

INSTRUCTIONS FOR USE

parkell®

INTEGRA™

ULTRASONIC SCALER

REF D680

A00545revE0220

DEVICE DESCRIPTION

The Parkell Integra™ is a magnetostrictive, auto-tuning, ultrasonic tooth scaler that operates at either 25 KHz or 30 KHz. It has an integrated, two-bottle, pump-driven fluid supply, and is also capable of obtaining fluid from an external water supply. The Integra automatically detects whether the handpiece contains a 25 KHz or 30 KHz insert, and switches to the correct operating frequency. The Integra has an expanded low-power range to improve patient comfort, and a power-boosting, user-controlled TURBO feature to increase scaling power when needed for heavy deposits.

INTENDED USE/INDICATIONS

For removal of calculus, plaque and oral debris from teeth during dental prophylaxis/scaling.

CONTRAINDICATIONS TO USE

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.

IMPORTANT INFORMATION REGARDING USE OF NON-PARKELL INSERTS:

The unit is designed to work with Parkell inserts. For information about usage with non-Parkell inserts, please see our warranty policy.

WARNINGS

- The water supply to the scaler should always be turned off whenever the device is being connected, disconnected, or when not in use.
- Do not run this device dry. Water must always flow through tip during use to cool handpiece and insert.
- The power supply line cord functions as the AC power disconnect device for the scaler.
- The transformer should be located above and away from any sources of water. As with all electrical devices, the unit should not be immersed in water or other liquids. Do not reach for the device if it has fallen into liquid until power is disconnected, and do not use the device after it has fallen into liquid. Return the device to Parkell for servicing.
- Modification of this device will void the warranty, and may violate safety codes, endangering the patient and/or the clinician.
- This equipment is not suitable for use in the presence of a flammable anesthetic gas mixture (when used along with air or oxygen).
- This equipment produces electromagnetic energy and may cause interference with other nearby electronic devices. Should this occur, changing the position or location of the device may be necessary.

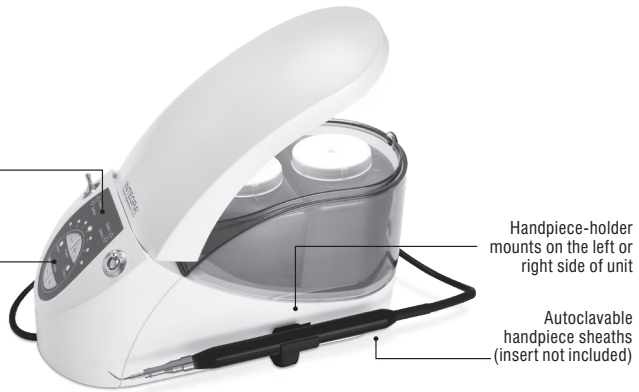


Shown with Parkell's Burnett Power-Tip Insert (not included)

Automatically adjusts operating frequency to match either 25KHz or 30KHz inserts

Easy-to-clean touch panel resists all standard disinfectants

Digital fluid and power controls mean fast, precise settings (use the Smart Foot Pedal for hands-free power adjustment)



Handpiece-holder mounts on the left or right side of unit

Autoclavable handpiece sheaths (insert not included)

CLINICAL PRECAUTIONS

- Protect patient's eyes, lips, cheeks, tongue or other vulnerable tissues from contact with the vibrating scaler tip.
- Protect the patient's clothing from water damage when using this device.
- Clinicians should wear eye protection and facemask when using this device.
- Keep the long axis of the insert tip parallel to the long axis of the tooth while maintaining gentle contact with the root to "wipe" deposits from the tooth. Prolonged perpendicular contact between the insert tip and the tooth will damage the tooth by gouging it.

INDIVIDUALIZATION OF TREATMENT

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.

THE INTEGRA IS SUPPLIED WITH:

- (1) Magnetostrictive Scaler Control Unit with integrated, pump-driven, two-bottle water supply, attached handpiece, foot controller and water line (with male quick-connect coupler).
- (1) Detachable Foot Controller.
- (2) Autoclavable handpiece sheaths (one attached) (REF D576).
- (2) Fluid Bottles with screw-on caps.
- (1) Bottle Lock.
- (2) Inline water filters (one attached to water line) (REF D419).
- (1) Transformer with cable (REF D408/GS257-120V, D403/GS438-230V).
- (1) Instructions for Use

INSERTS

The unit is designed to work with Parkell inserts. For information about usage with non-Parkell inserts, please see our warranty policy at www.parkell.com.

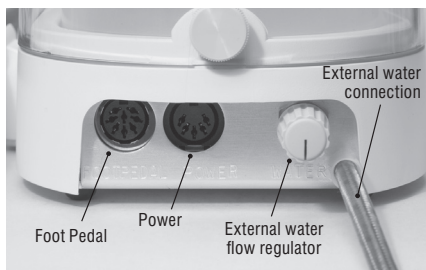
The scaler automatically adjusts the operating frequency to match that of the insert in the handpiece without operator intervention. Brand new inserts may initially fit tightly in the handpiece, and may be inserted and removed more easily by using a slight twisting motion, or by lubricating the insert "O" ring with water. Old, worn or blunt inserts will scale poorly and generate excess heat, and should be replaced when necessary.

SPECIFICATIONS

- Operating frequencies – 25KHz and 30KHz.
- Operating temperature – between 50°F (10°C) and 95°F (35°C).
- Operates at relative humidity of 10-80% (non-condensing).
- Weight: 35 oz. / Dimensions: 5" W x 6" H x 11.5" D.
- Power: 120VAC model - 60 Hz, 120VA / 230VAC model - 50 Hz, 120VA / 100 VAC model – 50/60 Hz, 120VA.
- Transport and storage conditions: 10-40°C, 10-80% RH (non-condensing).

ADDITIONAL SPECIFICATIONS

- Protection against electric shock: Class 1, Type B applied part.
- Protection Against Ingress of Liquids
 1. Foot Switch & Scaler - IPX1 (drip-proof).
 2. Power Supply - IPX0 (ordinary).
- Mode of operation of equipment: Intermittent – 66% duty cycle, 10 minutes on, 5 minutes off.



USING THE INTERNAL FLUID SUPPLY BOTTLES

The Parkell Integra is equipped with two internal bottles which can supply the fluid that flows through the handpiece for cooling and lavage during use. The bottles may be filled with drinking-quality water, or diluted with anti-microbials at a ratio of 4 parts water to 1 part chlorhexidine or mouthwash. If fluids other than water are used in the bottles, the system should be flushed with plain water after each use.

To fill the bottles:

1. Open the Integra cover. You will see two bottles, with the bottle-lock holding them in place.
2. Using finger and thumb, gently squeeze the two retaining lugs of the bottle-lock and remove it from the unit.
3. Remove the bottles from the unit. Unscrew and remove the caps from them.
4. Fill the bottles up to the fill line marked on the side.
5. Replace the caps on the bottles, making sure they are screwed on all the way.
6. Replace the bottles in the rear of the Integra, making sure they are standing upright in the base of the unit.
7. Replace the bottle-lock over the bottles. Look for the word "Top" on the bottle-lock to make sure it is in correctly. As before, using finger and thumb, squeeze the two retaining lugs and gently press the bottle-lock down. Release the lugs. They should locate into the side of the clear cover and hold the bottles firmly in place.
8. Completely close the Integra lid. If not fully closed, the unit will not be able to draw fluid from the bottles.
9. Monitor the fluid level in the bottles regularly during use and refill as required. A constant fluid flow is necessary for correct operation of the Integra during scaling.



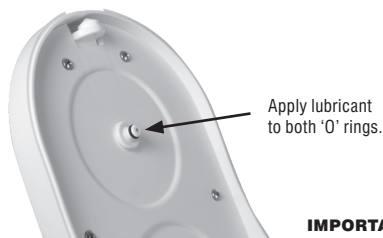
INSTALLING THE SCALER

Locate the device where the control panel will be easy to reach during scaling procedures, and where the water filter at the rear of the unit may be periodically changed without difficulty. The scaler requires access to a grounded electrical outlet and an optional connection to a source of drinking-quality water from the building water supply. Alternatively, the unit may receive fluid exclusively from the internal bottle supply.

WATER CONNECTION

If the clinician chooses to operate the Integra on city water, before plugging in the device, they should connect the scaler's water line through the included filter disk to a drinking-quality water supply (15-35 psi optimal), free of sediment, at room temperature. An external, office-wide water filter is recommended to minimize frequent changes of the device's in-line water filter. The male quick-connect that comes on the end of the water hose is the standard fitting presently used in the dental industry. If you are replacing a scaler that uses an Adec-type or other type of connection, remove the old fitting from the unit hose and attach it to the new water line. Check for leaks at all hose and filter connections before use, and tighten if necessary.

Bottle-Lock
(DO NOT DISCARD)



IMPORTANT:

The lid must be closed completely for the unit to function correctly with the internal fluid system. If the lid does not close completely or it sticks, then the two black 'O' rings on the underside of the cover may be dry and require a little lubrication. Apply a **very thin layer** of Vaseline to each 'O' ring with a Q-Tip. Just a thin layer is all that is necessary.



CONTROLLING THE FLUID FLOW

The water source is selected using the two toggle switches on the front of the unit.

- The left switch selects the fluid source between “External”, from the rear connector to the city water, or “Internal”, from the bottles inside the Integra.
- The right switch selects the fluid source between the “Front” or the “Rear” bottle.

When using the internal bottle water source, room temperature, sterile, deionized or distilled water is preferred. 4 parts water may be mixed with 1 part FDA-approved mouthwash for a pleasant-tasting irrigation fluid.

The fluid-control buttons on the touch panel control the output of the pump from the internal bottles only. If you are using an external water source, water flow is adjusted using the water control knob on the back of the unit.

If you are using the internal bottles as a fluid source, the flow is controlled by using the WATER (+) and (–) buttons on the touch panel at the front of the unit. When you press either button the display will start to flash to indicate that it is now showing the water flow rate (1 is the lowest; 7 is the highest). As you hold the button the flow will change as shown by the display. When you release the button the display will return to showing the power level after a few seconds. When in operation, the sound of the pump will speed up or slow down depending on the fluid flow setting. If fluid does not flow through the insert when the foot pedal is depressed, consult the Troubleshooting section later in these instructions.

HOW TO REPLACE THE FILTER DISK

If an external water source is used, the water filter disk on the rear hose of the unit should be replaced every 3-4 months, or when it becomes dark or clogged with debris, or when water flow is impeded. Replacement filters are available from Parkell (REF D419 – ten per package). To change the filter:

1. Make sure all water valves from the water supply to the Integra are shut off before changing the filter.
2. Disconnect the scaler water supply hose from the water supply at the quick-connect.

3. Remove the old filter disk by holding it in one hand and twisting off the hose connectors on either side. They rotate in opposite directions.
4. Install the new filter disk in the same position as the old one, and tighten the connectors by hand in reverse. Do not use a tool.
5. Reconnect the scaler water supply hose to the water supply via the quick-connect, open the control valve and check for leaks.
6. Note: If the filter becomes clogged and you do not have a replacement disk, the hose connectors may be locked together TEMPORARILY without the filter disk to allow emergency operation only.

ELECTRICAL CONNECTION

The scaler must only be powered via the Transformer Assembly that is supplied with the device by Parkell. The scaler and its separate transformer generate a minimal amount of heat. Avoid covering them, to allow normal cooling.

1. Plug the transformer power cord connector into the “PWR” receptacle on the back of the scaler, with the arrow on the plug on top.
2. Plug the foot pedal into the “FTPEDAL” receptacle on the back of the scaler, with the arrow on the plug on top.
3. Plug the transformer power cord into a grounded electrical outlet.

USE OF AUTOCLAVABLE SHEATHS AND ULTRASONIC INSERTS

1. The Integra handpiece is provided with the autoclavable handpiece sheath attached. Prior to use, the sheath should be removed and sterilized in a steam autoclave. To remove it, hold the handpiece at the base with one hand and turn the sheath counter-clockwise with the other, taking care not to twist or damage the hose. The sheath will unscrew and slip off. Confirm that the orange O-ring is still present on the end of the handpiece.
2. To replace the sheath, lubricate the O-ring on the handpiece with water to assure a good seal. Slide the sheath over the handpiece carefully to avoid damaging or dislodging the O-ring and gently thread the sheath onto the handpiece clockwise, until there is no gap between the two. Do not overtighten.

TURNING THE SCALER ON AND OFF

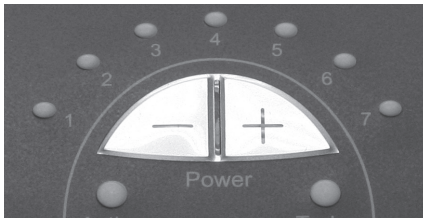
To turn the scaler on, press any button on the touch panel. The display will illuminate to indicate that the scaler is on.

To turn the scaler off, press the WATER minus (–) button and the POWER minus (–) buttons at the same time. The display will go out, indicating that the unit is off. The unit will remember any settings you made when it is turned on again.

Press the foot-pedal to activate the scaling function. Release the foot-pedal to deactivate. Whenever you release the pedal, the ACTIVE light on the front panel will instantly turn off. If you were scaling in the TURBO mode, the TURBO light will also turn off.

To conserve power, the Integra will go to “sleep” if it is not used for about 30 minutes. The display will go out and the unit will not respond to the foot pedal. To “wake up” the Integra, simply press any of the buttons on the touch panel.

SAFETY NOTES: Turning off the POWER does not shut off the external water connection. Make sure to turn off any external water sources to the Integra every time you are not using the unit. The pedal should be placed where it will not accidentally be pressed when the device is not in use.



When you adjust the power using either the touch panel or the foot pedal, color-coded lights indicate the operating power.

CONTROLLING THE POWER OUTPUT

The Integra gives you three ways to adjust the scaling power: The POWER (+) and (-) buttons on the touch panel at the front of the unit, the silver-colored POWER button on the foot pedal, and the TURBO mode. When you adjust the power using any of these methods, color-coded lights on the touch panel indicate the operating power setting and mode.

Use the POWER (+) and (-) buttons on the touch panel to set the initial power for the scaling procedure at hand. Power is usually set at 3 – 4 to start. The color-coded LEDs will show the current power setting. When the foot pedal is partially depressed (to the first position), the insert will begin vibrating and water will flow.

If the Power is set for the 1 – 2, the blue “Perio” lights will illuminate, and the tip will vibrate at a much lower power than a traditional scaler when the foot pedal is depressed. This allows more comfortable debridement for sensitive patients.

You can also adjust the power by depressing the POWER button on the top of the foot pedal with your foot. If you press and release (tap) the button, the power will increase by one step (i.e. from 4 to 5 as shown by the display). If you press the button and hold it down, the power will decrease in steps. In either case, the color-coded LEDs will show any change in the current power setting.

Note: There is a small switch on the rear of the foot pedal to allow you to enable or disable the POWER button. If the switch is in the UP position, the POWER button is enabled. If the switch is in the DOWN position, it is disabled.

THE TURBO MODE

For short-term increases in power during scaling, simply increase foot-pressure on the pedal. The TURBO light will illuminate. This will instantly boost scaling power to a point midway between the current setting and the scaler’s maximum power. Engaging the TURBO mode at a low power setting causes a significant boost in power. Engaging the TURBO mode at high power causes very little change in power.

To return to normal scaling power, lighten foot pressure. The TURBO light will go out. The TURBO mode allows you to scale at lower power than usual, because you do not have to allow for occasional pieces of tenacious calculus.



If you encounter hard-to-remove accretions during debridement, simply use the TURBO mode to eliminate them. The TURBO mode does not change water flow, so extended use of the feature may require a water adjustment.

CLINICAL SUGGESTIONS ON TOOTH SCALING

- Ultrasonic scalers should be used by trained, licensed professionals only.
- If patient is new to ultrasonic scaling, explain to them what to expect. Usually, the patient should not experience discomfort, but if this occurs, adjust power and water controls, and lighten up on your handpiece pressure.
- Inserts and handpiece sheaths must be sterilized before each use.
- **DO NOT OPERATE UNIT WITHOUT WATER FLOWING.**
- Do not test a scaler tip with your fingers while the unit is operating. The tip will feel hot, and the test will not be valid as to how the patient will feel.
- Use of face mask by the clinician and high-volume intraoral suction is strongly recommended when operating this device, to avoid inhalation of microbially-contaminated aerosols.
- If you are using the internal water bottles to supply fluid to the unit, you may fill them with FDA-approved mouthwashes in a ratio of 4 parts water to 1 part mouthwash. Fill the bottles outside of the scaler, replace the lids and then carefully place the bottles into the plastic housing. Do not overfill the bottles.

- Use the lowest effective scaling power for the case at hand. This keeps heat generation to a minimum. Red-zone power is best reserved for patients anesthesia.
- Before using the insert in the oral cavity, adjust the water spray over a sink or cuspidor until desired mist is obtained. For maximum patient comfort, use a good flow of water as a coolant, lubricant and to flush out debris.
- Hold the handpiece in a comfortable pen-grasp. To remove deposits from teeth, always use a light brushing stroke with the side of the insert tip, in contact with and parallel to the root surface. Excess pressure will not improve scaling action, but may cause heating and pain to the patient. Keep the scaler insert in motion at all times, using repeated gentle strokes to remove all tenacious deposits.
- Do not use the point of the insert on the tooth surface. You may gouge the tooth.
- Pause occasionally during scaling by removing foot from pedal to evaluate deposit removal.
- Exercise caution near ceramic or resin restorations, as they can discolor or fracture if stressed.

COMMON OPERATOR ERRORS THAT MAY RESULT IN POOR CLINICAL PERFORMANCE

- Failure to keep insert tip parallel to the long axis of the tooth.
- Excessive use of hand pressure.
- Failure to use the lowest effective power setting for the case at hand.
- Insufficient water flow.
- Use of a heated water supply causing excessive water temperature at the insert tip.
- Scaling with the point of the insert instead of the side.
- Using inserts that are damaged, bent or worn out.

CLEANING AND INFECTION CONTROL

Consult www.CDC.gov for the most current guidelines for infection control in dental health-care settings.

DO NOT AUTOCLAVE the Integra control unit, as autoclave heat will destroy it. The control unit should be cleaned of debris with a water-damp paper towel, disinfected by wiping with a paper towel that has been saturated with an EPA-registered low-level (HIV/HBV claim) to intermediate-level (tuberculocidal claim) hospital disinfectant, wiped of chemical residue with a water-damp paper towel, and dried. Utilize the surface disinfecting protocol of the disinfectant manufacturer.

- 1) Autoclaving does not remove debris that has accumulated on the sheath or the insert. Failure to adequately remove debris will result in inadequate

sterilization. The sheath and insert must be washed in soap and water either manually or in an ultrasonic cleaner, rinsed in running water and dried prior to bagging them for processing in a steam autoclave.

- 2) Sheaths and inserts may be sterilized in any conventional steam autoclave following manufacturer's instructions. A typical gravity steam cycle is 270° F (132° C) for 15 minutes at a minimum of 15 psi, followed by a 15-minute minimum cool-down period. 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.

- 3) DO NOT USE DRY HEAT OR CHEMCLAVE on the sheath or the insert.



TROUBLESHOOTING THE INTEGRA (when in doubt, contact Parkell for advice)

Unit does not operate (LED's do not light):

- Transformer cable disconnected from wall outlet or scaler. Reconnect properly.
- Wall outlet not live. Reconnect properly.
- Unit is in "sleep" mode. Press any button on the panel to wake it up.
- Foot pedal or cable is damaged. Contact Parkell.
- Unit fuse has failed. Contact Parkell.

Insert does not vibrate properly:

- Faulty, damaged or worn insert. Replace.
- Insert not correctly seated in handpiece. Reinsert properly.
- Power control not correctly adjusted. Readjust.
- Use of non-compatible, non-Parkell insert.

Excess heat at handle or tip of insert:

- Faulty, damaged or worn insert. Replace.
- Too little water flow. Insert or filter may be blocked. Inspect and clear blockage, or replace insert or filter.
- Power too high for the amount of water. Increase water flow.
- Excessive hand pressure applied. Correct technique.
- Heated water being used. Use room temperature water only.

No water spray when foot pedal is depressed:

- Water line blocked or kinked. Correct.
- Water passage in the scaling insert clogged. Inspect and clear blockage, or replace insert.
- Water filter clogged. Replace.
- No water supply connected. Correct.
- Water bottles empty.
- Water switch set to “External” without connection to city water.
- Lid not fully closed.

Insert does not go into handpiece correctly:

- Insert stack is bent. Straighten plates carefully by hand and reinsert.
- O-ring is too tight. Lubricate O-ring with water and use twisting motion to seat insert.
- Autoclavable handpiece sheath is not attached to handpiece.

Insert falls out of handpiece or water leaks from front of handpiece:

- O-ring damaged or worn. Replace O-ring on insert and/or handpiece.

Insert comes out of handpiece when pedal is depressed:

- Water pressure is too high. Adjust water pressure to 15-35 psi at dental unit connection or in floor junction box, adjust water flow rate or replace insert O-ring.

Water leaks at base of handpiece:

- Orange O-ring at end of handpiece is missing or damaged.

USER MAINTENANCE AND AUTHORIZED SERVICE

The Parkell Integra requires very little maintenance for years of trouble-free operation. There are no user-serviceable parts inside the control unit or the foot pedal. Opening the cases will void all warranties. Authorized Parkell personnel must make all internal repairs.

Parkell urges all scaler users to monitor the condition of the water filter periodically and change the filter whenever noticeable darkening of the disk occurs, or when water flow decreases. Failure to periodically change the water filter will result in contamination and clogging of the internal water components, as well as costly and unnecessary service calls.

The ultrasonic inserts, handpiece sheaths, power supply, water filter, water hose, bottle-lock and irrigant bottles are all detachable and may be replaced by the user. Contact Parkell for a list of authorized inserts and available replacement parts.

Within the US, all repairs must be made by Parkell. We maintain a complete service and parts facility in our factory at 300 Executive Drive, Edgewood, NY 11717. After calling our factory for advice, equipment needing service in the US should be returned, freight pre-paid, via approved common carrier (e.g. USPS, UPS, FedEx), and adequately insured. Return all accessories with the unit, and include a written explanation of the problem. Pack in the original box, add plenty of cushioning material, and overbox the unit during shipping. Transit should maintain a dry temperature of 50°F-110°F. You will be contacted for approval of the repair, along with any associated costs, before any work requiring payment. The unit will be repaired and returned to you.

Outside the US, repairs must be made by a Parkell-authorized facility.

If you have any questions or problems with the installation or use of your Integra, call Technical Support Service at **1-800-243-7446**, M-F from 8:30 AM to 5:30 PM EST. Outside of the USA or Canada, call **+1 631-249-1134**.









CONFORMANCE TO STANDARDS

Parkell's Integra is TUV listed and conforms to IEC 60601-1, 60601-1-2 and CAN/CSA C22.2 No. 601.1. Parkell's quality system is certified to ISO13485.

WARRANTY

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

EXPLANATION OF SYMBOLS USED

	Professional use only
	Serial number
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Non-sterile
	Temperature limit
	Do not use if package is damaged. This symbol is on packaging.
	Follow instructions for use
	Keep dry
	Do not dispose this product into the ordinary municipal waste or garbage system
	Package contents
	Catalogue / stock number
	Manufacturer
	Referenced to ground at high frequencies
	Ground Terminal
	Type BF Equipment
	Dangerous high voltage

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

parkell®

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 MADE IN USA