medela

# Guidelines for Cleaning, Disinfecting and Sterilizing Medela Healthcare Products

## REPROCESSING GUIDE

Precious life – Progressive care

# Contents

# Reprocessing Guide (Cleaning / Disinfection / Sterilization)

## 1 General Information

This Guide is intended to give general instructions on how medical devices supplied by Medela AG may be processed or reprocessed to prepare them for Re-Use and gives advice on cleaning, disinfecting or sterilizing products supplied by Medela AG.

Equipment, operators, cleaning detergents / disinfectant agents and procedures have a contribution to the efficacy of the processing and reprocessing of medical products.

These guidelines are for healthcare professionals, such as nurses and infection control practitioners, who work in a hospital environment.

## 2 Requirements for Single Use and Re-Use

| Type | Use for | Requirements |
|---|---|---|
| **Re-Use**<br><br>*e.g.*<br>*tubing* | ➲ more than one patient<br><br>multiple uses possible | – Requires reprocessing after each use<br>– Must be checked regularly for damage and appearance and replaced if necessary |
| **Single Use**<br>  <br>*e.g.*<br>*filters* | ➲ one patient only<br><br>once only | – Ready for use<br>– Use immediately after opening the packaging<br>– Must be disposed after using<br>– Not to be used by more than one person in order to avoid possible health risks<br>– Reuse could cause cross contamination<br>– Reprocessing could cause loss of mechanical, chemical and / or biological characteristics |

**Note:**
Medela AG does not define the maximum number of uses appropriate for reprocessing and reusing of medical devices. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the device before use is the best method of determining the end of serviceable life for the medical device. Refer to Chapter 19 of the suction pumps' Instructions for Use for additional re-placement guidelines.

**Not all products are available in all markets.**

## 3 Staff

Staff should use suitable personal protective clothing and equipment at all times. In particular take note of the instructions provided by the cleaning detergent / disinfecting agent manufacturer for correct handling and use of the product.

## 4 Definitions

### 4.1 Material abbreviations

| | |
|---|---|
| ABS | Poly(Acrylonitrile Butadiene Styrene) |
| ASA | Poly(Acrylic Styrene Acrylonitrile) |
| PA | Polyamide |
| PC | Polycarbonate |
| POM | Polyoxymethylene (Acetal) |
| PP | Polypropylene |
| PS | Polystyrene |
| PSU | Polysulfone |
| TPE | Thermoplastic Elastomer |

### 4.2 Point of Use

Reprocessing already begins at the point of use, which includes initial cleaning and measures to prevent drying of soil and contaminants in and on the device and should be carried out directly after application (within a maximum of 2 hours after use).

### 4.3 Initial Cleaning and Rinsing with sterile cold Water

The first step of decontamination is initial cleaning with sterile cold water (< 40 °C, < 104 °F). The purpose of the initial cleaning is the removal of all visible soils from an item and the reduction of the number of particulates, microorganisms and potential pyrogens. Many soils, including proteinaceous blood components such as albumin and hemoglobin, are water-soluble and can be easily washed away with water alone.

### 4.4 Thorough Cleaning

Thorough cleaning consists of the removal, usually with detergent and water, of adherent soil (e.g., blood, protein substances and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination (Disinfection / Terminal Sterilization).

### 4.5 Disinfection

Disinfection is a process that removes, inactivates or destroys blood-borne pathogens and other microorganisms by physical or chemical means on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, for use or for disposal. Disinfection processes do not ensure the same margin of safety associated with sterilization processes.

### 4.6 Thorough Disinfection or Terminal Sterilization

The complete elimination or destruction of all forms of microbial life accomplished in health care facilities by either physical or chemical processes.

## 5 List of Non-Critical Medical Products

Recommended cleaning methods have been validated by Medela AG to current international guidelines for cleaning.

### Electric and electronic equipment and accessories

| Picture | Item No | Description | Material |
|---|---|---|---|
|  | 014.0XXX | Clario / Clario Toni<br>Motor unit AC-version<br>Motor unit AC / DC-version | Housing:<br>Plastics (ABS) |
|  | 074.0006 | Clario / Clario Toni vacuum gauge | Metals<br>(stainless)<br>Plastics<br>(various) |
|  | 074.0007 | Clario / Clario Toni carrying bag | Plastics<br>(PE coated with<br>PET) |
|  | 026.XXXX | Vario 8 AC + AC / DC<br>Vario 8 c/i AC / DC<br>Vario 18 AC + AC / DC<br>Vario 18 c/i AC / DC | Housing<br>Plastics (ABS) |
|  | 077.0105 | Vario jar adapter | Plastics (ABS) |
|  | 077.0511 | Trolley small | Metals<br>(Zinc-coated<br>steel) |
|  | 077.0821 | Vario rail holder | Metals<br>(AlMgSi) |
|  | 077.0823 | Vario universal holder | Metals<br>(Aluminum) |

| Picture | Item No | Description | Material |
|---|---|---|---|
|  | 077.0831<br>077.0832 | Vario carrying bag<br>Vario car connection cable | Plastics<br>(Polyester with PVC coating) |
|  | 087.0000 | Invia Liberty pump | Housing: Plastics (ABS)<br>Holder: Plastics (PAA)<br>Button: Plastics (POM) |
|  | 079.0037 | Docking station | Housing: Plastics (PC)<br>Knob: Plastics (PA66) |
|  | 077.0148 | Mains adapter winternational | n/a |
|  | 071.0000<br>071.0001 | Basic suction pump, rack and portable versions | Housing<br>Plastics (ABS) |
|  | 071.0002<br>071.0003 | Dominant Flex suction pump, rack and portable versions | Housing<br>Plastic (ABS) |
|  | 071.0034<br>071.0035 | Trolley to Dominant Flex and Basic suction pumps | PS-coated metal |
|  | 077.0104<br>077.0521<br>077.0152 | Clampholder | Plastics (PA)<br><br>Metals (Aluminum) |
|  | 077.0723 | Foot On/Off switch | Various plastics |

| Picture | Item No | Description | Material |
|---|---|---|---|
|  | 077.0731 | Foot vacuum regulator | Various plastics |
|  | 077.0751<br>077.0752 | Tubing holders | Metals (stainless) |
|  | 017.0015 | Apgar Timer | Housing:<br>Plastics (PC/ABS) |
|  | 077.0523 | Wall bracket, single | Plastics (ASA) |
|  | 079.0000<br>079.0002<br>079.0003 | Thopaz drainage pump | Housing:<br>Plastics (ABS) |
|  | 079.1000<br>079.1002<br>079.1003 | Thopaz+ digital cardio-thoracic drainage system | Housing:<br>Plastics (ABS) |
|  | 079.0031 | Carrying strap Thopaz | Textiles, Plastics (ABS) |
|  | 079.1006 | Carrying strap Thopaz+ | Textiles, Plastics (ABS) |
|  | 079.0036<br>079.0040 | Holder with standard rail | Metals (stainless, aluminium) |
|  | 079.0038 | Adapter docking station for Thopaz canister 2l | Plastics (PP) |
|  | 077.1456 | Vacuum gauge | Metals (stainless)<br>Various plastics |

## 6 Processing Instructions

The sequence of steps required to prepare medical devices for reprocessing are summarized in the chart below.

More detailed instructions for each step are given on the following pages.

### Point of Use

- Disassembly
- Manual Initial Cleaning

### Thorough Cleaning

- Manual Thorough Cleaning
- Drying

### Disinfection

- Manual Disinfection
- Drying

### Storage

- Inspection
- Reassembly

## 7 Point of Use

### 7.1 Utensils and Equipment

- Personal Protective Equipment (PPE: Disposable gloves, Proper protective gear).
- Lint free nonwoven wipes.
- Sterile cold water (< 40 °C, < 104 °F).

### 7.2 Procedure Disassembly

- Disinfect your hands.
- Put on disposable gloves and proper protective gear.
- Disassemble if possible.

| | |
|---|---|
|  | Housing suction pumps: remove Safety Set as shown.<br>Suction pumps in general: Remove all accessories if attached. |

### 7.3 Procedure Manual Initial Cleaning

- Directly after application (within a maximum of 2 hours postoperatively) wipe the surfaces to remove all gross debris by using a lint free nonwoven wipe wetted with sterile cold water (< 40 °C, < 104 °F).
- Ensure that all surfaces are thoroughly wetted.
- Wipe again using another wipe and keep moist for a minimum of 5 minutes then repeat it with another wipe.
- Dispose of protective gloves.
- Disinfect your hands.

### 7.4 Cautions

- Before cleaning electrical devices, disconnect the power plug from the power socket.
- Clean all surfaces immediately after use (maximum 2 hours postoperatively) to avoid residues from drying and to prevent growth of microorganisms.
- Never use steel brushes or steel wool for cleaning.
- Water temperatures higher than 45 °C (113 °F) can cause protein coagulation which may affect the efficacy of the process.
- Never place the device in water or other liquids.

## 8 Thorough Cleaning

### 8.1 Utensils and Equipment

- Personal Protective Equipment (PPE: Disposable gloves, Proper protective gear).
- Lint free nonwoven wipes wetted with an enzymatic detergent.
- Sterile cold water (< 40 °C, < 104 °F).

### 8.2 Procedure Manual Thorough Cleaning

- Disinfect your hands.
- Put on disposable gloves and proper protective equipment.
- Use the wipes wetted with an enzymatic detergent according to the manufacturer's instructions for use.
- Ensure that all surfaces are thoroughly wetted.
- Check surfaces for visible dirt and repeat these steps if necessary.
- At the end use a wipe wetted with sterile cold water (< 40 °C, < 104 °F) to wipe surfaces. Repeat these steps if necessary.

### 8.3 Procedure Drying

- Allow surfaces to dry from the enzymatic detergent according to the manufacturer's instructions for use.
- Dispose of protective gloves.
- Disinfect your hands.

### 8.4 Cautions

- Before cleaning electrical devices, disconnect the power plug from the power socket.
- Never use steel brushes or steel wool for cleaning.
- Water temperatures higher than 45 °C (113 °F) can cause protein coagulation which may affect the efficacy of the process.
- Never place the device in water or other liquids.

## 9 Intermediate Level Disinfection

### 9.1 Utensils and Equipment

- Personal Protective Equipment (PPE: Disposable gloves, Proper protective gear).
- Disinfecting wipes.

### 9.2 Procedure Manual Disinfection

- Disinfect your hands.
- Put on disposable gloves and proper protective equipment.
- Use disinfecting wipes according to the manufacturer's instructions for use.
- After 5 minutes wipe with another disinfecting wipe.

### 9.3 Procedure Drying

- Allow the surface to dry for a minimum of 5 minutes.
- Dispose of protective gloves.
- Disinfect your hands.

### 9.4 Caution

- Never place the device in water or other liquids.

### 9.5 Recommended agent:

- CaviWipes®
  Metrex® Research
  Address: 1717 West Collins Avenue, Orange, CA 92867, U.S.A.
  Homepage: http://www.metrex.com
  Phone: (800) 841 1428
  Email: metrexcustcare@sybrondental.com
- Mikrozid® AF Wipes
  Schülke&Mayr GmbH
  Address: Robert-Koch Str. 2, 22851 Norderstedt, GERMANY
  Homepage: http://www.schuelke.com
  Phone: +49 (0) 40 521 00 0
  Email: info@schuelke.com

## 10 Storage

### 10.1 Procedure Reassembly and Storage

– Where appropriate the cleaned, disinfected and checked medical products should be reassembled again and prepared for Re-Use.

| | |
|---|---|
|  | Housing suction pumps: Reattach Safety Set as shown<br>Suction pumps in general: Configure pump with necessary accessories |

– Sufficient protection of the medical products must be provided in order to keep medical products dry and dust free.

### 10.2 Cautions

– Store medical products dry and dust free.

# Processing Instructions for thermal sensitive Non-Critical Medical Products at Health Care Facilities

## 11 List of thermal sensitive Non-Critical Medical Products

Recommended cleaning methods have been validated by Medela AG to current international guidelines for cleaning.

Thermo sensitive medical products

| Picture | Item No | Description | Material |
|---|---|---|---|
|  | 074.0001 | Clario / Clario Toni canister Set consists of canister, lid with plugs for closing and floater (074.0010) | Jar: Plastics (PC)<br>Lid: Plastics (TPE-E)<br>Plugs: Plastics (PE)<br>Floater: Plastics (TPE-V) |
|  | 074.0002<br>014.0030 | Clario / Clario Toni SafetyChamber is a set consisting of lid, housing, 2 valves (074.0008) | Housing:<br>Plastics (PBT+ASA)<br>Lid: Plastics (TPE-E)<br>Valves: Elastomers (MQ) |
|  | 014.0005 | Clario / Clario Toni vacuum regulator Knob | Plastics (TPE-V) |
|  | 077.0082<br>077.0085 | PC suction jar, 1.5l<br>PC suction jar, 2.5l | Plastics (PC) |
|  | 077.0531<br>077.0532 | Quiver, 280 ml with holder<br>Quiver, 480 ml with holder | Plastics (PP) |

## 12 Processing Instructions

The sequence of steps required to prepare medical devices for reprocessing are summarized in the chart below.

More detailed instructions for each step are given on the following pages.

### Point of Use

- Disassembly
- Manual Initial Cleaning

### Thorough Cleaning

- Automated Cleaning with Washer Disinfector

### Thermal Disinfection

- Automated Disinfection with Washer Disinfector
- Inspection

### Storage

- Reassembly
- Packaging
- Storage

## 13 Point of Use

### 13.1 Utensils and Equipment

- Personal Protective Equipment (PPE: Disposable gloves, Proper protective gear)
- Sterile cold water (< 40 °C, < 104 °F)

### 13.2 Procedure Disassembly

- Disinfect your hands.
- Put on disposable gloves and proper protective equipment.
- PC jars:
  - When used with the disposable liners from Medela: remove liners according to suction pump's Instructions for Use, chapter 10
  - Remove jar from clamp holder
- Quiver:
  - Remove from holder

### 13.3 Procedure Initial Cleaning with Rinsing Water

- Remove gross debris.
- Rinse all parts with sterile cold water (< 40 °C, < 104 °F) for 3 minutes.
- Dispose of protective gloves.
- Disinfect your hands.

### 13.4 Cautions

- Clean all parts immediately after use (maximum 2 hours postoperatively) to avoid drying of residues and to prevent growth of microorganisms.
- Never use steel brushes or steel wool for cleaning.
- Water temperatures higher than 45 °C (113 °F) can cause protein coagulation which may affect the efficacy of the process.

## 14 Thorough Cleaning and Thermal Disinfection

### 14.1 Utensils and Equipment

- Disposable gloves

### 14.2 Procedure Automated Cleaning and Disinfection with Washer Disinfector

- Disinfect your hands.
- Put on disposable gloves.
- Load items into the washer disinfector.
- Choose the washer disinfector washing cycle.
- Operate the washer disinfector.

- On completion, unload the washer disinfector.
- Visually check for remaining soil and dryness. If soil remains, repeat the procedure Cleaning and Disinfection with Washer Disinfector.
- Remaining wetness may be removed with medical grade compressed air or by heating in an oven below 110 °C (230 °F).

### 14.3 Procedure Inspection

- Check the parts visually for damage and throw away at first signs of damage or weakness.
- Dispose of protective gloves.
- Disinfect your hands.

### 14.4 Cautions

- Water temperatures higher than 45 °C (113 °F) during the cleaning cycle can cause protein coagulation which may affect the efficacy of the process.
- Avoid contact between items (movement during washing could cause damage).
- Arrange items so that channels and openings are always oriented downwards
- Please follow Instructions for Use of manufacturer:
  - for washing disinfector and
  - for detergents and disinfectants
- If available, attach tubing to nozzles in washer disinfector.

### 14.5 Recommended agents for thorough cleaning and thermal disinfection:

- neodisher® FA as the Liquid Detergent and
  neodisher® Z as the Liquid Neutralizing Agent
  Miele, Inc.
  Address: 9 Independence Way, Princeton, NJ 08540, U.S.A.
  Homepage: http://www.miele.us
  Phone: (800) 991 9380
  Email: proinfo@mieleusa.com

- neodisher® FA as the Liquid Detergent and
  neodisher® Z as the Liquid Neutralizing Agent
  Chemische Fabrik Dr. Weigert GmbH & Co. KG
  Mühlenhagen 85, D-20539 Hamburg, GERMANY
  Homepage: http://www.drweigert.com

## 15 Storage

### 15.1 Procedure Reassembly and Storage

- Where appropriate, the cleaned, disinfected and checked medical products should be prepared for Re-Use.
- Sufficient protection of the medical products must be provided in order to keep medical products dry and dust free.

### 15.2 Cautions

- Store medical products dry and dust free.

# Processing Instructions for re-sterilizable Non-Critical Medical Products at Health Care Facilities

## 16 List of re-sterilizable Non-Critical Medical Products

Recommended cleaning methods have been validated by Medela AG to current international guidelines for cleaning.

Sterilizable Medical Products

| Picture | Item No | Descrip-tion | Material |
|---|---|---|---|
|  | 077.0420 / 077.0430<br>077.0440 / 077.0450 | Lid | Plastics<br>(PA, TPE, POM) |
|  | 077.0110 / 077.0120<br>077.0125 / 077.0130<br>077.0150 / 077.0155 | Suction jar PSU | Plastics (PSU) |
|  | 077.0900 / 077.0901<br>077.0902 / 077.0905<br>077.0970 / 077.0095<br>077.0542 / 077.0912<br>077.0913 / 077.0921<br>077.0922 / 077.0931<br>077.0961 / 077.0185 | Silicone tubing | Elastomers (Silicone)<br>Plastics (POM)<br>Elastomers (silicone o-ring) |
|  | 077.1018<br>077.1019 | Coupling pieces | Plastics (POM)<br>Elastomers (silicone o-ring) |
|  | 077.1022 | Drainage valve | Plastics (PSU)<br>Elastomers (silicone o-rings, bellows) |
|  | 077.0563 | Change-over valve | Plastics (PSU, PA)<br>Elastomers (silicone tubing) |

| | | | |
|---|---|---|---|
|  | 077.0651 / 077.0701<br>077.0702 / 077.0703<br>077.0704 / 077.0705<br>077.0706 / 077.0707<br>077.0715 / 077.0716<br>077.0711 | Assembled products and sets | Jar: PSU<br>Lid: PA, TPE, POM |
|  | 077.0029 / 077.0030<br>077.0031 / 077.0038<br>077.0175 / 077.0176<br>077.0177 | Malmström Cups | Metals (stainless)<br>Elastomers (silicone) |
|  | 077.1041 / 077.1042<br>077.1043 / 077.1044<br>077.0173 / 077.0172<br>077.0171 | Bird Cups | Metals (stainless)<br>Plastics (PP, POM)<br>Tubing: Elastomeres (Silicone) |
|  | 077.0063<br>077.0174 | Bird Posterior Cup | Metals (stainless)<br>Plastics (PP, POM)<br>Tubing: Elastomeres (Silicone) |
|  | 077.0078 | Reusable Silc Cup with trum-pet valve | Metals (stainless)<br>Elastomers (silicone) |
|  | 077.0761<br>077.0762 | Reusable Silc Cups | Metals (stainless)<br>Elastomers (silicone) |
|  | 077.0080 | CaesAid Cups for Caesarean sections | Elastomers (silicone) |
|  | 077.0081 | Manual Vacuum Extractor | Metals<br>Plastics (PP)<br>Elastomers (silicone) |

## 17 Processing Instructions

The sequence of steps required to prepare medical devices for reprocessing are summarized in the chart below.

More detailed instructions for each step are given on the following pages.

### Point of Use

- Disassembly
- Manual Initial Cleaning

### Thorough Cleaning

- Automated Cleaning with Washer Disinfector

### Thermal Disinfection / Sterilization

- Automated Disinfection with Washer Disinfector
- Inspection, Packaging
- Terminal Sterilisation by Steam

### Storage

- Storage

## 18 Point of Use

### 18.1 Utensils and Equipment

- Personal Protective Equipment (PPE: Disposable gloves, Proper protective gear)
- Sterile cold water (< 40 °C, < 104 °F)

### 18.2 Procedure Disassembly

- Disinfect your hands.
- Put on disposable gloves and proper protective equipment.
- Disassemble the product (according to the instructions sheets delivered with the product) into individual parts.
- Change-over valve:
  - Disassemble according to instruction sheet supplied with product

### 18.3 Procedure Initial Cleaning with Rinsing Water

- Rinse all parts with sterile cold water (< 40 °C, < 104 °F) for 3 minutes
- Dispose of protective gloves.
- Disinfect your hands.

### 18.4 Cautions

- Clean all parts immediately after use (maximum 2 hours postoperatively) to avoid drying of residues and to prevent growth of microorganisms.
- Never use steel brushes or steel wool for cleaning.
- Water temperatures higher than 45 °C (113 °F) can cause protein coagulation which may affect the efficacy of the process.

## 19 Thorough Cleaning and Thermal Disinfection

### 19.1 Utensils and Equipment

- Disposable gloves

### 19.2 Procedure Automated Cleaning and Disinfection with Washer Disinfector

- Disinfect your hands.
- Put on disposable gloves.
- Load items into the washer disinfector.
- Choose the washer disinfector washing cycle.
- Operate the washer disinfector.
- On completion unload the washer disinfector.
- Visually check for remaining soil and dryness. If soil remains repeat the procedure Cleaning and Disinfection with Washer Disinfector.
- Remaining wetness may be removed with medical grade compressed air or by heating in an oven below 110 °C (230 °F).

### 19.3 Procedure Inspection

- Check the parts visually for damage and throw away at first signs of damage or weakness.
- Dispose of protective gloves.
- Disinfect your hands.

### 19.4 Cautions

- Water temperatures higher than 45 °C (113 °F) during the cleaning cycle can cause protein coagulation which may affect the efficacy of the process.
- Avoid contact between items (movement during washing could cause damage)
- Arrange items so that channels and openings are always oriented downwards.
- Please follow Instructions for Use of manufacturer:
  - for washing disinfector and
  - for detergents and disinfectants
- If available, attach tubing to nozzles in washer disinfector.

**19.5 Recommended agents for thorough cleaning and thermal disinfection:**

- neodisher® FA as the Liquid Detergent and
  neodisher® Z as the Liquid Neutralizing Agent
  Miele, Inc.
  Address: 9 Independence Way, Princeton, NJ 08540, U.S.A.
  Homepage: http://www.miele.us
  Phone: (800) 991 9380
  Email: proinfo@mieleusa.com
- neodisher® FA as the Liquid Detergent and
  neodisher® Z as the Liquid Neutralizing Agent
  Chemische Fabrik Dr. Weigert GmbH & Co. KG
  Adress: Mühlenhagen 85, D-20539 Hamburg, GERMANY
  Homepage: http://www.drweigert.com
  Phone: +49 (0) 407 89 60 0
  Email: info@drweigert.de

## 20 Terminal Sterilisation

### 20.1 Utensils and Equipment

- Steam Steriliser
- Sterilisation cycle Information

| | |
|---|---|
| Method | Moist Heat Sterilisation according to ANSI/AAMI ST79 |
| Cycle | Gravity-displacement Steam Steriliser |
| Temperature | 135 °C (275 °F) |
| Exposure Time | 10 minutes |
| Pressure | 0.1 to 2.2 bar (2 to 22 psia) |
| Drying Time | 20 minutes (minimum, in chamber) |
| Cooling Time | 20 minutes (minimum, at room temperature) |

### 20.2 Procedure Terminal Sterilisation

- Visually check for remaining soil and dryness. If soil remains repeat the procedure Cleaning and Disinfection with Washer Disinfector.
- Handle items that need terminal sterilizing according to internal hospital guidelines.
- Load items into the Steam Steriliser.
- Choose the sterilisation cycle.
- Operate the Steam Steriliser
- On completion unload the Steam Steriliser.

### 20.3 Cautions

- Do not stack items in the steriliser. Place items correctly and loosely into the basket, shelf, or cart of the steriliser so as not to impede the penetration of the sterilant.
- Please follow Instructions for Use of manufacturer for Steam Steriliser.

## 21 Storage

### 21.1 Procedure Storage

- Where appropriate the cleaned, disinfected and checked medical products should be assembled for re-use according to the instruction sheets delivered with assembled products.
- Sufficient protection of the medical products must be provided in order to keep medical products dry and dust free.
- Ensure that the sterile storage area is a well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes.
- Store sterile items so the packaging is not compromised (e.g. punctured, bent). After disinfection, store the components in clean foil until required for use.
- Label sterilized items with a load number that indicates the steriliser used, the cycle or load number, the date of sterilisation, and, if applicable, the expiration date according to in-house hospital policy.
- The shelf life of a packaged sterile item depends on the quality of the wrapper, the storage conditions and the conditions during transport, the amount of handling, and other events (moisture) that compromise the integrity of the package.
- Evaluate packages before use for loss of integrity (e.g., torn, wet and punctured). The pack can be used unless the integrity of the packaging is compromised, repack and reprocess before use.

### 21.2 Cautions

- Store medical products dry and dust free.

## Disassembly and Reassembly Chart

See instructions from the suction pump's instructions for use and individual instruction sheets supplied with accessories for disassembly.

## References


- U.S. Food and Drug Administration (FDA)
  Draft Guidance for Industry and FDA Staff: May 2, 2011
  Processing/Reprocessing Medical Devices in Health Care Settings:
  Validation Methods and Labeling
- AAMI TIR12:2004, Arlington, VA: AAMI, 2004. Technical Information Report
  Association for the Advancement of Medical Instrumentation
  Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI TIR30:2003, Arlington, VA: AAMI, 2003. Technical Information Report
  Association for the Advancement of Medical Instrumentation
  A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- ANSI/AAMI ST79: 2010 & A1: 2010 & A2:2011 & A3:2012
  Association for the Advancement of Medical Instrumentation
  Comprehensive Guide to Steam Sterilisation and Sterility Assurance in Health Care Facilities
- Centers for Disease Control and Prevention (CDC)
  Guideline for Disinfection and Sterilisation in Healthcare Facilities, 2008
- EN ISO 17664:2004:
  Sterilisation von Medizinprodukten
  Vom Hersteller bereitzustellende Informationen für die Aufbereitung von resterilisierbaren Medizinprodukten

## Phone numbers

For additional information on the device, including questions on infection control procedures, please call:
USA (+1) 877 735 1626, International (+41) 41 562 51 51

Medela AG
Lättichstrasse 4b
6341 Baar, Switzerland
www.medela.com

**International Sales**
Medela AG
Lättichstrasse 4b
6341 Baar, Switzerland
Phone +41 41 562 51 51
Fax +41 41 562 51 00
ism@medela.ch
www.medela.com

**Local contact:**