

Medisafe

®

Medisafe Consumables Catalogue

Endoscopy, Hospitals, Dental, Pre-Cleaning & Wash Monitoring

SONMEDICA, S.A.

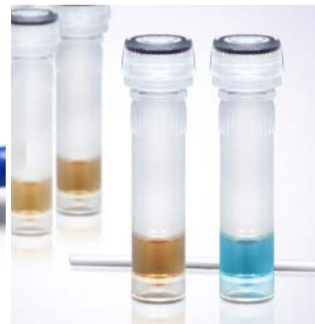
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World Leaders in Hi-Tech Surgical Reprocessing Solutions

Introduction

Medisafe

World Leaders in Hi-Tech Surgical Reprocessing Solutions

Medisafe's principal business is focused on a unique, innovative approach to the design, development and manufacture of equipment and associated consumables and accessories that will reprocess complex and critical surgical instruments, from a small practice to a major acute hospital.

Valisafe

Routine monitoring of the complete decontamination process...

Valisafe's innovated range of unique decontamination process and sterility assurance products ensures simple, continuous and consistent monitoring. Our experienced team is dedicated to ensuring that every variable of the decontamination and sterilization process is monitored.

We consider it vital that you are able to validate (to yourself and others) that your objectives and practices have been met when reprocessing instruments and that the equipment functions according to the manufacturer's specifications.

Our Vision

With the new surgical advancements made over the past decade, it's reasonable to assume that most surgical procedures in the future will ideally be carried out with the "minimum of invasion". Type "Trans-luminal" or "incisionless surgery" into your internet tool bar and you will get an indication of how complex surgical instruments will be in the future. These new, complex instruments will be expensive and therefore, require complex and repeatable reprocessing systems. We will continue to lead the market with innovative solutions as surgical techniques continue to evolve!

We're passionate about our products, product development and how they benefit our customers. Medisafe is constantly innovating to meet the needs customers have today and the expectation they will have tomorrow.

Our Values

Innovation, opportunity and growth – our ethos is to innovate and create new opportunities and possibilities. Our approach to innovation puts us ahead of the competition. This creates opportunities for growth and in turn allows new and existing staff or team members to grow with the company and fulfil their goals.

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 Valisafe (a division of Medisafe International)

Key:
 USM: Unit Sales Multiple



Medisafe Endoscopy

Medisafe has a range of products to assist with your endoscopy requirements, guiding you through the entire process, from clinical procedure disposables which aid in theatre to decontamination of scopes, from bedside through to your endoscope decontamination suite.

Biopsy Forceps

USM: 10

Medisafe has an extensive range of single use Biopsy Forceps, which includes both oval and alligator cup and can be supplied with or without needle.

All of our Biopsy Forceps are supplied with a ribbed coated sheath to aid insertion, and the swinging jaw mechanism aids tangential biopsies. Our Biopsy Forceps have unique colour coded retractors which helps to identify the compatibility area. Both the oval and alligator forceps can be supplied with needle which can offer improved anchorage of foreign bodies and mucosal tissue biopsies.

Medisafe's Biopsy Forceps offer a unique colour coded handle system for clear identification purpose.

Order Code	Forceps Head Type	Shaft Length (cm)	Retractor Colour	Minimum Working Channel (mm)	Box Quantity	Needle
M20703	Oval	180	Orange	2.3	10	-
M20704	Oval	230	Racing Green	2.3	10	-
M20705	Oval	180	Cream	2.3	10	✓
M20706	Oval	230	Mint Green	2.3	10	✓
M20707	Alligator	180	Orange	2.3	10	-
M20708	Alligator	230	Racing Green	2.3	10	-
M20709	Alligator	180	Cream	2.3	10	✓
M20710	Alligator	230	Green	2.3	10	✓
M20711	Oval	120	Blue	1.8	10	-
M20715	Oval	180	Blue	1.8	10	-



Disposable Polypectomy Snare

USM: 10

Medisafe's Polypectomy Snares allows for optimum comfort and speed during colonoscopic polypectomy and endoscopic mucosal resection.

- Smooth open and close mechanism for optimum ease of use
- Available in 6 different size loop diameters to allow for the effective resection of all size polyps
- Oval and hexagonal options available
- Integral handle gauge allowing you to estimate the size of the captured polyp
- Smooth sheath to prevent scope damage
- Single use

Order Code	Disposable Polypectomy Snare	Length (cm)	Minimum Working Channel (mm)	Box Quantity
M20724	Oval	230	2.4 / 10	10
M20725	Oval	230	2.4 / 15	10
M20726	Oval	230	2.4 / 20	10
M20727	Oval	230	2.4 / 25	10
M20741	Oval	230	2.4 / 35	10
M20728	Hexagonal	230	2.4 / 15	10
M20729	Hexagonal	230	2.4 / 20	10
M20730	Hexagonal	230	2.4 / 25	10



USM: 10

Sclerotherapy Needle

Used to introduce a sclerosing agent or vasoconstrictor to control bleeding within the digestive system. It can also be effectively used to aid mucosal and polyp resection.

- Easy grip handle
- Needle designed for optimum facilitation of injection
- Strong but smooth pushable sheath
- Easy loading
- Available in different lengths and gauges



Order #

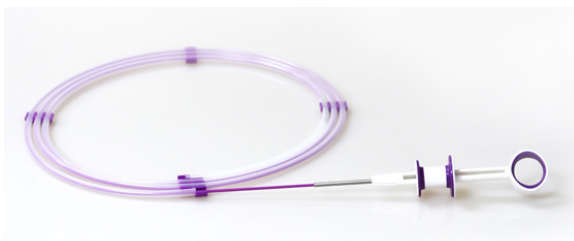
M20732 - Injection Needle – 23G, 6mm, 230cm (box 10)
M20739 - Injection Needle – 25G, 4mm, 230cm (box 10)

USM: 5

Hemoclip

Medisafe are pleased to introduce our new Haemostasis Clip for optimum comfort, speed and dexterity during surgery.

- Fully 360 degree rotatable and controlled by any part of the handle
- Can be repositioned and realigned
- Complete clip closure
- Ridged grooves make clip resistant to slippage
- Easy loading
- Smooth sheath prevents scope damage
- Opening range 11mm / working length 2300mm
- Single use



Order #

M20736 - Hemoclip 11mm - (box 5)
M20736.1 - Hemoclip 15mm - (box 5)

USM: 10

Polyp Trap

Medisafe's Polyp trap is an easy-to-use and useful device which captures and holds eliminated tissue specimens, with five chamber traps.

Designed to facilitate uninterrupted suction and eliminating the need to retrieve polyps from collected endoscopic effluent.

- Reduce risk of lost colonic tissue
- Eliminate manual manipulation after retrieval
- 5 Large numbered chambers for quick and easy transfer
- Individually packaged
- Single use to prevent cross-contamination



Order #

M20731 – Polyp trap (box 10)

Mouth Guards

USM: 100

- Prevents damage from endoscope
- Supplied with or without head-strap for added security
- Single piece mould offers added strength
- Large port for added comfort
- Easy access for suction
- Latex Free
- Individually wrapped – sterile
- Also available in paediatric sizes.

Order # M20701 – Mouth Guards with Strap (box 100)
M20737 – Paediatric Mouth Guard (box 100)



Biopsy Port Valves

USM: 100

- Soft TPE material allows for easy and smooth passage of endoscopic accessories
- Close fitting to enable secure anchor of Biopsy Valve to the Biopsy port
- Suitable for Olympus and Pentax Endoscopes
- Black, individually bagged
- Effective, low cost
- Sterile
- With tracking traceability

Order # M20702.1 – Port Valves - Olympus GI (box 100)
M20702.2 – Port Valves - Pentax (box 100)



Scope Brushes

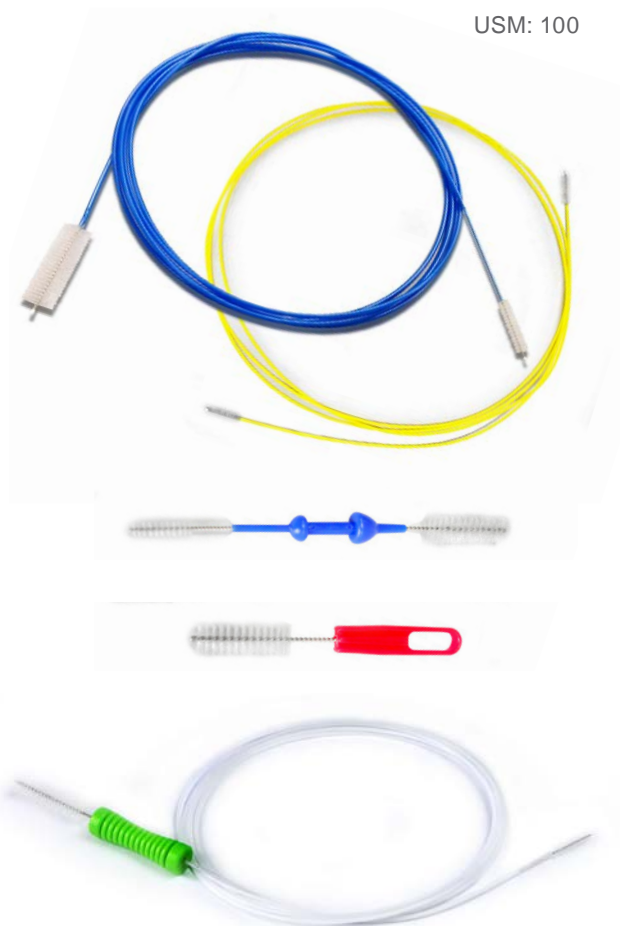
USM: 100

Fully disposable double ended cleaning brush 240cm in length 5mm bristle diameter to clean channels 2.0mm and larger.

The leading brush will push any gross matter through the channel and the alternate end will work to carefully pull any remaining debris away without causing damage to the scope.

- ‘Super Glide Bobble’ prevents scratches and snagging of expensive scopes
- Semi-textured “Super Glide Grip Tube” with high grasp security
- Soft, active nylon bristles
- Easy insertion of brush into long sensitive endoscope
- Increased cleaning efficiency

Order Code	Forceps Head Type	"Glide Wire" Length (cm)	"Glide Wire" Diameter (mm)	Brush Diameter (mm)	Qty
M20300	Double Ended Cleaning Brush (YELLOW)	230	2.3	5	100
M20301	Port Cleaning Brush (RED)	10.5	3.5	10	100
M20302	Combination Channel/Port Brush (Both Above)	10.5	3.5	1	100
M20306	Double Ended Port/Valve Brush (BLUE)	15.5	40/20	10/5	100
M20700	Double Ended Cleaning Brush	230	1.7	10/5	100
M20699	Double Ended Cleaning Brush	230mm	2mm	2mm	100
M20698	Double Ended Cleaning Brush	150cm	1.5mm	1.5mm	100
M20307	Double Ended Cleaning Brush	230cm	3mm	3mm	100
M20695	Double Ended Cleaning Brush (with handle)	230cm	1.7	10/5	100



USM: 200



Standard length

Longer length

Disposable Face Visors

Inexpensive visor one size to fit all design, strong but lightweight. Easy to put on or take off. Fits over glasses and replaces goggles, in some cases even masks. Unbreakable and glare resistant.

- Latex free
- Anti Fog (both sides)
- Contoured foam for better fit and comfort
- Lightweight & comfortable to wear
- Fits comfortably with a surgical mask & over prescription eyewear

Order

V3505040 - Standard Length - 33cm x 19cm - pack of 200
V3505040.1 - Longer Length - 33cm x 25cm - pack of 200

USM: 10 / 25



Full Face Visors

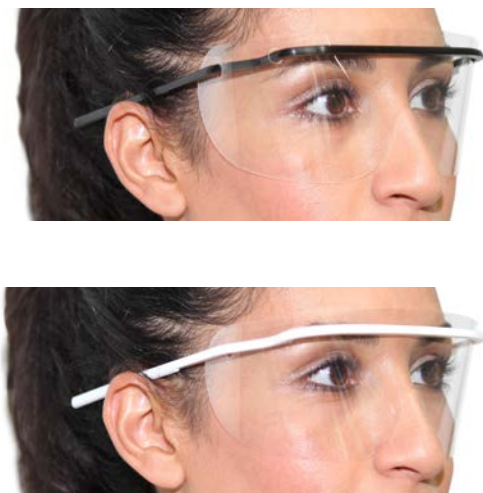
The anti-fog, latex free eyeshields are designed to protect your eyes and face by preventing exposure from hazardous or infectious substances.

- 10 stylish colours for easy identification
- Lightweight & comfortable to wear
- Optical grade lens
- "Wraparound" design provides both front & side eye protection

Order

MED1000.05 - Full Face Visor - pack of 10
MED1000.06 - Full Face Visor Shields - pack of 25
MED1000.03 - Starter Pack - 3 Face Visors & 15 Shields

USM: 20 / 50



Eyeshield Lenses and Frames

Anti-fog Eyeshield Lenses and 10 colours frames for easy identification. Clearly unique protection for your eyes against bodily fluids, flying debris, splashes and aerosols.

The frames are available in the following colours: blue, red, purple, light green, medium green, dark green, yellow, black, white and fluorescent pink.

Order

MED100.91 - Eye Frames - pack of 20
MED100.92 - Eye Lenses - pack of 50
MED100.84 - Frames and Lenses - pack of 10 frames & 25 lenses

Disposable Waterproof Gown

The disposable waterproof gown consists of an apron style neck, two waist level ties and long sleeves with in-built thumb loops to secure them in place. Its quick-off system ensures fast and simple removal of the apron as it can be ripped off after use.

- Waterproof material
- In-built thumb loops to prevent them from rising up
- Quick-off system allows fast and simple undressing
- Packed individually

Order # M20289 - Disposable Waterproof Gown - pack of 100



USM: 100

Waterproof Gowns

The front of gown and sleeves are made of high risk fibre material and the back is made of airy non-woven fabric, which has an opening with two tie belts at the neck and waist. The gown has overlapped stitched seams and sleeve cuffs are knitted.

- Breathable
- Front Part - high risk fibre
- Back Part - Polypropylene non-woven fabric, antistatic
- Sleeve- high risk fibre
- Knitted cuff - 100% polyester
- Sewing thread - 100% polyester 17-18 tex

Order # M20296.1 - M - pack of 100
M20296 - L - pack of 100
M20296.2 - XL - pack of 100



USM: 100

Disposable Gowns

Medisafe's disposable gowns are an ideal use for visitors. Our gowns consist of soft non-woven fabric, with an open back and two tie-belts. The outer ending of the arm piece is an overlock-seam bordered elastic strap.

- Used as a visitor gown
- Polypropylene non-woven fabric, antistatic
- Knitted cuff- 100% polyester
- Sewing thread - 100% polyester 17-18 tex

Order # M20293.1 - L - Disposable Gown - pack of 100



USM: 100

Colonoscopy Shorts

- Single use unisex design
- Available in 2 sizes: Large & XLarge
- Comfortable and lightweight
- 2 options available – with either flap and fixing point or slit
- Also suitable for flexible cystoscopy

Order #

M20280 – Blue Colonoscopy Shorts – Large with Slit (box 100)
M20279 – Green Colonoscopy Shorts – X-Large with Slit (box 100)
M20291 – Blue Colonoscopy Shorts – Large with Flap + Velcro Fixing Point (box 100)
M20292 – Green Colonoscopy Shorts – X-Large with Flap + Velcro Fixing Point (box 100)



USM: 100

USM: 56/24



◀ Scope Pre-Clean

Scope Sponge (Dry) ▶



Scope Pre-Clean

- Complete kit designed for the initial flush and wipe of endoscope post procedure
- For use with all endoscopes
- Contoured “scope shaped” sponge included
- Single use, prevents cross contamination
- Starts cleaning and prevents coagulation on contact
- Use container to suction / flush channels
- Neutral or Enzymatic detergent
- Non-hazardous
- Easy to store, transport & dispose of

Order

M20190 – Scope Pre-Clean (200ml Enzymatic) (box 56)
MED7830 – Scope Pre-Clean (200ml Neutral) (box 56)
M20199 – Scope Sponge (Dry) (box 100)

USM: 100



Eco Pre-Clean

- Low-cost solution
- Two Tiered Design – 250ml or 500ml – suitable for all types of endoscopes
- Neutral or Enzymatic detergent sachet option included - just add water
- Scope sponge included
- Starts cleaning on contact and prevents coagulation
- Non-hazardous
- Single Use
- Easy to store, transport and dispose of

Order

M20198 – Eco Pre Clean (with Enzyme sachet detergent) (box 100)
MED7832 – Eco Pre Clean (with Neutral sachet detergent) (box 100)

USM: 100



New Eco Pre-Clean Bagasse Tray (Biodegradable)

- Low-cost solution
- New bagasse tray is biodegradable and can be macerated
- Suitable for all types of endoscopes
- Neutral detergent sachet included - just add water
- Scope sponge included
- Starts cleaning on contact and prevents coagulation
- Single Use
- Easy to store, transport and dispose of

Order

MED7833 – Eco Pre Clean Bagasse Tray (with Neutral sachet detergent) (box 100)

Shelf Life: 2 years



Enzyme Foam Spray

A multi enzymatic foam spray ‘pre-soak’ for surgical instruments to prevent ‘post-op residual soil from building up. Instruments reprocessed as soon as possible after use will be more easily cleaned than those left for a number of hours. Where immediate reprocessing is not possible, Enzyme Foam Spray is intended to maintain a moist or wet environment to aid subsequent processing.

- Powerful multi- enzymatic instrument soak with long lasting foam
- A pre-soak to prevent blood and debris coagulation
- pH neutral
- Prevents stubborn organic encrustation on instruments
- Bacteriostatic

Order

MED8050 - 6 x 500ml

3E-Zyme Scope Plus

Shelf Life: 2 years

Concentrated 3E-Zyme Scope Plus cleaning solution removes organic matter and fatty deposits from surgical instruments in as little as 30 seconds. Our unique non-foaming formula allows deeper penetration and cleaning inside endoscopes, fine lumened and cannulated instruments.

[Can be supplied with Automatic Dose Pump & Digital Alarm Thermometer.](#)

[M10184 - 1 pump / M20515 - 1 Thermometer \(Page 21\)](#)

Order # M20029 - 4L
M20200 - 10L



Neutrasafe

Shelf Life: 2 years

High performance neutral detergent – pH neutral with no enzymes. Ideal for use with ophthalmic and endoscopy applications. The formulation reduces surface tension which allows deeper and more thorough cleaning of the most complex instruments. It absorbs the residues and holds them in suspension leaving other instruments free from cross contamination.

[Can be supplied with Automatic Dose Pump & Digital Alarm Thermometer.](#)

[M10184 - 1 pump / M20515 - 1 Thermometer \(Page 21\)](#)

Order # MED8031 - 4L



EndoCheck

USM: 1

Process challenge device designed for fine lumen devices and endoscope channels tests your machine's complex lumen cleaning performance. Ingeniously designed to represent a difficult cleaning challenge, EndoCheck allows quick and easy visual indication when used in conjunction with Valisafe CEI.

- Soil removal efficacy system
- For use with scopes
- Use with Valisafe CEI indicators

Order # V3502150 - EndoCheck (each)



CEI (Cleaning Efficacy Indicator)

USM: 50

Real blood test soil for use with Process Challenge Devices. CEI is designed for the validation and routine monitoring of the cleaning process for washer disinfectors / ultrasonic cleaners. Complies to ISO 15883 Part 5.

This is a visual indicator that helps you to identify that the load has been cleaned efficiently and can be used as a daily check. We use materials to closely replicate your dirty instruments using real blood and additives layered onto a stainless steel plate. Therefore recreating your dirty instrument.

Order # V3502080 - CEI (box 50)
V3502082 - CEI (box 10)



Scope-Check / Instru-Check

USM: 25

The Brilliant Blue Scope Check protein test is a rapid test that has the ability to detect low levels of protein on all types of flexible endoscopes. The Scope Check complies to CFPP 01-06 and is recognised as being one of the most sensitive tests available – detecting down to 1ug of protein within 10 seconds. The result is identified by a clear and concise colour change of the reagent. The 2.5m long swabs are supplied with 3 different diameter swabs, ensuring that all types of endoscopes can be tested on a weekly basis in line with CFPP 01-06.

Order # V3504095 - Scope-Check / Instru-Check - 25 vials & 25 short swabs
V3505010 - Scope-Check - 25 vials & 25 x 1.9mm swab
V3505005 - Scope-Check - 25 vials & 25 x 2.8mm swab
V3505013 - Scope-Check - 25 vials & 25 x 3.7mm swab





Personal Protection

Medisafe's personal protection range reduces the risk of harm to personnel, exposed to potentially hazardous biological debris and splashes.

From our diverse range of eye protection to waterproof gowns, you can ensure that your personnel are adequately and safely protected.

Disposable Face Visors

USM: 200

Inexpensive visor one size to fit all design, strong but lightweight. Easy to put on or take off. Fits over glasses and replaces goggles, in some cases even masks. Unbreakable and glare resistant.

- Latex free
- Anti Fog (both sides)
- Protects from harmful debris & splashes
- Contoured foam for better fit and comfort
- Lightweight & comfortable to wear
- Fits comfortably with a surgical mask & over prescription eyewear

Order

V3505040 - Standard Length - 33cm x 19cm - pack of 200
V3505040.1 - Longer Length - 33cm x 25cm - pack of 200



▲ Longer length

▲ Standard length

Full Face Visors, Eyeshield Frames & Lenses

USM: Various

The anti-fog, latex free shields are designed to protect your eyes and face from accidents by preventing exposure from hazardous or infectious substances.

- 10 stylish colours for easy identification
- Lightweight & comfortable to wear
- Optical grade lens
- "Wraparound" design provides both front & side eye protection

Order

MED1000.05 - Full Face Visor - pack of 10
MED1000.06 - Full Face Visor Shield - pack of 25
MED1000.03 - Starter Pack - 3 Face Visors & 15 Shields

MED100.80 - Eyeshield Frames - assorted colours - pack of 100
MED100.91 - Eyeshield Frames - assorted colours - pack of 20
MED100.81 - Eyeshield Lenses - pack of 250
MED100.92 - Eyeshield Lenses - pack of 50
MED100.84 - Frames & Lenses - pack of 10 frames & 25 lenses



▲ Full Face Visor



▲ Eyeshields



▲ Eyeshield lens



▲ Eyeshield frames

USM: 100



Waterproof Gowns

The front of gown and sleeves are made of high risk fibre material and the back is made of airy non-woven fabric, which has an opening with two tie belts at the neck and waist. The gown has overlocked stitched seams and sleeve cuffs are knitted.

- Breathable
- Front Part- high risk fibre
- Back Part- Polypropylene non-woven fabric, antistatic
- Sleeve- high risk fibre
- Knitted cuff - 100% polyester
- Sewing thread - 100% polyester 17-18 tex

Order #

M20296.1 - M - pack of 100
M20296 - L - pack of 100
M20296.2 - XL - pack of 100

M20296.10 - M - pack of 10
M20296.20 - XL - pack of 10

USM: 100



Disposable Gowns

Our gowns consist of soft non-woven fabric, with an open back and two tie-belts. The outer ending of the arm piece is an overlock-seam bordered elastic strap.

- Polypropylene non-woven fabric, antistatic
- Knitted cuff- 100% polyester
- Sewing thread - 100% polyester 17-18 tex

Order #

M20293.1 - L - Disposable Gown - pack of 100

USM: 100



Disposable Waterproof Gown

The disposable waterproof gown consists of an apron style neck, two waist level ties and long sleeves with in-built thumb loops to secure them in place. Its quick-off system ensures fast and simple removal of the apron as it can be ripped off after use.

- Waterproof material
- In-built thumb loops to prevent them from rising up
- Quick-off system allows fast and simple undressing
- Packed individually

Order #

M20289 - Disposable Waterproof Gown - pack of 100



Pre Cleaning

Point of Use Preparation
& Transportation Kit

Medisafe offers a complete range of instrument cleaning products to aid your cleaning process.

EN ISO 15883-2: 2009 “The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. Users should be aware that some medical devices might require pre-treatment”

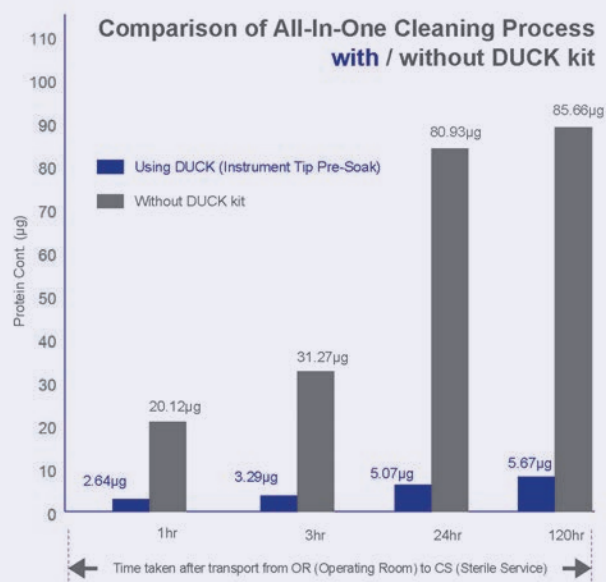
DOH, CFPP 01-01, Page 20 “Prions are hydrophobic proteins. The attachment of hydrophobic proteins to surfaces becomes less reversible if they are allowed to dry fully onto a surface. Keeping the environment around soiled instruments at or near saturation humidities (moist) prevents full attachment of hydrophobic proteins such that they are more efficiently removed by cleaning.”

Pre cleaning is the first critical step to reprocessing instruments...

Soiled surgical instruments that have prolonged periods of time between use in the operating theatre and the decontamination process are more difficult to decontaminate.

It is recommended that surgical instruments should be kept moist, which prevents soil from drying on to the surgical instrument surfaces. Pre-soaking with an enzymatic detergent not only keeps the soil moist but also begins to break down soil, making the decontamination process easier.

As complex/ lumened instruments are very delicate and harder to clean on the inside, the Distal Duck Kit assists in the pre-cleaning stage. By keeping the instrument moist and flushing the port down with detergent this starts the cleaning process while in transit and helps the CSSD staff when manually cleaning the instrument.



USM: 1



Distal Duck Kit

Medisafe's Distal Duck Kit is unique and tailored to robotic and complex instruments; the kit contains 5 x Distal Duck™ tip soakers, where the instrument tip is placed into each vial with a blended formulation of enzymatic detergent that activates at room temperature, to reduce manual cleaning.

- For use with da Vinci robotic, complex and lumened instruments
Check with instrument manufacturer's IFU's
- Retains moisture around instrument tips with unique formula that activates at room temperature for easy cleaning
- Use as instrument soaker between point of use (OR) and reprocessing (CSSD)
- Distal Duck is also an instrument protector
- Includes syringe and 100ml enzymatic detergent for rear flush port
- Includes Duck Bag™ humidity pack to keep instruments moist during transport
- Quick and convenient to use

Order #

M20400 - 1x Distal Duck Kit

Distal Duck Tip Soaker & Distal Tip Soaker ~ Mini Duck

USM: 250

Use the Medisafe Distal Duck Tip Soaker to keep complex instruments moist after use. The effective 4-Zyme pre soaking solution is safe for use with all complex surgical instruments, pH neutral (non corrosive), residual free and safe for instrument transportation.

- Suitable for all instruments
- 4 Active Enzymes - works at room temperature
- pH Neutral - non-corrosive
- Safe, quick and convenient use
- No more pre-soaking in CSSD

Distal Tip Soaker ►
~ Mini Duck



Order #

M20413 - Distal Duck Tip Soaker - 250 Vials
M20411 - Distal Tip Soaker ~ Mini Duck - 250 Vials

Duck Bag™ (Humidity Pack)

USM: 50

The Medisafe Duck Bag™ is a pre-moistened instrument bag, designed to maintain a safe and sealed humid environment for contaminated instruments. It can be used for the following applications: Domiciliary care, out of hours emergencies, overnight and weekends and as a pre-soak if waiting for a full load (w/d).

- No addition of water required: bags ready for immediate use
- Prevents gross bioburden from drying on instrument

Available in 3 sizes:

- Half Din - 420mm W x 470mm D
- Full Din - 400mm W x 780mm D
- Super-Size - 600mm W x 1000mm D

Order #

M20350 - Duck Bag Half Din
M20358 - Duck Bag Full Din
M20359 - Duck Bag Super-Size



*Basket not included

Enzyme Foam Spray

Shelf Life: 2 years

Enzymatic Foam Spray ensures instruments remain moist between use and reprocessing.

Medisafe Enzyme Foam Spray is ideal for keeping soiled surgical instruments moist (endoscopes, laryngoscopes, biopsy forceps, hemostats) to reduce Bioburden adhesion prior to decontamination and reduce cleaning time.

Order #

MED8050 - 6x500ml





Detergents & Chemistries

Medisafe's portfolio of machine and instrument-friendly detergents are suitable for soaking baked-on debris, pre-washing, ultrasonic cleaning, deluge washing, surface cleaning, tunnel washing, endoscope processing & more.

Enzymatic detergents are designed specifically to digest all residues and deposits normally found on surgical instruments and apparatus including proteins, lipids, carbohydrates and mucopolysaccharides.

Mild alkaline detergents are designed specifically for delicate instruments at higher temperature washing to give the cleaning benefits of an alkaline detergent with the protection offered by an enzymatic detergent.

Medisafe's detergent range also boasts rust inhibitors, lubricants for surgical instruments and water treatment to prevent scale.

*Available in other languages, please ask.

3E-Zyme

Shelf Life: 2 years

Our triple enzymatic, concentrated cleaning solution has been specially formulated with three active enzymes to effectively clean even the most difficult cannulated / lumen instruments.

Low foaming 3E-Zyme works great in a variety of cleaning situations such as pre-soaking instruments in ultrasonic cleaning units, tunnel washing and/or endoscope reprocessing units, pH neutral, biodegradable and environmentally friendly.

Order #	MED8035 - 4L
	MED8010 - 5L
	MED8037 - 10L
	MED8027 - 200L Drum



3E-Zyme Scope Plus

Shelf Life: 2 years

Concentrated 3E-Zyme Scope Plus cleaning solution removes organic matter and fatty deposits from surgical instruments in as little as 30 seconds.

Our unique non foaming formula allows deeper penetration and cleaning inside endoscopes, fine lumened and cannulated instruments.

Order #	M20029 - 4L
	MED8015 - 5L
	M20200 - 10L



4-Zyme

Shelf Life: 2 years

Enhanced enzymatic detergent containing a low temperature protease that allows for cleaning of instruments at room temperatures (less than 25°C). 4-Zyme uses a combination of four high performance enzymes.

These are fully effective against and digest all residues and deposits normally found on surgical instruments and apparatus including proteins, lipids, carbohydrates and mucopolysaccharides.

Order #	MED8020 - 5L
	MED8021 - 10L



EDA +

Shelf Life: 2 years

Enzyme Detergent Alkaline+ is a specially blended multi enzymatic detergent with mild alkaline booster, its a low foaming surgical instrument cleaner and pre-soak concentrate for use with manual cleaning, washer disinfectors and ultrasonic cleaners.

It's mild alkaline content is safe for use with delicate instruments. EDA+ will remove all blood, fat, carbohydrates, starches and protein.

Order #	MED7704 - 1L (Box of 6)
	MED7700 - 5L
	MED7701 - 10L



Shelf Life: 2 years



Medi-pH-Safe

Alkaline detergent with mild pH properties – ideal for general/lumen instrument cleaning and safe for use with ophthalmic and aluminium based devices.

Compatible with both ultrasonic cleaners and washer disinfectors, its mild alkaline composition facilitates fast, efficient cleaning at high temperatures. Medi-pH-Safe is a low foaming detergent which offers a lower dilution rate that is suitable for dental instruments.

Order # M20011 - 5L
M20008 - 10L

Shelf Life: 2 years



Neutrasafe

High Performance neutral detergent – pH neutral with no enzymes. Ideal for use with ophthalmic and endoscopic applications.

The formulation reduces surface tension which allows deeper and more thorough cleaning of the most complex instruments. It absorbs the residues and holds them in suspension leaving other instruments free from cross contamination.

Order # MED8031 - 4L
MED8030 - 5L

Shelf Life: 2 years



Ezee-Lube

Rust inhibitor and steam penetrable lubricant for surgical instruments. Improves instrument life and reduces repair costs.

Ezee-Lube maintains lubrication and retains sharpness on all instruments after autoclaving, especially those with hinged or moving parts.

Order # MED8036 - 10L

Specific minimum order required - Please ask.

Shelf Life: 2 years



AWT

Scale preventer and water conditioner for use with all Medisafe equipment. Neutralising hard water salts to prevent scale deposition within the machine and on cleaned and disinfected surgical instruments.

Regardless of its hardness is perfectly balanced to optimise the machine's performance.

Order # M20059 - 4L
MED1000.09 - 6x500ml

Shelf Life: 2 years



Decono-zyme Advanced

Water-soluble sachets filled with enzymatic gel - easy to use and allows for the correct dosage of detergent without the need for measuring.

Carefully formulated for optimum cleaning performance whilst facilitating the machine's maximum mechanical efficiency. The Decono-zyme Advanced gel pack contains the correct amount of viscous fluid (Gel) for one cycle / ultrasonic bath.

Order # M20510 - box of 20 sachets (30ml)

Enzyme Foam Spray

Enzymatic Foam Spray ensures instruments remain moist between use and reprocessing. Medisafe Enzyme Foam Spray is ideal for keeping soiled surgical instruments moist (endoscopes, laryngoscopes, biopsy forceps, hemostats) to reduce Bioburden adhesion prior to decontamination and reduce cleaning time.

Order # MED8050 - 6x500ml



Shelf Life: 2 years

Neutra-Soak

Eco and instrument friendly, non enzymatic pH neutral pre soak is an effective method of preventing post op residual soil from accumulating. Ideal use on endoscopes.

- Non-foaming, non-corrosive
- Enzyme free
- pH neutral
- Biodegradable
- Odourless

Order # MED8012 - 6x500ml

Specific minimum order required - Please ask.



Shelf Life: 2 years

Thermometer

Easily visible at the sink to closely monitor the correct temperature of wash water, to enhance your detergents performance.

Ideal for cleaning sinks and for optimum performance, the thermometer should be used in conjunction with Medisafe's Automatic Dose Pump.

Order # M20515 - 1 Thermometer



USM: 1

Dispenser Pump

Use to ensure accurate dosage of detergent without the need to lift heavy bottles. Suitable for both manual cleaning and automated processes when auto dosing is not available. Available for 4L, 5L and 10L containers.

Order # MED8038 - 4L & 5L
M20540 - 10L



USM: 1

Dose Pump (Detergent Dosing for Manual Washing)

Automated detergent dosing to assist manual cleaning.

- One touch operation
- Measured calibration dose
- Quick installation
- Alkaline/ Enzyme/ Neutral detergent-compatible
- Auto dose machine option

Order # M10184D - 1 x Pump - Type D India Plug
M10184E - 1 x Pump - Type E Euro Plug
M10184G - 1 x Pump - Type G UK Plug



USM: 1



Cleaning Brushes

Medisafe offers you a complete line of surgical instrument cleaning brushes to meet the growing demands of Central Sterile Reprocessing departments. Surgical instrument cleaning is the single most important step to proper disinfection and Sterilization.

Our brushes are made for surgical instrument cleaning and care. We have brushes to fit every cleaning application you have. They are manufactured from twisted surgical stainless steel with white medical-grade nylon bristles.

Medisafe Cleaning Brushes for your toughest cleaning applications:

- Pre-packaged, 3-pack
- High quality, for surgical instrument cleaning and care
- Extra small suction brushes
- Large general instrument brushes
- Pipe cleaners in 10+ styles

Frazier Suction Tube Cleaning Brushes

Medisafe's Frazier brushes give optimum cleaning for the inside of suction tubes. All brushes are 9 inches in length and are available in a wide range of sizes.

Frazier Suction 6 French

Total length: 220mm (9")
Brush length: 25mm (1")
Brush diameter: 2mm (0.08)

MED100.10



Frazier Suction 7 French

Total length: 220mm (9")
Brush length: 25mm (1")
Brush diameter: 2.3mm (0.09)

MED100.11



Frazier Suction 8 French

Total length: 220mm (9")
Brush length: 25mm (1")
Brush diameter: 2.6mm (0.10)

MED100.12



Frazier Suction 9 French

Total length: 220mm (9")
Brush length: 25mm (1")
Brush diameter: 3mm (0.12)

MED100.13



Frazier Suction 10 French

Total length: 220mm (9")
Brush length: 25mm (1")
Brush diameter: 3.3mm (0.13)

MED100.14



Frazier Suction 11 French

Total length: 220mm (9")
Brush length: 25mm (1")
Brush diameter: 3.6mm (0.14)

MED100.15



Frazier Suction 12 French

Total length: 220mm (9")
Brush length: 25mm (1")
Brush diameter: 4mm (0.16)

MED100.16



Baron Suction Tube Cleaning Brushes

Our thin brushes are ideal to clean the smallest Baron suction tubes.

Baron Suction 3 French

Total length: 185mm (7")
Brush length: 10mm (0.4")
Brush diameter: 1mm (0.04)

MED100.17



Baron Suction 5 French

Total length: 195mm (8")
Brush length: 15mm (0.6")
Brush diameter: 1.6mm (0.06)

MED100.18



Nylon Twisted Wire Cleaning Brushes

USM 3 per pack

Medisafe's Nylon Twisted brushes have stainless steel handles and are perfect to clean a wide range of instruments and devices. With our varied range of lengths and brush diameters, you will be sure to find the perfect brush for any application.



Total length: 300mm (12")
Brush length: 28mm (1.1")
Brush diameter: 2mm (0.8")
MED100.19



Total length: 300mm (12")
Brush length: 28mm (1.1")
Brush diameter: 3mm (0.12")
MED100.20



Total length: 300mm (12")
Brush length: 50mm (2.0")
Brush diameter: 4mm (0.16")
MED100.21



Total length: 300mm (12")
Brush length: 55mm (2.2")
Brush diameter: 5mm (0.20")
MED100.22



Total length: 300mm (12")
Brush length: 85mm (3.3")
Brush diameter: 6mm (0.24")
MED100.23



Total length: 400mm (16")
Brush length: 55mm (2.2")
Brush diameter: 5mm (0.20")
MED100.24



Total length: 400mm (16")
Brush length: 80mm (3.3")
Brush diameter: 7mm (0.28")
MED100.25



Total length: 400mm (16")
Brush length: 85mm (3.3")
Brush diameter: 10mm (0.4")
MED100.26



Total length: 400mm (16")
Brush length: 85mm (3.3")
Brush diameter: 12mm (0.5")
MED100.27



Total length: 610mm (24")
Brush length: 35mm (1.4")
Brush diameter: 2.5mm (0.1")
MED100.28



Total length: 610mm (24")
Brush length: 60mm (2.4")
Brush diameter: 5mm (0.20")
MED100.29



Total length: 610mm (24")
Brush length: 90mm (3.5")
Brush diameter: 7mm (0.28")
MED100.30



Total length: 610mm (24")
Brush length: 90mm (3.5")
Brush diameter: 10mm (0.4")
MED100.31



Total length: 350mm (14")
Brush length: 110mm (4.3")
Brush diameter: 10mm (0.4")
MED100.36



Total length: 350mm (14")
Brush length: 100mm (3.9")
Brush diameter: 2.5mm (0.1")
MED100.42



Total length: 500mm (20")
Brush length: 110mm (4.3")
Brush diameter: 10mm (0.4")
MED100.51

Laryngeal Cleaning Brushes

USM: 3

Nylon 0.20 Laryngeal Cleaning Brush
Total length: 260mm (10")
Brush length: 100mm (3.9")
Brush diameter: 10mm (0.4")

MED100.62



Nylon 0.15 Laryngeal Cleaning Brush
Total length: 250mm (9.8")
Brush length: 70mm (2.8")
Brush diameter: 7mm (0.28")

MED100.63



Laparoscopic Trumpet Valve

USM: 3

This double-ended brush with superfine soft nylon bristles is great for cleaning laparoscopic and general instruments.

Total length: 128mm (5")
Brush length: 30mm (1.2") & 25mm (1"),
Brush width: 7mm (0.28") & 5mm (0.2"),

MED100.32



Laparoscopic Brush

USM: 3

Our Laparoscopic double ended nylon or stainless steel brush, with different diameters (6mm & 8mm) is ideal to clean valves channels and barrels.

Total length: 177mm (7") Smaller brush width: 25mm (1")
Longer brush width: 40mm (1.5")

MED100.33 - Nylon
MED100.74 - Stainless Steel



Tracheostomy Brushes

USM: 3

Medisafe's Tracheostomy Brushes are used to clean the outer and inner tubes and ensure they are kept free of dry mucus and debris.

Tracheostomy 000-5 Tube Size
Total length: 105mm (4"), Brush length: 50mm (2")
Brush diameter: 13mm (0.5")

MED100.49



Tracheostomy 6-12 Tube Size
Total length: 200mm (8"), Brush length: 100mm (3.9")
Brush diameter: 13mm (0.5")

MED100.48



Flexible Bone Reamer Cleaning Brushes

USM: 3

Our bendable brushes are ideal to clean the inner channel of flexible bone reamers, and other general use instruments.

Total length: 800mm (31")
Brush length: 80mm (3.1")
Brush diameter: 3mm (0.12")

MED100.57



Total length: 800mm (31")
Brush length: 80mm (3.1")
Brush diameter: 5mm (0.20")

MED100.58



Total length: 800mm (31")
Brush length: 80mm (3.1")
Brush diameter: 7mm (0.28")

MED100.59

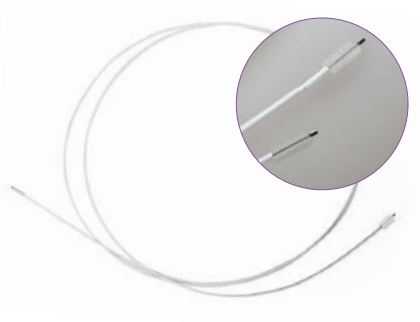


Double-ended 3/6mm Bristle Brush

USM: 3

Double Ended Bristle Brush (white)

MED100.50



USM: 3



Large Instrument 130mm Nylon Bristle

MED100.47

Total length: 254mm (10")
Brush length: 25mm (1")
Brush width: 130mm (5")

Large Instrument 64mm Nylon Bristle

MED100.46

Total length: 200mm (8")
Brush length: 175mm (7")
Brush width: 65mm (2.52")

USM: 3



Utility Nylon 230mm

MED100.40

Total length: 230mm (9")
Brush length: 45mm (2")
Brush width: 100mm (4")

Utility Nylon 510mm

MED100.41

Total length: 510mm (20")
Brush length: 45mm (2")
Brush width: 100mm (4")

USM: 3



General Brushes - Nylon / Stainless Steel

General instrument cleaning brush with either nylon or stainless steel bristles. These brushes are made exclusively for fine instrument cleaning and care. We have a brush designed to fit every cleaning application you have. The Nylon brush can also be used to clean da Vinci instruments.

Nylon:
MED100.43

Stainless:
MED100.38

Total length: 185mm (7.2")
Brush length: 13mm (0.5")
Brush width: 32mm (1.25")

USM: 3



Upright Brushes - Nylon / Stainless Steel

Upright instrument cleaning brush with either nylon or stainless steel bristles.

These brushes are made exclusively for fine instrument cleaning and care. We have a brush designed to fit every cleaning application you have. All brushes are medical quality and won't leave bristles inside the instrument. The Nylon brush can also be used to clean da Vinci instruments.

Nylon:
MED100.44

Stainless:
MED100.45

Total Length: 135mm (5.1")
Brush length: 15mm (0.6")
Brush width: 20mm (0.78")

USM: 3



Twisted Wire Jar Brushes 130mm

MED100.52

Total length: 300mm (11.8")
Brush length: 130mm (2.36")
Brush diameter: 35mm (1.37")

Wooden Jar Brushes 140mm

MED100.53

Total length: 340mm (13.38")
Brush length: 140mm (5.5")
Brush diameter: 70mm (2.75")

USM: 3

Acetabular Cleaning Brush

This heavy duty, double-ended cleaning brush is specially designed to clean challenging acetabular bone reamers. The "Pig Tail" rounded, circular brush head is designed to effectively clean inside the reamer, while the rigid straight brush on the reverse side is used for cleaning individual cutting holes.

Total length: 8" with handle, double ended brush
Round head diameter: 44.5mm (1.75")
Straight brush length: 20mm (0.8")
Straight brush diameter 8mm (0.3")

MED100.72

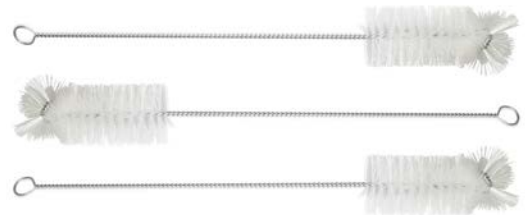
Quiver Brush

USM: 3

Ideally used to clean the inside of quivers, that hold diathermy forceps and instruments during surgical procedures.

- Easy to use, with a long eye handle
- Natural Nylon Bristles making it easier to clean the deposits after surgery
- Fits firmly into the tube of a quiver, brushing all sides and bottom

Total length: 510mm (20")
Brush length: 150mm (6")
Brush diameter: 60mm (2.36")

MED100.73

Pipe Cleaners

USM: 100

Our Pipe cleaners are great for removing moisture and residue from the inside of cannulated instruments.

Total length: 300mm (12")
Brush diameter: 3mm (0.12")

MED100.34

Total length: 300mm (12")
Brush diameter: 6mm (0.25")

MED100.35

Stain Rust Remover Pad

USM: 3

Our remover pad is ideal for cleaning rust and hard stains from surgical instruments. Pack of 3

Size: 150mm x 100mm

MED100.37

Disposable Sterilized Scrub Brushes

USM: Various

Sterile surgical scrub brushes with Nylon bristles on the underside and a soft sponge on top. All brushes come with a nail cleaner. Single use product.

Sterilized - Disposable Scrub Brushes - 1x Dispenser with 30 Brushes
Iodine - Disposable Scrub Brushes - 1x Dispenser with 30 Brushes
Chlorhexidine - Disposable Scrub Brushes - 1x Dispenser with 30 Brushes

MED101.01
MED101.07
MED101.08



USM: 1



Rechargeable Waterproof Brush Kit

Medisafe's New Rechargeable Waterproof Brush Kit is used to clean surgical instruments in the manual cleaning stage, making the process easier and saving you time CSSD.

The brush kit comes complete with 4 diverse brush heads including a hard brush, fine brush, crevice cleaning brush and a scouring pad.

- Fully waterproof & rechargeable
- Autoclavable brush heads
- Ergonomically designed anti-slip handle
- 4 Replaceable brush heads
- Lightweight & easy to use
- Includes two 3.6V batteries with charger & adapter
- Suitable for manual cleaning

Order

MED2600 - Brush Kit
MED2602 - Fine Brush Replacement - pack of 4
MED2603 - Hard Brush Replacement - pack of 4
MED2604 - Crevice Brush Replacement - pack of 4
MED2601 - Scouring Pad Replacement - pack of 4



Scope Brushes

Fully disposable double ended cleaning brush 240cm in length 5mm bristle diameter to clean channels 2.0mm and larger.

The leading brush will push any gross matter through the channel and the alternate end will work to carefully pull any remaining debris away without causing damage to the scope.

- 'Super Glide Bobble' prevents scratches and snagging of expensive scopes
- Semi-textured "Super Glide Grip Tube" with high grasp security
- Soft, active nylon bristles
- Easy insertion of brush into long sensitive endoscope
- Increased cleaning efficiency

Order Code	Forceps Head Type	"Glide Wire" Length (cm)	"Glide Wire" Diameter (mm)	Brush Diameter (mm)	Qty
M20300	Double Ended Cleaning Brush (YELLOW)	230	2.3	5	100
M20301	Port Cleaning Brush (RED)	10.5	3.5	10	100
M20302	Combination Channel/Port Brush (Both Above)	10.5	3.5	1	100
M20306	Double Ended Port/Valve Brush (BLUE)	15.5	40/20	10/5	100
M20700	Double Ended Cleaning Brush	230	1.7	10/5	100
M20699	Double Ended Cleaning Brush	230mm	2mm	2mm	100
M20698	Double Ended Cleaning Brush	150cm	1.5mm	1.5mm	100
M20307	Double Ended Cleaning Brush	230cm	3mm	3mm	100
M20695	Double Ended Cleaning Brush (with handle)	230cm	1.7	10/5	100





Accessories

Medisafe offer a complete range of accessories to optimise and facilitate your reprocessing requirements.

Solutions for traceability are also available, ensuring easy connection to Washer Disinfectors and Ultrasonic Cleaners and compliance to all relevant standards.

AbsorbeZe Sheet

USM: 25

AbsorbeZe Sheets and Pads are the ideal solution for dealing with spillages quickly and safely. Absorbs up to 5 litres of fluid.

Length:	Width:	USM:
138 cm	70 cm	25

Order # MED101.05 - Pack of 25



LoadSafe

USM: 1 Mat

Prevent wrapping and packing from tearing and ensure that your packaged instrument baskets and wire trays remain in place throughout your entire process.

- Non-slip properties
- Packaged instruments remain in place
- Complies with European Directive 2002/72/EC
- Resistant to chemicals and bacteria wear
- Temperature resistant from -40 °C to 200°C
- 3mm thickness
- Suitable for use with washer disinfectors & autoclaves

Order # M20316 - 1 Mat



ID Security Tags

USM: 100

Easy identification tags for instruments. Printed ID Tags allow you to quickly identify the action needed for that tray.

Length:	Width:	USM:
138 cm	70 cm	100

Order # MED100.06 - Blue (Sharpen)
MED100.07 - Red (Repair)



Printer Rolls

USM: 1

High quality coated thermal printer paper is especially used in our Medi-Printer.

- Printer durability - 5 years
- Coated with colour developing thermosensitive formulation
- 112mm x 48mm (25")
- Non-toxic

Order # MED1014.1 x 1 Roll



USM: 10



Distal Connectors

Easy connection of lumen instruments that do not have a luer lock/slip luer port – suitable for use with all SI Series machines.

Order #

MED1246.1.0 - Red 1mm Distal Connectors - pack 10
 MED1246.3.0 - Blue 5mm Distal Connectors - pack 10
 MED1246.2.0 - Yellow 8mm Distal Connectors - pack 10
 MED1246.4.0 - Green 12mm Distal Connectors - pack 10

USM: 10



Small Distal Connectors

Small Distal Connectors allows you to connect fine, delicate, complex or non-ported instruments to a flush system to allow irrigation of the internal parts. Suitable for use with all SI Series machines

Order #

MED5003 - Red 1mm - pack10
 MED5013 - Blue 5mm - pack 10
 MED5023 - Yellow 8mm - pack10
 MED5043 - Assorted - pack 10

USM: 1



Artemis Inspection Lamp

Refer to HTM 01-05 with regards to visual inspection of your instruments. "After cleaning, inspect instruments for cleanliness and check for any wear or damage before Sterilization. The satisfactory completion of this step means that these instruments may be clearly designated as ready for Sterilization". Compact, free standing, mains powered with LED lights for longevity.

Order #

M20548 - Inspection Lamp

USM: 100



Disposable Filters

Filters to keep Medisafe equipment in efficient, working order.

Change filters at every water change to keep Medisafe equipment in efficient working order. Available in packs of 24 or 100.

For use with SI Digital, SI Auto, SI Digital PC+, SI SA and Reliance Digital/PC+ ranges.

Order #

MED3080 - pack 100

SI SA & SI Digital Hose & Luer

- This hose is for use in the Medisafe SI SA or SI Digital washers **only**
- The luer lock is compatible with many instruments and Medisafe's Distal Connectors

Order # MED3084.1 - without port nozzle - pack 12
MED3084.3 - with port nozzle -pack 12



SI PCF Hose & Luer

- This hose is for use in the Medisafe SI PCF washers **only**
- The luer lock is compatible with many instruments and Medisafe's Distal Connectors

Order # M20005 - 24cm - pack 24



SI PCF da Vinci Si Hose & Luer

- This hose is for use in the Medisafe SI PCF **only**
- This hose is for use with ISI da Vinci instruments **only**
- The slip luer is compatible with the da Vinci S, SS & Si instruments **only**

Order # M20065 - 24cm ISI - single
M20066 - 24cm ISI - pack 10



SI PCF da Vinci Xi Hose & Luer

- This hose is for use in the Medisafe SI PCF **only**
- This hose is for use with ISI da Vinci instruments **only**
- The luer is compatible with the da Vinci Xi instruments **only**

Order # M18965 - IS4000 Hose & Luer set - Complete set



Hose & Luer Assembly – Niagara da Vinci

Easy connect slip luer. Reinforced. Connect da Vinci EndoWrist® instruments to the flushing manifold. Designed specially for use with EndoWrist® instruments, these hose & luer slips allow for smooth, secure connection to the flush port on the instrument housing, ensuring delivery of the cleaning solution to the EndoWrist® instrument.

Order # M20134 - pack 10



Xi Niagara Luer Connector

Order # MP20966- single



Niagara Single Site Secondary Connection

Order # M20031 - pack 5





The ICTMIMS Care System is designed to protect your instruments throughout the reprocessing cycle until “point of use”. After usage the instruments can be returned again to the Care System to minimise potential damage to instruments during transit.

Washing, disinfection and sterilization efficiency is improved over conventional trays and baskets with large open areas for greater efficiencies during the wash process and disinfection cycles.

Optho Standard (Without flushing accessory)

Order # MED9000

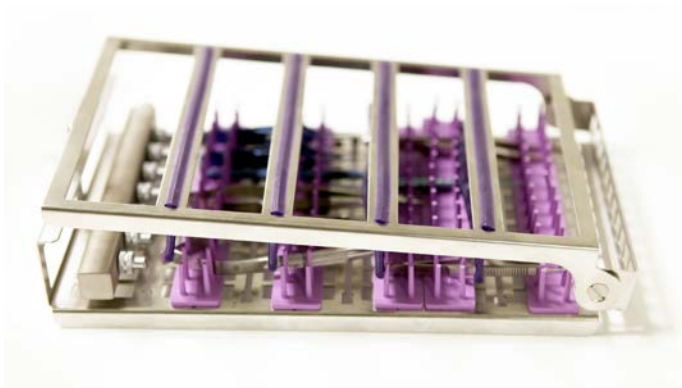
Optho Single (With single 7 port flushing accessory)

Order # MED9011

Optho Double (With double 7 port flushing accessory)

Order # MED9012

Height:	Depth:	Width:
1.7"	6.3"	10.2"

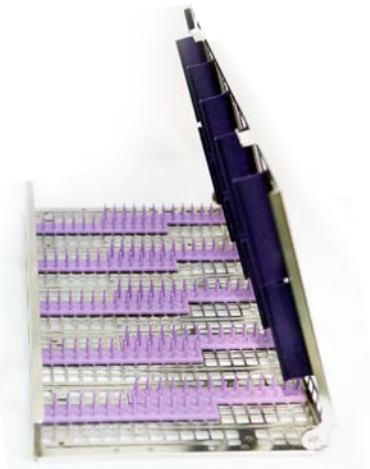


Full Size ICTMIMS Clam Shell

Comes with millipede and pressure ball mouldings as shown.
Add optional Flushing Manifold - MED9007

Height:	Depth:	Width:
1.7"	18.9"	9.8"

Order # MED9004 - Full size



Half Size ICTMIMS Clam Shell

Comes with millipede and pressure ball mouldings as shown.
Add optional Flushing Manifold - MED9007

Height:	Depth:	Width:
1.7"	9.4"	9.8"

Order # MED9003 - Half size



Flushing Manifold

Supplied complete with silicone and hose and connection.

For use with MED9003 & MED9004

Order # MED9007- Flushing manifold



Plumbing Kit

Standard phaco plumbing kit.

Supplied complete with components shown.

For use with all Optho, Half & Full sizes.

Order # MED9013- Phaco plumbing kit



Flow Closing / Blanking Plugs

Supplied complete with silicone and hose and connection.

For use with MED9003 & MED9004

Order # MED9014



Millipede Moulding Replacement

Supplied as shown

Order # MED8162



Single/Double Pressure Ball Strip Replacement

Single ball strip - 9 inches length (3.28 ft)

Double ball strip - 39 inches length (3.28 ft)

Order # MED8163 - Single ball strip
MED8159 - Double ball strip





Valisafe Detergents & Chemistries

Valisafe's portfolio of machine and instrument-friendly detergents are suitable for soaking baked-on debris, pre-washing, ultrasonic cleaning, deluge washing, surface cleaning, tunnel washing, endoscope processing & more.

Enzymatic detergents designed specifically to digest all residues and deposits normally found on surgical instruments and apparatus including proteins, lipids, carbohydrates and mucopolysaccharides.

Mild alkaline detergent designed specifically for delicate instruments at higher temperature washing to give the cleaning benefits of an alkaline detergent with the protection offered by an enzymatic detergent.

Valisafe's detergent range also boasts rust inhibitors, lubricants for surgical instruments and water treatment to prevent scale.

*Available in other languages - Please ask.

Valizyme

Shelf Life: 2 years

Valizyme uses a combination of three high performance enzymes. These are fully effective against and digest all residues and deposits normally found on surgical instruments and apparatus including proteins, lipids, carbohydrates and mucopolysaccharides.

Order # MED7800 - 5L

Specific minimum order required - Please ask.



Valizyme Foam Spray

Shelf Life: 2 years

A Multi-Enzymatic Foam Spray 'pre-soak' for surgical instruments to prevent 'post-op residual soil from building up.

Instruments reprocessed as soon as possible after use will be more easily cleaned than those left for a number of hours. Where immediate reprocessing is not possible, Enzyme Foam Spray is intended to maintain a moist or wet environment to aid subsequent reprocessing.

Order # MED8050V - 6 x 500ml

Specific minimum order required - Please ask.



Vali-pH-safe

Shelf Life: 2 years

Vali-pH-Safe will remove blood, fat, carbohydrates, starches and protein while its discerning alkaline solution eliminates scale and mineral deposits left from hard water to ensure that critical surgical instruments are kept in an exceptional condition.

Order # MED7810 - 5L

Specific minimum order required - Please ask.



Vali-glide

Shelf Life: 2 years

Vali-glide is a rust inhibitor and lubricant for critical surgical instruments. Vali-glide maintains lubrication and retains sharpness on all instruments after autoclaving especially those with hinged or moving elements.

Order # MED7820 - 5L

Specific minimum order required - Please ask.





Sterilization Monitoring & Cleaning Efficacy

Valisafe's innovation of a complete range of unique decontamination process and sterility assurance products for the advancing market ensures simple, continuous and consistent monitoring of every decontamination/sterilization cycle and every item.

We consider vital, the use of correct equipment when reprocessing instruments and therefore our rationale is that, through your practices and protocols, you are able to prove (not only to yourselves but to others) that your objectives have been met.

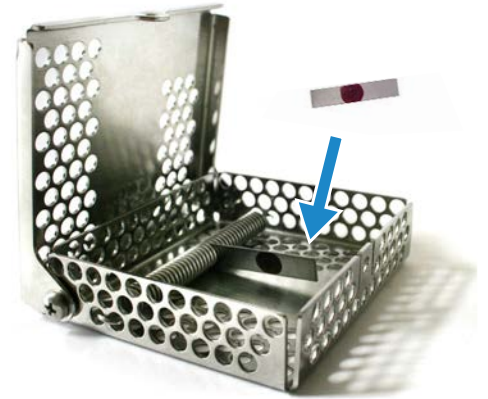
PCD Starter Kit

USM: Various

The Standard PCD (Process Challenge Device) & CEI (Cleaning Efficacy Indicator) kit has been designed to closely replicate a hard-to-clean dirty instrument.

- Easy to use – place CEI in PCD & load into full machine
- Easy to read – visual inspection that soil has been removed

This is a visual indicator that helps you to identify that the load has been cleaned efficiently and can be used as a daily test as advised by HTM 01-01 or weekly / quarterly check. We use materials to closely replicate your dirty instruments using real blood and additives layered onto a stainless steel plate. Therefore recreating your dirty instrument.



CEI (Cleaning Efficacy Indicator)

Real blood test soil for use with Process Challenge Devices. CEI is designed for the validation and routine monitoring of the cleaning process for Washer Disinfectors / Ultrasonic Cleaners. Complies to ISO 15883 Part 5.



Order # M20230 - PCD Starter Kit (1 x PCD & 12 x CEI)
V3502080 - CEI indicators - pack of 50
V3502090 - Standard PCD basket

PCD for MIS HP

USM: 1

Process Challenge Device for MIS instruments to be used in conjunction with Valisafe CEI for High Pressured washer disinfectors and ultrasonic cleaners. Test your machine's High Pressure (HP) lumen cleaning performance – the MIS HP is suitable for 0.4 to 4 bar pressure.

- For monitoring the cleaning efficiency of washer disinfectors/Sonic Irrigators or MIS or other lumen devices.
- Simulates cannulated instruments for MIS
- Easy to use – Easy to read



Order # V3502105 - 1 PCD for MIS HP

Fine Lumen Check - FLC1 1mm / FLC2 2mm & Endocheck

USM: 1

Process Challenge Device specifically designed to test your machine's lumen cleaning performance to be used in conjunction with Valisafe CEI for high pressure AER. Ingeniously designed to represent a difficult cleaning challenge.



Order # V3502120- FLC1 - 1 PCD
V3502130- FLC2 - 1 PCD
V3502150 - Endocheck - 1 PCD

USM: 25



Brilliant Blue Distal Check

Use Brilliant Blue Distal Check for the fast detection of protein residues left behind on complex surgical instrument tip. Simply immerse the tip of your complex surgical instrument in the solution contained within the distal holder, by inserting the tip and leave for 5 seconds. If protein is present the reagent will turn from brown to blue within 10 seconds.

Order # MED7910 -BB Distal-Check 25 vials

USM: Various



Scope-Check / Instru-Check

The Brilliant Blue Scope-Check / Instru-Check protein test is a rapid test that has the ability to detect residual proteins left behind on the surfaces of washer disinfectors, ultrasonic cleaners, endoscopes and other hard to clean surgical instruments. This protein test is based on a dye-binding solution used in clinical chemistry and can detect protein residues within 1 µg sensitivity.

- Conforms to BS EN ISO 15883
- Result within 10 seconds
- Easy to use - no incubation required
- Clear colour change
- Cost effective
- For use with: Endoscopes, WD / Ultrasonic surfaces & Surgical instruments

Order # V3504095 - Scope-Check / Instru-Check Standard Kit - 25 vials & 25 x standard swabs
 V3505005 - Scope-Check 2.8mm - 25 vials & 25 x 2.8mm swabs
 V3505010 - Scope-check 1.9mm - 25 vials & 25 x 1.9mm swabs
 V3505013 - Scope-Check 3.7mm - 25 vials & 25 x 3.7mm swabs

USM: 1

Shelf Life: 2 years



Process Indicator Pen

Process Indicator Pen for use on all wrapping materials to indicate items that have been exposed to the steam sterilization process. Record additional critical data. Universally applicable the PIP can indicate your specific information requirements, such as surgeon's/patient's name, tray name or any other information required through your protocols.

Order # V3502140 - Process Indicator Pen - 1 pen

USM: 1

Shelf Life: 3 years



3 Line Duplex Label & Gun

This simple to use dual indicator label for steam and formaldehyde sterilization processes creates a direct link between the process and the patient. Compatible with all manual traceability systems, it is very suitable to hospital, clinic, GP departments and for both large and table top sterilizers. Used in conjunction with the 3 Line Label Gun, the information about the pack can be printed by the gun or hand written during the preparation process.

- Label conforms to EN ISO 11140-1 Type 1
- Dual Adhesive indicator for record keeping
- Dual Indicators – steam and formaldehyde on each label
- Records; process date, expiry date, operator number, sterilizer number and cycle number
- Non-toxic & lead free

Order # V3504054 - 3 Line Duplex Labels - 24 rolls of 500 labels
 V3504060 - 3 Line Label Gun - 1 unit
 V3505055 - Ink Cardrige - 1 unit

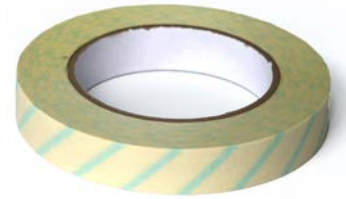
Autoclave Tape

USM: 72 Rolls

Shelf Life: 2 years

Valisafe's Autoclave Tape for steam sterilization enables the user to see at a glance that an item has been processed. The easy to interpret black stripes prove that the pack has been exposed to the steam sterilization process.

The tape is made from good quality masking paper which is lead free, with colour changing water-based Ink, made with acrylic pressure sensitive adhesive and is individually packed.



Order # V3504040 - Autoclave Tape 19mm - 72 rolls per box

Daily Bowie and Dick Test Pack - Standard

USM: 20

Shelf Life: 3 years

Colour change: pink to brown or darker

Use this test at the beginning of each working shift in every pre vacuum B.1 assisted steam sterilizer to ensure rapid and even steam penetration into a small porous load. This non-toxic test is not a test of sterility but a test of the mechanical function of the steriliser to ensure rapid and even steam penetration into a small porous load. The Valisafe B&D test pack fulfils the requirements of both EN 285 and EN ISO 17665.

⌚ 3 - 3.5min



134°C - 137°C

Order # V3501020 - B&D Daily Test Pack (Standard) - box of 20



Daily Bowie and Dick Test Pack

USM: 20

Shelf Life: 3 years

Colour change: blue to pink

Use this test at the beginning of each working shift in every vacuum assisted steam sterilizer to ensure rapid and even steam penetration into a small porous load. This non-toxic test is not a test of sterility but a test of the mechanical function of the steriliser to ensure rapid and even steam penetration into a small porous load. The Valisafe B&D test pack fulfils the requirements of both EN 285 and EN ISO 17665.

⌚ 3 - 3.5min



134°C - 137°C

Order # V3501024 - B&D Daily Test Pack - box of 20



Daily Bowie and Dick Test Sheet

USM: 50

Shelf Life: 3 years

Colour change: pink to brown or darker

Incorporated into the original Bowie and Dick towel pack at the beginning of each working shift in every vacuum assisted steam sterilizer to ensure rapid and even steam penetration into a small porous load. The Valisafe B&D test sheet offers an economical yet accurate way of ensuring the sterilizer is functioning correctly at the beginning of each working day.

⌚ 3 - 3.5min



134°C - 137°C

Order # V3501210 - B&D Test Sheet - box of 50



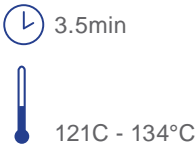
USM:500 Shelf Life: 3 years



Type 4 Dual multi Parameter Indicators

Colour change: blue to dark grey or black

The Valisafe Type 4 Dual Multi Parameter indicators offer an economical yet effective way of monitoring your steam sterilization processes. With one accurate calibration worldwide it is a secure and safe monitoring system yet simple and easy to use. Unlike most other Type 4 indicators available today the Valisafe indicator is non toxic - another sign of its advanced technology.



Order #

V3502038 - Type 4 Dual Indicators - 250 indicators split to 500

USM: 250 Shelf Life: 3 years



Type 6 Indicator

Colour change: pink to brown or darker

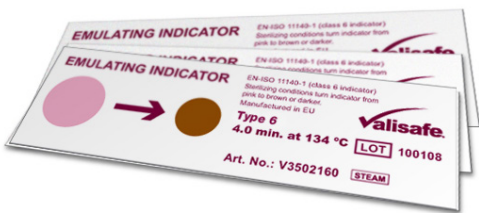
Routine monitoring of sterility assurance levels in every tray and/or pack. These indicators are calibrated specifically to your cycle requirements. Valisafe Type 6 indicators offer validated security that every tray or item has been effectively processed, thereby providing a direct link between the sterility of the items and the patient.



Order #

V3502060 - Type 6 Indicators (3.5min at 134°C) - pack of 250
V3502065 - Type 6 Indicators (5.3min at 134°C or 15 min at 121°C) - pack of 250

USM: 250 Shelf Life: 3 years



Type 6 Indicator

Colour change: pink to brown or darker

The Valisafe Type 6 chemical indicators offer the highest level of proof of the achievement of sterility assurance levels in your trays and items. These indicators are calibrated specifically to your cycle requirements. Valisafe Type 6 indicators offer validated security that every tray or item has been effectively processed, thereby providing a direct link between the sterility of the items and the patient.



Order #

V3502160 - Type 6 Indicators (4.0min at 134°C) - pack of 250
V3502070 - Type 6 Indicators (7.0min at 134°C or 20 min at 121°C) - pack of 250

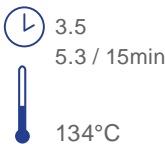
USM: 250 Shelf Life: 2 years



Self-adhesive Type 6 Indicator

Colour change: purple to green or dark green

The Valisafe Type 6 self adhesive chemical indicators offer the highest level of proof of the achievement of sterility assurance levels in your trays and items. These indicators are calibrated specifically to your cycle requirements. The indicators offer validated security that every tray or item has been effectively processed, thereby providing a direct link between the sterility of the items and the patient. Self Adhesive to provide ease of use in any document or traceability system.



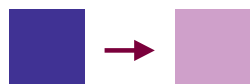
Order #

V3504065 - Type 6 Indicators (3.5 min at 134°C) - pack of 250
V3504068 - Type 6 Indicators (5.3 min at 134°C or 15min at 121°C) - pack of 250

Plasma Indicator

USM: 250 Shelf Life: 3 years

Colour change: blue to pink



Ensure that your VHP sterilization process was effective. The Valisafe VHP (Plasma) process indicator is designed for use in a VHP sterilizer. The indicator will exhibit a clear colour change when exposed to hydrogen peroxide during the diffusion stage of the process. When utilised properly, the VHP indicator will give clear visual confirmation that the item was exposed to hydrogen peroxide.



Order # V3503970 - Plasma Indicator - 250 indicators


Loadcheck

USM: 250 Shelf Life: 3 years


Colour change: pink to brown or darker

The Valisafe Loadcheck is designed to be used in conjunction with the Valisafe in pack monitoring systems. Placed in the chamber with the load and read on completion of the cycle it provides immediate physical independent confirmation that the cycle parameters have been met in the chamber - for confident release of the load.

Order # V3502030 - 3.5 min at 134°C Loadcheck
V3503917 - 4 min at 134°C / 12 min at 121°C Loadcheck
V3503910 - 5.3 min at 134°C / 15 min at 121°C Loadcheck
V3503920 - 7.0 min at 134°C / 20 min at 121°C Loadcheck



3.5
4.0 - 12min
5.3 - 15min
7.0 - 20min



134°C / 121°C



EN 867 Part 5 Helix Device


USM: 250 Shelf Life: 3 years

Colour change: blue to black

Use in conjunction with your in-pack monitoring systems and read on completion of the cycle to ensure that your Type B table top sterilizer is performing correctly. This device, therefore, has the capability to provide you with effectively sterilized items in your practice. Used in conjunction with the Valisafe indicators you can be sure sterility assurance levels have been met.



3.5min



134°C

Order # V3502034 - Helix Device - 250 indicators



USM: 1

Ultrasonic Foil Test

The Foil Test is designed to show the operating cycle of an ultrasonic functions correctly when instruments are being processed, no matter where they are placed within the tank.

The ultrasonic activity can be investigated by the erosion pattern created on the aluminium foil exposed in the tank for a short period.

- Ideal width for performing the foil test
- High quality foil, does not perish


Order #

MED1002 - Foil test - 411m roll
MED1005 - Foil test - 50m roll

USM: 100 / 1

ValiSpore Biological Indicators and Incubator

Steam & EO Biological indicators to be used in conjunction with Valispor Incubator V3504035.

Valispor biological indicators for Steam and Ethylene Oxide contain a known quantity of bacterial spores inoculated onto filter paper & placed inside a plastic culture, with a crushable glass ampoule containing the culture medium (traceable to a recognisable culture identified in USP and ISO 11138).

- Conforms to ISO 11138
- Easy to incubate – no laboratory conditions for culturing
- Dramatic colour change for positive cultures
- Results in 24 hours for steam and 48 hours for Ethylene Oxide
- Non-toxic


Order #

V3504000- ValiSpore Steam 10 x 5 - 100 indicators
V3504005- ValiSpore Steam 10 x 6 - 100 indicators
V3504010- Valispor EO - 100 indicators
V3504035 - ValiSpore Incubator - 1 unit

Specific minimum order required - Please ask.

USM: 250

Shelf Life: 5 years

Seal Check

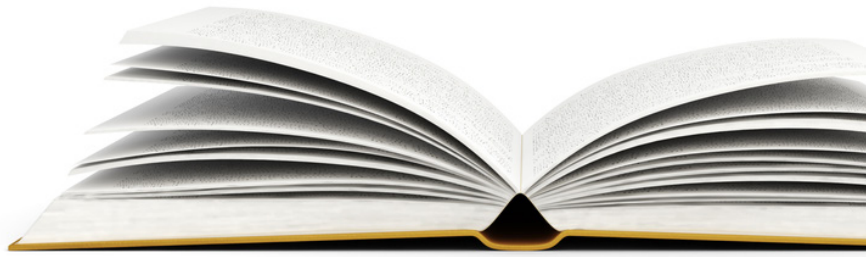
Routine monitoring of a heat sealing device to ensure optimum sealing seams are achieved for packaging of instruments.

The Valisafe Seal Check is for use as a routine monitor of a sealing device and for operational qualification within the framework of process validation in accordance with ENISO 11607-2 2006.

- Routine monitor for sealing device
- In accordance with ENISO 11607-2 2006
- Records sealing time, temperature and pressure
- Cost effective
- Easy to interpret


Order #

V3505030- Seal Check- 250 indicators



Education

The growing concerns regarding HAIs and cross-contamination has directed attention to issues of a safe, repeatable decontamination process of medical surgical instruments from both the government and healthcare sectors.

This section contains information that has been compiled by several international experts in the field of medical device decontamination and is intended to provides information and guidance to those technicians and managers involved in reprocessing instruments.

This section is not intended to overrule national or other local policies relating to reprocessing procedures, nor is it intended to replace manufacturers' IFU reprocessing instructions.

It is not intended to be a training document, although the contents may be a complement to your existing training programs.

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1. Introduction

Concerns about risks of cross-infection have directed attention to issues of safe decontamination of medical devices from both the public and professional domains. Medical devices that can be safely and repeatedly decontaminated are vital if potential risks of cross infection are to be managed.

2. Scope

The aim of this document is to provide risk based general guidance on the minimum requirements for the safe decontamination of reusable medical devices at point of use. This document highlights key steps in the decontamination of medical devices and draws the reader's attention to the need to maintain documented, quality controlled procedures in order to ensure processed medical devices are 'fit for use' when they reach the point of use.

3. Reasons for Decontamination

The need for scrupulous attention to decontamination procedures has been highlighted internationally for the medical and dental professions, as well as the public, due to incidents of infections including HIV and Hepatitis B and C. Therefore, it is important that those undertaking decontamination procedures should have an understanding of infection control practices carried out in their organisation. These practices are designed to reduce the potential for transmission of infection from one patient to another through poor environmental conditions, failure of care practices or through inappropriately prepared surgical instruments and other medical equipment. The choice of decontamination method may be related to the infection risk associated with the intended use of the device; this is shown in the following table.

Risk	Application of item	Recommendation
High	- in close contact with a break in the skin or mucous membrane - introduced into sterile body areas	Sterilization
Intermediate	- in contact with mucous membrane - contaminated with particularly virulent or readily transmissible organisms - prior to use on immunocompromised patients	Sterilization or disinfection required Cleaning may be acceptable in some agreed evidence based situations
Low	- in contact with healthy skin - not in contact with patient	Cleaning

Fig. 1 – Spaulding Criteria for classification of Medical Devices (MAC Manual Part 1)

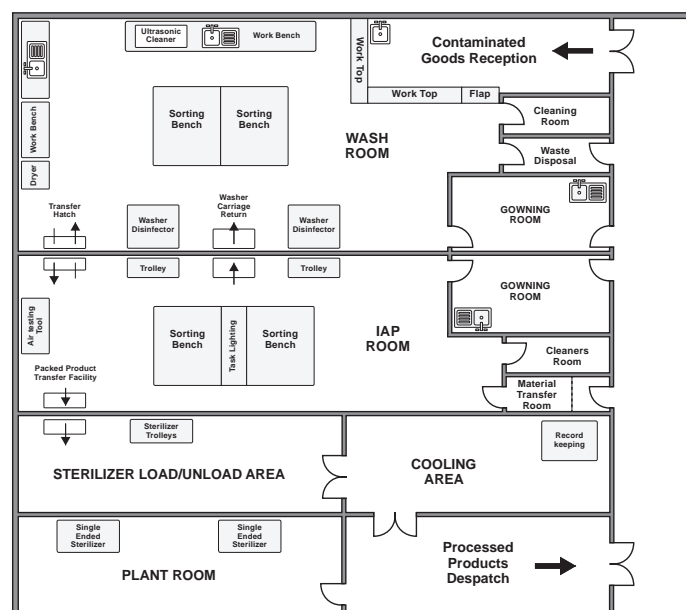
4. General Requirements for Decontamination

4.1 The Working environment

4.1.1. Typical Departmental Layout

Fig. 2 – Typical Decontamination Services Department ►
(Health Building Note 13 - UK)

It is important to ensure there is separation between the clean and dirty activity areas (see figure 2). There should be a one way directional flow which involves both people and products. There should be controlled Heating Ventilation and Air Conditioning (HVAC) and adequate provisions of utilities (i.e. water, electricity). Materials used for constructing the department should be robust and easy to clean; floors and ceilings should be covered to promote easy cleaning; worktops should be made from nonlinting materials e.g. Stainless Steel.



4.2 The Decontamination Process

- The process starts at the point of use - care should be taken that devices are safely contained for transportation
- Receipt into decontamination area
- Initial sorting and disassembly of medical devices
- Cleaning process
- Inspection, testing, assembly and packaging
- Sterilization or disinfection
- Storage and distribution
- Quality assurance and traceability of medical devices

4.3 Workflow within Decontamination Services

Decontamination Flow in SSD

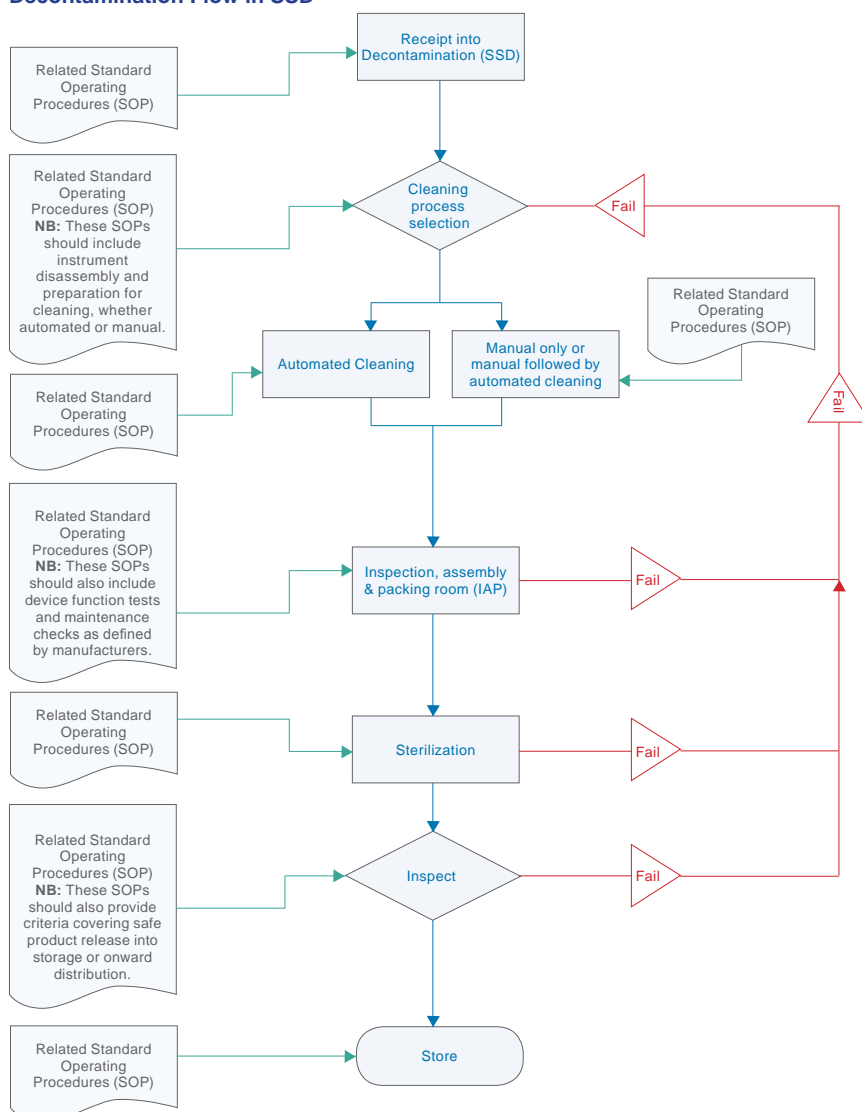


Fig. 3 – Workflow diagram for Decontamination Services ►

4.4 Key Processing Equipment

4.4.1 Selection of equipment needs to be fit for intended purpose, installed, commissioned, operated and maintained in accordance with the equipment manufacturer's recommendations and any legal requirements.

4.4.2 Key processing equipment includes:

- Automated Washer Disinfectors including automated endoscope reprocessors
- Ultrasonic Cleaners
- Heat sealing equipment
- Sterilizers

4.4.3 All automated processes should be routinely monitored, maintained and documented.

4.4.4 Verification/ validation of equipment should be carried out at least once a year.

4.4.5 Policies and Standard Operating Procedures (SOP) should be documented and based on regulations and recognised, evidence based standards and current best practice.

4.5 Loan Equipment

Loan devices should be controlled and processed in the same manner as in-house items. There should be a policy for loaned instruments in place to ensure patient safety. All supporting reprocessing documentation should be adequate, appropriate, device specific and accompany the loan devices.

4.6 Environmental Cleaning

Develop & document a departmental cleaning schedule:

- All work areas, stands, tables, countertops, sinks, and equipment surfaces should be cleaned daily
- Floors must be cleaned daily
- Sinks must be cleaned at the end of each shift as a minimum and more frequently where necessary
- Sinks used for cleaning endoscopes, respiratory equipment must be thoroughly cleaned between each use
- Spillages must be dealt with immediately
- All furniture should be easy to clean; only essential furniture should be present

4.7 Raw Material Acquisition and Storage

Raw materials, e.g. cleaning chemicals, dressings, drapes, wrappers, indicators etc., should be obtained in accordance with local policies. Each category of material should be stored in clean, ventilated, temperature controlled storage and following the supplier's instructions for storage. The store should be kept secure. Care should be taken to ensure shipping containers are removed from materials prior to the materials entering user work areas; raw materials to be used in the Inspection, Assembly and Packing area (IAP), must be protected within the area until they are required for use.

5. Key Stages of Decontamination Processing

5.1 Key Stage 1 – Procedures at Point of Use

5.1.1 All devices that have either been opened and/or used should be regarded as contaminated and therefore a potential hazard.

5.1.2 Sharps, single use devices and disposable products must be removed and discarded at point of use. Place sharps in puncture proof containers and dispose of accordingly.

5.1.3 Gross debris should be removed from medical devices and any pre-treatment recommended by the device manufacturer undertaken at point of use. This can be achieved by either soaking, rinsing, wiping or flushing. Do not use saline.

5.1.4 Rinsing should be conducted below 35 degrees Celsius to avoid coagulation of proteins.

5.1.5 Flushing is specifically required for lumen instruments or MIS (minimally invasive surgery) to prevent soil drying and adhering within the lumen.

5.1.6 Used devices should be placed in a closed, leak proof container ready for transportation. These containers may only be reused after cleaning.

5.1.7 Ideally devices should be transported in moist condition but without excess liquid.

5.1.8 Fragile items should be protected during transportation.

5.2 Key Stage 2 – Receipt into Decontamination Area

5.2.1 Unload received items carefully to avoid personal injury or damage to devices.

5.2.2 Sort and prioritise medical devices based on facility and user requirement.

5.2.3 Disassemble and/or pre-clean where indicated. Special attention should be given to all lumen instruments.

5.3 Key Stage 3 – Cleaning and Disinfection Process

Cleaning is a process intended to physically remove organic matter and infectious agents from devices.

Since the process is dependent upon many factors, where automated washer disinfectors or endoscope reprocessors are used, an integral thermal or chemical disinfectant cycle is used to ensure devices are fit to handle.

5.3.1 Criteria for cleaning:

The following should be considered:

- The potential level of contamination (Bioburden)
- Type of processing equipment available
- Types of medical devices to be processed
- Best possible water quality available

5.3.2 Water quality, pressure and storage:

- a) Quality - water should be tested for hardness, pH, mineral and chemical and microbial content; either in-house or by an external service.
- b) Pressure - high pressure nozzle required for lumen items (5 bar or 75 psi)
- c) Water storage - in a closed container where the contents are moved within 24 hours to avoid contamination (biofilm) and stagnation.

5.3.3 Choice and application of detergents

- a) Detergents should be compatible with water quality, cleaning equipment and devices to be cleaned
- b) The parameters of the process (time and temperature) will be determined by the type of detergent
- c) Selection of detergent may be Alkaline, Enzymatic or Neutral
- d) Concentration, temperature and time – must be used as recommended by the manufacturer.

5.3.4 Methods of Cleaning

There are two methods of cleaning:

- Manual cleaning
- Use of an automated washer disinfectant. Automated methods are preferred where available since they are controlled processes which can be validated.

5.3.4.1 Manual Cleaning

There are two purposes of manual cleaning:

- As pre-cleaning prior to using an automated Washer Disinfectant
- As a cleaning method where other methods are not available or appropriate.

Methods:

- Immersion
- Non-immersion (See appendix 1)

5.3.4.2 Automated Washer Disinfectors (AWD)

A typical AWD cycle includes:

- Pre-wash
- Wash
- Rinse
- Thermal disinfection
- Dry

5.3.4.3 Routine Daily WD

Performance tests and practices include:-

- a) Mechanical function tests i.e. spray arms are clean and free moving, clean drain, check filters, check racks for debris, door seals
- b) Check water supply and pressure
- c) Check detergent levels and ensures detergent lines is connected and dispensing.

5.3.4.4 Loading and load configuration

Devices must be loaded in such a way that allows the cleaning solution (water and detergent) to reach all surfaces of the load and spray arms to move freely. All lumen devices must be connected and secured properly. If connection of lumen is not possible, hollow items should be first cleaned manually and then processed.

5.3.4.5 Choice of correct cycle depends on the type of medical device being processed.

5.3.4.6 Machine specific racks and manifolds must be used.

5.3.4.7 Instrument wash baskets must fit the rack and also hold the largest item to be cleaned

5.3.5 Use of Ultrasonic Cleaners

Ultrasonic Cleaners are available either as stand-alone units or as an integral part of an automated process; ultrasound is a useful method for cleaning lumen and micro surgery devices as well as pre-cleaning for devices such as orthopaedic reamers.

- The units must be located in the cleaning area of the decontamination facility
- Methodology – see appendix 2

5.3.6 Disinfection

After cleaning, devices need to be disinfected to render them safe for further handling. Disinfection may be achieved either by the use of an appropriate disinfectant solution or where automated Washer Disinfectors are used, in the thermal rinse cycle of the machine.

5.4 Key Stage 4 - Inspection, Assembly and Packing (IAP)

This is the area within the department which has the highest environmental standards in order to protect medical devices from re-contamination during their inspection, reassembly of devices, testing, checking set content and packing.

5.4.1 Inspection of all products for cleanliness

- Use magnification for fine and delicate instruments
- Check functionality – lubrication, replace and repair
- Assemble sets according to packing list
- Place chemical indicator in every pack as per national recommendations
- Wherever possible, dressing and draping materials should not be included in surgical instrument sets. Where these have to be included, they should be independently wrapped within the pack

5.4.2 Packaging

Packaging is essential to maintain the sterility of medical devices until opened at point of use. The type and method of packaging should enable both the sterilant to penetrate the package and allow the aseptic removal of contents.

Packaging material should be:

- Suitable for size and weight of devices to be packed
- Compatible with sterilization processes
- Strong enough to withstand sterilization, transportation and storage to point of use application
- Capable of bearing a label to show contents, process date and manufacturing facility
- Enable application of external indicators for process control to identify that an item has been processed
- Permit adequate sealing of the pack to ensure integrity

5.5 Key Stage 5 – Terminal Processing (Sterilization or High Level Disinfection)

Sterilization is the final step in the decontamination processing of reusable medical devices and renders them safe for intended use. This is generally achieved using a steam autoclave which is suitable for the majority of reusable devices. For those devices which are heat and/or pressure sensitive, other methods of low temperature sterilization may be used. In the case of flexible endoscopes it is common to use a sporicidal disinfectant to achieve high level disinfection of the device.

5.5.1 Steam Autoclave

5.5.1.1 Daily tests

- a) A warm up cycle should be carried out at the beginning of each working day or according to local recommendations
 - b) Check the inside chamber for damage including the drain (visual check)
 - c) Check door seals intact (wipe with a lint-free cloth)
 - d) Perform air leak test once a month or according to local recommendations
 - e) Undertake Bowie Dick or equivalent steam penetration test daily (only for pre vacuum steam sterilizers)
- NB: There are no daily steam penetration tests for downward displacement/ gravity machines.

5.5.2 Mechanism for loading and unloading sterilizers:

Use trolleys/carriages/baskets that are specific to the sterilizer being used and validated.

5.5.3 Correct load configuration is required to ensure effective air removal and steam penetration to the entire load.

Factors for consideration are:

- a) Heavy items to be placed lower than the lighter items otherwise items may be wet after the sterilization process.

- b) Place peel pouches on their side, paper to paper or if necessary to lie flat, place with paper side down
- c) Do not overload (pack loosely - no stacking) as it may compromise steam penetration
- d) Loads must not touch any surface of the chamber
- e) Rigid container systems should not be stacked unless they were designed for that purpose
- f) Surfaces that could collect water, such as the bottoms of pans or trays, must be positioned sideways (unless otherwise specified by the manufacturer) so that any condensate that is present will drain out
- g) Mixed loads may be more difficult to achieve steam penetration.

5.5.4 Choice of sterilization cycle is dependent on load content and local recommendations.

5.5.5 Prior to release of the load, check and record:

- Sterilization cycle printout (time, temperature and pressure)
- Process indicators
- Packaging integrity
- Dryness of packs

5.5.6 Low temp. sterilization (Ethylene Oxide/ Formaldehyde/ Hydrogen Peroxide/ Technologies/ Irradiation/ Ozone) are very specific sterilization processes and guidance from the manufacturers must be applied.

5.5.7 Disinfectants for use in automated endoscope reprocessors, or for high level terminal disinfection of endoscopes will depend on local policy and preferences.

5.6 Key Stage 6 – Storage and Distribution of Processed Goods

5.6.1 Storage:

Following sterilization packs are vulnerable and must therefore be treated with care; they should not be handled until cooled. Thereafter packs should be handled as little as possible and stored in clean, pest and vermin-free, secure and dry conditions to keep them free from recontamination prior to distribution. The following points should be considered:

- Store away from direct sunlight
- Have good internal air circulation
- Open racks rather than wooden shelves are recommended (Bottom shelf should not be below 12 inches (300 mm) from the floor and 18 inches (45 cm) from the ceiling)
- Windows and doors in the storage area must be kept closed
- Clean and sterile items must not be stored on the floor, on window sills, near or under sinks
- Prevention of recontamination by storing correctly to avoid damage to packs
- Position the shelves and racks to hold items so that they do not touch surfaces such as walls, floor, ceilings and lights and water sprinklers

- Sterile and non-sterile products should not be stored together
- Stock rotation – ‘First-In First-Out (FIFO) principle’
- Access to the storage area must be restricted to persons whose normal responsibilities require them to enter this area. Persons in street attire must not be allowed into the storage area

5.6.2 Distribution

This may be internal or external to the organisation and may or may not be under the direct responsibility of the sterile services department.

Key considerations include:

- Despatch in a manner that maintains the integrity of the medical device
- Secure and robust transportation systems
- A system for product recall should be in place
- Optimum storage conditions at point of use

6. Quality Assurance and Control

Included in this section:

- 6.1 Quality Management System
 - 6.1.1 Documentation and Record Keeping
 - 6.1.2 Device Tracking and Traceability
 - 6.1.3 Product Release System
- 6.2 Infection Prevention and Control
- 6.3 Occupational Health and Safety
- 6.4 Education and Training of Staff
- 6.5 Risk Management

6.1 Quality Management

6.1.1 Documentation and Record Keeping – this includes Quality Policy Document, Quality Control Procedures followed by Standing Operating Procedures (SOPs). Records of all activities should be documented and maintained for the required legal period.

6.1.2 Device Tracking and Traceability – a valid system for tracking and traceability (to the patient and back to reprocessor) is an integral part of patient safety requirements. However simple, it should enable the use of a medical device to be recalled if required.

6.1.3 Product Release System – refers to the integrated system of tests, controls and back up procedures intended to ensure that reprocessed medical devices are fit for use.

6.2 Infection Prevention and Control – Staff need to be aware of:

- Infection prevention policy and provision within facility
- Provision and practice for hand hygiene
- Dress codes, personal hygiene and use of Personal Protective Equipment (PPE)
- Waste management (clinical and non clinical) policies
- Safe disposal of sharps
- Incident reporting mechanisms
- Environmental control and testing.

6.3 Occupational Health and Safety

- Pre-employment questionnaire where legally required for health clearance
- Facility-provided uniform should be worn and should preferably be lint-free
- Appropriate Personal Protective Equipment (PPE) must be worn in the designated area of the SSD according to the national and local requirements.

6.3.1 In the decontamination cleaning area this will normally consist of:

- Waterproof gowns/ apron
- Hair covering
- Gloves – preferably made from chemically inert material (nitrile)
- Eye and facial protection
- Robust footwear (open sandals are not recommended)

6.3.2. Inspection Assembly & Packing area:

- Hair covering
- Clean overgown or uniform made from lint-free material

6.3.3 Sterilization area

- Uniform
- Heat-resistant gloves

6.4 Education and training of staff

In the interests of patient and personal safety, it is important that those working within Decontamination Services (SSD) have sufficient numeracy, literacy, comprehension and dexterity skills to fulfil their role within the facility and meet any legal requirements. Effective and appropriate training and competency assessment programs should be in place to support all grades of personnel and help career and personal development within the field.

6.5 Risk Management

Ensure that any deviations from normal operating procedures, such as errors and accidents, are identified, investigated and evaluated, and that any corrective and preventative action (CAPA) is taken when required.

7. Glossary of Terms

Terms and definitions

- **Batch:**
defined quantity of product, intended or purported to be uniform in character and quality, which has been produced during a defined cycle of manufacture
- **Bioburden:**
population of viable microorganisms on or in product and/or sterile barrier system
- **Biological indicator:**
test system containing viable microorganisms providing a defined resistance to a specified sterilization process
- **Calibration:**
set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards
- **Change control:**
assessment and determination of the appropriateness of a proposed alteration to product or procedure
- **Chemical indicator:**
non-biological indicator test system that reveals change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process
- **Cleaning:**
removal of contamination from an item to the extent necessary for further processing or for intended use
- **Corrective action:**
action to eliminate the cause of a detected nonconformity or other undesirable situation

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

NOTE 3 There is a distinction between correction and corrective action.

- **Correction:**
action to eliminate a detected nonconformity

NOTE A correction can be made in conjunction with a corrective action.

- **Culture conditions:**
combination of growth media and manner of incubation used to promote germination, growth, and/or multiplication of microorganisms

NOTE The manner of incubation may include the temperature, time and any other conditions specified for incubation.

- **D value:**
D10 value time or dose required to achieve inactivation of 90 % of a population of the test microorganism under stated conditions
- **Design qualification:**
verification that the proposed specification for the facility, equipment, or system is suitable for the intended use
- **Development:**
act of elaborating a specification
- **Environmental control:**
application of engineering and/or procedural systems to maintain conditions in defined areas within specified limits

NOTE Such systems can include air and fluid filters, surface disinfection, protective clothing and administrative procedures.

- **Establish:**
determine by theoretical evaluation and confirm by experimentation period for which the process parameters are maintained within their specified tolerances
- **Fault:**
one or more of the process parameters lying outside of its/ their specified tolerance(s)
- **Health care product(s):**
medical device(s), including in vitro diagnostic medical device(s), or medicinal product(s), including biopharmaceutical(s)
- **Inactivation:**
loss of ability of microorganisms to grow and/or multiply
- **Installation qualification:**
IQ Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification
- **Material safety data sheet:**
MSDS document specifying the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely
- **Medical device:**
instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
 - diagnosis, prevention, monitoring, treatment, or alleviation of disease;
 - diagnosis, monitoring, treatment, alleviation of, or compensation for an injury;
 - investigation, replacement, modification, or support of the anatomy or of a physiological process;
 - supporting or sustaining life;
 - control of conception;
 - disinfection of medical devices;
 - providing information for medical purposes by means of in-vitro examination of specimens derived from the human body; and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [ISO13485:2003]

NOTE This definition from ISO 13485:2003 was developed by the Global Harmonization Task Force (GHTF 2002).

- **Microbial characterization:**
process by which microorganisms are grouped into categories

NOTE Categories can be broadly based, for example, on the use of selective media, colony or cellular morphology, staining properties, or other characteristics.

- **Microorganism:**
entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses

NOTE A specific standard might not require demonstration of the effectiveness of the sterilization process in inactivating all types of microorganisms, identified in the definition above, for validation and/or routine control of the sterilization process.

- **Operational qualification:**
OQ process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures
- **Packaging system:**
combination of the sterile barrier system and protective packaging
- **Parametric release:**
declaration that product is sterile, based on records demonstrating that the process parameters were delivered within specified tolerances
- **Performance qualification:**
PQ process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification
- **Preformed sterile barrier system:**
sterile barrier system that is supplied partially assembled for filling and final closure or sealing **EXAMPLES** Pouches, bags and open reusable containers
- **Preventive action:**
action to eliminate the cause of a potential nonconformity or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential nonconformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. [ISO 9000:2005] 2.33

- **Process challenge device:**
PCD item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process
- **Process parameter:**
specified value for a process variable

NOTE The specification for a sterilization process includes the process parameters and their tolerances.

- **Process variable:**
condition within a sterilization process, changes in which alter microbicidal effectiveness

EXAMPLES Time, temperature, pressure, concentration, humidity, wavelength.

- **Product:** result of a process

NOTE For the purposes of sterilization standards, product is tangible and can be raw material(s), intermediate(s), sub-assembly(ies), and health care product(s).

- **Protective packaging:**
configuration of materials designed to prevent damage to the sterile barrier system and its contents until the point of use
- **Reference microorganism:**
microbial strain obtained from a recognized culture collection
- **Requalification:**
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process
- **Services:**
supplies from an external source, needed for the function of equipment **examples** electricity, water, compressed air, drainage

- **Specify:**
stipulate in detail within an approved document
- **Sterile:**
free from viable microorganisms
- **Sterile barrier system:**
minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use
- **Sterility assurance level:**
SAL probability of a single viable microorganism occurring on an item after sterilization

NOTE The term SAL takes a quantitative value, generally 10⁻⁶ or 10⁻³. When applying this quantitative value to assurance of sterility, an SAL of 10⁻⁶ has a lower value but provides a greater assurance of sterility than an SAL of 10⁻³.

- **Sterilization:**
validated process used to render product free from viable microorganisms

NOTE In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

- **Sterilization load:**
product to be, or that has been, sterilized together using a given sterilization process
- **Sterilization process:**
series of actions or operations needed to achieve the specified requirements for sterility

NOTE This series of actions includes pre-treatment of product (if necessary), exposure under defined conditions to the sterilizing agent and any necessary post treatment. The sterilization process does not include any cleaning, disinfection, or packaging operations that precede sterilization.

- **Sterilizing agent:**
physical or chemical entity, or combination of entities having sufficient microbicidal activity to achieve sterility under defined conditions
- **Survivor curve:**
graphical representation of the inactivation of a population of microorganisms with increasing exposure to a microbicidal agent under stated conditions
- **Terminal sterilization:**
process whereby product is sterilized within its sterile barrier system
- **Test for sterility:**
technical operation defined in a Pharmacopoeia performed on product following exposure to a test of sterility. Technical operation performed as part of development, validation, or requalification to determine the presence or absence of viable microorganisms on product or portions thereof
- **Validation:**
documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

8. Useful References

EN 285: 2006 Sterilization. Steam sterilizers. Large sterilizers

ISO 11138 - Sterilization of health care products -- Biological indicators

ISO 11140 - Sterilization of health care products -- Chemical indicators

ISO 11607 - Packaging for terminally sterilized medical devices

ISO 13485 - Medical devices -- Quality management systems -- Requirements for regulatory purposes

ISO 15882 - Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results

ISO 15883 - Washer-disinfectors -- Requirements and tests for washer-disinfectors

ISO 17664 - Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices

ISO 17665 - Sterilization of health care products -- Moist heat

In addition to the above there are a number of National and Regional standards and recommendations that apply..

Appendix 1 - Method for Manual Cleaning

1. Essential Equipment

- Waterproof Personal Protective Equipment (PPE) including gloves, visor, gown or apron must always be worn. Footwear and hair cover as per local recommendations
- Two sinks or other receptacles (one for washing and one for rinsing) of sufficient size to hold the cleaning solution and immerse products to be cleaned if required
- A suitable surface to drain products after rinsing
- Reusable good quality brushes which can withstand daily cleaning and thermal disinfection should be used and inspected for damage after use. Metal brushes should not be used as they damage instruments. Where possible, single use brushes are preferred
- Lint-free cleaning and drying cloths should be used and inspected for damage and soil after each use

2. Method

2.1 Immersion: (Wearing PPE)

- Fill the sink (not wash-hand basin) or other appropriate receptacle with sufficient warm water to enable complete immersion of the device to be washed. An appropriate detergent should be added at the manufacturer's recommended dose for the volume of water being used.

- Immerse the item fully to displace air as all surfaces must be exposed to the washing solution.
- Using brushes, clothes and water jet sprays where necessary (under the solution surface to avoid the risk of aerosol) remove all visible contamination.
- Remove the product from the solution and drain over the wash solution before passing to the rinse sink.
- Rinse thoroughly with fresh water (whilst still ensuring the product is under water) and then place on the draining surface.
- Hand-dry using a clean, absorbent, non-linting cloth.

2.2 Non-immersion (Wearing PPE)

- If the medical device is electrical, ensure that it is not connected to any power outlet and any protective caps for power inlets are in place before beginning cleaning.
- Starting with the upper parts of the product, wipe surfaces thoroughly with the washing solution whilst ensuring that no liquid enters critical areas, including air or power inlets.
- Rinse the cleaning cloth periodically and repeat the above process until all visible soil is removed.
- Rinse the product using a fresh cloth and clean water.
- Dry the product with a clean non-linting cloth.
- Dispose of any single-use cleaning materials in accordance with local guidelines.
- NB: The cleaning solution and rinse water must be changed when visibly soiled.

2.3 Chemical disinfection

- If disinfection is the last step before use it should always follow manual cleaning.
- Disinfection after manual cleaning is to protect the staff. Wipe the item with 70% isopropyl alcohol and allow to dry. The disinfection effect is the vaporisation of alcohol.

Appendix 2

Method for use of Ultra Sonic Cleaners

1. Daily routine preparation of the ultrasonic machine:

- a) Fill with water to required level
 - b) Add detergent at correct concentration
 - c) Connect lumen items where possible
 - d) Devices need to be placed in the tank in such a way as to ensure air removal
 - e) De-gas
 - f) Close lid
 - g) The machine must have a regular cleaning procedure i.e. at least once in a 24 hour period. If multiply cycles are being run this may lead to a temperature build up in water therefore the water will need to be drained and refilled.
 - h) If the machine is not in use it must be left clean and dry
 - i) Solution should be changed when visibly soiled - and at least daily.
- Process efficacy tests may vary but should be carried as per local recommendations or at least quarterly.

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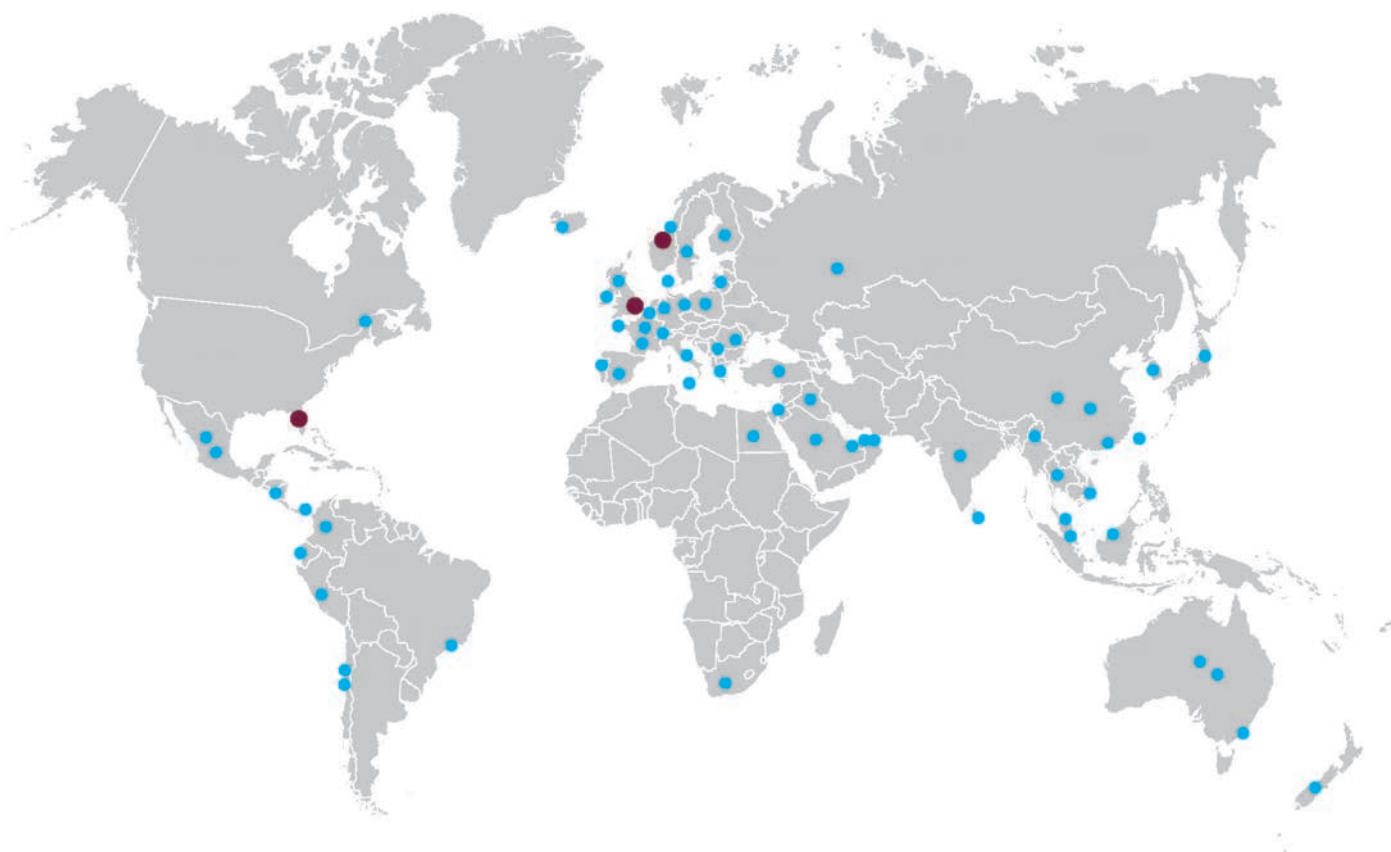
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