

Caution: Federal Law restricts this device to sale by or on the order of a properly licensed practitioner.

Parkell, Inc.

Integra™ Ultrasonic Tooth Scaler Model D680



Device Description:

The Integra is an autotune ultrasonic tooth scaler that operates at either 25KHz or 30KHz. The Integra automatically detects whether the handpiece contains a 25KHz or 30KHz insert, and switches operating frequency to match. A dramatically expanded low-power range improves comfort during debridement.

Intended use/indications:

For removal of calculus and plaque during dental prophylaxis.

Contraindications:

Not for use if the patient or operator is wearing a pacemaker, or any other internal electronic device.

Precautions:

Caution: Water flow during use must be sufficient to cool handpiece and insert. Do not run this device dry.

IMPORTANT: The water supply line to the scaler should always be turned off whenever the device is being connected, disconnected, or when not in use.

Caution: Do not allow prolonged contact of tip with lips, cheeks, tongue or other soft tissues.

Caution: Take precautions to prevent transmission of contagious diseases from ultrasonic aerosols.

Caution: Use the sides of the tip to remove deposits from the tooth. Do not gouge the tooth with the point.

Caution: Precautions should be taken to guard against entrance of water from any

source into the transformer. The transformer should be located away from any source of water.

Individualization of treatment:

- If patient or operator is pregnant, consult physician concerning advisability of using ultrasonic scalers.
- Like all scalers of this type, the handpiece produces a small magnetic field. It has been reported that this can cause some sensitive patient monitoring devices such as pulse oximeters to give inconsistent or inaccurate readings.

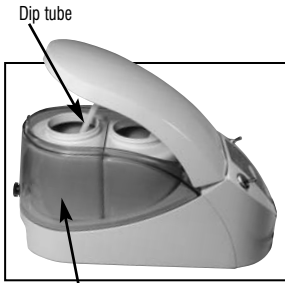
Conformance to Standards:

The Parkell Integra conforms to IEC60601-1 and CAN/CSA C22.2 No. 601.1.

The device is CE marked - certified to European Medical Device Directive (93/42/EEC). Parkell's quality system is certified to ISO9001/13485.

Included in your unit are:

- 1-Scaler Unit with an attached handpiece, and 2-autoclavable handpiece sheaths
- 2-fluid bottles, 1-water line with male quick-connect coupler, and 1-detachable foot controller
- 2-In-line Water Filters (Stock No. D419)
- 1-Transformer with cable (Stock No. D408-120V, D403-230V)
- Instructions and Warranty registration card.



Dip tube

Easily-removable dual reservoirs give you a choice of irrigants

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.)

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



Autoclavable handpiece sheaths

Handpiece-holder mounts on left or right

Ultrasonic inserts are not included with the Parkell Integra. However, this scaler will accept any scaler insert manufactured by Parkell, Cavitrion/Dentsply®, Hu-Friedy®, or other “Cavitrion-compatibles”.

Specifications:

- Operating frequencies - 25KHz and 30KHz
- Operates at room temperature between 50°F and 95°F (10°C - 35°C)
- Weight: 35 oz. / Dimensions: 5”W x 6”H x 11.5”D
- Power: 120VAC model - 60Hz, 120VA; 230VAC model - 50Hz, 120VA; 100VAC model - 50/60Hz, 120VA;

Locating your Integra Scaler:

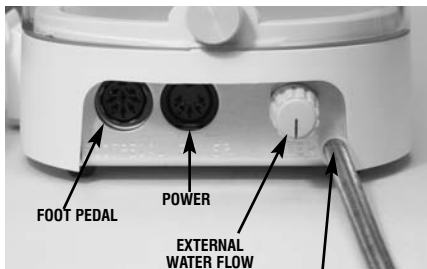
- Locate the device where the control panel will be easy to reach during scaling procedures.
- The scaler requires a grounded electrical

outlet and optionally, a source of drinking-quality, sediment free water at 20-50 psi. We suggest that an external water filter be used to minimize the frequent changes of the device’s in-line water filter. Change the in-line filter when it becomes visibly discolored.

- The scaler and its separate transformer generate a minimal amount of heat. Avoid covering them, as this will prevent normal cooling by the air.

Connecting your Integra to the Water Supply:

Before plugging in the device, connect the scaler’s water line to a supply of drinking quality water (20-50psi). The male quick-connect that comes on the end of the water hose is the same as that currently fitted to the Cavitrion® scaler. If you are replacing an older scaler that uses a different type of connection, remove the fitting from the old unit and attach it to the water line.



FOOT PEDAL

POWER

EXTERNAL WATER FLOW REGULATOR

EXTERNAL WATER CONNECTION



EXTERNAL WATER SOURCE

INTERNAL BOTTLE

REAR BOTTLE

FRONT BOTTLE

figure 1

IMPORTANT: The water line to the scaler should be turned off whenever the device is not in use.

If you are using the internal water bottles to supply fluid to the unit, fill them with the appropriate fluid such as water-diluted Peridex or mouthwash. Do not overfill the bottles. Take care to avoid spills when placing the bottles into the scaler.

Connecting your Integra to the Electrical Connection: (See figure 1)

The scaler must be powered via the Transformer Assembly supplied with the scaler.

- 1) Plug the transformer cable into the back of the scaler.
- 2) Plug the transformer into the nearest grounded outlet.
- 3) Plug the foot pedal into the back of the scaler, to allow it to control the device.

Scaling Inserts:

The Integra accepts any Parkell ultrasonic scaling insert as well as 25K or 30K inserts designed for Cavitron® scalers. The scaler automatically adjusts the operating frequency to match the frequency of the insert in the handpiece (either 25KHz or 30KHz) without operator intervention.

Brand new inserts may fit very tightly in the handpiece. Using a slight twisting motion when inserting and lubricating the “O” ring with water or Vaseline® will make insertion easier.

Old, worn or blunt inserts will provide poor scaling action and excess heat, and should be replaced.

Turning the scaler on and off:

Press any button on the touch panel. The display will light to indicate the scaler is on.

To turn the scaler off, press the water minus (–) button and while holding it down press the power minus (–) button. The display will go out showing that the unit is off. The unit will



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

remember any settings you made when it is turned on again.

To conserve electricity 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.

Controlling the power:

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, a button on the foot pedal and a Turbo mode.

Use buttons on the touch panel to set the initial power for the scaling procedure at hand. Alternatively you can adjust the power by pressing the button on the top of the foot pedal. 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: The foot pedal power adjustment feature can be disabled. There is a small switch on the rear of the foot pedal to allow you to turn this on and off).



A tip powered by the Integra will begin oscillating at much lower amplitude (power) than

a tip in a traditional scaler. This permits more comfortable debridement of sensitive patients.

For short-term increases in power during the procedure, 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. (In other words, increasing foot-pressure when the scaler is operating at a low setting will cause a major boost in power. Increasing foot-pressure when the scaler is already operating at maximum power will produce no significant increase.)

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 residual calculus. If you encounter hard-to-remove accretions during debridement, simply use the Turbo feature to eliminate them. (The Turbo mode does not change the water flow, so extended procedures may require a water adjustment.)

Selecting the water source:

The water source is selected using the two toggle switches on the front of the unit. One switch selects the source, either external or from the internal bottles. The other switch allows the user to choose which bottle is used as a source.

Controlling the water flow:

If you are using an external water source, turn the water control on the back of the unit counter-clockwise to increase the flow. If you are using the internal bottles as a 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 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. If water does not flow through the insert when the foot pedal is depressed, the water passage in the scaling insert may be clogged or the bottle(s) may be empty.

Infection control:

When removing the autoclavable handpiece sheath, hold the handpiece at the base with one hand and turn the top counter-clockwise with the other, taking care not to twist the hose. The sheath will unscrew and slip off.



Sheaths can be sterilized in any conventional steam autoclave, following manufacturers standard procedures. **DO NOT USE DRY HEAT OR CHEMCLAVE.**

Note: (The sheath must be washed in soap and water and rinsed in running water prior to autoclaving.) Autoclaving does not remove debris that has accumulated on the sheath. Failure to adequately remove debris may result in inadequate sterilization.

Before replacing the sheath, lubricate the O-ring on the handpiece with petroleum jelly to assure a water-tight seal. Slide the sheath over the handpiece carefully to avoid damaging or dislodging this O-ring, and screw the sheath in place. (Do not overtighten.)



The exterior case of the scaler may be wiped with a cloth dampened by any standard surface cleaner as desired.

How to replace the filter disk (time required: 10 seconds.)

The water filter disk should be replaced when it becomes very dark or so clogged with debris that water flow is impeded.

- 1) Disconnect the scaler from the water supply.
- 2) 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.)
- 3) Install the replacement filter disk, and firmly tighten the connectors using hand pressure.
- 4) Reconnect the scaler to the water supply and check for leaks.

Note: If the filter becomes clogged and you do not have a replacement disk, the hose connectors can be locked together without the filter disk to allow emergency operation.

If you have any questions, please contact Parkell Service Dept. at (1-800-243-7446). Replacement Filters (10 per package): Stock No. D419

General comments on scaling:

- Ultrasonic scalers should be used only by trained, licensed professionals.
- Inserts and the handpiece sheath should be sterilized before each use.
- Do not operate unit without water flowing.
- Use of face mask is recommended when operating this device, to avoid inhalation of contaminated aerosol by the operator. High-volume suction to remove this aerosol from the dental environment (as close to the source as possible) is also recommended.
- Use the lowest effective scaling power for the case at hand. This keeps heat generation to a minimum.
- Before using the insert in the oral cavity, adjust the water spray over sink or cuspidor until desired mist is obtained. For maximum patient comfort, use a good flow of water which acts as coolant, lubricant and lavage to flush out debris.
- If patient is new to ultrasonic scaling, tell him/her what to expect. If procedure becomes uncomfortable, adjust power and water controls accordingly.
- Grasp handpiece in a comfortable manner, like holding a pen. To remove deposits

from teeth, always use a light brushing stroke with the side of the insert tip in contact with the tooth 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 and use repeated gentle strokes to remove all tenacious deposits.

- Exercise caution near porcelain and resin restorations as they can fracture.
- Occasionally turn unit off to evaluate deposit removal with an explorer.
- If you test any scaler tip on your fingers while operating, it will feel uncomfortably hot. This is not a true test of how it feels on a tooth. To operate, adjust the power control to the minimum setting for the case at hand (start at zero). With a good water flow, the patient will not experience any uncomfortable heat.

Common operator errors:

- Failure to keep insert tip parallel with the long axis of the tooth surface.
- Excessive use of hand pressure.
- Failure to use the lowest effective power setting for the case at hand.
- Insufficient water flow.
- Scaling with the point of the insert instead of the side.

These failures in procedure can result in ineffective or incomplete removal of deposits and possible damage to the pulp or tooth structure.

TROUBLESHOOTING

Unit does not operate ("power on" indicator does not light)

- Transformer cable disconnected from wall outlet or scaler
- Wall outlet not live
- Unit fuse has failed (Contact Parkell)

Insert does not vibrate properly

- Faulty, damaged or worn insert
- Insert not correctly seated in handpiece
- Power control not correctly adjusted

Excess heat at handpiece or tip of insert

- Faulty, damaged or worn insert
- Too little water flow (insert blocked)

- Power too high for the amount of water
- Excessive hand pressure applied

No water spray

- Water line blocked or kinked
- Water filter clogged
- Water canal in insert blocked
- No water supply
- Water bottles empty

Insert does not go into handpiece

- Lubricate 'O' ring with Vaseline® and use twisting motion to seat insert

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

- 'O' ring damaged or worn. Replace 'O' ring on insert.


Additional Specifications:


- Protection Against Electric Shock - Class 1, Type B applied part
- Equipment not suitable for use in the presence of a flammable anesthetic mixture (when used with air or with oxygen).
- Protection Against Ingress of Liquids - Pulp Tester - IPX0 (Ordinary)
- Mode of Operation of Equipment - Continuous.
- Operating conditions: 15-35°C, 10-80% RH (non-condensing)
- Transport and Storage conditions: 10-40°C, 10-80% RH (non-condensing)

This equipment produces electromagnetic

energy and may cause interference with other electronic devices. Should this occur, changing the positioning or location of the device may be necessary.

The power supply line cord is the AC power disconnect device for the scaler.

The symbol  on the scaler indicates the Protective Earth connection.

The symbol  is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the scaler.

Service:

The handpiece sheath, power supply, water filter, dip tubes, bottles and ultrasonic inserts are all detachable and may be replaced by the user. Contact Parkell for a list of authorized inserts. Otherwise, there are No User Serviceable Items in this scaler, including the foot controller.

For service, return the unit freight prepaid and carefully packed to **Parkell Repair Dept., 300 Executive Drive, Edgewood, NY 11717**, with an explanation of problem. During the warranty period, the unit will be repaired and returned to you. After the warranty period, we will call with an estimate and request approval.

If you have any questions or a problem with the installation or use of your scaler, please call our Toll-Free Technical Support Service at 1-800-243-7446 from 8AM to 6:30PM Eastern time (outside USA and Canada, call 631-249-1134).

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