

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



parkell*inc.*

Manual/Autotune Clean Machine® Ultrasonic Tooth Scaler

DEVICE DESCRIPTION:

The Manual/Autotune Clean Machine is an ultrasonic tooth scaler that operates at 25KHz. In the manual mode it permits frequency tuning for ultra-low power applications. In its autotune mode it self-tunes to the insert's optimal frequency.

INTENDED USE/INDICATIONS:

For removal of calculus and plaque during dental prophylaxis.

CONTRAINDICATIONS:

- Do not use this device if the patient or operator is wearing a pacemaker.

Warning: As with all electrical products, the unit should not be immersed in water or other liquids. 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 modify this device. Modification may violate safety codes and endanger patient and operator. Any modification will void the warranty.

PRECAUTIONS:

Caution: Water flow through tip during use must be sufficient to cool handpiece.

Caution: Do not allow prolonged contact of tip with lips or cheek.

Caution: All ultrasonic scalers produce aerosols, take precautions to prevent transmission of contagious diseases.

Caution: Use the long axis of the insert tip to wipe accretions from the tooth. Do not gouge the tooth with the tip.

Caution: Water supply to scaler should always be shut off or disconnected when scaler is not in use.

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 (eg Pulse Oximeter) to give inconsistent or inaccurate readings.

CONFORMANCE TO STANDARDS:

The Parkell Clean Machine conforms to IEC 60601-1. Parkell's quality system is certified to ISO9001/ISO13485. Certified to CAN/CSA C22.2 No. 601.1.

The device is CE marked—certified to European Medical Device Directive (93/42/EEC).

HOW SUPPLIED:

You receive...

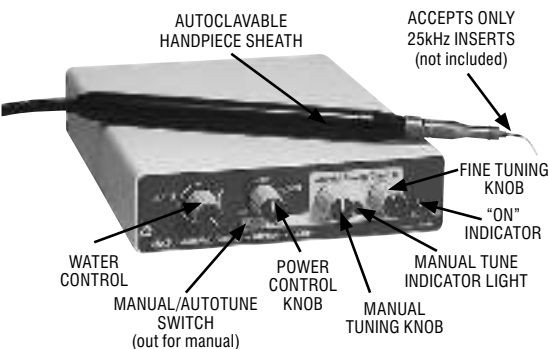
- A Scaler Unit with attached handpiece, foot controller and water line with male quick-connect coupler.
- 2 Autoclavable handpiece sheaths
- In-line water filter
- Transformer with cable
- Instructions
- Warranty registration card

Does not include inserts. This scaler will accept any 25KHz scaler insert manufactured by Parkell, Cavitron/Dentsply®, or Hu-Friedy®.

INSTALLING YOUR SCALER

Locate the device where the control panel will be easy to reach during scaling procedures. The scaler requires access to a grounded electrical outlet and a source of drinking-quality water.

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



TURNING ON THE SCALER

The unit does not have a traditional on/off switch. The foot pedal turns the unit off each time you remove your foot. Because of this, the pedal should be placed where it will not be accidentally hit when the device is not in use.

HOW TO MANUALLY TUNE SCALER

Every insert has a slightly different operating frequency. In its "auto-tune" mode, your scaler automatically adjusts its frequency to match the insert in the handpiece.

Some operators believe that manual tuning allows better control at the low power settings used in subgingival scaling.

In its manual mode, you adjust the frequency yourself. (**Note:** The unit must be tuned each time the insert is changed.)

- 1) Gently pull the power knob outward to switch the scaler to its manual mode. (The "Manual Tune" indicator will light.)



- 2) Turn the POWER and FINE TUNING knobs to the 12 o'clock position. (This will assure that the scaler is sufficiently in tune to trigger the water flow.)



- 3) Seat the insert you will be using into the handpiece, step on the foot pedal to activate it, and turn the manual TUNING knob to adjust the instrument frequency to match your specific tip.
- 4) Once the approximate frequency has been set, adjust the power, and water flow for the case at hand, and make any minor tuning adjustments using the "FINE TUNING" knob.

CONTROLLING THE POWER

Use the POWER CONTROL knob to set the initial power for the scaling procedure at hand.

With the foot pedal depressed, turn the power control knob in a clockwise direction to increase the amount of tip motion. This



WATER CONNECTION

Before plugging in the device, connect the scaler's water line to a supply of drinking quality water (20-50psi). Water should be clean and free of sediment. We suggest that an external water filter be used to minimize the frequent changes of the device's built-in water filter.

The male quick-connect that comes on the end of the water hose is the same as that currently fitted to the Cavitron® 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.

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

ELECTRICAL CONNECTION

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



- 1) Plug the transformer cable into the back of the scaler.
- 2) Then plug the transformer into any grounded outlet. From this point on, simply stepping on the pedal will turn on the scaler.

INSERTS

The scaler accepts any 25KHz Parkell insert as well as 25K inserts designed for Cavitron® scalers.

Brand new inserts fit very tightly in the handpiece. Using a slight twisting motion when inserting and lubricating the "O" ring with water will make insertion easier. Old, worn or blunt instruments will provide poor scaling action and should be replaced.

control is calibrated to give a useful range of operating power for most clinical procedures.

Some guidelines for power setting.

For general calculus removal start with power set to “Med”. Higher settings may be used to remove tenacious accretions. Higher settings require more water flow to keep the handpiece cool.

For subgingival debridement, start with power set to “Lo” or between “Lo” and “Med”. Follow guidelines from the insert (tip) manufacturer. For example the **maximum** power recommended for thin subgingival tips (Cavitron® Slimline®, Parkell® Perio) is “Med.”

CONTROLLING THE WATER FLOW

Turn the water control counter clockwise to increase the flow. (Notice the arrow printed on the control panel.) If water does not flow through the insert when the foot pedal is depressed, the water passage in the scaling insert may be clogged.



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 (e.g. Validator Plus®), @132-135°C for 15 min. for gravity displacement & 4 min. for prevacuum cycles. **DO NOT USE DRY HEAT OR CHEMCLAVE.**



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

Before replacing the sheath, lubricate the O-ring on 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.)

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 call the Parkell Service Dept. at (1-800-243-7446)

Replacement Filters (10 per package):
Order Number D419

GENERAL COMMENTS CONCERNING SCALING

- The Clean Machine should be used only by trained, licensed professionals.
- Inserts and handpiece sheath should be sterilized before each use.
- Do not operate unit without scaler insert in handpiece and water flowing.
- Use of face mask is recommended when operating this device, to avoid inhalation of bacterially-contaminated aerosol by the operator. High-speed 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 scaler insert 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 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 good or 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 INCLUDE:

- Failure to keep insert 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.

SPECIFICATIONS

- Operating frequency—Approximately 24,500 cycles per second.
- Operates at room temperature between 50°F and 100°F (10°C - 38°C)
- Weight—35 oz.; Size—1fi”H x 5fi”W x 7”D
- Power: 110V, 50/60Hz, 100VA (230V units available)

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 handle
- Power control not correctly adjusted

Excess heat at handle 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

Insert does not go into handpiece

- Lubricate ‘O’ ring with water 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.

SERVICE

For service, return unit, freight prepaid, carefully packed with explanation of problem to the address below. The unit will be repaired and returned to the purchaser.

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 9am to 5:30pm Eastern time (outside USA and Canada, call 631-249-1134).

EC|REP European Authorized Representative
(Not a dealer/distributor):
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