

INSTRUCTION FOR CLEANING, DISINFECTION AND STERILIZATION OF CORCYM REUSABLE ACCESSORIES AT HEALTH CARE FACILITIES

The following instruction shall be performed only by qualified and trained personnel.

Cleaning Instructions

The accessories have been designed by CORCYM devoting particular care to their shape and to the material selection so that they can be cleaned, disinfected and sterilized following different procedures. CORCYM has validated the methods described below.

It is recommended that devices are reprocessed as soon as possible following use.

Preparation before cleaning

- Before placing the devices into the washer-disinfector, rinse them under running (reverse osmosis/deionized) RO/DI water to remove gross soil.
- While rinsing, use clean lint free cloths to facilitate the removal of the soil.
- Check that no visible soil is on the tool.
- Place the devices into the washer-disinfector and choose one of the following automated cleaning procedures:

Automated washing/disinfection with enzymatic* detergent

Washer/disinfector must comply with EN ISO 15883 series.

Insert the accessories into the washer/disinfector, selecting the baskets and/or position most suitable for ensuring that all parts of the accessories are exposed to the water jets, and set the following cycle parameters:

Phase	Recirculation Time (minutes)	Temperature	Water Quality	Cleaning Agent	Additional Information
Pre-washing	02:00	< 40 °C (< 104 °F)	tap water	not applicable	Do not use detergents or additives. Drain when complete.
Washing	05:00	45 °C÷55 °C 113 °F÷131 °F	tap water	Enzymatic detergent*	Follow the instructions in the washer/disinfector manual for an adequate

					concentration of enzymatic detergent. Drain when complete.
Rinsing	02:00	45 °C÷55 °C 113 °F÷131 °F	tap water	not applicable	Drain when complete.
Thermal Rinsing	01:00	90 °C÷93 °C 194 °F÷199 °F	RO/DI water**	not applicable	-
Drying	10:00	90 °C 194 °F	not applicable	not applicable	-

* The cleaning validation was conducted with a STERIS Reliance® Genfore Washer-Disinfector, using Prolystica® 2x Enzymatic Presoak and Cleaner (Steris®) at a Concentration of 1/8 oz per gallon (1ml/liter). It is recommended to use a concentration of 1/4 oz per gallon (2 ml/liter).

** Microbiological limits (for EU): endotoxin ≤10 EU/ml and bioburden ≤10 cfu/ml.

Automated washing/disinfection with neutral* detergent

Washer/disinfector must comply with EN ISO 15883 series.

Insert the accessories into the washer/disinfector, selecting the most suitable baskets and/or position to ensure that all parts of the accessories are exposed to the water jets. Then set the following cycle parameters:

Phase	Recirculation Time (minutes)	Temperature	Water Quality	Cleaning Agent	Additional Information
Pre-washing	02:00	< 40 °C (< 104 °F)	tap water	not applicable	Do not use detergents or additives. Drain when complete.
Washing	05:00	45 °C÷55 °C 113°F÷131°F	tap water	neutral detergent*	Follow the instructions in the washer/disinfector manual for an adequate concentration of neutral detergent. Drain when complete.
Rinsing	02:00	45 °C÷55 °C 113 °F÷131 °F	tap water	not applicable	Drain when complete.

Thermal Rinsing	01:00	90 °C ÷ 93 °C 194 °F to 199 °F	RO/DI water**	not applicable	-
Drying	10:00	90 °C 194 °F	not applicable	not applicable	-

* The cleaning validation was conducted with a STERIS Reliance® Genfore Washer-Disinfector, using Prolystica® 2x Neutral Detergent (Steris®) at a Concentration of 1/8 oz per gallon (1ml/liter). It is recommended to use a concentration of 1/4 oz per gallon (2 ml/liter).

**Microbiological limits (for EU): endotoxin ≤10 EU/ml and bioburden ≤10 cfu/ml.

Sterilization

For the sterilization, place the accessories in a suitable steam sterilizable package according to EN ISO 11607-1.

The accessories contained in this package can be steam sterilized, as per recommended ISO 17665-1 and ISO 17665-2 standards, in accordance with the following parameters:

Sterilizer Type	Sterilization Condition	Sterilization Condition (Recommended for EU)
	Pre-vacuum	Pre-vacuum
Minimum Temperature	132 °C 270 °F	134 °C 273 °F
Pulses	4	4
Exposure Time (minutes)	4	3
Drying Time (minutes)	30	30
Item	Wrapped accessory or tray	Wrapped accessory or tray

Processing limitations

Based on the test conducted by the Manufacturer, the reusable accessories listed in the table 1 can be cleaned, disinfected and sterilized up to 100 cycles using the cleaning, disinfection and sterilization methods described in this booklet. The accessories can also be cleaned, disinfected and sterilized up to 100 cycles using for the cleaning step an alkaline detergent (Prolystica 2x Alkaline detergent was used in the tests performed by

the manufacturer).

Note that changes to the indicated method may result in a reduced accessory life cycle.

It was determined that reusable accessories can withstand pre-vacuum steam sterilization cycles up to 137 °C (280 °F) with a duration of 18 minutes (recommended decontamination method for Transmissible Spongiform Encephalopathies).

In any case, the accessories should always be carefully inspected before use. Do not use the accessories if there are visible signs of cracking, crazing, or ageing that may affect function.