction

The setting time of BIO-C® SEALER will depend on the presence of moisture at the site it has been applied to the tooth structure. Water molecules present in the medium come in contact progressively with the particles of BIO-C® SEALER, causing hydration, setting of the cement and release of the active ions. These chemical reactions involve the hydration of Calcium Silicate compounds to produce a hydrated Calcium Silicate (C-S-H) gel, responsible for setting and formation of calcium hydroxide, according to the following equations:

$$2(3CaO.SiO_2) + 6H_2O = 3CaO.2SiO_2.3H_2O + 3\ Ca(OH)_2$$

Tricalcium Silicate + Water = C-S-H + Calcium Hydroxide

$$2(2CaO.SiO_2) + 4H_2O = 3CaO.2SiO_2.3H_2O + Ca(OH)_2$$

Dicalcium Silicate + Water = C-S-H + Calcium Hydroxide

$$CaO + H_2O = Ca(OH)_2$$

Calcium Oxide + Water = Calcium Hydroxide

The formed Calcium Hydroxide dissociates rapidly into ions Ca^{2+} and OH^-, increasing the pH of the medium, and consequently, making the environment inhospitable for bacterial growth. On the other hand, the Calcium ions will react with the CO_2 present in the bloodstream, forming Calcium Carbonate. An extracellular matrix rich in fibronectin is secreted when in contact with these products, triggering the formation of a hard tissue. Histologically, the stimulation for the deposition of this tissue is observed through Calcite granulations, around which there is great condensation of fibronectin, which provides cell adhesion and differentiation.

The setting process is attributed to the Hydrated Calcium Silicate gel crystals that bind and bypass the aggregates (radiopacifier) giving the product mechanical strength. The setting time is related to the humidity availability in the medium and will occur around 240 minutes*.

**Tests were performed according to ISO 6876:2012.*

Radiopacity

The product presents radiopacity ≥ 7 mm in the Aluminum, in accordance with ISO Standard 6876:2012.

The radiopacifier present in the product formula is Zirconium Oxide which, unlike other radiopacifiers used in Dentistry, does not promote tooth staining.

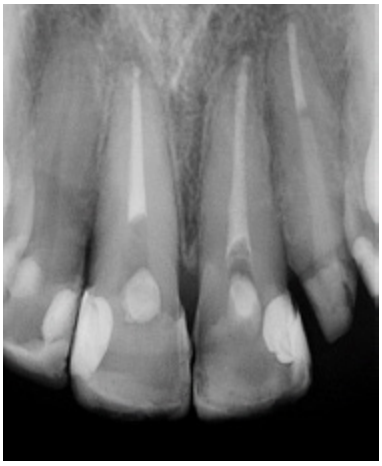


Image courtesy of Dr. Vicente Rocha.

Solubility

The solubility of BIO-C® SEALER, according to the tests carried out by ISO Standard 6876:2012, presented the following results:

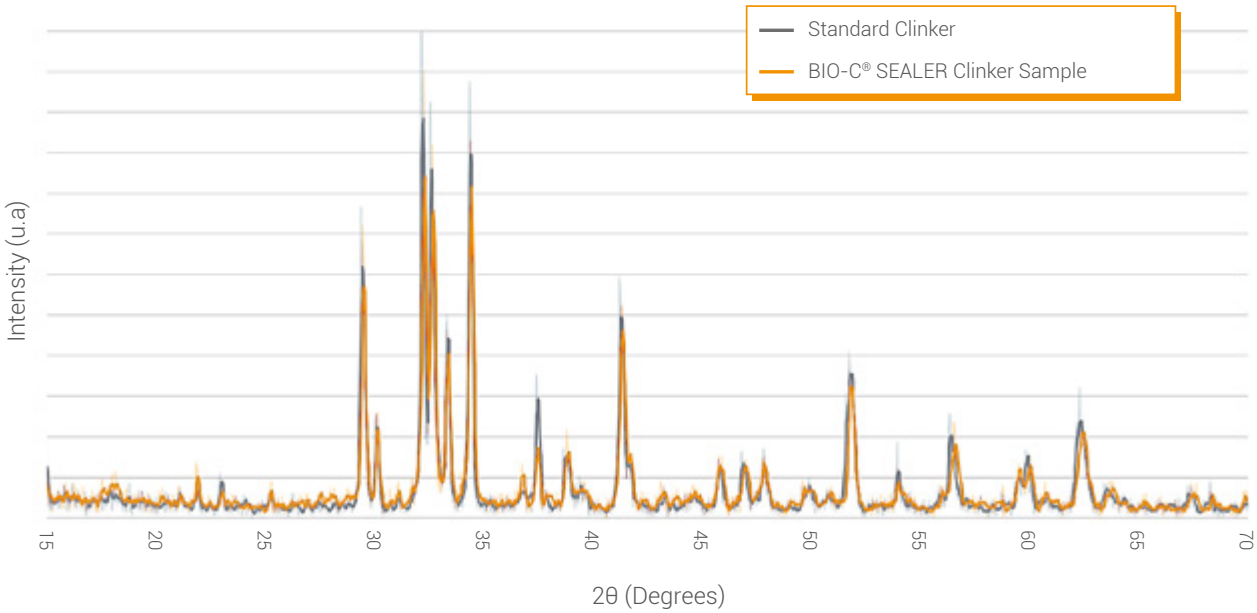
Solubility and desintegration of BIO-C® SEALER

SAMPLES	BIO-C® SEALER (%)
1	2.94
2	2.64
3	3.00
Average	**2.86**
Standard deviation	**0.19**

BIO-C® SEALER showed low solubility in accordance with ISO 6876:2012, ensuring adequate sealing of the filling material to the canal walls.

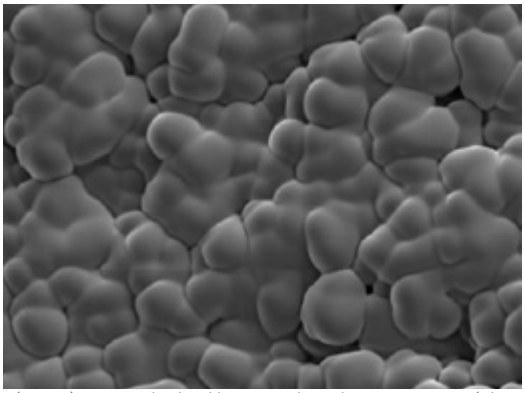
X-ray diffraction

These trials confirm the presence of Calcium Silicates, Calcium Oxide and Tricalcium Aluminate in the composition of BIO-C® SEALER. The presence of these crystalline structures is fundamental for the product to reach the ideal physical and biological properties.



Particle size

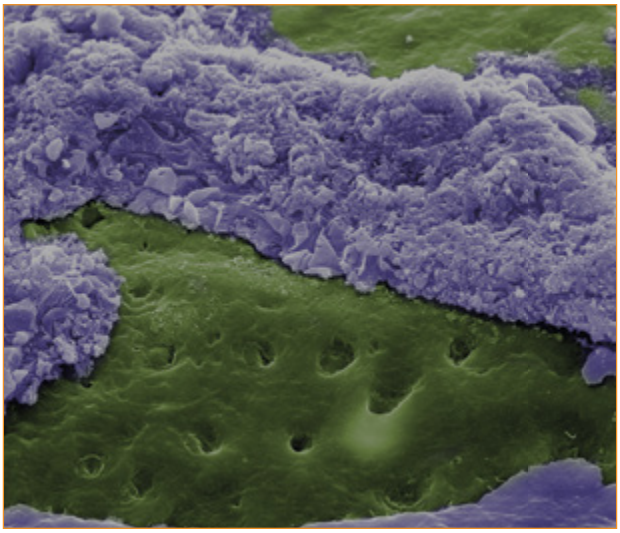
BIO-C® SEALER has a particle size of < 2 µm. Micronization improves rheological properties of the product, favoring the flow and penetration of the filling material into dentinal tubules. The reduced particle size makes the product more reactive, which favors the faster release of Ca^{2+} ions and OH^-, ions associated with the healing process of endodontic lesions.



SEM FEG (5000x): Image obtained by secondary electron capture. (Siqueira, C.P)

Chemical adhesion to dentin

The contact of BIO-C® SEALER with moisture and tissue fluids releases active ions that interact with the organic and inorganic matrix of the dentin, promoting the formation of an intermediate area, called the Mineral Infiltration Zone (MIZ). This area of mineral infiltration in the dentin provides an excellent biological seal, minimizing possibilities of bacterial infiltration, that would lead to recontamination and endodontic failure.



BIO-C® SEALER adhered to dentin.

Biocompatibility

The BIO-C® SEALER is a bioceramic endodontic cement composed of Calcium Silicates classified as "device with long-term external communication", that is, for more than 30 days (ISO Standard 7405). Based on this classification, and in compliance with the standards, cytotoxicity, skin irritation and sensitization tests were performed.

Cytotoxicity (ISO 10993-5)

The study of the cytotoxic potential of BIO-C® SEALER was performed *in vitro* using V-79 fibroblasts cell line. Cell viability was determined by the incorporation of MTT. The cytotoxicity presented is due to the high pH of the material, around 12, intentionally developed to render the environment inhospitable to bacterial proliferation.

In the presence of moisture, the formed Calcium Hydroxide raises the pH making the alkaline medium. Alkaline pH has a destructive effect on protein structures and can promote enzymatic denaturation as well as damage to the cell membrane.

However, the occurrence of chemical irritation by similar materials, such as Calcium Hydroxide, does not cause irreversible damages to the tissues. In practice, the presence of a non-extensive inflammatory process in underlying pulp and periapical tissues actually, leads to stimulation of tissue repair*.

Skin irritation and reactivity (ISO 10993-10)

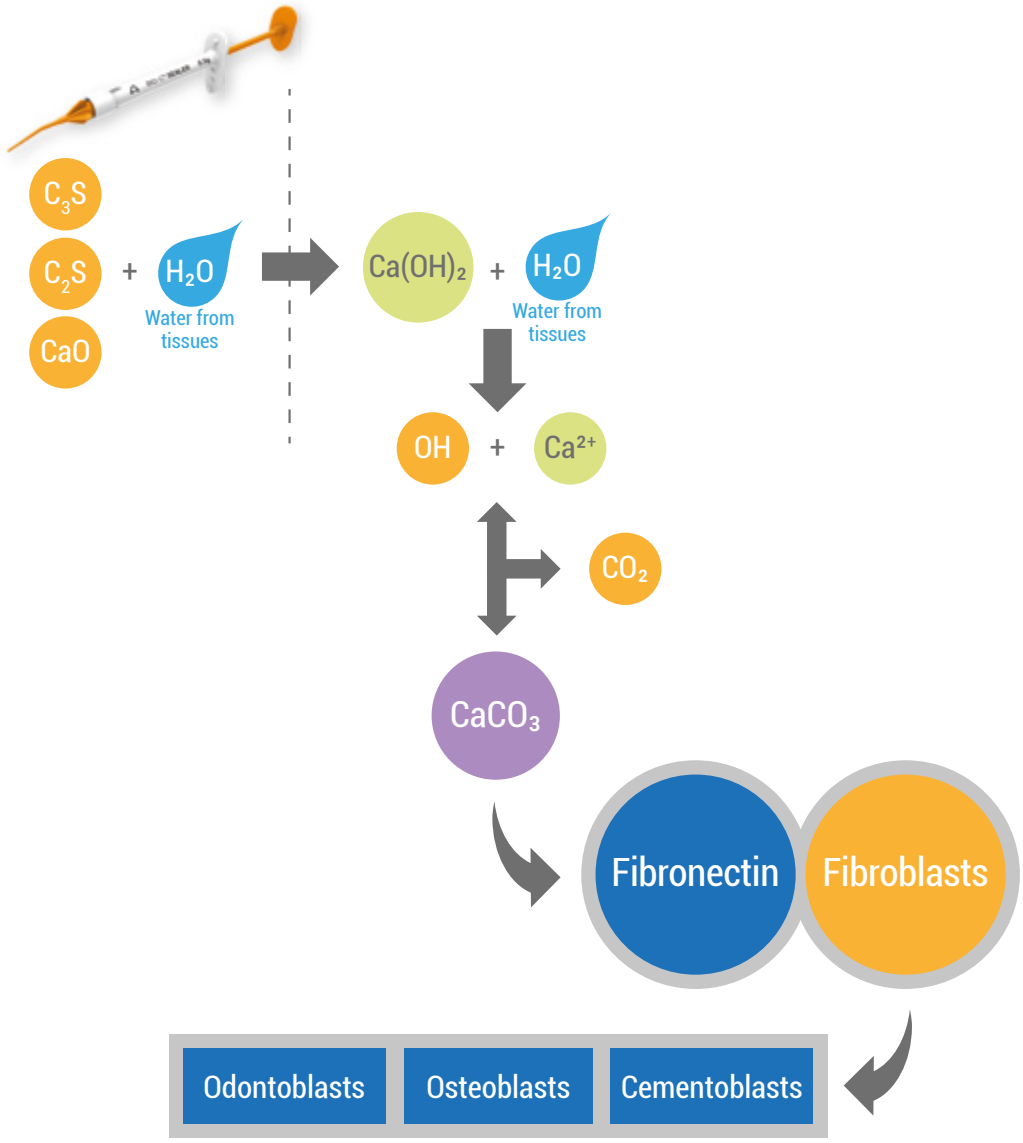
The possible irritant effects of BIO-C® SEALER were evaluated according to ISO 10993-10. Studies were conducted on oral mucosa of Syrian Hamsters. No macroscopic or microscopic changes were observed. The index of irritation obtained from the histopathological analyzes was null. It was therefore concluded that, under the study conditions, BIO-C® SEALER was classified as non-irritant to the oral mucosa of hamsters.

Skin sensitization (ISO 10993-10)

Cutaneous sensitization studies were conducted in CBA / J lineage mice according to ISO 10993-10, which determined that a sensitizing material induced lymphocyte proliferation in the lymph node near the site of application. Lymphocyte proliferation was assessed, by determining the incorporation of bromodeoxyuridine (BrdU) into the DNA of lymph node cells. According to the results obtained by the ELISA method, the stimulation index was 1.55. It is therefore concluded that BIO-C® SEALER is classified as a non-sensitizing material.

**Yoshino, P.; Nishiyama, C.K.; Modena, K.C.S.; Santos, C.F.; Sipert, C.R., "In Vitro Cytotoxicity of White MTA, MTA-Fillapex® and Portland Cement on Human Periodontal Ligament Fibroblasts", Brazilian Dental Journal (2013) 24 (2): 111-116..*

MECHANISM OF ACTION



The mechanisms of action of BIO-C® SEALER are closely associated with contact with tissue moisture and fluids. After the Calcium Oxide, present in the formulation of BIO-C® SEALER, comes into contact with the water present in the dentin tubules, Calcium Hydroxide is formed. Calcium Hydroxide also interacts with the fluids, dissociating in Calcium ion and Hydroxyl. The Hydroxyl ions are responsible for the pH increase, promoting bactericidal action of the product. The released Ca^{2+} ions react with CO_2 from the bloodstream, forming Calcium Carbonate (Calcite). An extracellular matrix rich in fibronectin is secreted as a result of the alkaline pH and attracted by Calcite, triggering the formation of hard tissue. Histologically, stimulation occurs to the deposition of this hard tissue, through granulations of Calcite, around which there is great condensation of fibronectin, which provides cell adhesion and differentiation.

5 REASONS TO USE BIO-C® SEALER

1

Ready to Use

No mixing required.
Apply directly to canal.

2

Bioactive

Stimulates tissue regeneration.

3

High alkalinity (pH ~ 12)

Bactericidal action.

4

High flow, setting expansion and chemical adhesion to dentin

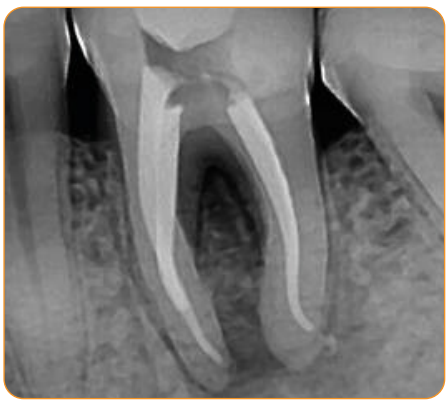
Prevent bacterial infiltration.

5

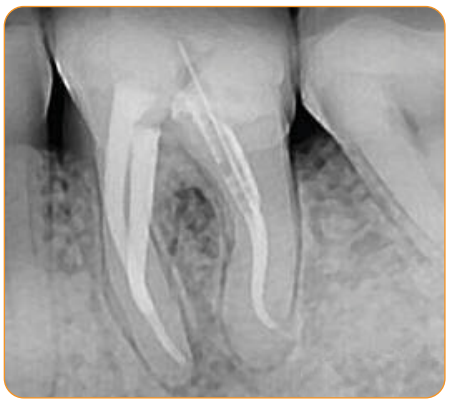
High radiopacity

Great radiographic visualization.

CLINICAL CASES

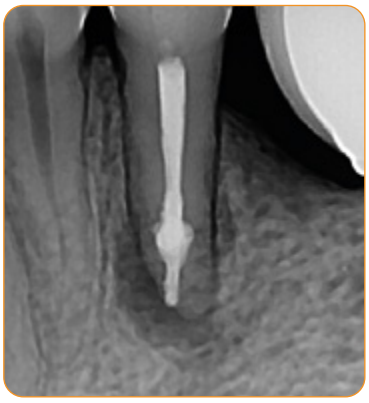


Initial



P. O. 10 months

Dental Surgeon	Dr. Warley Tavares
Start of treatment	04/2017
Sex of patient	Male
Age of patient	45 years-old
Initial diagnosis	Chronic Apical Periodontitis.
Used protocol	Instrumentation with NiTi, Sodium hypochlorite 2.5%, medication with Calcium Hydroxide for 10 days. Filling with gutta percha and BIO-C® SEALER.
Follow-up date	02/2018



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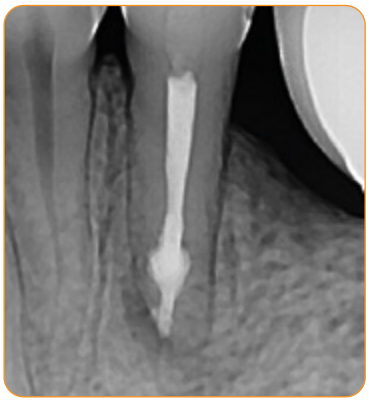
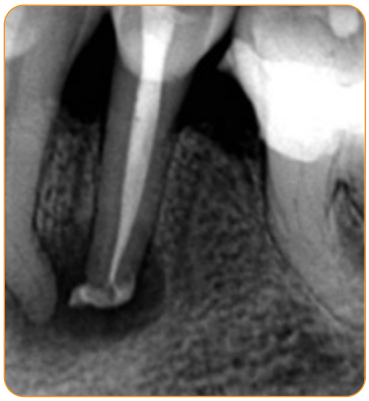


P. O. 3 months

Dental Surgeon	Dr. Warley Tavares
Start of treatment	12/2017
Sex of patient	Male
Age of patient	45 years-old
Initial diagnosis	Reabsorption, Necrosis, Chronic Apical Periodontitis.
Used protocol	Instrumentation with NiTi, Sodium hypochlorite 2.5%, medication with Calcium Hydroxide for 10 days. Filling with gutta percha and BIO-C® SEALER.
Follow-up date	03/2018



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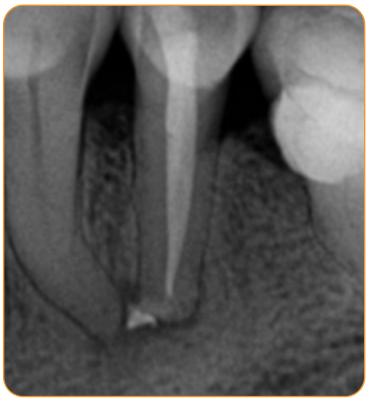
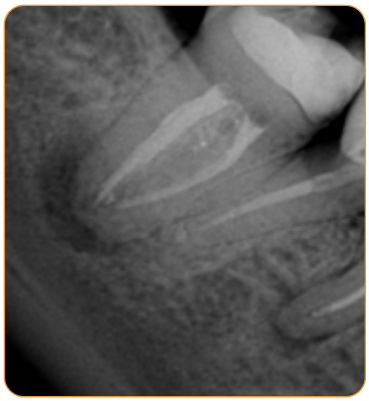


P. O. 9 months

Dental Surgeon	Dr. Patricia Ferrari
Start of treatment	03/2018
Sex of patient	Female
Age of patient	65 years-old
Initial diagnosis	Asymptomatic Primary Apical Periodontitis.
Used protocol	Chemical-Mechanical Preparation, Final cleaning systems, antimicrobial Photodynamic Therapy (aPDT) and Intracanal.
Follow-up date	12/2018



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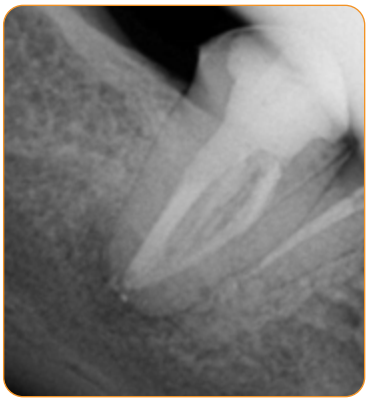
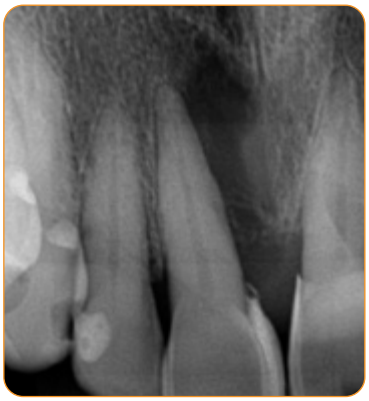


P. O. 2 months

Dental Surgeon	Dr. Patricia Ferrari
Start of treatment	07/2018
Sex of patient	Female
Age of patient	44 years-old
Initial diagnosis	Asymptomatic Apical Periodontitis.
Used protocol	Chemical-Mechanical Preparation, Final cleaning systems, antimicrobial Photodynamic Therapy (aPDT) and Intracanal.
Follow-up date	10/2018



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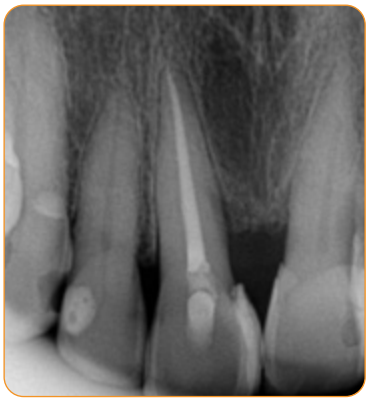

P. O. 4 months

Dental Surgeon	Dr. Patricia Ferrari
Start of treatment	06/2018
Sex of patient	Female
Age of patient	62 years-old
Initial diagnosis	Acute Periapical Abscess.
Used protocol	Chemical-Mechanical Preparation, Final cleaning systems, antimicrobial Photodynamic Therapy (aPDT) and Intracanal Medication.
Follow-up date	11/2018

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