

parkell[®]

SmarTemp[®]

Temporary Crown & Bridge Material

Instructions for Use

REF S337, S338, S340, S341,



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Rx Only—product is intended for use by a licensed dental professional. For Safety Data Sheet (SDS) go to www.parkell.com.

Description:

SmarTemp[®] Original and SmarTemp Dual Cure[®] are radiopaque, two-component, resin-based, provisional crown & bridge materials. SmarTemp Original is self-curing, and comes in a white cartridge. SmarTemp Dual Cure is both self-cured and light-curable, and comes in a black cartridge. SmarTemp products deliver high flexural strength for long span bridges, and excellent abrasion resistance to maintain proper occlusion, vertical dimension and interproximal contact during the provisional phase of treatment.

Indications for Use:

SmarTemp products are indicated for the fabrication of provisional resin inlays, onlays, laminate veneers, crowns or bridges.

Contraindications:

SmarTemp should not be used on patients with known sensitivity to methacrylates. If signs of tissue irritation such as redness appear, stop using immediately and consult a physician. Avoid contact with extra-oral soft tissues, skin or eyes. Contaminated skin or mucosa should be immediately wiped clean with alcohol, and then rinsed thoroughly with copious water. If eye contact should inadvertently occur, rinse the eye thoroughly with copious amounts of water and consult an ophthalmologist. Ingredients should not be swallowed. Use only as directed.

Pretreatment Considerations:

- All resins produce heat during polymerization. To avoid tissue irritation, provisional bridges containing a large volume of SmarTemp should be fabricated on a model outside of the mouth, or removed from the mouth at the onset of the rubbery stage. (See "Timing of Provisional Fabrication" section for more information on rubbery stage.)
- SmarTemp's setting properties are affected by temperature. If the material is stored in a refrigerator, it should be allowed to return to room temperature before use.
- To permit removal of the provisional restoration during fabrication on prepared teeth, all preparations should be lightly lubricated with a water-soluble lubricating gel or glycerin. Prep lubrication is essential to avoid "lock-on", especially if the preparation contains a composite resin core, has been sealed with a resin based bonding agent or has been desensitized with a resin-based, glutaraldehyde-containing desensitizer.
- Lubricants should be removed from the prepared tooth using acetone or ethyl alcohol prior to cementation of the provisional.
- Always block out undercuts to avoid lock-on.
- Always wear a face mask and goggles to prevent dust created during finishing from getting into the eyes and respiratory tract.

Timing of Provisional Fabrication:

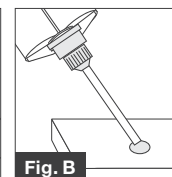
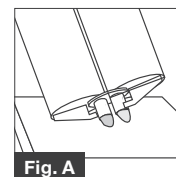
0:00 min	Start timer immediately before beginning to fill the matrix.
0:20 min	Matrix must be seated in mouth within 20 seconds of starting fill.
2:15 min	If rubbery, remove from mouth. If NOT rubbery, check again in 5 seconds.
3:15 min	If SmarTemp Dual-Cure is light-cured— light cure at $\geq 800 \text{ mW/cm}^2$ at 450-470nm for 20 seconds per surface and finish.
6:15 min	If SmarTemp (Original or Dual-Cure) is allowed to self-cure approximately 4 minutes after removing temp from mouth (when timer reads "6 min 15 secs", temp should be ready for finishing.

Note regarding timing:

- Times provided apply when SmarTemp is used at 23° C (Room temperature) Higher and lower room temperatures can shorten and lengthen these times respectively.
- For consistent results, bring cartridge temperature to 23°C and use a digital timer to strictly adhere to the timing recommendations above.

Directions for Use:

1. Create a pre-operative matrix using an impression, crown form, or plastic vacuum-form. If using SmarTemp Dual-Cure with a vacuum-formed clear plastic matrix, make sure to shield the material from the overhead light, to avoid premature curing.
2. To assure an accurate 1:1 mix, follow the "DOUBLE BLEED" procedure described below before each use of the cartridge.
 - a. Insert the cartridge into a "DS-50 (1:1 / 2:1)" impression gun (REF S343)
 - b. Remove the shipping cap, but do not discard as you will be using it later to recap and reseal the cartridge.
 - c. Express a small amount of material through both round orifices onto a pad (Fig A).
 - d. Attach a BLUE-base pointed mixing tip to the cartridge and bleed a small additional amount through the tip onto the pad (Fig B).
3. Start the timer and fill the matrix former by expressing SmarTemp directly from the cartridge.
4. Seat the filled matrix over the teeth in the mouth when the timer reads "20 seconds".
5. When the timer reads "2 minutes, 15 seconds" check the consistency of excess resin at the borders of the matrix. If it is rubbery, remove the provisional restoration from the mouth. If it is not yet rubbery, check the consistency every 5 seconds until it achieves a rubbery state and then remove it. If the restoration remains on the teeth when the matrix is withdrawn, gently remove it with a hand instrument or hemostat. **DO NOT LET IT FULLY SET IN THE PATIENTS MOUTH.**
6. If using SmarTemp Original, allow the provisional restoration to complete curing outside the mouth for approximately 4 more minutes, either on the bench or in lukewarm water. Avoid hot water, as it may cause distortion.
7. If using SmarTemp Dual-Cure, you may significantly accelerate the curing time by exposing the provisional restoration to a standard dental curing light (blue light with a wavelength between 450nm and 470nm) for 20 seconds per surface. Otherwise, the material will self-cure in approximately 4 more minutes.
8. Wipe the slippery oxygen-inhibited layer off the patient's teeth and the exterior and interior of the provisional using acetone or ethyl alcohol saturated onto an appropriately sized cotton pledget. Trim and polish the provisional.
9. If the prep is to be sealed apply as per manufacturers instructions now.
10. Cement the provisional with a cement appropriate for temporary restorations. If using a resin provisional luting product, resin based cores, sealers and desensitizers must be coated with a separating lubricant to prevent resin to resin "lock-on".



- Wipe the cap to remove any excess material prior to placing it back onto the MucoHard cartridge. This will prevent possible cross-contamination of the base and catalyst.

Making Additions to SmarTemp Provisional Restorations:

Corrections made immediately after fabrication may be made using more SmarTemp, light-cured flowable composite, or conventional composite, if the oxygen-inhibited layer has not been removed. Additions made after the provisional restoration has been in the mouth for a period of time will bond best if a thin layer of the restoration is first removed and the surface is primed with a “resin to resin adhesive” such as Parkell’s Add&Bond™

Troubleshooting:

- Product does not set:** Make sure you double-bleed the cartridge before each use. Also check the expiration date.
- Product leaves a slick coating on the tooth or the provisional:** This is normal behavior. See step 8 above.
- Product deforms in the matrix:** Provisional removed from matrix too soon. Follow timing recommendations above. If the material was cold, let it come to room temperature before use.
- Patient feels material heating up:** Do not leave patient alone during use of SmarTemp. Tell patient to alert you, either verbally or by raising their hand, when elevation of temperature is felt and remove provisional immediately from the patient’s mouth.

Storage:

Refrigeration is preferred to prolong shelf-life. However, for optimal setting characteristics, SmarTemp must warm to room temperature before use.

SmarTemp 50ml Kits Include:

- (1) 50ml automix split cartridge
- (10) Mixing Tips
- Instructions for use

Available Shades and Accessories:

- SmarTemp® Ultra Light (A1) [REF S337](#)
- SmarTemp® Light (A2) [REF S340](#)
- SmarTemp® Medium (A3.5) [REF S341](#)
- SmarTemp® Dual-Cure (A2) [REF S338](#)
- Blue Base Mixing Tip used with SmarTemp® and SmarTemp® Dual-Cure (30 tip refill) [REF S344](#)

Tips for Dental Practitioners for Cross-Contamination Control:

The following information should help dental practitioners reduce the risk of cross-contamination between patients when using multiple-use dental dispensers: apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient; use new, uncontaminated gloves when handling multiple-use dental dispensers; utilize dental assistants to dispense material for the dentist when appropriate; avoid contact of the reusable parts (e.g., the body of the multiple-use dental dispenser) with the patient’s mouth; do not reuse the multiple-use dental dispenser if it becomes contaminated; do not immerse multiple-use dental dispensers in a high level chemical disinfectant, as this may damage the dispenser and the material contained in the device; do not sterilize multiple-use dental dispensers, as this may damage the material contained in the device.

The cartridge and dispensing gun can be cleaned of debris with an EPA-registered low-level to intermediate-level hospital disinfectant. The used mixing tip should be discarded, and the original cap should be reattached to the cartridge to re-seal until next use. Utilize the surface disinfecting protocol of the disinfectant manufacturer. Consult www.CDC.gov for the most recent version of the “Guidelines for Infection Control in Dental Health-Care Settings”.

Disposal of Material:

Before disposal, the product should be fully mixed with the mixing tip, cured and then discarded in the general refuse. All cartridges and mixing tips may be disposed of in normal refuse.














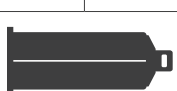

Events:

Reportable incidences should be reported to Parkell and the competent authority in which the user and or patient is established.

Warranty and Terms of Use:

For full Warranty and Terms of Use information, please go to www.parkell.com. Safety Data Sheets (SDS) are available at www.parkell.com. Parkell’s Quality System is certified to ISO 13485.

Explanation of Symbols Used

	• Professional use only
	• Follow instructions for use
	• Temperature limit
	• Store product tightly sealed away from direct sunlight.
	• Use-by date (expiration)
	• Batch code
	• Catalogue / stock number
	• Unique Device Identifier
	• Medical Device
	• Package contents
	• Do not use if package is damaged
	• Single use only
	• Manufacturer
	• 50ml Split Cartridge / paste
	• Mixing Tip