

C-Root SP



ROOT CANAL BIOCERAMIC SEALER

*Breakthrough Technology with
Strontium Silicate*

Global Patent: PCT/CN2019/097075

FDA Clearance: K212983

Registration/FEI Number: 3021971019

Owner/Operator Number: 10084370

US PATENT NO.17/266.102

EU PATENT NO.19847130.2



Revolutionary Formulation • Outstanding Quality • Competitive Pricing • Global Patent
Clinical Success in Asia • Superior Flow & Painless & Rapid Periapical Healing



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BEIJING C-ROOT DENTAL MEDICAL DEVICES CO. LTD

C-Root SP

Product Description

- **C-Root SP Injectable Root Canal Bioceramic Sealer** is a premixed, injectable silicate bio-ceramic paste material which solidifies in the presence of water. It is used to sealing the various complexities within the root canal system during obturation and promote mineralization. C-Root SP is a mixture containing strontium silicate, calcium, silicon, strontium and magnesium ions, which harden in the presence of water and promotes healing and dentin mineralization; It is bactericidal due to its high alkalinity prior to its final setting.
- C-Root SP is a newly patent awarded Bioceramic Root Canal Sealer. It is injectable white hard cement, which is designed for safe and effective permanent root canal filling and sealing.

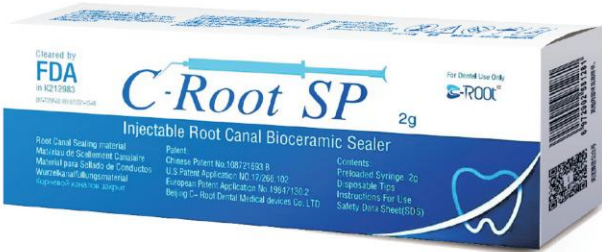
- **Composition:** Strontium Silicate, Zirconia, Calcium Phosphate and Calcium Hydroxide
- Advantages:** Excellent biocompatibility. Easy to use. Lateral canal filling ability. Excellent radiopacity. Mild postoperative reaction. Rapid periapical bone lesion healing. No shrinkage during setting.
- Used for:** Root Canal Sealing and Permanent Filling.
- Indications:** Permanent filling of root canal after it has been cleaned and disinfected properly.

It is suitable for lateral condensation/compaction technique, single cone obturation technique and vertical condensation techniques

C-Root SP

Strontium Silicate Bioceramics
Experience the extraordinary

Device Listing:D466741



C-ROOT SP INJECTABLE ROOT CANAL BIOCERAMIC SEALER

✓ Biocompatibility and Osteogenesis	✓ 3D sealing and filling	✓ High X-ray radio opacity
✓ Easy operation	✓ Chemically bonds to dentin	✓ Hydrophilicity
✓ No shrinkage	✓ High antibacterial (pH > 12)	✓ React to form hydroxyapatite
✓ Ideal working time	✓ Remineralization in dental tubules	✓ Affordability
✓ Lateral canal filled	✓ Rapid periapical healing	✓ Single cone technique
✓ Mild Post-Op Reaction	✓ Excellent flow characteristics	✓ Average fill 15-25 root canals per 2g

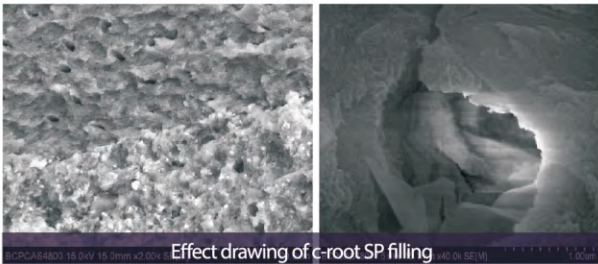
C-Root SP

Product Properties

01

GOOD SEALING, REMINERALIZATION IN DENTAL TUBULES TO GENERATE STRONTIUM HYDROXYAPATITE

- **C-Root SP** particles are relatively fine, which can be injected into the root canal , flow into the various anatomical complexities (including small lateral root canal, fins, cul-de-sacs). It can also penetrate the dental tubules (2-5 microns in diameter) for remineralization to form hydroxyapatite with strontium substituted, which effectively seals the canal.
- **C-Root SP** bioceramic premixed paste, is easy to operate and can be filled by single cone technique, which can save time and reduce the risk of root fracture.The price is reasonable and acceptable, it has great application value.



03

ANTIBACTERIAL

- Antibacterial efficacy of 100% of enterococcus faecalis and 99% of staphylococcus Aureus within 2 minutes of exposure. C-Root SP contains calcium hydroxide which is a potent bactericidal agent commonly used in root canal medicaments which enhances its bactericidal properties.

时间节点	杀灭对象	抗菌效果					
		×1		×10		×100	
2min	试验样品组重复 1						
	金黄色葡萄球菌	99%	100%	99%	100%	100%	100%
	粪肠球菌	100%	100%	100%	100%	100%	100%
	试验样品组重复 2						
	金黄色葡萄球菌	100%	100%	100%	100%	100%	100%
	粪肠球菌	100%	100%	100%	100%	100%	100%
	试验样品组重复 3						
	金黄色葡萄球菌	100%	100%	100%	100%	100%	100%
	粪肠球菌	100%	100%	100%	100%	100%	100%
	试验样品组重复 4						
	金黄色葡萄球菌	100%	100%	100%	100%	100%	100%
	粪肠球菌	100%	100%	100%	100%	100%	100%

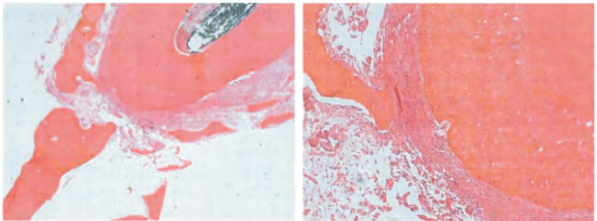
02

GOOD BIOCOMPATIBILITY

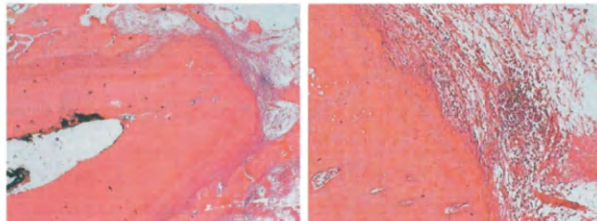
- **C-Root SP** has been tested for biocompatibility by The Dental medical device testing center, School of Stomatology, Peking University for up to 2 years and reported to be non-toxic, non irritating, non carcinogenic and non mutagenic with osteogenic potential and mild post operative reactions.

Endodontic Usage Test (REP/PDS64-2019-0014-GG-BGE) showed:

At the time period of 90 days, among the 10 test specimens (C-Root SP),10 specimens (C-Root SP) showed no inflammation.



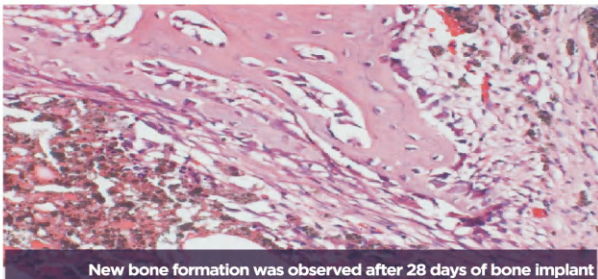
Among the 5 control specimens (other sealer), 4 specimens showed no inflammation, 1 specimens of periapical tissue showed moderate inflammation (See the figure below).



04

INDUCE OSTEOGENESIS AND ROOT END FORMATION

- C-Root SP is not easy to extrude compared to other sealers! Small amount of extrusion can induce osteogenesis and root end formation. Good apical sealing and osteogenic potential from the strontium silicate which promotes healing for long term success.



In vitro cytocompatibility and osteogenic potential of calcium silicate-based dental cements in a root canal-filling model

Abstract: To investigate the *in vitro* cytocompatibility and osteogenic potential of an experimental calcium silicate-based cement and the inflammatory response in human periodontal ligament stem cells (hPDLSCs).

Methods: Cellular responses, osteogenic-related gene expression, and the production of inflammatory cytokines including interleukin-1 α , IL-6 and IL-8 were studied in hPDLSCs exposed to the experimental root canal-filling material C-Root, the commercial tricalcium silicate-based material BioRoot RCS, and the epoxy resin-based material AH Plus. Differences were analyzed using one-way ANOVA with Bonferroni-adjusted pairwise comparison.



FDA
Fiscal Year 2023

CERTIFICATION OF REGISTRATION

This certifies that:

Name: BEIJING C.-ROOT DENTAL MEDICAL DEVICES CO., LTD.
Address: Room 301, Building 10, Yard 12, Middle Aiyuan Road, Maipo Town, Shunyi District, Beijing, Beijing, 101300, CHINA
 has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the U.S. Food & Drug Administration, through Registration/ID Number: 3021972019
 Owner/Operator Number: 12084370

Listing ID	Code	Premarket Substitution NO.	Device Name
D488741	K0F	K21-0883	RESIN, ROOT CANAL FILLING - injectable Root
D488740	ENX	510(k) exempt	FILE, PULP CANAL, ENDOCENTRIC - C-Root File

Aligned will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Aligned makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate - holder's device or establishment by the U.S Food and Drug Administration.

Aligned assumes no liability to any person or entity in connection with foregoing.

Date of verification: Oct.30, 2023
Date of expiration: Dec.31, 2023

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WHAT IS THE IDEAL ROOT CANAL BIO-CERAMIC SEALER

- ✓ No resorbable
 - ✓ Remineralization in dental tubules
 - ✓ Mild Post-OP Reaction
 - ✓ Osteogenesis



types of medical devices, EDTA root canal lubricating gel and Calcium hydroxide root canal medication paste, have been highly recommended by general dentists and Endodontic specialists. C-Root SP Injectable Root Canal Bioceramic Sealer, has been awarded the registration certificate of CFDA (gxzz 20213170769) of China and FDA certificate (K212983) of the United States of America . C-Root SP has global

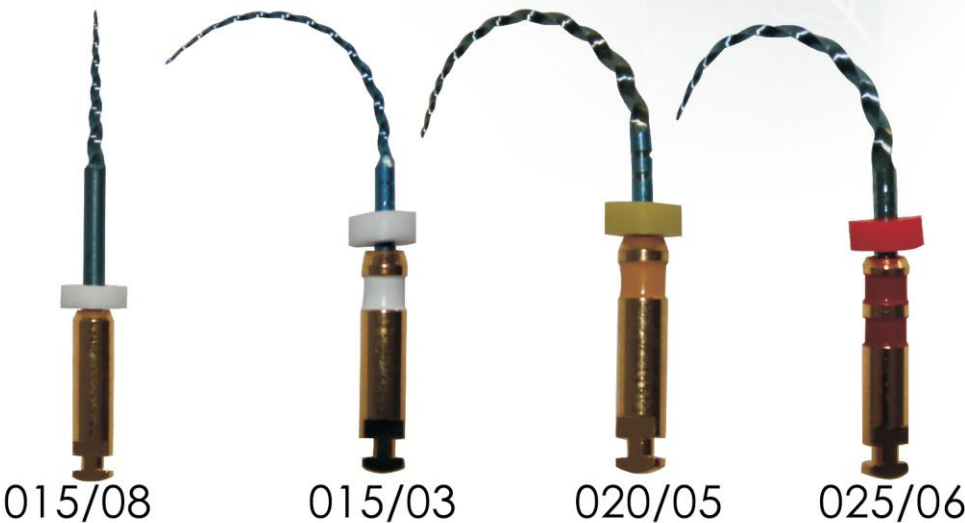
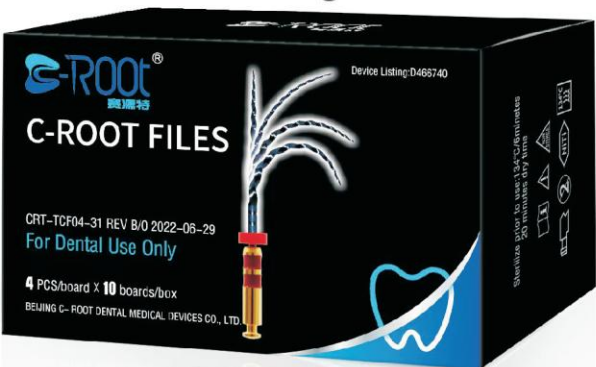
C-Root NiTi Files

Flexible, Fast Root Canal Preparation

Device Listing:D466740

C-Root NiTi Files .04 :
015/08 19mm 2.5N•cm 500RPM
015/03 21mm 1.5N•cm 300RPM
020/04 21mm 2.5N•cm 500RPM
025/04 21mm 2.5N•cm 500RPM

C-Root NiTi Files .06 :
015/08 19mm 2.5N•cm 500RPM
015/03 21mm 1.5N•cm 300RPM
020/05 21mm 2.5N•cm 500RPM
025/06 21mm 2.5N•cm 500RPM



EDTA ROOT CANAL LUBRICATING GEL

Lubrication and file fracture prevention.



DISINFECTION PASTE

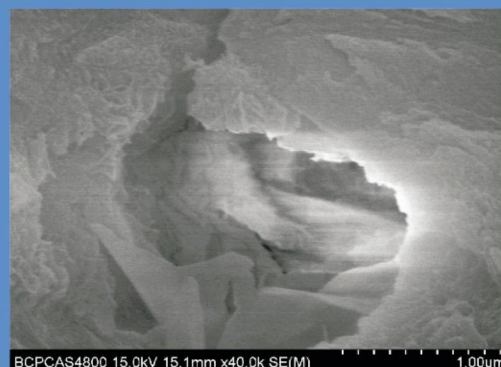
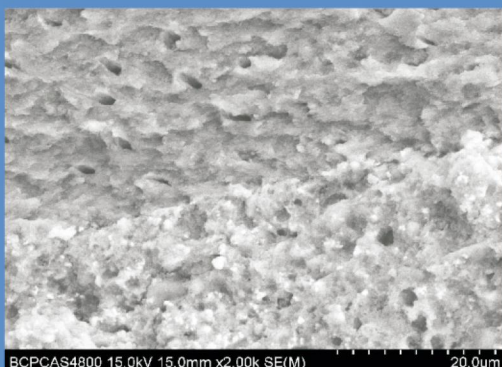
The recognized most effective root canal medicament



➤ **Composition:** 10% urea peroxide + 17% EDTA + glycerol + polyethylene glycol + carboxymethyl cellulose CMC + sodium hyaluronate

- ✓ Good flow
- ✓ X-ray radio opacity
- ✓ No setting
- ✓ Easy to take out
- ✓ Easy to put into root tip 1/ 3 part
- ✓ Complete sterilization, less pain during diagnosis and less postoperative reaction

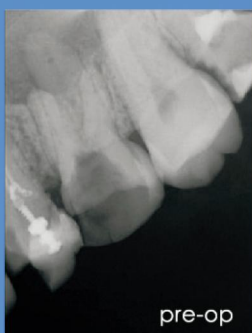
WHAT KIND OF FILLING DO YOU WANT?



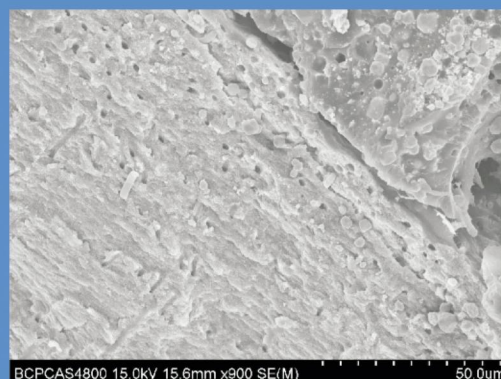
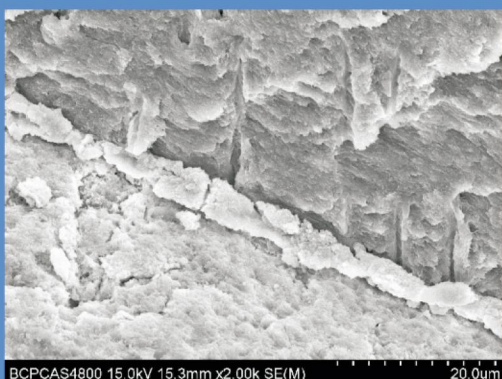
Chemical
Bonding

C-Root SP

Remineralization
of Dentinal Tubules



By Dr. Sun Yi , C-Root SP



C-Root is Your Ideal Choice.



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Website

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