

INSTRUCTIONS FOR USE**PARKELL PRODUCT
INFORMATION****MetaSEAL™ ROOT CANAL SEALER**
Stock No. S160*CAUTION: U.S. Federal Law restricts the use of this material to licensed professionals.***STORE IN A COOL, DRY LOCATION. AVOID EXCESSIVE HEAT AND MOISTURE.****DESCRIPTION**

Parkell's **MetaSEAL™** Root Canal Sealer is a self-etching, dual-cured, biocompatible, resin-based endodontic sealer that uses 4-META to enhance dentinal penetration and hybridization. MetaSEAL bonds to gutta percha or Resilon®, as well as root canal dentin, which results in complete sealing of the canal.

KIT CONTENTS

4.5ml Liquid, 5g Powder, Measuring Spoon, Spatulas, Mixing Pad, Instructions

PROPERTIES

Liquid/Powder Ratio	2-3 drops/1 scoop
Working time @ 23°C (73.4°F)	30 minutes
Initial set time @ 37°C (98.6°F)	10 minutes (DSC Method)
Final set time @ 37°C (98.6°F)	16 hours (ISO 6876 Method)
Radiopacity (mm aluminum)	3.00 +
Solubility	0.2 ± 0.1%
Film thickness	5 μm ± 1 μm

IMPORTANT CLINICAL NOTE: MetaSEAL is designed for use only with the following endodontic techniques:

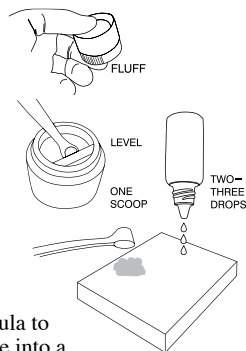
- 1) Cold obturation using spreaders or pluggers with a vertical or horizontal condensation technique.
- 2) "Thermafil®" or similar systems where part of the carrier remains in the canal.

MetaSEAL IS NOT TO BE USED FOR WARM CONDENSATION TECHNIQUES WHERE THE SPREADER OR PLUGGER MUST BE REMOVED FROM THE CANAL AFTER HEATING THE OBTURATING POINT.

USE OF HOT INSTRUMENTS WILL CAUSE RAPID SETTING OF THE SEALER, OFTEN BEFORE THE POINT IS FULLY PLACED. AVOID USE OF HOT INSTRUMENTS IN THE CANAL WHEN USING MetaSEAL.

DIRECTIONS FOR USE

- 1) Fit a point (gutta percha or Resilon®) to a prepared root canal so that it seats without binding, and achieves slight apical 'tugback'.
- 2) Dispense a minimum of 2 and a maximum of 3 drops of MetaSEAL Liquid onto a paper pad. The amount of liquid used can be adjusted within this range to change the cement's handling properties.
- 3) Dispense 1 level scoop of MetaSEAL powder onto the pad, next to the liquid. When measuring the powder, overfill the scoop and remove the excess by scraping the top of the scoop against the leveling bar in the jar.
- 4) If a greater quantity of cement is needed, increase each component uniformly (e.g. 4-6 drops/2 scoops).
- 5) Mix the liquid and powder thoroughly using a plastic (not metal) spatula to a uniform and homogeneous consistency (30 seconds.) Spread mixture into a thin film on the pad and protect from light to assure 30 minute working time.
- 6) To further thicken the viscosity of the cement, allow the material to sit on the pad for 2-4 minutes.

*Continued*

- 7) Apply mixed MetaSEAL to the entire length of the prepared root canal(s) using a disposable gutta percha point or the last hand file used.
 - a. Avoid absorbent paper points as a cement applicator, as they may thicken the cement by absorbing the liquid in the mix.
 - b. DO NOT USE A LENTULO SPIRAL OR OTHER ROTARY INSTRUMENT TO APPLY THE CEMENT. FRICTION WILL HEAT THE PRODUCT AND CAUSE IT TO SET PREMATURELY.**
- 8) Coat the fitted master point with MetaSEAL and insert it to the canal apex.
- 9) Check adequacy of root canal fill with a radiograph and adjust or refill, if necessary.
- 10) To create an instant coronal seal, light-cure (20-40 seconds, depending on the light) after canal obturation. MetaSEAL contains camphorquinone (CQ). Any light-curing device (halogen, LED, etc.) will polymerize it.
- 11) Wait for MetaSEAL to attain its initial self-cure set before attempting a post-hole preparation. This time will vary depending on canal depth, moisture, temperature and curing light intensity, but will never be less than 10 minutes. Although some dentists may successfully place the endodontic post on the same day as obturation, most doctors will be more comfortable waiting at least 24 hours before post placement.

WARNINGS

MetaSEAL is CONTRAINDICATED for use on or by persons who are methacrylate sensitive. MetaSEAL should NOT be swallowed.

TROUBLESHOOTING

■ MetaSEAL sets too quickly.

- Hot instruments or Lentulo spiral used. MetaSEAL was designed for the techniques listed in the “**IMPORTANT CLINICAL NOTE**” above. Heat or friction will dramatically shorten its setting time, and may even bond the obturating point directly to the instrument.
- Too much powder in the mix. The ratio of 2-3 drops to one level scoop of powder is important. Adding too much powder will reduce the sealer’s effectiveness and cause rapid setting.

■ The consistency is too thin, even after adjusting the liquid:powder ratio.

- If you prefer a thicker consistency, even after adjusting the liquid:powder ratio, spread the mixed MetaSEAL into a thin layer and leave it on the pad for 2-4 minutes before using.

■ After mixing, the material is lumpy —not smooth.

- Material was mixed with a metal spatula. Only plastic spatulas should be used to mix MetaSEAL.

■ The material does not set on the pad.

- MetaSEAL is heavily oxygen-inhibited and will not set when spread thin on the pad and exposed to air. Provided you use it within 30 minutes of mixing, MetaSEAL will set in the warmth and moisture of the canal. If you wish to monitor the set of the cement on the pad, fold the mixing paper over onto itself and place a heavy item on top of it. Place the paper in a location at about body temperature (37°C / 98.6°F). The cement will be isolated from the air, and should set in about 10-15 minutes.

QUALITY SYSTEM

Parkell’s quality system is certified to ISO13485/ISO9001. Material Safety Data Sheets (MSDS) are attached to these instructions, and can also be found at www.parkell.com.

WARRANTY

Parkell will replace defective material. **THIS WARRANTY IS IN LIEU OF ALL WARRANTIES OF MERCHANTABILITY, FITNESS FOR PURPOSE OR OTHER WARRANTIES, EXPRESS OR IMPLIED.** Parkell does not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described. Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection herewith.