SYSTEM 1™ Express

STERILE PROCESSING SYSTEM

SAFETY, ASSURANCE AND EFFICIENCY

One Integrated Approach to Healthcare

STERIS

Pioneer in liquid chemical sterilization

STERIS has over 21 years of experience with liquid chemical sterilant technology and oxidative chemistries. SYSTEM 1™ Express has excellent material compatibility and has extensive critical and semi-critical medical device reprocessing capabilities, including multi-channel flexible surgical endoscopes. Providing a high standard of patient care whether it's in your OR or GI department SYSTEM 1™ Express will help you reprocess with confidence.

Providing a higher standard of care through:

- **SAFETY** - Liquid chemical sterilization provides a higher level of safety compared to High Level Disinfection. Use of dedicated chemistries delivers a safe and reliable solution.
- **ASSURANCE** - Extensive medical device testing on material compatibility, microbial efficacy and device conformance with high levels of OEM device endorsements. Reliable and confirmed process, controlled parameters.
- **EFFICIENCY** - Sterile processed devices in only 18 minutes. Just in time point of use sterilization: clean, process and use.

Filtration System

Sterile Water

SAFETY

SYSTEM 1™ Express Processor

Consistent and controlled process

S40™ Sterilant

Eliminates all microbial life

Trays and Quick Connects

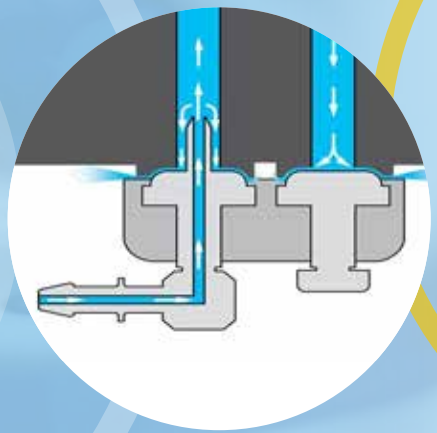
Optimal S40™ dilution flow

A higher standard of safety

The innovate design of SYSTEM 1™ Express helps ensure S40™ Sterilant reaches all parts of the endoscope including ports which are commonly shielded from germicide contact in AERs with tight fitting adapters.

Our Quick Connects provide you with the right fit for ports regardless of the endoscope you are processing from the STERIS list of approved & validated devices.

Sterilization of your flexible endoscopes increases your margin of safety by helping to reduce the risk. The alternatives to aldehydes and high level disinfection, SYSTEM 1™ Express Sterile Processing Systems, provide this higher standard of patient care, giving you and your patients well deserved piece of mind.



MaxFlow™ Adapters

Provide complete chemistry use-dilution flow to lumens adapter and ports

Liquid chemical sterilization of an endoscope in accordance with EN ISO 14937 implies that all elements of the scope are exposed to sterilant to achieve the desired microbiological kill rate. Only STERIS System 1™ **MaxFlow™** connectors ensure a controlled flow of sterilant over the entire surface of the endoscope connector to achieve this.

A proven process

The robust filtration system extensively treats potable water for the liquid chemical sterilization process. This water treatment process creates water for use in the SYSTEM 1™ Express Processor that is one of the highest quality available in any automated liquid reprocessing system.

Potable Water

Pre-filtration

Removes, some bacteria and inorganic particulates

MaxPure™ Filter

Removes, bacteria fungi and protozoa

Extensively treated water flows continuously through the internal MaxPure™ filter throughout the fill and rinse phases. The use-dilution has a neutral pH, and rinses safely down the drain. SYSTEM 1™ Express performs 2 quick rinse cycles reducing energy and water consumption.

ASSURANCE

Reliable and Confirmed Process Assurance

With robust, validated process monitoring, the routine use of the Verify Chemical Indicator and verification of processor performance, SYSTEM 1™ Express offers simplified process assurance. Use SYSTEM 1™ Express with confidence for processing heat-sensitive critical devices.

The SYSTEM 1™ Express processor is an intelligent system, offering validated process monitoring for immediate results and on-time starts, giving you confidence and assurance that processed heat-sensitive devices that are validated in the SYSTEM 1™ Express processor are safe for immediate use.

Effective liquid chemical sterilization performance is confirmed in two ways:

- Processor controlled parameters
- Chemical Indicator

After Exposure phase all devices are liquid chemically sterilized

Processor Controlled Parameters

The SYSTEM 1™ Express has been designed to monitor the critical parameters of liquid chemical sterilization and cancel the cycle if these parameters are not met. Those parameters include:

Exposure Time – The six-minute exposure phase at the minimum recommended concentration eliminates all microbial life.

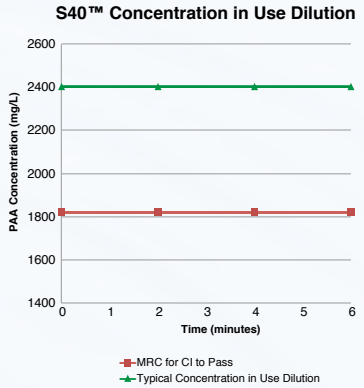
Exposure Temperature – Use dilution achieves a minimum temperature of 46 °C during the liquid chemical sterilization cycle.

Pass **Fail**

If any of the critical parameters of the Liquid Chemical Sterilization process fail, **SYSTEM 1™ Express** Processor will abort the cycle.

Chemical Indicator and Single Dose Sterilant

The Verify® SYSTEM 1™ Express Chemical Indicator provides routine monitoring, verifies and assures that the heat-sensitive critical devices are exposed to a minimum recommended concentration (MRC) of the S40™ Sterilant use dilution. This minimum concentration verifies that the use dilution achieves liquid chemical sterilization. The single use chemistry is designed to deliver a consistent dose of sterilant every cycle.



SYSTEM 1™ Express Provides Additional Verification for the Cycle

MaxPure™ Filter Integrity Test
Confirms the filter's capability to eliminate bacteria, fungi and protozoa > 0.1µ from the rinse water. The filter is tested at the end of every cycle to confirm its integrity.

STERIS Verify™ Biological Indicator to confirm sterility.

This kit tests the sporicidal activity of the S40™ and it uses the most resistant organism to PAA use dilution: Geobacillus stearothermophilus.

SYSTEM 1™ Express is CE Marked to the Medical Device Directive and the process is validatable to EN ISO 14973.

ASSURANCE

STERIS Device Testing

Scientifically superior

The STERIS Device Testing team is a unique and dedicated group of degree and PhD level scientists with over 70 years of experience that provides validations for Original Equipment Manufacturers (OEM). This service has been made available to device manufacturers since the late 1980s and supports all STERIS low temperature sterilization modalities.

Since the inception of the programme, STERIS Device Testing has performed numerous studies on thousands of medical devices and works with all OEMs to provide a service that benefits our mutual Customers, the healthcare organisations. No other company offers this level of global leading in-house testing, validation and support for scope sterilization technologies.

Discover our online compatibility matrix!

Devices that pass material compatibility and sterile efficacy testing are added to the STERIS Device Compatibility Matrix.

We constantly update the long list of instruments validated for use in STERIS SYSTEM 1™ Express Sterile Processor.

Compatibility Matrix

STERIS conducts thorough scientific testing to ensure our reprocessing solutions work properly with a wide range of medical devices.

Device performance

Ensures proper fit of the device in a specific container or processor

Material compatibility

A device or material sample is repeatedly processed exposing it to the sterilant or high level disinfectant and cycle to verify compatibility

Microbial efficacy

Confirms the medical device can be repeatedly and effectively sterilized, or high level disinfected

Broad device manufacturer endorsements

OLYMPUS

PENTAX MEDICAL

FUJINON

STORZ KARL STORZ — ENDOSKOPE

stryker

and many more...

EFFICIENCY

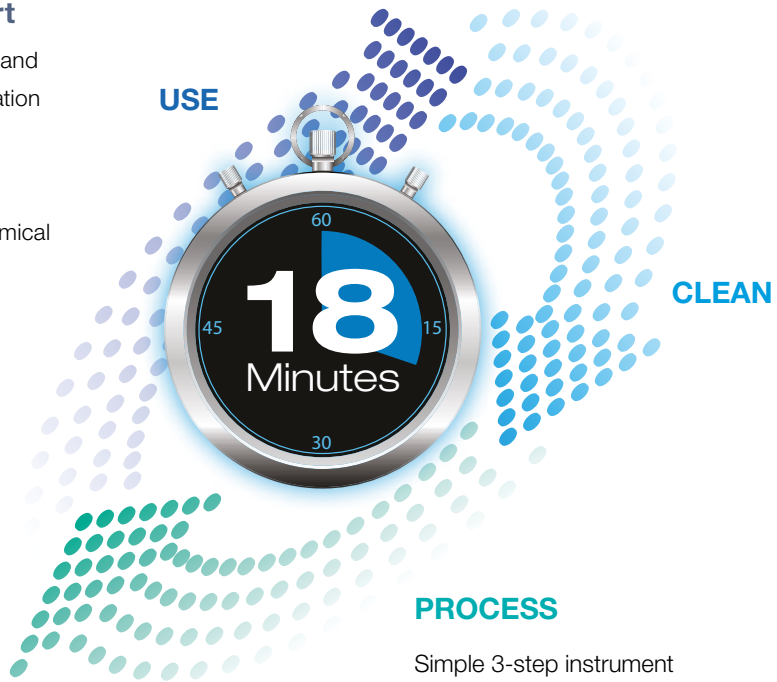
A simple process for an on-time start

Maintaining a tight schedule in the endoscopy suite and OR demands quick access. Liquid chemical sterilization provides reprocessing ease for clean, reusable, immersible critical and semi-critical devices.

S40™ Sterilant Concentrate is a powerful liquid chemical sterilant that eliminates all microbial life.

Its compact footprint makes SYSTEM 1™ Express convenient and ideal for a variety of locations.

- Increased productivity
- Reduced resources
- Minimal costly inventory
- Maximum surgical procedures



PROCESS

Simple 3-step instrument reprocessing streamlines the use to reuse turn-around time

Sterile processed device in only 18 minutes

1-2 minutes

Potable water enters the processor through a series of controlled filters

2-4 minutes

Treated water mixes with S40™ Sterilant Concentrate, creating a powerful peracetic acid use dilution to process the devices

4-10 minutes

6-minute exposure phase eliminates all microbial life

10-12 minutes

Use dilution rinses safely down the drain

12-18 minutes

2 treated rinse phases remove chemical residues

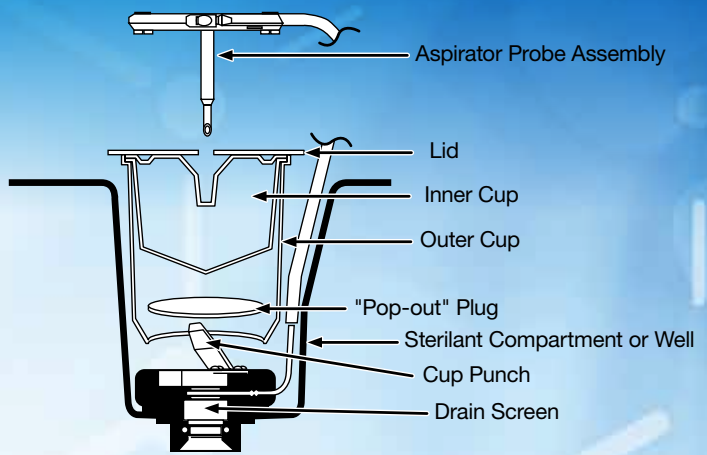
18 minutes

Validated critical and semi-critical devices are ready for immediate use

S40™ Sterilant Concentrate

- Single-use cartridge
- Oxidative chemistry, neutral pH
- Devices are liquid chemically sterilized at the end of the 6-minute exposure phase
- Gentle on devices
- Safe for the Operator
- Single-cup design minimises chance for contact with sterilant unlike bulk aldehyde-based chemistries
- Use Dilution is discharged safely down the drain
- Normal waste disposal
- No special ventilation is required

Sterilant or high level disinfectant	Sporidicidal activity
STERIS S40™[1]	6 minutes
Ortho-Phthalaldeyde CIDEX® OPA[2]	32 hours
CIDEX® Activated Glutaraldehyde Solution	10 hours



[1]STERIS 40™ Sterilant concentrate destroys all microorganisms including bacterial spores when used with STERIS SYSTEM 1™ Express Processor

[2]Data obtained from FDA website, 510(k) Summary K991487, October 1999.

[3]Data obtained from FDA website, 510(k) Summary K060618, April 2006, and CIDEX® Activated Glutaraldehyde Solution Brochure AD-110030-01-CT_B

[4]CIDEX is a registered trademark of Advanced Sterilization Products, a division of Johnson & Johnson Company.

TRAYS AND CONTAINERS

Trays and containers

Trays and containers for System 1™ Express Liquid Chemical Sterilant Processing System are specifically designed to meet the needs of a variety of device types. Combining these trays with device specific Quick Connects facilitates flow of S40™ Sterilant Dilution through lumens or channels to achieve liquid chemical sterilization.

Applications include:

- Flexible endocopes and accessories
- Long lumened rigid devices and cameras
- Laparoscopy and arthroscopy
- Microsurgical devices
- Thoroughly tested Quick Connects to facilitate processing of hundreds of flexible and rigid devices with internal channels

STERIS Quick Connects

The **STERIS Quick Connects** ensure sterilant use dilution contact at all device sites. Quick Connects are available for most flexible and rigid devices with internal channels and include device-specific processing instructions.

Consult the STERIS Device Compatibility Matrix to find the correct combination of STERIS Quick Connect and tray for your devices and endoscopes.

www.steris.com/products/quickconnects/SYSTEM1

Ultrasound Processing Tray

For large flexible endoscopes including 3D and ultrasonic colonoscopes, gastroscopes and bronchoscopes

C3000XL	Ultrasound Processing Tray

Universal Flexible Processing Tray

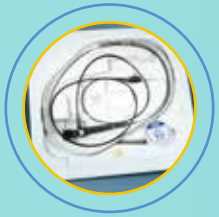
For a wide range of flexible devices used in upper and lower gastrointestinal endoscopy including colonoscopes, gastroscopes and duodenoscopes

C1160INT	Universal Flexible Processing Tray

General Processing Container/Tray

For procedure specific surgical sets, including those for general hard goods laproscopy and arthroscopy procedures including non lumened rigid devices cameras and cords

C1200INT	General Processing Container and Tray	C1202INT Tray only
C1201INT	Container (Base plus Lid)	C1601INT Lid only



Flexible Endoscope Processing Container/Tray

For a wide range of flexible endoscopes including angioscopes, cystoscopes bronchoscopes and choledochoscopes

C1140INT	Flexible Endoscope Processing Container and Tray	C1142INT Tray only
C1141INT	Container (Base plus Lid)	C1602INT Lid only

Directed Flow Processing Container/Tray

For long, lumened rigid devices and cameras including ureteroscopes hysteroscopes, cystoscopes and laparascopes

C1220INT	Directed Flow Processing Container and Tray	C1222INT Tray only
C1221INT	Container (Base plus Lid)	C1600INT Lid only

Microsurgical Rack

For delicate microsurgical devices used in ophthalmology, neurology and otolaryngology procedures including ENT devices. This rack fits inside the General Processing Container, securely positioning small devices

C1330INT	Microsurgical Rack

STERIS SYSTEM 1™ Express Processor, 220/240 V, 50 Hz	
P6502	English Language Version
P6503	Italian Language Version
P6507	Spanish Language Version
P6509	Portuguese Language Version
P6501	German Language Version
A1965	Workstation Cart for STERIS SYSTEM 1™ Express, 1 Cart (Cart only)
Consumables	
S4001	S40™ Sterilant for STERIS SYSTEM 1™ Express and STERIS SYSTEM 1™ PLUS Processors
LCC023	Chemical Indicator Monitoring Strips for S40™ - 2 Bottles of 60 Strips
C1390	Vacustat Clips to hold Chemical Indicator Strips - 2 Strips per Pack
LCB025	Biological Indicators Monitoring Strips and Culture Media for S40™ - 20 Vials + 20 Strips
400399	Incubator for Biological Indicators 56 °C (Adjusts 30-60 °C) Includes thermometer - 220 V
C1392	Incubator for Biological Indicators 56 °C (Adjusts 30-60 °C) Includes thermometer - 120 V

EXPRESS

Excellence in Patient Safety

Professional Education & Clinical Expertise

Get connected to STERIS University, encompassing training disciplines and quality Clinical Education, delivered by a team of expert industry professionals.

For more details, ask **educationdesk@steris.com** or visit **university.steris.com**

EMEA CLINICAL EDUCATION
STERIS UNIVERSITY

STERIS

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M10518EN, 2018-04, Rev.A. System 1E.

CE 0086

This product is a medical device and its CE Mark was delivered by an approved Notified Body.
To use this equipment safely, carefully read the instructions in the user manual and on the labelling.