

# SYSTEM 1<sup>®</sup>

Sterile Processing System

The proven, rapid, safe, and standardized low temperature sterile processing system for immersible surgical and diagnostic scopes, cameras, instruments, and accessories



STERIS<sup>®</sup>



## Flexibility Today For Tomorrow's Applications

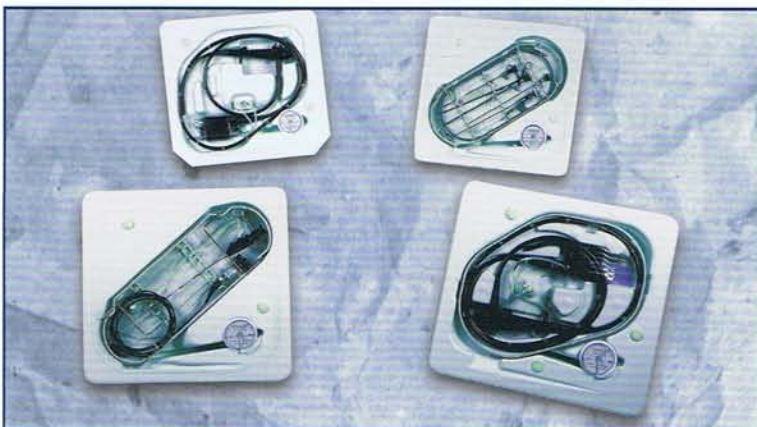
Interchangeable processing tray and container systems immediately adapt SYSTEM 1 processor to individual department sterile processing needs. Each JIT Tray system is configured to the unique design of the instrument types to be sterilized. For inquiries regarding specific device models, please contact STERIS at 800-JIT-4-USE.

- General Surgery (laparoscopes, cameras, light cords, microsurgical instruments, choledochoscopes, ultrasound probes, etc.)
- Orthopaedics (arthroscopes, cameras, light cords, instruments, etc.)
- Urology (flexible and rigid cystoscopes and ureteroscopes, resectoscopes, instruments, accessories, etc.)
- Gastrointestinal Endoscopy (flexible gastro, colono, and sigmoidoscopes, esophageal dilators, specific biopsy forceps, accessories, etc.)
- Bronchoscopy (bronchoscopes, accessories, etc.)
- ENT (flexible sinusopes, rigid ENT scopes, etc.)
- Anesthesiology (laryngoscope blades, intubation scopes)
- Cardiovascular (thoracosopes, angioscopes, etc.)
- Ophthalmology (planar lenses, microsurgical devices, etc.)
- General hard goods and hand instruments



- Optional Bar Code Scanner for positive identification on cycle printout:

- Operator
- Device
- Procedure
- Patients
- Physician.



# SYSTEM 1 Sterile Processing

The proven, rapid, safe, and standardized  
immersion surgical and diagnostic scope

## Sterile Processing ...Just In Time

Since a patient's medical history and examination cannot always identify the potentially infectious patient, sterilization of instruments between uses, even those used for "semi-critical" procedures, is one way to help ensure patient and staff safety.

Availability of sterilized instruments *Just In Time* for each procedure eliminates scheduling conflicts and the need to maintain a separate standard for known infectious or compromised patients.

*A single standard of patient care...availability of sterilized instruments for each patient procedure.*

With SYSTEM 1 processors, instruments can be safely sterilized at or near the area of use. This site of use sterile processing increases productivity and controls costs.

- Reduce costs by minimizing the number of devices required in inventory.
- Maximize the asset utilization of the devices already purchased.
- Reduce the potential for device damage due to transport and handling outside of using department.



# EM 1<sup>®</sup> sterilizing System

Low temperature sterile processing system for  
scopes, cameras, instruments, and accessories

Proven safe and effective  
...Guaranteed

STERIS offers the highest levels of process assurance of any manufacturer. The STERIS PROCESS, from preparation of STERIS 20 use dilution to the final sterile water rinse, is automated and standardized, reducing the potential for operator variability.

Continuous, microcomputer controlled monitoring of critical functions, Dual-line Digital display, and comprehensive printout for each cycle provides confidence in unattended operation.

SYSTEM 1 systems are the most widely used low temperature sterile processing systems in the world today. Extensive and ongoing testing conducted by STERIS and independent laboratories confirms biocidal efficacy and materials compatibility.

Leading device manufacturers participate in the STERIS Device Testing Program, ensuring that thousands of current and future devices are compatible with the STERIS PROCESS. Over 225 million devices have been effectively processed.

## START... A Simple Operation

A SYSTEM 1 Processor is easy to use.

- Step 1 - Select JIT Tray and place in Processor.
- Step 2 - Leak test flexible scopes and preclean devices per device manufacturer's guidelines.
- Step 3 - Position devices in tray or container per STERIS instructions. Most lumened devices require processing per the appropriate STERIS Quick Connect.
- Step 4 - Place one STERIS PROCESS Chemical Monitoring Strip in the tray/container.
- Step 5 - Insert sealed container of STERIS 20 sterilant.
- Step 6 - Close Processor lid.
- Step 7 - Press START.



- New printer assembly provides
  - Improved Q/A with permanent record of cycle
  - Increased efficiency with automated take-up reel
- Dual-line Digital display
  - Prompts Operator through process
  - Alerts Operator of cancelled cycles
  - Provides cycle countdown to increase staff efficiency



## Installation and Support ...In The Area

Quiet, safe operation, basic utility requirements, and compact size make SYSTEM 1 processors ideal for placement in a variety of locations...in the area of instrument use if desired.

- OR substerile room.
- OR suite.
- Special procedures suite.
- Endoscopy Lab.
- Ambulatory Surgery.
- ER, ICU.
- Central Sterile Services.
- Private Practice.

The following utilities should be available within five feet of the Processor:

### ELECTRICAL:

- 20 Amp, 120 VAC (Domestic)
- 10 Amp, 220 VAC (International)
- NEMA 5-20R Hospital Grade
- GFCI Receptacle

### WATER:

- Quality: Tap or other potable
- Pressure: 40-50 PSI (276-345 kPa)
- Flow: 4 GPM (15 LPM) @ 40 PSI (276 kPa)
- Temperature: 110°F-118°F (43°C-48°C)
- Connection: 3/4 inch (1.9 cm) male hose fitting

### DRAIN:

- Sink or other sanitary (non-backpressuring)

### SPACE AND WEIGHT REQUIREMENTS:

- Width: 38 inches (97 cm) minimum
- Height: 32 inches (81 cm) minimum
- Depth: 24 inches (61 cm) minimum
- Weight: 150 pounds (68 kg)
- Operating Weight: 200 pounds (91 kg)
- Mount: Countertop or equipment cart

## Maintenance...In Minutes

Maintenance is easily accomplished by the operator in minutes.

- General surface cleaning.
- Periodic replacement of:
  - Sterile Water Filter.
  - Sterile Air Filter.
  - Water Prefilters.
  - Printer Paper.

STERIS and SYSTEM 1 are registered marks of STERIS Corporation.

Patents #4,731,222 U.S.

#4,892,706 U.S.

#5,037,623 U.S.

#5,077,008 U.S.

#5,091,343 U.S.

#1,273,774 CANADA

#1,321,137 CANADA

#1,320,030 CANADA

#1,745,511 JAPAN

#1,852,815 JAPAN

#EPO 357 238 AUSTRIA

#EPO 357 238 AUSTRIA

#EPO 232 170 EUROPE

Other USA and International Patents Pending

Manufactured in USA

ETL #J99019953-002

Canadian DIN# 09145408

### Footnotes:

1. Cycle time is 30 minutes or less under optimum conditions. Actual time may vary because of incoming water temperature, water pressure, and filter status.
2. Center for Disease Control (CDC) Atlanta, GA.
3. PAA (Peroxyacetic acid, Peracetic acid) is employed in a wide variety of antimicrobial applications in health care and the food and beverage industry.
4. The sterile water filter used in the SYSTEM 1 processor is rated at 0.2 micron absolute to sterilize fluid passing through it. The filter integrity is verified through the Processor's DIAGNOSTICS mode which employs a procedure that is correlated to an FDA accepted bacterial challenge test.
5. Filter life is a function of water quality and number of cycles performed. To maximize sterile water filter life, the SYSTEM 1 processor employs an external prefilter system.

Manufactured exclusively by  
STERIS Corporation in c  
Mentor, OH facility which  
ISO 9001 certified.



SWEDISH TRADING CO., LTD.  
瑞典洋行有限公司



Unit 204, 2/F New Bright Building, 11 Sheung Yuet Road  
Kowloon Bay, Kowloon, Hong Kong.

Tel: (852) 2953 5111 Fax: (852) 2798 8262

E-mail: stc@swedishtrading.com Website: www.swedishtrading.com

香港九龍九龍灣常悅道11號新明大廈2樓204室

Publication ID #M1868E1  
GPSI Printed 05/2005, 5r  
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Technologies to Prevent Infection and Contamination™

# STERIS®



STERIS Corporation  
5960 Heisley Road  
Mentor, OH 44060-1834 ■ USA  
440-354-2600 ■ 800-548-4873  
www.steris.com

“Low temperature sterile processing in less than 30 minutes, that sounds too good to be true...”

## **INFECTION CONTROL WANTS THE PROCESS TO BE WELL DOCUMENTED, APPROVED FOR USE, AND ACHIEVABLE IN THE REAL WORLD**

The STERIS PROCESS is sterilization which, first and foremost, is safe for heat-sensitive, immersible instruments. The rapid, low temperature, liquid chemical STERIS PROCESS is equal in efficacy to steam or ethylene oxide sterilization.

- Multiple, published independent studies.
- Clinically proven and accepted.
- SYSTEM 1 Technical Data Monograph*.  
Efficacy, Toxicology, Materials Compatibility data.

UNIVERSAL PRECAUTIONS...treat all patients as potentially infectious.

CDC, 1988<sup>8</sup>

“...balancing quality patient care against the reality of financial constraints. It must be affordable.”

## **ADMINISTRATION WANTS EFFECTIVE, AFFORDABLE RISK MANAGEMENT**

Balance the risk of employee exposure to hazards in the work environment and the risk of disease transmission associated with disinfection against the affordability of sterile processing with SYSTEM 1 processors.

- Sterile instruments for each patient procedure every time.
- Reduced employee contact with contaminated instruments.
- Reduced employee exposure to hazardous chemicals, noxious fumes, chemical residues, and toxic gases associated with other techniques.
- No environmental controls or monitors required.
- Affordable per use cost.
- Multiple department applications.

“Endoscopic surgery, such as cystoscopy, is the most rapidly increasing type of minimally-invasive procedure performed today. But with so many patients and so few scopes...”

## **THE DOCTOR WANTS THE INSTRUMENT...NOW**

The STERIS PROCESS meets the doctor's need for instrument availability and is safe for routine sterile processing of delicate instruments.

- Less than 30 minute standard cycle.<sup>1</sup>
- Low temperature sterile processing. 50°C - 56°C (122°F - 132.8°F).
- Proven materials compatibility.

“Given a choice, I'd prefer a sterilized instrument to one that's been disinfected, if I were the patient...if it were practical.”

## **NURSING WANTS TO DO THE BEST FOR THE PATIENT**

STERIS SYSTEM 1 units overcome the practical obstacles to sterilization of instruments between patient procedures.

- Rapid, Just In Time for use...JIT™.
- Safe, non-toxic STERIS PROCESS.
- Automated, micro-processor controlled cycle.
- Unattended operation.
- Sterilized, not disinfected.

A single standard of practice...standardized, documented sterile processing which is safe for instruments.

“The doctor says there's nothing to worry about.”

## **THE PATIENT BELIEVES IT'S STERILE**

NOW...A sterilized instrument for each patient procedure *just in time*.

Chemistry...The Creative  
Power of the  
STERIS PROCESS



SYSTEM 1 processors utilize STERIS 20™ chemistry, a powerful chemical sterilant with a high degree of materials compatibility. The STERIS 20 formulation includes the active ingredient PAA<sup>3</sup> in combination with a proven chemical protection system developed to help ensure safe sterilization of even delicate instruments.

STERIS 20 sterilant has been extensively tested according to FDA recognized sterilization test methods. Under the standard conditions for use, STERIS 20 sterilant is sporicidal in 12 minutes.

The majority of high level disinfectants are not sporicidal under normal use conditions and therefore probably do not offer the STERIS PROCESS's high assurance that all microbial organisms have been destroyed.

- Optimal concentration of sterilant per cycle.
  - Single use packaging.
  - Automatic preparation of use dilution.
  - Continuous system monitoring.
- Gentle use dilution.
  - Effective in 12 minutes at 50°C (122°F).
  - Neutral pH.
  - Non-toxic.
  - No disposal precautions following standard cycle.

Normal Printout

<b>STERIS</b>	
	
SYSTEM 1	
DATE:	11-11-01
CYCLE START:	1:30:20P
OPERATOR ID: 12345678901245	
DEVICE ID: 12345	
PROCEDURE ID: 12	
PATIENT ID: 1234567890123456	
PHYSICIAN ID: 23456789012	
REMARKS: _____	
_____	
_____	
TEMP: 51 - 55 DEG. C	
CONCENTRATION: 202	
EXPOSURE TIME: 0.0 MIN	
FILL TIME: 0.9 MIN	
INLET TEMP: 44 DEG. C	
OPERATOR: 123456789012345	
SERIAL # 000000000000000	
CYCLE COUNT: 40	
CYCLE COMPLETE: 1:31:30P	
CHAMBER OPENED: 1:33:45P	

Cancelled Cycle

<b>STERIS</b>	
	
SYSTEM 1	
DATE:	11-11-01
CYCLE START:	10:16:09A
OPERATOR ID: 12345678901245	
DEVICE ID: 12345	
PROCEDURE ID: 12	
PATIENT ID: 1234567890123456	
PHYSICIAN ID: 23456789012	
REMARKS: _____	
_____	
_____	
<b>WARNING</b>	
STERILIZATION	
NOT COMPLETE	
HEAT PROBLEM	
SEE OPERATOR MANUAL	
TEMP: 41.9 - 42.2 DEG. C	
CONCENTRATION: 222	
EXPOSURE TIME: 0.0 MIN	
FILL TIME: 1.3 MIN	
INLET TEMP: 45 DEG. C	
OPERATOR ID: _____	
SERIAL # 000000000000000	
CYCLE COUNT: 13	
CYCLE CANCELLED: 10:33:52A	
CHAMBER OPENED: 10:34:32A	

Process  
and Load  
Quality Assurance

A comprehensive permanent printout accompanies each cycle for quality assurance records. The parameters critical to the STERIS PROCESS are monitored and documented for each cycle. If a process parameter cannot be met or maintained, the cycle will immediately CANCEL. The Dual Line Digital display and printout report fault conditions and alert the operator.

- Process parameters and load identification.
- Fault messages and diagnostic information.
- Positive audit trail between patient, device, operator, physician, and procedure.
  - Infection surveillance records.
  - Patient charting.
  - Reimbursement trigger.
  - Department records.
  - Release authorization.
  - Service maintenance records.

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<hr/>	
OPERATOR ID:	123456789012345
DEVICE ID:	12345
PROCEDURE ID:	12
PATIENT ID:	1234567890123456
PHYSICIAN ID:	23456789012
REMARKS:	_____
_____	_____
_____	_____
_____	_____
_____	_____
<hr/>	
TEMP:	51 - 55 DEG. C
CONCENTRATION:	200
EXPOSURE TIME:	0.0 MIN
FILL TIME:	0.9 MIN
INLET TEMP:	44 DEG. C
<hr/>	
OPERATOR:	123456789012345
SERIAL #:	00000000000000
CYCLE COUNT:	40
<hr/>	
CYCLE COMPLETE:	1:31:30P
CHAMBER OPENED:	1:32:45P

## Cancelled Cycle

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_____	_____
_____	_____
_____	_____
<hr/>	
<b>WARNING</b>	
STERILIZATION NOT COMPLETE HEAT PROBLEM SEE OPERATOR MANUAL	
<hr/>	
TEMP:	41.5 - 42.2 DEG. C
CONCENTRATION:	222
EXPOSURE TIME:	0.0 MIN
FILL TIME:	1.3 MIN
INLET TEMP:	46 DEG. C
<hr/>	
OPERATOR ID:	_____
SERIAL #:	00000000000000
CYCLE COUNT:	13
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