



2001 W. 86th Street  
Indianapolis, Indiana 46240  
www.stvincent.org

April 4, 2002

**Docket # 02D-0039**

Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5639 Fischers Lane, Room 1061, ( HFA-305)  
Rockville, MD 20852

Sirs,

The following comments and recommendations are submitted for your consideration and review for **Docket # 02D-0039**, Premarket Notification [510(k)], Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA.

**Section I C. Definitions**

(middle page 5)

**Trays-** includes trays that have lids and bottoms throughout the document.

**Section I D. Regulatory Authority and Classifications**

(bottom page 5)

1976 Medical Device amendment concerns:

- It would be unrealistic to think that ;
  1. Cassettes
  2. Trays
  3. Organizing trays
  4. Instrument Trays
  5. Closed containers
  6. Containers

Have not changed in some way over the course of 26 years.

For example:

02D-0039

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12

- Intended use
- Structural Design
- Material(s) used

**Question:**

Is the amendment still needed with the enactment of the SMD (Safe Medical Devices Act) act of 1990 and the appropriate development of the three regulatory Classes (I, II, III)?

**Suggestion:**

Updating amendment or removal of the amendment throughout the document.

**Section I. F**

Item 1. ( bottom page 6)

- *Is there a need for the 1976 amendment since the enactment of the Safe Medical Devices Act of 1990 and the appropriate development of the three regulatory Classes (I, II, III)?*

(Page 7 top)

- Submit percentage of surface area perforations required for containers, cassettes, trays, and instrument trays, organizing trays with the intended use of sterilization.

Example:

1. 19%-24% ( polymers(**do not perform well in steam**), closed container systems)
2. 24%-54% ( cassettes, trays, flash pans, organizing trays, instrument trays)

**Section II. C.**

(bottom page 8)

Information Requested

1. *Stress the use of Healthcare Standard sterilization cycles throughout the document.*

- Pre-Vac- 4 min sterilize 25 min dry at 270 degree
- Pre-Vac- 3 min sterilize 15-16 min dry at 275 degree
- Gravity- 15 min sterilize 30 min dry at 270 degree
- Gravity- 10 min sterilize 30 min dry at 275 degree
- Gravity- 30min sterilize 30 min dry at 250 degree
- Gravity- 30 min sterilize 30 min dry at 270 degree

Included with these comments are copies of autoclave manufacturer(s) recommended Healthcare sterilization cycles(steam,plasma). **Standard Healthcare cycles should be used for all methods of sterilization available.**

**The importance of minimizing number of cycles used in healthcare is of paramount importance. Industry needs to adhere to the current Healthcare sterilization standard cycles to permit and promote the assurance of sterility.** In addition, Healthcare facilities are required to increase productivity and the timely return/turn around of instrumentation for medical procedures throughout each working day with anticipation of case load for consecutive days. ***Industry needs to adhere to Healthcare standards and design devices using materials that will accomplish that goal.***

## **Section II. D.**

(top page 10)

### **Comparison of the New Device with Predicate Device.**

1)...sterilant penetration....porous enough(needs definition)...

Recommend: Hole perforations

- 19%-24% (polymers (**do not perform well in steam**), closed containers, etc...)
- 24%- 54% (cassettes, trays, flash pans, organizing trays, instrument trays, etc.)

2) Material Compatibility

... for which it is intended.... *(leaves industry open to develop cycles that are outside the standard healthcare cycles)*

**Utilize standard Healthcare sterilization cycles as a blueprint** (ETO, Plasma, Peracetic acid, liquid disinfectant, steam, and dry heat...)  
Refer to Section II. C (Information Requested)

(middle page 10)

3) Drying time

Must adhere to standard healthcare drying times. The **range for drying times is thus, 0 min to 30 min**. Industry should not develop medical devices that go beyond the Healthcare standard.

### **Section II F.**

Intended Use  
(last paragraph bottom page 11)

.... reasonable period of time....

Change to : **Following the standard Healthcare drying times(from 0 min to 30 min).**

Refer to comments in Section II. C. Information requested, bottom page 8.

(page 12 second page)

... Sterilization trays are not enclosed systems...

Generally, trays (**may or may not have**) lids...

### **Section III. Performance Information Testing**

(page 13 top)

- Sterilization cycles tested – **must adhere to standard healthcare cycles.**

- Recommendation 17-20 pound weight limits for all devices and or sets.  
Rationale: ergonomic, personnel safety set density...
- **Follow autoclave manufacturers recommendations for weight limits**

### Section III. A. Biological Indicators

Item 4.  
(middle page 14)

*.... Standard cycle time of sterilizers routinely used in healthcare setting...*  
**Phrase needs to be used throughout the document. This cannot be stressed enough.**

Item 5  
( bottom page 14)

Testing:

- *Done by outside testing facility with **no vested interest or perceived interest in the firm(s)** or outcomes of test performed.*
- *Validation testing results are to be provided to Healthcare Facilities on **testing facility letterhead and in report form.***
- *Validation/testing results are **not to be provided** on the firm(s) letterhead. This facilitates genuine results and fosters trust without the possibility of firm(s) false or inadequate interpretation of results.*

### Section III. D. Drying Aeration

(bottom page 18)

- 1) Drying times...
- 3) Plastic containers...
- 4) Containers with valves...

**Stress standard Healthcare cycles for drying times ranging from 0 min to 30 min for all cassettes, trays, flash pans, organizing trays, instrument trays, closed container systems regardless of chosen material.**

- 2) **Plastic containers**

**Add: Susceptible to recondensation post sterilization cycle continuing throughout drying and cool down process.**

**Section IV.**

(Page 21)

- Sterilization method and types....  
Refer to Section III. A. Item 5  
Industry needs to adhere to standard healthcare cycles for:
  - ETO
  - Plasma
  - Peracetic acid
  - Cold disinfection
  - Steam
  - Dry heat
  - Etc.

(Page 22)

- Instruction for validated method...
  - 1) Refer to Section III. A. Item 5
  - 2) Required to provide to healthcare prior to purchase.

If I can be of any further assistance or there is a need for further clarification, please feel free to contact me.

Becki Harter IR Coordinator  
Surgery Administration  
St. Vincent Hospital  
2001 W. 86<sup>th</sup> street  
Indianapolis, IN.

46240

317-338-3581 (voice mail)

317-338-6368 (fax)

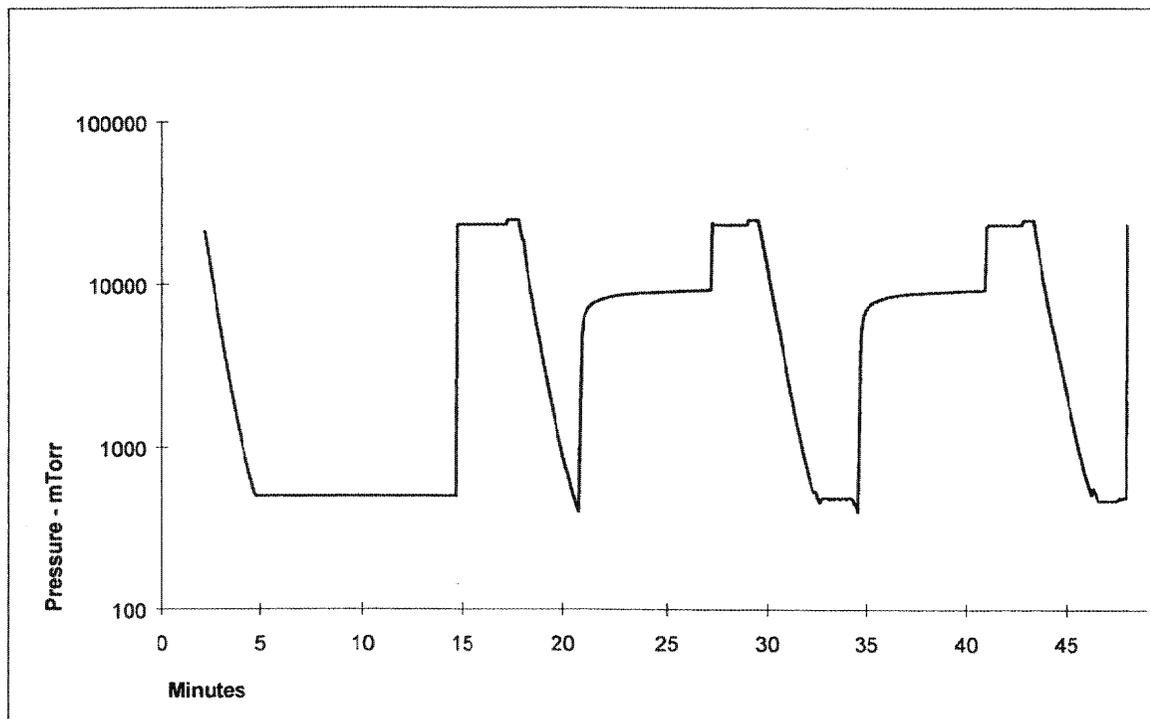
[beharter@stvincent.org](mailto:beharter@stvincent.org)

## The Phases of the STERRAD® 100S Sterilizer, Continued

Phases	Order	Stages	Pressure	Approx. Time
Pre-Exposure Plasma	1	Vacuum Stage	0.7 Torr	20 min.
		Pre-Exposure Plasma Stage	0.5 Torr	
Exposure 1	2	Injection Stage	6-14 Torr	17 min.
		Diffusion Stage	Max 15 Torr*	
		Plasma Stage	0.45-0.8 Torr	
Exposure 2	3	Injection Stage	6-14 Torr	17 min.
		Diffusion Stage	Max 15 Torr*	
		Plasma Stage	0.45-0.8 Torr	
Vent	4	Vent Stage	760 Torr	1 min.

\* Diffusion pressure is actually at atmospheric pressure, however, the maximum display reading is 15 Torr.

### Typical STERRAD® 100S Cycle Process Curve



The Eagle Century Steam Sterilizer is equipped with the following factory programmed set sterilization cycles and cycle values:

#### PREVACUUM CONFIGURATION

CYCLES	RECOMMENDED LOADS	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
FLASH	Unwrapped Instrument tray with a single instrument.	270°F (132°C)	3 minutes	1 minute
FLASH	Unwrapped instrument tray with non-porous multiple instruments, maximum weight 17lbs.	270°F (132°C)	10 minutes	1 minute
EXPRESS	Single wrapped instrument tray with a single instrument. Non-porous goods only.	270°F (132°C)	4 minutes	3 minutes
PREVAC	Up to two double wrapped instrument trays, maximum weight 17 lbs. Up to six fabric packs.	270°F (132°C)	5 minutes	20 minutes <sup>1</sup>

<sup>1</sup>Five minute Dry Time can be used for processing a single fabric pack.

#### GRAVITY CONFIGURATION

CYCLES	RECOMMENDED LOADS	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
FLASH	Unwrapped Instrument tray with a single instrument.	270°F (132°C)	3 minutes	1 minute
FLASH	Unwrapped instrument tray with non-porous multiple instruments, maximum weight 17lbs.	270°F (132°C)	10 minutes	1 minute
GRAVITY	Up to two double wrapped trays, maximum weight 17 lbs.	270°F (132°C)	15 minutes	30 minutes
GRAVITY	Fabric Packs.	250°F (121°C)	30 minutes <sup>2</sup>	15 minutes

<sup>2</sup> A 270°F (132°C) cycle adjusted to 25 minute Sterilize Time can be used for processing fabric packs.

equipment with multiple default cycle parameters. These represent the most common applications. STERIS provides these cycles for ease of configuration. It is the user's responsibility to configure prior to use and to validate efficacy by use of biological indicators. Reference AAMI standards for a guide to qualifying sterilization cycles and to ensure that proper sterility assurance level (SAL) and shelf life retention acceptance criteria are met.

**SMALL GRAVITY STERILIZERS:**

Default Cycles	Recommended Load	Sterilize Temp	Sterilize Time	Dry Time
FLASH	Unwrapped Goods	270°F (132°C)	3 minutes	1 minute
FLASH	Unwrapped Goods	270°F (132°C)	10 minutes	1 minute
GRAVITY	Wrapped and Unwrapped Goods	270°F (132°C)	15 minutes	30 minutes
GRAVITY	Wrapped and Unwrapped Goods	250°F (121°C)	30 minutes	15 minutes

**MEDIUM GRAVITY STERILIZERS**

Default Cycles	Recommended Load	Sterilize Temp	Sterilize Time	Dry Time
GRAVITY	Wrapped and Unwrapped Goods	270°F (132°C)	15 minutes	30 minute
GRAVITY	Wrapped and Unwrapped Goods	270°F (132°C)	30 minutes	15 minute
GRAVITY	Wrapped and Unwrapped Goods	270°F (132°C)	30 minutes	30 minutes
LIQUID	See Table 5-1	250°F (121°C)	45 minutes	0 minutes

**SMALL PREVACUUM STERILIZERS:**

Default Cycles	Recommended Load	Sterilize Temp.	Sterilize Time	Dry Time
EXPRESS	Wrapped Instruments	270°F (132°C)	4 minutes	3 minutes
PREVAC	Wrapped and Unwrapped Goods	270°F (132°C)	4 minutes	20 minutes
FLASH	Unwrapped Goods	270°F (132°C)	3 minutes	1 minute
FLASH	Unwrapped Goods	270°F (132°C)	10 minutes	1 minute

**MEDIUM PREVACUUM STERILIZERS:**

Default Cycles	Recommended Load	Sterilize Temp.	Sterilize Time	Dry Time
PREVAC	Wrapped and Unwrapped Goods	270°F (132°C)	4 minutes	5 minutes
PREVAC	Wrapped and Unwrapped Goods	270°F (132°C)	4 minutes	20 minutes
GRAVITY	Wrapped and Unwrapped Goods	250°F (121°C)	30 minutes	15 minutes
LIQUID	See Table 5-1	250°F (121°C)	45 minutes	0 minutes

Table 2-1. Load Chart

CYCLE TYPE	FACTORY SETTINGS					LOAD CONFIGURATION <sup>2</sup>
	122HC	133HC	EXP. TEMP.	EXP. TIME	DRY TIME <sup>1</sup>	
Gravity (grv)	P1	( <sup>3</sup> )	250°F (121°C)	30 min.	30 min. (gravity dry)	<ul style="list-style-type: none"> <li>• Double-wrapped instrument trays, up to 16 lbs. (2 max.)</li> <li>• Fabric packs (2 max. in 16"x16" chamber, 12 max. in 20"x20" chamber)</li> </ul>
	P2	( <sup>3</sup> )	275°F (135°C)	10 min.	30 min. (gravity dry)	<ul style="list-style-type: none"> <li>• Double-wrapped instrument trays, up to 16 lbs. (2 max.)</li> <li>• Fabric packs (2 max. in 16"x16" chamber, 12 max. in 20"x20" chamber)</li> </ul>
Flash 3+ (f 3)	P3	P3	275°F (135°C)	3 min.	0 min.	<ul style="list-style-type: none"> <li>• Unwrapped single instrument</li> <li>• Unwrapped non-porous instrument trays, up to 16 lbs. (2 max.)</li> </ul>
	P4					
Flash 10+ (f10)	P5	P4	275°F (135°C)	10 min.	0 min.	<ul style="list-style-type: none"> <li>• Unwrapped single instrument</li> <li>• Unwrapped porous and non-porous instrument trays, up to 16 lbs. (2 max.)</li> </ul>
	P6					
Prevacuum (vac)		P1	275°F (135°C)	3 min.	16 min.	<ul style="list-style-type: none"> <li>• Double-wrapped instrument trays, up to 16 lbs. (2 max.)</li> <li>• Fabric packs (2 max. in 16"x16" chamber, 12 max. in 20"x20" chamber)</li> </ul>
		P2	275°F (135°C)	3 min.	3 min.	<ul style="list-style-type: none"> <li>• Single-wrapped single instrument</li> <li>• Single-wrapped instrument trays, up to 16 lbs. (2 max.)</li> <li>• Fabric packs (2 max. in 16"x16" chamber, 12 max. in 20"x20" chamber)</li> </ul>
Bowie-Dick Test (vac)		P5	273°F (134°C)	3.5 min	0 min.	S.M.A.R.T Pack or equivalent (1 max.)
Vacuum Leak Test (lkt) <sup>4</sup>		P6	268°F (131°C)	3 min.	15 dry+ 5 dwell+ 15 test	Empty chamber
Liquids (liq)	( <sup>3</sup> )	( <sup>3</sup> )	250°F (121°C)	30 min.	0.75 psi/min. <sup>5</sup>	Up to 250 mL containers (40 max. in 16"x16" chamber, 168 max. in 20"x20" chamber)
			250°F (121°C)	45 min.	0.75 psi/min. <sup>5</sup>	Up to 1000 mL containers (15 max. in 16"x16" chamber, 32 max. in 20"x20" chamber)

<sup>1</sup>Factory set drying time is the recommended minimum drying time. Extended drying time may be required depending on local conditions. Gravity cycle drying time may be reduced by selecting vacuum drying phase (see Supervisor Manual).

<sup>2</sup>Refer to AAMI Standards ST46 *Good Hospital Practice: Steam Sterilization and Sterility Assurance* and ST37 *Good Hospital Practice: Flash Sterilization — Steam Sterilization of Patient Care Items for Immediate Use*.

<sup>3</sup>Cycle available but not assigned.

<sup>4</sup>Vacuum leak test cycle parameters are not adjustable.

<sup>5</sup>Cooldown rate

Table 2-1. Load Chart

CYCLE TYPE	FACTORY SETTINGS				LOAD CONFIGURATION <sup>2</sup>	
	CYCLE NO.	EXP. TEMP.	EXP. TIME	DRY TIME <sup>1</sup>		
Prevacuum (vac)	P1	275°F (135°C)	3 min.	16 min.	Wrapped instrument trays, up to 16 lbs. • 36" length – 10 max. • 51" length – 15 max. • 60" length – 20 max.	Fabric packs • 36" length – 24 max. • 51" length – 36 max. • 60" length – 48 max.
	P2	275°F (135°C)	3 min.	3 min.	Fabric packs • 36" length – 24 max. • 51" length – 36 max. • 60" length – 48 max.	
Gravity (grv)	P3	250°F (121°C)	30 min.	30 min.	Wrapped instrument trays, up to 16 lbs. • 36" length – 10 max. • 51" length – 15 max. • 60" length – 20 max.	Fabric packs • 36" length – 24 max. • 51" length – 36 max. • 60" length – 48 max.
	P4	275°F (135°C)	10 min.	30 min.	Wrapped instrument trays, up to 16 lbs. • 36" length – 10 max. • 51" length – 15 max. • 60" length – 20 max.	Fabric packs • 36" length – 24 max. • 51" length – 36 max. • 60" length – 48 max.
Bowie-Dick Test (vac)	P5	273°F (134°C)	3.5 min	0 min.	S.M.A.R.T Pack or equivalent (1 max.)	
Vacuum Leak Test (lkt) <sup>4</sup>	P6	268°F (131°C)	3 min.	15 dry +5 dwell +15 test	Empty chamber	
Flash (fls)	— <sup>3</sup>	275°F (135°C)	10 min.	0 min.	• Unwrapped single non-porous instrument • Unwrapped non-porous instrument trays (up to 16 lbs. maximum)	
Liquids (liq)	— <sup>3</sup>	250°F (121°C)	45 min.	0.75 psi/min. <sup>5</sup>	Up to 1000 mL containers • 36" length – 112 max. • 51" length – 154 max. • 60" length – 196 max.	

<sup>1</sup>Factory set drying time is the recommended minimum drying time. Extended drying time may be required depending on local conditions.

<sup>2</sup>Refer to AAMI standards ST46 *Good Hospital Practice: Steam Sterilization and Sterility Assurance* and ST37 *Good Hospital Practice: Flash Sterilization — Steam Sterilization of Patient Care Items for Immediate Use*.

<sup>3</sup>Cycle available but not assigned.

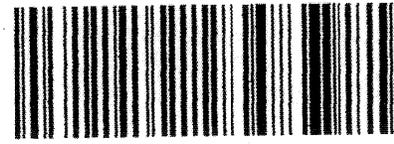
<sup>4</sup>Vacuum leak test cycle parameters are not adjustable.

<sup>5</sup>Cooldown rate

Becki Harter  
Instrument Room Coordinator  
St. Vincent Hospital  
2920 Plaza Drive, #F  
Inianapolis, IN  
46268

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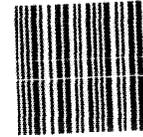
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5639 Fischers Lane, Room 1061, (HFA-305)  
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