



Instructions for Use



(REF D700SE-110, REF D700SE-230)

A00619revD0321

Device Description

The Sensimatic® 700SE Electrosurge is a dental electrosurgery unit that features a low-impedance, high radiofrequency (1.4 – 1.7 MHz) to cut and coagulate soft tissue.

Indications/Intended for Uses

The Sensimatic 700SE is useful in numerous routine restorative and operative dentistry procedures including:

- Access to subgingival caries
- Removal of inflamed marginal tissue prior to
- Crown cementation
- Bleeding control and coagulation
- Troughing for crown impressions
- Pericoronal flap excision
- Edentulous ridge recontouring and tissue trimming
- Sculpting tissue for acceptance of an ovait pontic.
- Excision of hyperplastic and hypertrophic tissue
- Gingivectomy/gingivoplasty
- Frenectomy
- Esthetic tissue recontouring
- Exposing teeth for orthodontic eruption

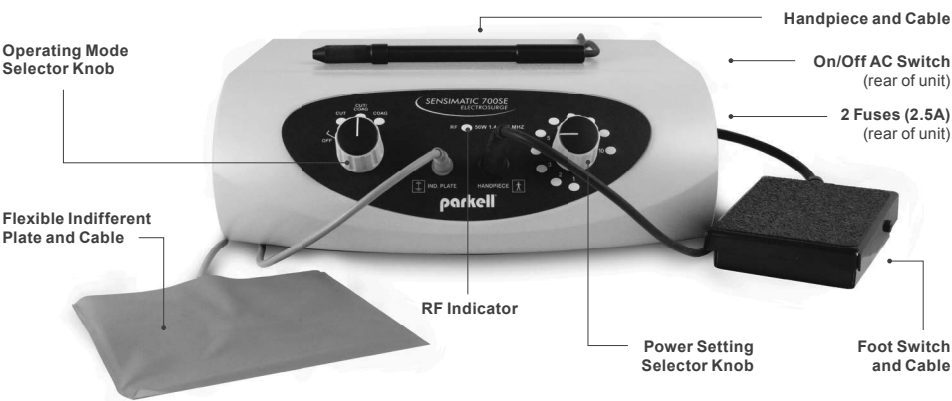
- Periodontal flap surgery
- Controlling localized bleeding
- Tissue biopsy
- Crown lengthening
- Implant surgery—**IMPORTANT NOTE:** Although electrosurgical devices allow clean, smooth incisions with lessened bleeding, they are recommended only for first-stage, implant placement surgery. Metal implants should not be touched with an active electrode. Therefore, use of these devices in later stages of implant surgical procedures is to be avoided.

Contraindications

Because of the potential for electromagnetic interference, this device should not be used on patients or by clinicians with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic devices, or in close proximity to sensitive patient monitoring devices such as pulse oximeters.

If patient or operator is pregnant, or has any medical condition which might be affected by this device during treatment, consult a physician prior to use.

In the event of any adverse reaction from the patient, discontinue the scaling procedure.





Warnings

- **DO NOT OPEN CASE: NO USER SERVICEABLE PARTS INSIDE.**

- Internal repairs are to be made only by Parkell personnel. To avoid the risk of electric shock, this equipment must only be connected to a properly grounded electrical outlet.
- Always exert caution during use. Electrosurgery units are designed to allow controlled destruction of soft tissue and must be used carefully.
- Do not use in any situation where the electrode will touch metal restorations, implants, bone or teeth as this may result in electric shock, bone necrosis or implant rejection.
- Stop use immediately at the first sign of tissue blanching and avoid prolonged tissue contact. Allow tissue to cool for an appropriate interval between cuts. Excessive exposure may retard healing and cause sloughing.
- Do not use in the presence of flammable or explosive gases. Use of dental nitrous oxide/oxygen analgesia is acceptable. Solvents of adhesives should be allowed to

evaporate before the use of electrosurgery. Some material may be ignited by sparks produced in normal use of the equipment (for example, cotton wool and gauze when saturated with oxygen). Endogenous gases may be ignited by electrosurgery.

- The unit should not be immersed in water or other liquids. Avoid placing where it can fall or be pulled into liquid. Do not reach for the device if it has fallen into liquid. Do not use the device after it has fallen into liquid. Return it to Parkell for servicing.
- Do not open the case of the unit—there are no user serviceable parts inside.
- Do not modify this device. Modification may violate safety codes and endanger patient and operator. Any modification will void the warranty.
- Interference produced by the operation of high frequency surgical equipment may adversely influence the operation of other electrical equipment. In case of interference, de-energize unit and increase distance to susceptible equipment. Connection to a different power circuit may also reduce interference.

Clinical Precautions

- **Caution:** Do not operate the electrosurgery unit without using the patient indifferent pad. The pad should not touch the patient's bare skin, but should always have a thin layer of clothing between it and the skin.
- **Caution:** Always turn power off before touching the electrode. After locking the electrode in the handpiece, examine it carefully to assure that the metal shaft is fully seated with no metal exposed at the base.
- **Caution:** Be sure the handpiece, cable and electrodes are completely dry before using. Inspect the handpiece and cables regularly to ensure their integrity.
- **Caution:** Before each use, inspect the electrode to assure that the plastic sheathing (insulation) covering the metal shaft is intact. Do not bend the electrode where it is insulated, as this may crack the plastic sheath.
- **Caution:** Release footswitch before inserting or removing the handpiece from the patient's mouth.
- **Caution:** Do not allow cables to be coiled or twisted around metal objects.

Conformance to Standards

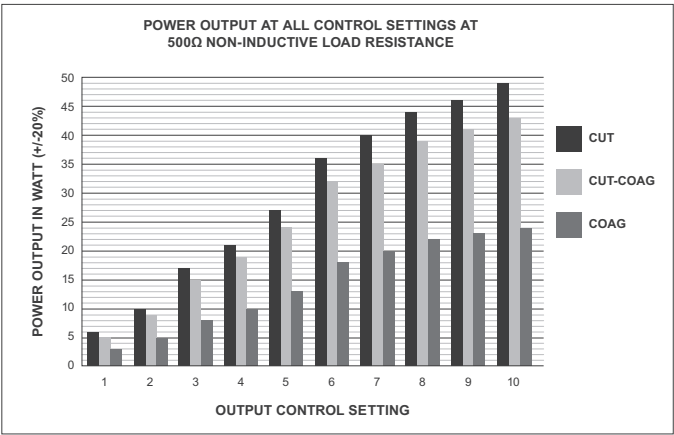
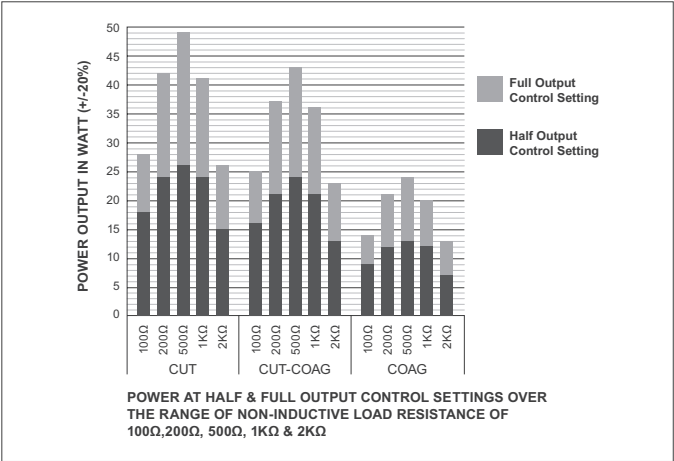
The Sensimatic 700SE Electrosurge is ETL listed and conforms to IEC 60601-1, 60601-1-2 and 60601-2-2. Parkell's quality system is certified to ISO13485. Certified to CAN/CSA C22.2 No. 601.1.

What's Included

- (1) Sensimatic 700SE power unit
- (6) Different Electrodes; Scalpel Point—T2, Large Loop—T5, Vertical Loop—T8, Horizontal Loop—T16, Hemostasis Ball—C3, Troughing Point—AP1.5
- (1) Foot switch
- (1) Handpiece and cable
- (2) Self-stick handpiece holding clips
- (1) Indifferent Plate and Cable
- (1) AC Power Cord
- Operator's Manual / Instructions for Use

Specifications

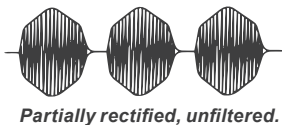
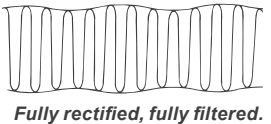
- Power Requirements:**
Line Voltage: 120 Volts
+/- 10% AC, 60 Hz,
2 amps maximum
- Optional:** 100 Volts
+/- 10% AC, 50/60 Hz,
2 Amps maximum, 230
Volts +/- 10%, 50/60 Hz,
1.2 amps maximum
- Fuses:** T2.5AH, 250 V,
5x20mm (Both line and
neutral fused)
- Operating Frequency:**
1.4 -1.7 MHz (megahertz)
- Maximum Power
Output:** 50 Watts rms
(@ 500 Ohm load)
approximate
- Maximum Output
Voltage (no load):**
300 Volts rms
- Operating
Environmental
Conditions:** 10-35°C,
30-75%rh, 700-1060hPa
- Transport and Storage
Conditions:** 10-43°C,
10-90%rh non-condens-
ing, 500-1060hPa)
- Unit Size:**
3 ¼" H x 7 ¾" D x 9 ¼" W
(83mm x 191mm x
235mm)
- Weight:** 6.1 pounds
(2.8 kg)
- The attachment plug is used as the mains disconnecting device.



High-Frequency (RF) Output Modes

The Sensimatic generates three different high frequency waveforms. Each has differing surgical characteristics, which cause different histological effects on soft tissue.

- RF Mode No. 1 – “CUT MODE” (cutting with least coagulation):** A filtered, unmodulated current for cutting with the least amount of coagulation. Suited for closed wound surgery where incisions will be sutured.
- RF Mode No. 2 – “CUT/COAG MODE” (cutting with balanced coagulation):** A fully rectified, modulated, undamped current for cutting with coagulation when control of bleeding is desired. It is the most widely employed current in dentistry and is suited for cutting procedures where incisions will not be sutured.
- RF Mode No. 3 – “COAG MODE” (full coagulation without cutting):** A partially-rectified current for coagulation without cutting. This waveform has been found most effective for precise pin-point surface coagulation with minimal tissue destruction.



Get the Most Out of Your New Parkell Electrosurgical Device

If this is your first electrosurgery device, we've got a few simple tips to improve the treatment outcome, protect your warranty, and assure that your unit runs right for a long time.

- Always use the indifferent electrode plate provided with the unit to assure that the least amount of power is required for the procedure being performed. Lower power means less tissue trauma, less post-operative pain and shorter healing times for the patient.
- Fully insert clean, tissue-free electrodes into the handpiece to assure that they transmit all power directly to the patient. Replace electrodes when necessary to maintain performance.
- Electrosurgery is best performed on moist (but not wet) gingival tissues. Dry tissues will cause the electrode to drag, and will require higher power to cut properly.
- Proceed slowly and carefully. Remember, you can always remove more tissue, but you can't add tissue if you remove too much.
- Work under adequate anesthesia whenever using the electrosurgery device.
- Use high volume evacuation to control burnt tissue odor, and low volume evacuation to manage irrigating fluid accumulation in your patient's throat.
- **PARKELL'S ELECTROSURGERY DEVICES SHOULD NOT BE ALTERED BY THE USER IN ANY WAY. FOR EXAMPLE, NEVER CUT OR REMOVE THE COMPANY-INSTALLED FOOT-PEDAL CORD, TO SHORTEN OR LENGTHEN IT. UNAUTHORIZED CHANGES TO THE UNIT WILL INSTANTLY VOID YOUR WARRANTY.**

If you need a special cord length, or if you have any questions about your new unit, please E-mail our Technical Support Service at: techsupport@parkell.com.

Instructions for Use

CONNECTING THE UNIT:

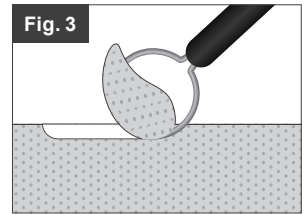
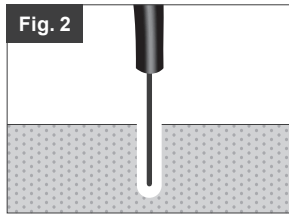
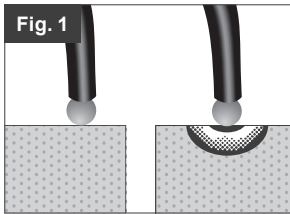
1. Locate the device where it will be convenient. Make sure the AC power rocker switch in the rear of the unit is in the OFF position before connecting the power cord. Plug power cord into the back of unit and then plug the power plug into a grounded electrical outlet. **NEVER OPERATE THE UNIT WITHOUT COMPLETE AND PROPER GROUNDING.**
2. Plug the patient indifferent plate and surgical handpiece into the matching color-coded sockets on the front panel.
3. The patient indifferent plate must be used for all dental procedures. The entire area of the disper-

sive electrode should be placed in firm, nonconductive contact with the patient, preferably against the patient's upper back, contacting the maximum possible area. Do not place the indifferent plate in contact with bare skin. Do not attach the indifferent plate to metal frame of chair. The patient, operator or assistant should not come into contact with metal parts, such as metal arm rests of chairs. Use only non-conducting (plastic) instruments (mirror, retractor, saliva evacuation tube, etc.) when performing procedures.

4. Make sure the unit is turned off before touching or changing electrodes. Select the appropriate electrode for the procedure and make sure the metal electrode is clean, and that the plastic sheathing (insulation) is in good condition. Insert electrode into surgical handpiece, making sure it is fully seated with no metal shaft exposed. Turn the collar of the handpiece until electrode is locked in place.
5. Push the AC rocker switch on the rear of the unit to the ON position. Turn the mode selector knob on the front panel from OFF to the chosen operating wave form and the power output knob to select the power for the case at hand. The appropriate indicator LEDs will light to show that the unit is on. Always verify settings before using.

OPERATING THE UNIT:

1. Always verify power settings before use.
 - a. Use the lowest possible power setting for the procedure at hand. Once the power is set, the 700SE's power output is adjusted automatically by the unit in response to the tissue condition at the operative site. This eliminates the need for repeated minor power adjustments.
 - b. For coagulation with ball electrodes, an appropriate initial power setting is "3" (Fig. 1). Coagulation is related to the length of time the electrode is in contact with the tissue, the size of the electrode, the circular or spotting motion used during tissue contact and the power level. Whitish blanching at the site indicates coagulation has occurred.
 - c. For incisions using needle-type electrodes, an appropriate initial power setting is "4" (Fig. 2).
 - d. For excisions using small loop-type electrodes, an appropriate initial power setting is "5". (Fig. 3)
 - e. When using larger loop electrodes, an appropriate initial power setting is "6".
 - f. For fulguration (carbonization of tissue), use mode #1. An appropriate initial power setting is "8".
 - g. If a clean electrode drags during cutting, or if hemostasis does not occur during coagulation, increase the power to the next higher setting until desired therapeutic results are achieved.



2. Good hand support and finger rests are necessary before tissue is contacted. To activate the handpiece, assure that the electrode is safely positioned within the surgical field and depress the foot pedal. When the handpiece is active, the green RF indicator LED will light and an audio tone will sound.
3. Tissues being operated upon should ALWAYS be slightly moist to dissipate heat and maintain conductivity. However, excess moisture will lessen effectiveness and may cause patient discomfort. The right moisture balance makes for the best treatment.
4. Local anesthesia is indicated for all electrosurgical treatment.
5. To avoid minor shocks, use only non-conducting (plastic) instruments (mirror/retractor,
6. Saliva evacuation tube, etc.) when performing electrosurgical procedures.
7. Operate with the electrode tip as perpendicular as possible to the plane of surgical intervention. Keep the electrode in constant, controlled, uninterrupted motion. Cut with a light, smooth, even stroke. Avoid electrode penetrations of more than 1mm in depth. For deep incisions, make repeated shallow penetrations with a back and forth, wiping stroke, and allow approximately 10 seconds between incisions for the tissue to cool.
8. Periodically wipe carbonized tissue tags from the electrode with an alcohol-moistened wipe, making sure to de-energize the unit first by removing your foot from the foot pedal. The electrode must be clean to maximize the precision of the incision.
9. Familiarize yourself with the use of the Sensi-matic 700SE Electrosurge by practicing on a fresh piece of moist, lean beef or pork at room temperature. Cover the indifferent plate with a plastic bag and place the meat directly on top of it. Work in a well ventilated area to avoid breathing the cutting fumes.

Important Information About Electrodes

- **ALWAYS TURN THE POWER UNIT OFF BEFORE TOUCHING OR CHANGING ELECTRODES, AND KEEP YOUR FOOT OFF THE FOOT PEDAL DURING THIS PROCEDURE.**

- Before each use, make sure the plastic insulation sheathing covering the electrode is completely intact. Replace the electrode if damaged. Check the integrity of the handpiece and cable at this time as well.
- Make sure the electrode is fully seated in the handpiece (with no metal shaft exposed) and is locked in the handpiece.
- **DO NOT BEND THE METAL SHAFT OF THE ELECTRODE**, as you may damage the plastic insulation sheathing. If you want to alter the shape of the bare metal cutting portion of the electrode, do so only before its first use by bending the cutting wire at the end of the electrode away from the start of the insulation, using the appropriate orthodontic plier, to avoid nicking or breaking the wire.
- Electrodes must be kept spotlessly clean. Dirty electrodes will impair their function, and cause unnecessary tissue damage. Between uses, wipe electrodes clean with an alcohol-moistened pad to remove charred tissue.
- While electrodes may be autoclaved several times, they are a consumable item, and are meant to be periodically replaced. They are not covered by the warranty.

Odor Control

Clinical use of electrosurgery generates fumes from the tissues being treated, which will create unpleasant odors in the operator. This should be explained in advance to the patient. Use of high volume oral evacuation equipment by the dental assistant during surgery will remove most of the odor. Air fresheners sprayed in the room prior to surgery will also help to minimize odors. You may also find it helpful to apply a small dab of mentholated petrolatum ointment (e.g. Vicks® VapoRub®) on the upper lip of the patient to mask odors.

Common Clinical Problems and Their Causes

- **Excessive elimination of tissue or excessive thinning of a gingival collar.**
 - Improper electrode selection (e.g. using a wide loop electrode on the labial surface of lower anterior teeth where a straight needle electrode is indicated).
 - Power set too high.
 - Poor surgical technique or case selection.

■ **Dragging electrode action (even at the recommended dial setting).**

- Dirty electrode.
- Excessively dry field.
- Too deep tissue penetration (more than 2mm).
- Failure to use the indifferent plate.
- Inadequate contact between the patient and indifferent plate (sometimes due to extra thick clothing).
- Impediment at site of contact.
- Power set too low.

■ **Retarded healing or tissue sloughing.**

- Power set too high.
- Dirty electrode.
- Electrode penetration too deep.
- Electrode movement not controlled well by operator (e.g. motion too slow, erratic electrode motion, staying too long in one spot, picking or pecking at tissue). Use a constant, controlled, even motion.
- Poor moisture control—operative site must be moist, but not too wet.
- Poor surgical technique or case selection.

Cleaning and Infection Control

- Rinse the Handpiece and Electrodes under warm running water for 30 seconds to remove any external or internal soil or debris.
- Using a soft soapy cleaning brush to assist in the cleaning, if necessary. Use non-ammoniated detergent or dishwashing soap. Do not use ammoniated cleansers or disinfectants.
- Rinse the item again under warm running water for 30 seconds to remove any residual soap and blot dry with a dry lint-free towel.
- Wipe device with a lint-free towel that has been saturated in an EPA-approved, hospital-grade intermediate or high-level disinfectant (minimum 2.5% Glutaraldehyde solution), following the instructions for use provided by the disinfectant manufacturer.
- Dry with a dry lint-free towel.
- Handpiece and Electrodes may be sterilized in any conventional steam autoclave following manufacturer's instructions. A typical steam sterilization cycle is 132 +/- 2°C for 4 minutes (Vacuum), or 132 +/- 2°C for 15 minutes (Gravity), followed by a 15-minute minimum cool-down period.
- Use a steam sterilization pouch that is compliant with ISO 1140-1 Type 4 and 11607 standards. Once items are sterilized, adhere to the shelf-life specified by the pouch manufacturer. After sterilization, inspect the device in the autoclave bag for integrity. If suspicion about the item exists, discard it and order a replacement from Parkell or your dealer.

• **DO NOT USE DRY HEAT OR CHEMCLAVE ON THE HANDPIECE AND ELECTRODES.**

Service and Parts

Within the U.S., all repairs must be made by Parkell. Outside the U.S., repairs must be made by a Parkell-authorized facility.

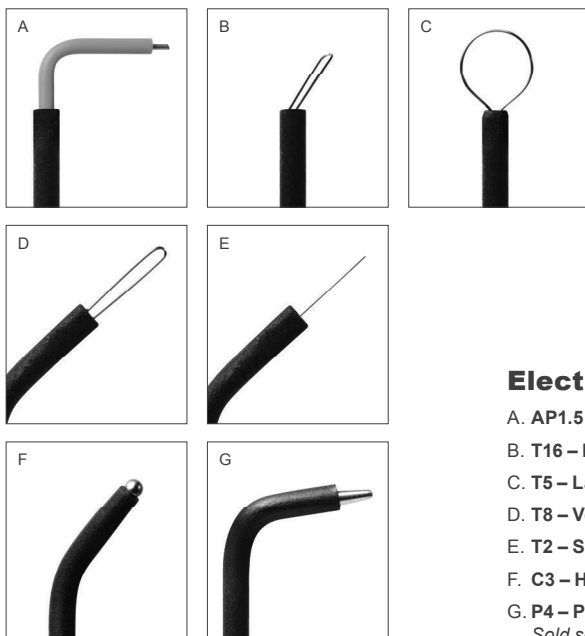
Complete service and parts facility exists at Parkell, Inc., 300 Executive Drive, Edgewood, NY 11717. Equipment needing service should be returned, freight pre-paid via United Parcel Service and insured for original purchase price. Include unit with all accessories, except electrodes. Ship in original carton. Add plenty of cushioning material and over-box to protect your unit during shipping.

REPLACEMENT PARTS

- Electrode Handpiece with cable (REF D702)
- Patient Indifferent Plate with cable (REF D703)
- Patient Indifferent Plate (REF D634)
- Interchangeable Dental Electrodes (See page 7. Not shown at actual size).

Recommended Electrodes for Specific Applications

- **Access to Subgingival Caries**—Provides a clean, dry restorative field; #T2, #T8, #T16.
- **Cementing Restorations**—For more retentive cementation; #T5, #T8, #T16.
- **Bleeding Control and Coagulation**—For a cleaner operative field; #C3, #P4.
- **Widening Gingival Sulcus**—Provides space for impression material beyond prep margin; #AP 1.5, #P4.
- **Lengthen Clinical Crowns**—To create a workable clinical crown length; #T2, #T8, #T16.
- **Esthetic Tissue Contouring**—For a more esthetic appearance; #T2, #T8, #T16.
- **Recontour Edentulous Ridges**—To make impression taking more accurate and comfortable, or for the preparation of ovate pontic sites; #T2, #T5, #T8, #T16, #P4.
- **Removal of Hyperplastic and Hypertrophic Tissue**—Ideal in case of medication-induced gingival hyperplasia; #T2, #T5, #T8, #T16, #P4.
- **Pericoronitis**—To expose partially-erupted third molars; #T5, #T8, #T16.
- **Performing Gingivectomy or Gingivoplasty**; #T2, #T5, #T8, #T16, #P4.
- **Frenectomy**—Relieve excess muscle tension and tissue pull and improve esthetics; #T2.
- **Exposing Teeth with Delayed Eruption**—Allow orthodontic eruption to proceed; #T2, #T5, #T8, #T16.



Electrodes:

- A. **AP1.5 – Troughing Point** (REF S397-AP1.5)
- B. **T16 – Horizontal Loop** (REF S397-T16)
- C. **T5 – Large Tissue Shaving Loop** (REF S397-T05)
- D. **T8 – Vertical Loop** (REF S397-T08)
- E. **T2 – Scalpel Point** (REF S397-T02)
- F. **C3 – Hemostasis Ball** (REF S397-C03)
- G. **P4 – Proximal Hemostasis Tip** (REF S397-P04).
Sold separately, not included with unit.

• **Performing Tissue Biopsy**— Controlled removal of suspect lesions with minimal tissue damage; #T2, #T5.

• **Exposing Pre-Placement Implant Sites**— For fast exposure of the implant placement site; #T2, #T8, #T16. **IMPORTANT: AVOID CONTACT WITH THE BONE.**

• **Periodontal Flaps**— Controlled, sharp incisions for better healing; #T2.

• **Controlling Bleeding of Nicked Gingival Papillae**— For accurate impressions after crown preparation; #P4.

• **Reshaping of Gingival Sulcus into Healthy U-shape**—After crown preparation; #P4.

• **Pericoronitis**— To expose partially-erupted third molars; #T5, #T8, #T16.

• **Performing Gingivectomy or Gingivoplasty**; #T2, #T5, #T8, #T16, #P4.

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• **Reshaping of Gingival Sulcus into Healthy U-shape**— After crown preparation; #P4.

Warranty and Terms of Use

For full Warranty and Terms of Use information, please see www.parkell.com. Parkell's Quality System is certified to ISO 13485.

Electrodes are meant to be periodically replaced and as such are not covered by the warranty.

Explanation of Symbols Used

	Qualified User Symbol
	Serial Number
	Catalogue / stock number
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Non-Sterile
	Temperature limitations
	Do not use if package is damaged
	Follow instructions for use
	Keep dry
	Do not dispose this product into the ordinary municipal waste or garbage system
	Package contents
	Manufacturer
	Referenced to ground at high frequencies
	Protective Earth Connection
	Type BF Equipment
	Dangerous high voltage

This precision dental device was designed,
manufactured and is serviced in the United States of America by:



 300 Executive Drive, Edgewood, NY 11717
Toll-Free: (800) 243-7446 • Phone: (631) 249-1134 • www.parkell.com

