General Cleaning & Maintenance Surgical Instruments

Cleaning & Disinfecting

The United States CDC (Center for Disease Control) guidelines recommend cleaning and disinfection with a detergent or enzymatic cleaner.

1. Detergent selection considerations
   - 1.1. Applicable detergent for cleaning devices.
   - 1.2. Compatibility of detergent with thermal disinfector unit. Use according to manufacturer's guidelines.
   - 1.3. Compatibility of detergent with disinfectant.
   - 1.4. Instructions according to the manufacturer's guidelines for use of the detergent concerning concentration and soak time.
2. Disinfectant selection considerations
   - 2.1. Applicable disinfectant for disinfection of devices.
   - 2.2. Compatibility of disinfectant with detergent.
   - 2.3. Approved efficiency of disinfectant, i.e., DGHM/VAH, RKI approval or CE marking or at least intermediate level disinfectant.
   - 2.4. Instructions according to the manufacturer's guidelines for use of the detergent concerning concentration and soak time.
3. Mandatory preparation for cleaning and disinfecting procedures
   - 3.1. Remove any debris from devices and attachments immediately after use.
   - 3.2. Use a soft brush to remove debris. Do not use metal brushes or abrasive instruments to remove debris.
   - 3.3. Thoroughly rinse to remove detergent and disinfectant.
   - 3.4. Follow manufacturer's guidelines for detergents and disinfectants.

Sterilization Directions

4. Deposit parts in an autoclave bag. Autoclave and sterilize according to the following instructions.
   - 4.1. Autoclave at a temperature of 134 °C and pressure of 3 atm for 3 minutes, according to EN ISO 17655-1.
5. Original packaging cannot be autoclaved.

Maintenance

1. After every use and when contaminated, prepare instruments for cleaning, disinfecting and sterilizing.
2. Avoid all contact between disassembled parts during the cleaning and disinfecting process.
3. After cleaning and disinfection instruments, sterilize according to local regulations. Refer to "Sterilization Procedure" section.
4. Store device according to "Storage and Use" section.

Storage & Use

- Handle contaminated devices with protective gloves and local regulations.
- Contaminated devices should be contained and transported according local regulations.
- Reprocess devices immediately after use for best care of device.
- Remove excess debris with cloth/paper wipes.
- Avoid allowing debris to dry and fixate on device.
- Store sterilized devices in a dry and dust-free environment.
- Sterilization can only be preserved if devices remain packaged, impermeable to microorganisms, following a validated process.
- Status of the sterilization must be marked on the package or container.
- Keep sterile and non-sterile products separate.
- Do not sterilize in Park Dental's original packaging.
- This device should be observed for deterioration. In the event of a defect, return to Park Dental. Do not use.
- If parts are lost, reorder from Park Dental.

Customer Information

No person is authorized to provide information which deviates from the information within this document.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Warranty

Park Dental Research Corporation warrants this product to be free of defects for a period of one (1) year from the purchase date. At its option, PDR will replace or refund the purchase price of this device, to the original purchaser, for returned items due to defects in material and workmanship. If a defect is found in a product, the product should not be used. This warranty covers only the cost of the product and not clinical and professional fee associated with the use of the product.

Limitation of Liability

Park Dental Research Corporation is not liable for any damages due to changes made to product by the user. It is the manufacturer's intention that the product be utilized in a manner that has been submitted to the appropriate governing regulatory bodies. The user is responsible for determining the suitability of the product for its intended application.

PARK DENTAL Research Corporation
2401 N Commerce
Ardmore, OK 73401
580.224-9124 (fax)
580.798.4730 (voice)
www.parkdentalresearch.com
Made in the USA

EC REP
Emergo Europe Molenstraat 15
2513 BH, The Hague
The Netherlands

CE 0473