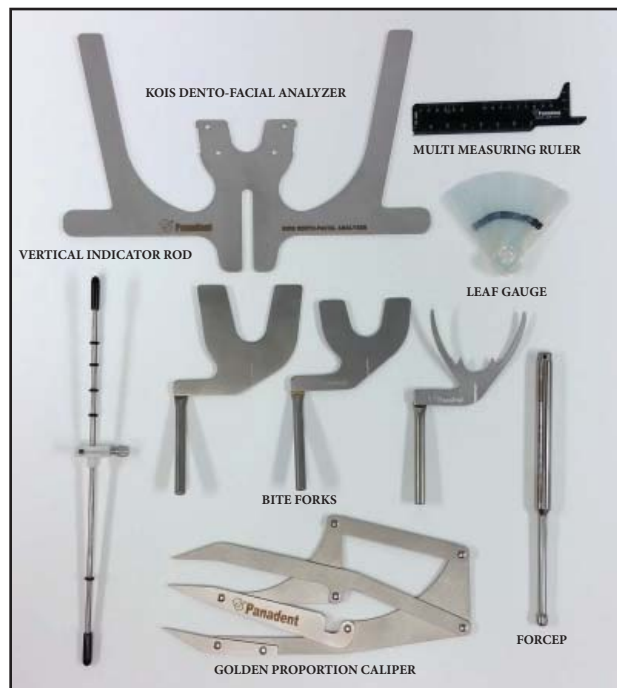




## Instructions for Cleaning, Disinfection and Sterilization of Panadent Products



### General Information

All metal, plastic and rubber products/components are to be cleaned and disinfected or sterilized prior to each use. In addition, cleaning and disinfection or sterilization is also required for the first use of non-sterile reusable components after removal from the protective packaging. Effective cleaning is an indispensable requirement for proper sterilization.

The user is responsible for the sterility of the instruments. Therefore, please ensure that only validated procedures are used for cleaning, disinfection and sterilization. The sterilization equipment must also be maintained and checked regularly, as well as the validated parameters applied to each cleaning and sterilization cycle.

These instructions provide the procedures on **manual cleaning** of Panadent metal, plastic and rubber products/components. The staff should use suitable **protective clothing and equipment** at all times. In particular take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

### Reusable Products:

Type and Description	Material	Intended Use	Specification	Comments
<b>Kois Dento- Facial Analyzer</b>	Stainless Steel	For more than one patient	Cleaning and Sterilization	Reusable via appropriate cleaning, disinfection and/or sterilization
<b>Vertical Indicator Rod</b>	Stainless Steel, Plastic and Rubber O-Rings		Cleaning and Disinfection	
<b>Leaf Gauge</b>	Plastic	Multiple uses possible	Cleaning and Disinfection	
<b>Multi Measuring Ruler</b>	Aluminum		Cleaning and Sterilization	
<b>Golden Proportion Caliper</b>	Stainless Steel		Cleaning and Sterilization	
<b>Bite Forks</b>	Stainless Steel	Must be checked regularly for damage and appearance and replaced if necessary. If damaged, must be discarded via biohazard waste	Cleaning and Sterilization	
<b>Forcep</b>	Stainless Steel		Cleaning and Sterilization	

### PRECAUTIONS

Steam sterilization (moist heat) is NOT recommended for plastic or rubber products/components

- An autoclave cycle has been validated as being capable of achieving sterile medical devices; however autoclave design and performance can affect the efficacy of the process.
- Use the recommended instructions and materials when cleaning and disinfecting or sterilizing Panadent products/components.

### Cleaning Detergents

Use All-in-one Enzyme Detergent with a neutral pH range between 6.0 and 8.0 only, in order to avoid damaging products/components. Enzymatic detergents help with the removal of organic matter, such as blood. Detergents should be used according to their manufacturer's recommended concentration levels. Manufacturers may provide information about specific materials that may be damaged by their detergents.

### Recommended Cleaning Detergent:

- All-in-one Hospital Grade Enzymatic Detergent

### Water

Use only the purest quality of water for cleaning. Water hardness is a serious consideration since deposits left on medical products may not be properly decontaminated. Use deionized water in order to reduce this problem. The final rinse water should be bacterial free and contains no endotoxins.

### Brushes

Use anti-microbial nylon brushes or nonabrasive (soft) medical scrub brush to clean with the recommended detergent.

## CLEANING INSTRUCTIONS

Step	Solution	Time (Minutes)	Temp	Instruction
1	Hospital Grade Enzymatic Detergent	14-15	Room Temp	Immerse and soak for required time
2	Hospital Grade Enzymatic Detergent	14-15	Room Temp	Clean thoroughly – Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to ensure all channels and screw threads are clean. Inspect for visible soil on exposed surfaces
3	Water	Minimum of 1 minute	Warm, as delivered from hot water tap	Rinse thoroughly for required time immediately after Step 2
4	Air	As required	Ambient	Allow to air dry in clean area. Blow lumens with clean air using filtered air source or syringe

### Inspect Instruments

- Inspect device for visible soil
- If soil is visible with the unaided eye, repeat Cleaning Instructions

## HIGH LEVEL DISINFECTION INSTRUCTIONS

Use Cidex disinfectant manufactured by Johnson and Johnson. Ensure a minimum effective concentration (MEC) of Cidex – 2.4% glutaraldehyde using Cidex Test Strips

### Procedure

- Equilibrate a water bath of Cidex to 25°C +/- 2°C
- Fully immerse in the Cidex and ensure all air bubbles are removed from the surface by agitating vigorously
- Use sterile lint-free cloth to wipe the product/ component underneath the disinfectant to ensure contact with all surfaces
- Use a syringe to flush any debris with the disinfectant
- Allow to soak for 45 minutes
- Thoroughly rinse by fully immersing them in pure water, agitating and allowing it to set for a minimum of 1 minute
- Repeat the rinsing step one more time
- Dry using a sterile lint-free cloth

### Packaging

- Double wrap the instrument(s) with CSR wrap
- The packaging for terminally sterilized medical devices should fulfill the following requirements:
  - Suitable for steam sterilization (temperature resistance up to at least 141°C, sufficient steam permeability)
  - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage

## STERILIZATION INSTRUCTIONS

### USA

Method	Moist heat sterilization
Cycle	Pre-Vacuum (Pre-Vac), wrapped
Temperature	270°F (132°C)
Exposure Time	4 minutes
Pressure	2-15 PSIA
Drying Time	30 minutes (minimum, in chamber)
Cool Time	60 minutes (minimum, at room temperature)


### EUROPE/CANADA

Method	Moist heat sterilization
Cycle	Gravity, wrapped
Exposure Time	4 minutes
Temperature	132-137°C (270-277°F)
Drying Time	Recommended: 30 minutes (minimum, in chamber)

### Storage of Instruments

Please store the medical devices in the sterilization packaging in a dry and dust-free place. The shelf life is depending on the sterile barrier employed, storage manner, environmental and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by each health care facility.



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