



FAMI Packaging System

FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer
Instruction for Use (version 1.0)

Read before use



REF 136.113



FAMI Ltda.
Al. São Caetano 2790
09560-500, São Caetano do Sul/SP, BR

Alameda São Caetano, 2790 | Santa Maria | CEP 09560 500 | São Caetano do Sul / SP / Brazil

+55 11 3775 0300 ✉ info@fami.com.br 🏠 www.fami.com.br

📱 [f](#) [in](#) [@](#) [x](#) [v](#) /famitecmec





Europe representative



Easy Medical Device Comm V
Guldenberg 1 bus 2-4,
2000 Antwerpen, Belgium

UK representative

Easy Medical Device Limited
125 Deansgate Manchester M3 2LH
United Kingdom

REF 136.113 FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer
Instructions for Use
FAMI Ltda. 2023
2023-09

Document number en_DTec002_Rev01

This document provides instructions for use of the FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer.

Controlled copy

Table of Contents

Introduction	06
Warning, precaution and information symbols in this manual	07
FAMI Basket for the Versius Ultrasonic Dissector description	10
Receiving new FAMI processing basket	11
Dropped or damaged FAMI processing basket	11
Disposal	11
Intended use	12
Characteristics of the product	12
Contraindications	12
 Procedures	 12
Instruction for use	12
Reprocessing procedures overview	13
Initial manual cleaning	14
Main cleaning: Full manual cleaning	17
Main cleaning: Automated cleaning and thermal disinfection	20
Preparation for sterilisation	22
Sterilisation	26
Appendix A	
FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer	29
Appendix B Validated equipment and parameters	30
Glossary	32

Introduction

This manual provides instructions for use of the FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer, including cleaning, disinfection and sterilisation. These instructions must be read and fully understood before reprocessing the basket.

These instructions have been validated by FAMI. This does not preclude the statutory requirements of the sterile services department to undertake process monitoring, testing and quality control to ensure the effectiveness of the cleaning, disinfection, and sterilisation procedures.

The FAMI Processing Basket of the Versius Ultrasonic Dissector Transducer is supplied non-sterile and must be fully reprocessed before first use.

This product must be used for cleaning, sterilisation, storage, and transportation of Versius Ultrasonic Dissector Transducer only.

If there are any questions regarding these instructions or if any basket shows signs of defects or damage, please contact FAMI technical support.



FAMI Ltda.
Al. São Caetano 2790
09560-500, São Caetano do Sul/SP, BR
Tel: +55 11 3775-0300

For technical support:
If your system requires technical support or service, please call our technical support line:
Tel: +55 11 3775-0334
Email: servicos@fami.com.br

Warning, precaution and information symbols in this manual



This symbol indicates a warning. Warnings in these reprocessing instructions indicate situations that could result in serious injury to the patient or user.



This symbol indicates a precaution. Precautions in these reprocessing instructions indicate situations that could result in minor or moderate injury to the patient or user, or damage to the FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer.



This symbol indicates an information point. Information points indicate important reference information.

Full list of warnings



Only use this basket for reprocessing and transport Versius ultrasonic dissector transducer.



Always rinse the entire reprocessing basket under running critical water to ensure contaminants and residue are removed during full manual cleaning.



Only use validated parameter settings during automated cleaning and thermal disinfection. Parameter setting that have not been validated could result in damage to, or ineffective cleaning of the basket.



Only use ISO 15883 validated washer/disinfectors.



Always repeat the entire cleaning process, including initial manual cleaning, if any soil is present on the ultrasonic dissector reprocessing basket during the inspection stage.



Ensure that the sterilisation procedure conforms with ISO 17665-1.



Only use validated parameter settings during steam sterilisation parameter settings. Parameter setting that have not been validated could result in damage to, or ineffective cleaning of the basket.

 Ensure that the basket cool down gradually to room temperature before transportation or use. Sudden changes in temperature could result in ineffective sterilisation of the basket.

 Always store and transport the basket in the specified environmental conditions. Incorrect storage and transportation could lead to damage to the basket and/or to the instruments and/or to the steam-permeable sterilisation pouch or interleaved sterilisation wrap.

Full list of precautions

 Test the closure of the lid, fixation of the intermediate tray in the basket, fixation of the instruments in the silicone supports to ensure they are secure before transport and reprocessing.

 Avoid exposure to saline to minimize the chance of corrosion.

 Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of the basket.

 Do not use abrasive metal or hard brushes as this may damage the basket.

 Do not use a sponge to clean the basket.

 Do not soak or rinse the basket in hot water as this could cause proteins to aggregate, making it more difficult for proteins to be removed.

 To avoid splashes and aerosolization, immerse the basket completely while brushing and cleaning.

Full list of information points

-  Start initial manual cleaning of the basket within 4 hours of finishing point-of-use preparation.
-  Visually inspect the basket for any wear and tear or sharps, which may compromise the performance, and for rust. Baskets must follow and complete the full reprocessing and sterilisation cycle before each use.
-  Carefully inspect the basket between uses to verify proper functioning.
-  Damaged baskets should be replaced to prevent potential patient/user injury and loss of metal fragments into the surgical site.
-  Send the ultrasonic dissector reprocessing basket for reprocessing as soon as possible.

FAMI Basket for the Versius Ultrasonic Dissector Transducer description

The key features of the FAMI Basket for the Versius Ultrasonic Dissector are shown in Figure 1.

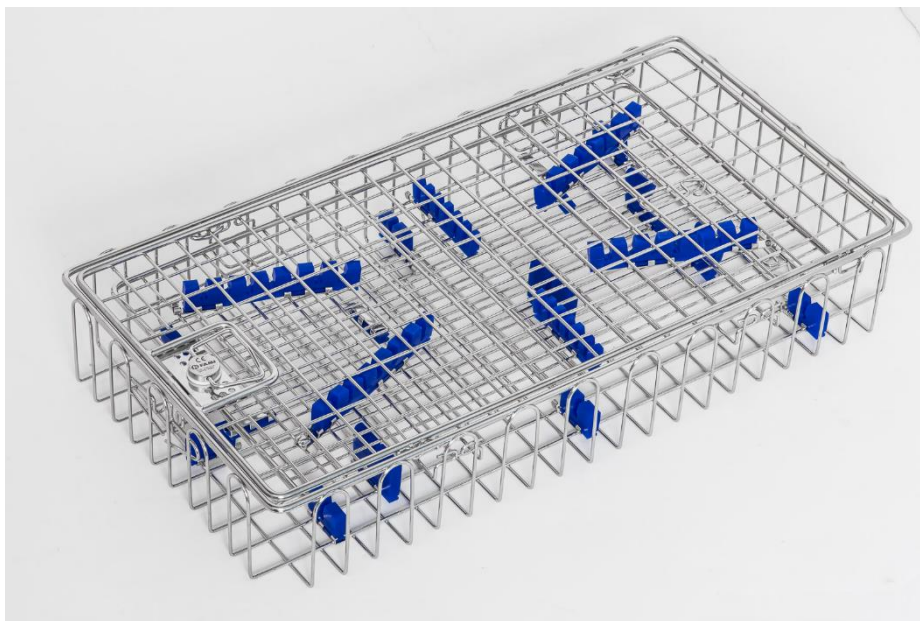


Figure 1. FAMI Basket for the Versius Ultrasonic Dissector key features

Figure 2 shows how the reprocessed portion of the ultrasonic dissector combines with the single-use chassis.

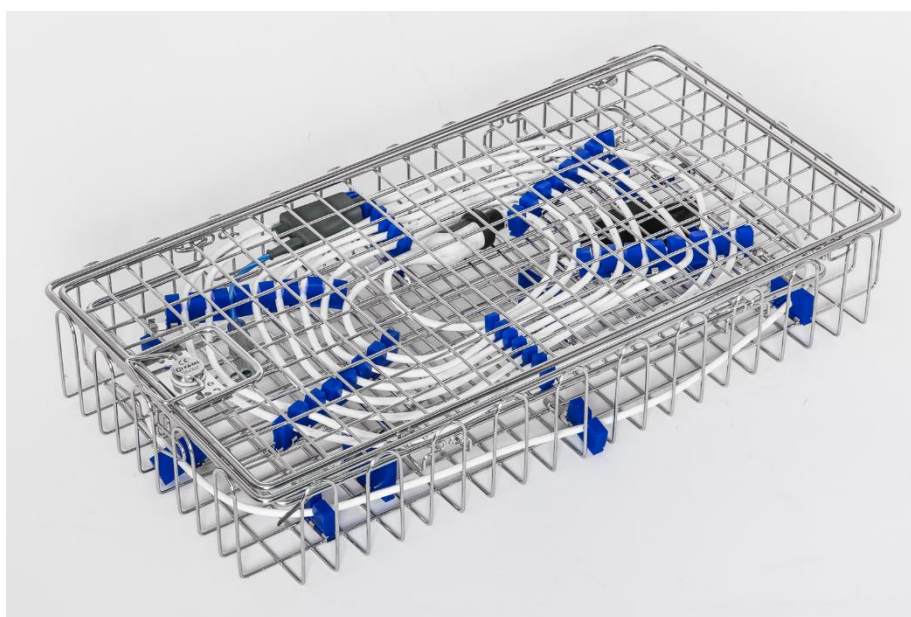


Figure 2. Combined Versius Ultrasonic Dissector



Receiving new FAMI processing basket

FAMI Processing Basket for the Versius ultrasonic dissector transducers are shipped non-sterile and in individual boxes. Reprocessing is required before first use.

Dropped or damaged FAMI processing basket

If the basket has been dropped or damaged, check if there was physical damage to the surface of the wires, if so, dispose the basket.

Disposal

Dispose of the basket following the hospital procedure for processing biologically contaminated materials.

Intended use

FAMI Processing Basket is a reusable protective packaging for the Versius ultrasonic dissector transducers during storage, transport, and sterilization.

The FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch.

Characteristics of the product

The FAMI Processing Basket for the Versius ultrasonic dissector transducer is entirely manufactured with stainless steel AISI 304 wires, it has rounded corners, smooth finish and silicone supports to hold the Versius ultrasonic dissector transducers.

Versius Robotic System baskets are sturdy and cost-effective, optimizing drying and sterilization processes. They are versatile and can be used throughout the processing cycle, offering numerous advantages over perforated cases/boxes and wire baskets without lids. The baskets are lighter than cases/boxes, thanks to the wide spacing of the wires, reducing the weight of the load to be sterilized and contributing to the good performance of the sterilization equipment.

Contraindications

There are no contraindications and/or adverse effects.

Procedures

Instruction for use

The Versius ultrasonic dissector transducer should be secured onto the silicone holders of the basket, and afterward, the basket lid should be closed to protect the instrument during storage and transportation. Following the surgical procedure, the Versius ultrasonic dissector transducer should be reattached to the silicone holders of the basket, the lid should be positioned and closed, and the basket with the instruments securely fixed inside should be sent for reprocessing procedures.

The reprocessing procedures must be followed according to the information on the following pages of this manual.

Reprocessing procedures overview

Outline of all procedures



Initial manual cleaning

Warnings

 Only use this basket for reprocessing and transport Versius Ultrasonic Dissector Transducer.

Precautions

 Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of the basket.

 Do not use abrasive metal or hard brushes as this may damage the basket.

 Do not use a sponge to clean the basket.

 Do not soak or rinse the basket in hot water as this could cause proteins to aggregate, making it more difficult for proteins to be removed.

 To avoid splashes and aerosolization, immerse the basket completely while brushing and cleaning.

Information points

 Start initial manual cleaning of the basket within 4 hours of finishing point-of-use preparation.

 Visually inspect the basket for any wear and tear or sharps, which may compromise the performance, and for rust. Baskets must follow and complete the full reprocessing and sterilisation cycle before each use.

 Carefully inspect the basket between uses to verify proper functioning.

 Damaged baskets should be replaced to prevent potential patient/user injury and loss of metal fragments into the surgical site.

Equipment required



ph 7-11 enzymatic detergent premixed according to the manufacturer's instructions.



Sink of container large enough for the ultrasonic dissector basket.



Soft-bristled nylon brush (brush head size: 25-50 mm)



Cold water

Tap water, less than 45°C (113 °F)

Step 1 Remove basket inside from container



Start initial manual cleaning of the ultrasonic dissector reprocessing basket within 4 hours of finishing point-of-use preparation.

1. Remove the ultrasonic dissector reprocessing basket inside from the container.
2. Drain the container of the enzymatic detergent or water.

Step 2 Soak the basket

- A**
1. Fill the sink or container with enough fresh pH 7–11 enzymatic detergent, diluted to the manufacturer's recommendations, to completely immerse the ultrasonic dissector transducer and cable.
 2. Place the basket in the sink or container.

- B**
- Leave the basket to soak for a minimum of 10 minutes (unless the detergent manufacturer's instructions recommend a longer soaking period).

- C**
- Remove the ultrasonic dissector transducer and cable from the basket.

Step 3 Brush ultrasonic dissector reprocessing basket

- A**
- Use a soft-bristled nylon brush only, brush the reprocessing basket thoroughly while it is fully immersed.

- B**
- Drain the sink or container of the detergent.

Step 4 Rinse ultrasonic dissector reprocessing basket

Rinse the ultrasonic dissector reprocessing basket under running cold water to remove visible soil and cleaning solutions.

If any soil is visible after rinsing, repeat steps 3 and 4.

Main cleaning: Full manual cleaning

Warnings



Only use this basket for reprocessing and transport Versius Ultrasonic Dissector Transducer.



Always rinse the entire reprocessing basket under running critical water to ensure contaminants and residue are removed during full manual cleaning.

Precautions



Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of the basket.



Do not use abrasive metal or hard brushes as this may damage the basket.



Do not use a sponge to clean the basket.



Do not soak or rinse the basket in hot water as this could cause proteins to aggregate, making it more difficult for proteins to be removed.



To avoid splashes and aerosolization, immerse the basket completely while brushing and cleaning.

Information points



Start initial manual cleaning of the basket within 4 hours of finishing point-of-use preparation.



Visually inspect the basket for any wear and tear or sharps, which may compromise the performance, and for rust. Baskets must follow and complete the full reprocessing and sterilisation cycle before each use.



Carefully inspect the basket between uses to verify proper functioning.

i Damaged baskets should be replaced to prevent potential patient/user injury and loss of metal fragments into the surgical site.

Equipment required



ph 7-11 enzymatic detergent premixed according to the manufacturer's instructions.



Sink of container large enough for the ultrasonic dissector basket.



Soft-bristled nylon brush (brush head size: 25-50 mm)



Cold water
Tap water, less than 45°C (113 °F)



Running critical water

Step 1 Soak ultrasonic dissector reprocessing basket

- A** 1. Fill the sink or container with enough fresh pH 7–11 enzymatic detergent, diluted to the manufacturer's recommendations, to completely immerse the ultrasonic dissector reprocessing basket.
2. Place the reprocessing basket in the sink or container.

- B** Leave the reprocessing basket to soak for a minimum of 10 minutes (unless the detergent manufacturer's instructions recommend a longer soaking period).

Step 2 Brush ultrasonic dissector reprocessing basket

- A** Use a soft-bristled nylon brush only, brush the reprocessing basket thoroughly while it is fully immersed for 2 minutes minimum.

- B** Drain the sink or container of the detergent.

Step 3 Rinse ultrasonic dissector reprocessing basket

- A** Rinse the ultrasonic dissector reprocessing basket under running cold water to remove cleaning solutions.

- B** Rinse the entire ultrasonic dissector reprocessing basket under running critical water for a minimum of 1 minute and 30 seconds to remove cleaning solutions.
- Only use critical water in this step.**

Main cleaning: Automated cleaning and thermal disinfection

Warnings



Only use this basket for reprocessing and transport Versius Ultrasonic Dissector Transducer.



Only use validated parameter settings during automated cleaning and thermal disinfection. Parameter setting that have not been validated could result in damage to, or ineffective cleaning of the basket.



Only use ISO 15883 validated washer/disinfectors.

Precautions



Only use validated cleaning solutions. Cleaning solutions that have not been validated may result in damage to, or ineffective cleaning of the basket.

Information points



Carefully inspect the basket between uses to verify proper functioning.



Damaged baskets should be replaced to prevent potential patient/user injury and loss of metal fragments into the surgical site.

Equipment required



ph 7-11 enzymatic detergent premixed according to the manufacturer's instructions.



Washer/disinfector, cycle in compliance with ISO 15883 and with the following parameters of appendix B.

Step 1 Load basket into washer/disinfector

Carefully load the reprocessing basket into the washer/disinfector.

Step 2 Run washer/disinfector cycle

Set the parameters and run the washer/disinfector cycle in compliance with ISO 15883. The cycle should include the parameters shown in the table below:

Washer/disinfector parameters for automated cleaning and thermal disinfection

Stage of cycle	Parameter setting	Minimum time
Pre-cleaning	Cold water (< 45 °C / 113 °F)	2 minutes
Cleaning	Hot water (> 45 °C / 113 °F)	2 minutes
Rinsing	Critical hot water (> 45 °C / 113 °F)	2 minutes
Thermal disinfection	Follow the national requirements for the A ₀ value (see ISO 15883)	
Drying Hot	Hot air (115 °C / 239 °F)	5 minutes

Carry out thermal disinfection in compliance with ISO 15883 and follow the national requirements with regard to the A₀ value (see ISO 15883). Thermal disinfection was validated with A₀ = 3000 and A₀ = 600.

Step 3 Remove basket from washer/disinfector

Remove the reprocessing basket from the washer/disinfector after cycle finishes and allow the basket to cool down.

Preparation for sterilisation

Warnings



Only use this basket for reprocessing and transport Versius ultrasonic dissector transducer.



Always repeat the entire cleaning process, including initial manual cleaning, if any soil is present on the ultrasonic dissector reprocessing basket during the inspection stage.

Precautions



Test the closure of the lid, fixation of the intermediate tray in the basket, fixation of the instruments in the silicone supports to ensure they are secure before transport and reprocessing.

Information points



Carefully inspect the basket between uses to verify proper functioning.



Damaged baskets should be replaced to prevent potential patient/user injury and loss of metal fragments into the surgical site.

Equipment required

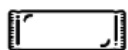


Lint-free cloth



Magnifying glass (magnification between 2x and 4x)

For packing the reprocessing basket containing the ultrasonic dissector transducer and cable, choose either:



Steam-permeable sterilisation pouch with window and large enough for the basket.

Or



Interleaved sterilisation wrap (ISO 11607-1 and EN 868-2 compliant), large enough to wrap the basket.

Step 1 Dry ultrasonic dissector reprocessing basket

Dry the ultrasonic dissector reprocessing basket with a lint-free cloth.

Step 2 Inspect ultrasonic dissector reprocessing basket

A Use a magnifying glass to inspect the ultrasonic dissector reprocessing basket for any remaining soil.

Pay particular attention to crevices, holes, and difficult-to-clean areas.



Always repeat the entire cleaning process, including initial manual cleaning, if any soil is present on the ultrasonic dissector reprocessing basket during the inspection stage.

B Use a magnifying glass to inspect the ultrasonic dissector reprocessing basket for any damage. In particular, check for:

- Bent or damaged basket
- Sharp edges
- Damaged cable connector
- Loose or missing parts
- Rough surfaces
- Moisture

If the ultrasonic dissector reprocessing basket show signs of defects or damage, please FAMI Customer Services.

Step 3 **Pack basket**

A Place the intermediate tray and the lid on the basket and secure it in place.

B Pack the basket in either a steam-permeable sterilisation pouch or interleaved sterilisation wrap.
Follow ISO 11607-1 and EN 868-2 and all applicable local and hospital guidelines when packing the basket for sterilisation.

Sterilisation

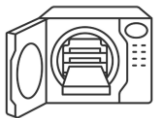
Warnings

-  Only use this basket for reprocessing and transport Versius ultrasonic dissector transducer.
-  Ensure that the sterilisation procedure conforms with ISO 17665-1.
-  Only use validated parameter settings during steam sterilisation parameter settings. Parameter setting that have not been validated could result in damage to, or ineffective cleaning of the basket.
-  Ensure that the basket cool down gradually to room temperature before transportation or use. Sudden changes in temperature could result in ineffective sterilisation of the basket.
-  Always store and transport the basket in the specified environmental conditions. Incorrect storage and transportation could lead to damage to the basket and/or to the instruments and/or to the steam-permeable sterilisation pouch or interleaved sterilisation wrap.

Information points

-  Carefully inspect the basket between uses to verify proper functioning.
-  Damaged baskets should be replaced to prevent potential patient/user injury and loss of metal fragments into the surgical site.
-  Send the ultrasonic dissector reprocessing basket for reprocessing as soon as possible.

Equipment required



Steam steriliser with dynamic air removal (pre-vacuum) cycle, in compliance with ISO 17665-1 and with the parameters of Appendix B.

Step 1 Place the basket into steam sterilizer

Place the intermediate tray and the lid on the basket and secure it in place.

Step 2 Run sterilizer

Set the parameters and run the sterilisation cycle (according to ISO 17665-1):

Pre-vacuum steam sterilisation parameters

Parameter	Value
Temperature	134-137 °C (273-279 °F)
Exposure time	3-18 minutes (holding time)
Dry time	20 minutes (minimum)

OR

Parameter	Value
Temperature	121 °C (250 °F)
Exposure time	20 minutes (holding time)
Dry time	20 minutes (minimum)

OR

Parameter	Value
Temperature	132 °C (270 °F)
Exposure time	4 minutes (holding time)
Dry time	20 minutes (minimum)



Ensure that the sterilisation procedure conforms with ISO 17665-1.

Step 3 **Leave basket to cool down**

1. Remove the wrapped or pouched basket containing the ultrasonic dissector reprocessing basket from the sterilizer after the cycle finishes.
2. Leave the wrapped or pouched basket containing the ultrasonic dissector reprocessing basket to cool down before transportation or use.



Ensure that the basket cool down gradually to room temperature before transportation or use. Sudden changes in temperature could result in ineffective sterilisation of the basket.

Reprocessing is complete.

Appendix A

FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer

FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer

Reference number (REF)	Description	Maximum number of reprocessing cycles
136.113	FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer	Undetermined

Appendix B

Validated equipment and parameters

Washer/disinfector parameters for automated cleaning and thermal disinfection

Stage of cycle	Parameter setting	Minimum time
Pre-cleaning	Cold water (< 45 °C / 113 °F)	2 minutes
Cleaning	Hot water (> 45 °C / 113 °F)	2 minutes
Rinsing	Critical hot water (> 45 °C / 113 °F)	2 minutes
Thermal disinfection	Follow the national requirements for the A ₀ value (see ISO 15883)	
Drying Hot	Hot air (115 °C / 239 °F)	5 minutes

Carry out thermal disinfection in compliance with ISO 15883 and follow the national requirements with regard to the A₀ value (see ISO 15883).
Thermal disinfection was validated with A₀ = 3000 and A₀ = 600.

Pre-vacuum steam sterilisation parameters

Parameter	Value
Temperature	134-137 °C (273-279 °F)
Exposure time	3-18 minutes (holding time)
Dry time	20 minutes (minimum)

OR

Parameter	Value
Temperature	121 °C (250 °F)
Exposure time	20 minutes (holding time)
Dry time	20 minutes (minimum)

OR

Parameter	Value
Temperature	132 °C (270 °F)
Exposure time	4 minutes (holding time)
Dry time	20 minutes (minimum)



Ensure that the sterilisation procedure conforms with ISO 17665-1.

The validated drying times for the parameters outlined were 20 minutes. Drying times are likely to vary depending on the steriliser and loading conditions.

The maximum sterilisation parameters validated were 134 °C (273 °F) for 20 minutes.

Glossary

A ₀ value	Time taken to reduce the number of microorganisms to an acceptable level based on the temperature of the thermal disinfection cycle.
Aerosolization	The process or act of converting some physical substance into the form of particles small and light enough to be carried in the air, i.e. into an aerosol. The sink or container used during cleaning should be deep enough to allow complete immersion of the ultrasonic dissector transducer and cable so that aerosols are not generated.
ABNT NBR ISO 11607-1	International standard adopted by the American National Standards Institute (ANSI), Association for the Advancement of Medical Instrumentation (AAMI), and the International Organization for Standardization (ISO) for the packaging of sterilised medical devices.
Cold water	Tap water, less than 45 °C (113 °F).
Critical water	Water treated extensively to ensure that it is free from microorganisms, inorganic and organic material. Examples are: deionised water, reverse osmosis and distilled water.
Disinfection	Treatment of items to reduce the number of microorganisms to an acceptable level.
Enzymatic detergent	Cleaning substance that uses enzyme proteins to remove soil. Reprocessing the ultrasonic dissector transducer and cable uses pH 7-11 enzymatic detergent.
Hot water	Tap water, greater than 45° C (113 °F); maximum temperature 95 °C (203 °F).
Immerse	Place an item under the surface of a liquid so it is fully covered.
Interleaved sterilisation wrap	Packaging material used to wrap medical devices for sterilisation.
ISO 15883	International Organization for Standardization (ISO) standard for Washer-disinfectors.
ISO 17665-1	International Organization for Standardization (ISO) standard for Sterilisation of health care products with moist heat.
Pouch	Flat bag (usually with a widow) that an item is put into before sterilisation. The bag has a strip on one end that is peeled off to reveal and adhesive seal which then closes and seals the bag.

Running water	Water continuously flowing over the item being cleaned.
Soil	Material including blood and protein that may be on an ultrasonic dissector reprocessing basket and must be cleaned off before sterilisation.
Steam-permeable	Allows steam through to sterilise the item inside.
Ultrasonic dissector reprocessing basket	Basket for the reprocessing, sterilisation, storage and transportation of the Versius Ultrasonic Dissector Transducer and cable. This basket must be used when reprocessing, sterilising, storing and transporting the transducer and cable.
Versius	A Versius product supplied by CMR Surgical for use with the Versius Surgical System: a connected system of bedside units, surgeon console, endoscopic camera, instruments, drapes and cables.