



October 28, 2021

STERIS Corporation  
% Anthoy Piotrkowski  
Director, Regulatory Affairs  
STERIS Corporation  
5960 Heisley Rd  
Mentor, OH 44060

Re: K212424

Trade/Device Name: AMSCO 400 Small Steam Sterilizers, AMSCO 400 Medium Steam Sterilizers  
Regulation Number: 21 CFR 880.6880  
Regulation Name: Steam Sterilizer  
Regulatory Class: Class II  
Product Code: FLE  
Dated: September 24, 2021  
Received: September 27, 2021

Dear Anthoy Piotrkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Clarence W. Murray, III, Ph.D.  
Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K212424/S001

Device Name

Amsco 400 Small Steam Sterilizer

Indications for Use (Describe)

The Amsco 400 Small Steam Sterilizer models 16, 16C, 16CS, 16S, 20, 20C, 20CS, and 20S are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

- *Prevacuum (Models 16, 16C and 20, 20C)* – are equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP) (Models 16CS, 16S and 20CS, 20S)* – are equipped with SFPP, Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The Amsco 400 Small *Prevacuum* Steam Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 4-1):

**Table 4-1.**

Amsco 400 Small *Prevacuum* Steam Sterilizer Models 16, 16, 20, 20C factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. Refer to Table 4-3 for recommended quantities.
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. Refer to Table 4-3 for recommended quantities.
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Prevac (Immediate Use)	270°F (132°C)	4 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. Refer to Table 4-3 for recommended quantities.
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. Refer to Table 4-3 for recommended quantities.
Gravity (Immediate Use)	270°F (132°C)	3 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.

Gravity (Immediate Use)	270°F (132°C)	10 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Liquid*	250°F (121°C)	45 minutes	N/A	Validated with 3 1000ml bottles. Refer to Table 4-4 for recommended full load quantities.
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

\*The liquid cycle is for non-patient contact use only.

The Amsco 400 Small *Steam Flush Pressure-Pulse* (SFPP) Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 4-2):

**Table 4-2.**

Amsco 400 Small *Steam Flush Pressure-Pulse* (SFPP) Sterilizer Models 16S, 16CS, 20S, 20CS factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
SFPP	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. Refer to Table 4-3 for recommended quantities.
SFPP	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. Refer to Table 4-3 for recommended quantities.
SFPP	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
SFPP	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. Refer to Table 4-3 for recommended quantities.
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. Refer to Table 4-3 for recommended quantities.
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Prevac (Immediate Use)	270°F (132°C)	4 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. Refer to Table 4-3 for recommended quantities.
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. Refer to Table 4-3 for recommended quantities.

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Gravity (Immediate Use)	270°F (132°C)	3 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Gravity (Immediate Use)	270°F (132°C)	10 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4-3 for recommended quantities.
Liquid*	250°F (121°C)	45 minutes	N/A	Validated with 3 1000ml bottles. Refer to Table 4-4 for recommended full load quantities.
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

\*The liquid cycle is for non-patient contact use only.

The following table lists STERIS's recommended loads by sterilizer size:

**Table 4-3**

Amsco 400 Small Steam Sterilizer recommended loads per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
16" x 16" x 26"	2	4
20" x 20" x 38"	3	6

The following table is a guideline for liquid cycle processing:

**Table 4-4**

Amsco 400 Small Steam Sterilizer Liquid\* Cycle Guideline

Sterilizer Size	Number of Containers for full load	Number of Containers for validation	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
16" x 16" x 26"	15	3	1000 ml	45 minutes
20" x 20" x 38"	32	3	1000 ml	45 minutes

\*The liquid cycle is for non-patient contact use only.

The Amsco 400 Small Steam Sterilizer is offered in the following chamber sizes:

- 16" x 16" x 26" (Models 16, 16C, 16CS, and 16S)
- 20" x 20" x 38" (Models 20, 20C, 20CS, and 20S)

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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*PRAStaff@fda.hhs.gov*

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## Indications for Use

510(k) Number (if known)  
K212424/S001

Device Name

AMSCO 400 Medium Steam Sterilizers (Models 39SL and 39CSL)

Indications for Use (Describe)

The AMSCO 400 Medium Steam Sterilizers (Models 39SL and 39CSL) are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in the following configuration:

- *Prevacuum* – equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The AMSCO 400 Medium *Prevacuum* Steam Sterilizers are equipped with the following factory-programmed sterilization cycles and cycle values (Table 4.5):

**Table 4.5.**

AMSCO 400 Medium *Prevacuum* Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. Refer to Table 4.6 for recommended quantities.
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. Refer to Table 4.6 for recommended quantities.
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4.6 for recommended quantities.
Prevac (Immediate Use)	270°F (132°C)	4 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table A-2 for recommended quantities.
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. Refer to Table 4.6 for recommended quantities.
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4.6 for recommended quantities.
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4.6 for recommended quantities.
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. Refer to Table 4.6 for recommended quantities.
Gravity (Immediate Use)	270°F (132°C)	3 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4.6 for recommended quantities.
Gravity (Immediate Use)	270°F (132°C)	10 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4.6 for recommended quantities.
Liquid*	250°F (121°C)	45 minutes	N/A	Validated with 3 1000ml bottles. Refer to Table 4.7 for recommended full load quantities.
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

\*The liquid cycle is for non-patient contact use only.

The following table lists STERIS' full loads by sterilizer size:

**Table 4.6**  
AMSCO 400 Medium Steam Sterilizer full load per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 26" x 39"	4	12

The following table is a guideline for liquid cycle processing:

**Table 4.7**  
AMSCO 400 Medium Steam  
Sterilizer Liquid Cycle Guideline

Sterilizer Size	Number of Containers for full load	Number of Containers for validation	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
26" x 26" x 39"	80	3	1000 ml	45 minutes

\*The liquid cycle is for non-patient contact use only.

The AMSCO 400 Medium Steam Sterilizer is offered in the following chamber sizes:

- 26" x 26" x 39" (Models 39SL and 39CSL)

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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PRAStaff@fda.hhs.gov

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## Indications for Use

510(k) Number (if known)  
K212424/S001

Device Name

AMSCO 400 Medium Steam Sterilizers (Models 36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL and 60CSL)

Indications for Use (Describe)

The AMSCO 400 Medium Steam Sterilizers (Models 36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL and 60CSL) are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in the following configuration:

- *Prevacuum* – equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles

The Amsco 400 Small *Prevacuum* Steam Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 4.8):

**Table 4.8.**

Amsco 400 Medium *Prevacuum* Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. Refer to Table 4.9 for recommended quantities.
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. Refer to Table 4.9 for recommended quantities.
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4.9 for recommended quantities.
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. Refer to Table 4.9 for recommended quantities.
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4.9 for recommended quantities.
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Table 4.9 for recommended quantities.
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. Refer to Table 4.9 for recommended quantities.
Liquid*	250°F (121°C)	45 minutes	N/A	Validated with 3 1000ml bottles. Refer to Table 4.10 for recommended full load quantities.
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

\*The liquid cycle is for non-patient contact use only.

The following table lists STERIS's recommended loads by sterilizer size:

**Table 4.9**

Amsco 400 Medium Steam Sterilizer recommended loads per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 37.5" x 36"	9	18

26" x 37.5" x 48"	12	30
26" x 37.5" x 60"	15	36

The following table is a guideline for liquid cycle processing:

**Table 4.10**  
AMSCO 400 Medium Steam Sterilizer Liquid Cycle Guideline

Sterilizer Size	Number of Containers for full load	Number of Containers for validation	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
26" x 37.5" x 36"	112	3	1000 ml	45 minutes
26" x 37.5" x 48"	154	3	1000 ml	45 minutes
26" x 37.5" x 60"	196	3	1000 ml	45 minutes

\*The liquid cycle is for non-patient contact use only.

The AMSCO 400 Medium Steam Sterilizer is offered in the following chamber sizes:

- 26" x 37.5" x 36" (Models 36H, 36CH, 36SL, 36CSL)
- 26" x 37.5" x 48" (Models 48H, 48CH, 48SL, 48CSL)
- 26" x 37.5" x 60" (Models 60H, 48CH, 48SL, 48CSL)

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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STERIS®



**K212424/S001**  
**510(k) Summary**  
**For**  
**AMSCO 400 Small Steam Sterilizers**

STERIS Corporation  
5960 Heisley Road  
Mentor, OH 44060  
Phone: (440) 354-2600  
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Contact: Tony Piotrkowski  
Director, Regulatory Affairs

Telephone: (440) 392-7437  
Email: [tony\\_piotrkowski@steris.com](mailto:tony_piotrkowski@steris.com)

Summary Date: August 3, 2021

**STERIS Corporation Special Premarket Notification [510(k)]  
Modifications to AMSCO 400 Steam Sterilizers**

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**1. Device Name**

Trade Name: AMSCO 400 Small Steam Sterilizer (cleared as AMSCO Chimeron Small Steam Sterilizer)

Device Class: Class II

Common/usual Name: Steam Sterilizer

Classification Name: Sterilizer, Steam

Classification Number: 21 CFR 880.6880

Product Code: FLE

**2. Predicate Devices**

**K111223** - AMSCO Chimeron Small Steam Sterilizer (renamed AMSCO 400 before commercialization)

The proposed device is identical to the predicate except for the modification to replace an obsolete control chip.

**3. Description of Devices**

The AMSCO 400 Steam Sterilizers are the same as the predicate devices except for the specific modifications described in this submission. There are no differences in the indications for use or technology (including features and principles of operation) between the proposed and predicate devices. Therefore, the differences between the proposed and predicate devices are limited to the described modifications, and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

**4. Intended Use / Indications for Use**

The Amsco 400 Small Steam Sterilizer models 16, 16C, 16CS, 16S, 20, 20C, 20CS, and 20S are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

- *Prevacuum (Models 16, 16C and 20, 20C)* – are equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP) (Models 16CS, 16S and 20CS, 20S)* – are equipped with SFPP, Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

**STERIS Corporation Special Premarket Notification [510(k)]  
Modifications to AMSCO 400 Steam Sterilizers**

The Amsco 400 Small *Prevacuum* Steam Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 4-1):

**Table 4-1.**  
Amsco 400 Small *Prevacuum* Steam Sterilizer Models 16, 16, 20, 20C factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Prevac (Immediate Use)	270°F (132°C)	4 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity (Immediate Use)	270°F (132°C)	3 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity (Immediate Use)	270°F (132°C)	10 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Liquid*	250°F (121°C)	45 minutes	N/A	<i>Validated with 3 1000ml bottles. Refer to Table 4-4 for recommended full load quantities.</i>
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

\*The liquid cycle is for non-patient contact use only.

**STERIS Corporation Special Premarket Notification [510(k)]  
Modifications to AMSCO 400 Steam Sterilizers**

The Amsco 400 Small *Steam Flush Pressure-Pulse* (SFPP) Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 4-2):

**Table 4-2.**  
Amsco 400 Small *Steam Flush Pressure-Pulse* (SFPP) Sterilizer Models 16S, 16CS, 20S, 20CS factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
SFPP	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
SFPP	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
SFPP	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
SFPP	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Prevac (Immediate Use)	270°F (132°C)	4 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity (Immediate Use)	270°F (132°C)	3 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Gravity (Immediate Use)	270°F (132°C)	10 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4-3 for recommended quantities.</i>
Liquid*	250°F (121°C)	45 minutes	N/A	<i>Validated with 3 1000ml bottles. Refer to Table 4-4 for recommended full load quantities.</i>

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Modifications to AMSCO 400 Steam Sterilizers**

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

\*The liquid cycle is for non-patient contact use only.

The following table lists STERIS’s recommended loads by sterilizer size:

**Table 4-3**

Amsco 400 Small Steam Sterilizer recommended loads per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
16” x 16” x 26”	2	4
20” x 20” x 38”	3	6

The following table is a guideline for liquid cycle processing:

**Table 4-4**

Amsco 400 Small Steam Sterilizer Liquid\* Cycle Guideline

Sterilizer Size	Number of Containers for full load	Number of Containers for validation	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
16” x 16” x 26”	15	3	1000 ml	45 minutes
20” x 20” x 38”	32	3	1000 ml	45 minutes

\*The liquid cycle is for non-patient contact use only.

The Amsco 400 Small Steam Sterilizer is offered in the following chamber sizes:

- 16” x 16” x 26” (Models 16, 16C, 16CS, and 16S)
- 20” x 20” x 38” (Models 20, 20C, 20CS, and 20S)

**5. Summary of Nonclinical Tests**

The modified sterilizers have the same indications for use, intended use and same technological characteristics as the predicate devices. Performance testing to demonstrate substantial equivalence to the predicate, using the same methods as were used to validate the original design, is summarized below.

Test	Result	Conclusion
Software validation per IEC 62304	All safety and functional tests pass	PASS

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Modifications to AMSCO 400 Steam Sterilizers**

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**6. Conclusion**

Based on the intended use, technological characteristics and non-clinical performance data, the AMSCO 400 Small Steam Sterilizer is as safe, as effective and performs as well or better than the legally marketed predicate device K111223, Class II (21 CFR 880.6880), product code FLE.



**K212424/S001  
510(k) Summary  
For  
AMSCO 400 Medium 26" x 26" Steam Sterilizers**

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Summary Date: August 3, 2021

**STERIS Corporation Special Premarket Notification [510(k)]  
Modifications to AMSCO 400 Steam Sterilizers**

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**6. Device Name**

Trade Name: AMSCO 400 Medium 26" x 26" Steam Sterilizer  
Device Class: Class II  
Common/usual Name: Steam Sterilizer  
Classification Name: Sterilizer, Steam  
Classification Number: 21 CFR 880.6880  
Product Code: FLE

**7. Predicate Devices**

**K112403** - Chimeron Medium 26" x 26" Steam Sterilizer (renamed AMSCO 400 before commercialization)

The proposed device is identical to the predicate except for the modification to replace an obsolete control chip.

**8. Description of Devices**

The AMSCO 400 Steam Sterilizers are the same as the predicate devices except for the specific modifications described in this submission. There are no differences in the indications for use or technology (including features and principles of operation) between the proposed and predicate devices. Therefore, the differences between the proposed and predicate devices are limited to the described modifications, and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

**9. Intended Use / Indications for Use**

The AMSCO 400 Medium Steam Sterilizers (Models 39SL and 39CSL) are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in the following configuration:

- *Prevacuum* – equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The AMSCO 400 Medium *Prevacuum* Steam Sterilizers are equipped with the following factory-programmed sterilization cycles and cycle values (Table 4.5):

**STERIS Corporation Special Premarket Notification [510(k)]  
Modifications to AMSCO 400 Steam Sterilizers**

**Table 4.5.**

AMSCO 400 Medium *Prevacuum* Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. <i>Refer to Table 4.6 for recommended quantities.</i>
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. <i>Refer to Table 4.6 for recommended quantities.</i>
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4.6 for recommended quantities.</i>
Prevac (Immediate Use)	270°F (132°C)	4 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table A-2 for recommended quantities.</i>
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. <i>Refer to Table 4.6 for recommended quantities.</i>
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4.6 for recommended quantities.</i>
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4.6 for recommended quantities.</i>
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. <i>Refer to Table 4.6 for recommended quantities.</i>
Gravity (Immediate Use)	270°F (132°C)	3 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4.6 for recommended quantities.</i>
Gravity (Immediate Use)	270°F (132°C)	10 minutes	1 minutes	Unwrapped instrument tray with a single instrument or multiple unwrapped instrument trays, non-porous load, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4.6 for recommended quantities.</i>
Liquid*	250°F (121°C)	45 minutes	N/A	<i>Validated with 3 1000ml bottles. Refer to Table 4.7 for recommended full load quantities.</i>
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

\*The liquid cycle is for non-patient contact use only.

The following table lists STERIS' full loads by sterilizer size:

**Table 4.6**

AMSCO 400 Medium Steam Sterilizer full load per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 26" x 39"	4	12

**STERIS Corporation Special Premarket Notification [510(k)]  
Modifications to AMSCO 400 Steam Sterilizers**

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The following table is a guideline for liquid cycle processing:

**Table 4.7**  
AMSCO 400 Medium Steam  
Sterilizer Liquid Cycle Guideline

Sterilizer Size	Number of Containers for full load	Number of Containers for validation	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
26" x 26" x 39"	80	3	1000 ml	45 minutes

\*The liquid cycle is for non-patient contact use only.

The AMSCO 400 Medium Steam Sterilizer is offered in the following chamber sizes:

- 26" x 26" x 39" (Models 39SL and 39CSL)

**10. Summary of Nonclinical Tests**

The modified sterilizers have the same indications for use, intended use and same technological characteristics as the predicate devices. Performance testing to demonstrate substantial equivalence to the predicate, using the same methods as were used to validate the original design, is summarized below.

Test	Result	Conclusion
Software validation per IEC 62304	All safety and functional tests pass	PASS

**6. Conclusion**

Based on the intended use, technological characteristics and non-clinical performance data, the AMSCO 400 Medium 26" x 26" Steam Sterilizer is as safe, as effective and performs as well or better than the legally marketed predicate device K112403, Class II (21 CFR 880.6880), product code FLE.

**K212424/S001  
510(k) Summary  
For  
AMSCO 400 Medium Steam Sterilizers**

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Summary Date: August 3, 2021

**STERIS Corporation Special Premarket Notification [510(k)]  
Modifications to AMSCO 400 Steam Sterilizers**

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**11. Device Name**

Trade Name: AMSCO 400 Medium Steam Sterilizer

Device Class: Class II

Common/usual Name: Steam Sterilizer

Classification Name: Sterilizer, Steam

Classification Number: 21 CFR 880.6880

Product Code: FLE

**12. Predicate Devices**

**K112055** – AMSCO 400 Medium Steam Sterilizer (renamed AMSCO 400 before commercialization)

The proposed device is identical to the predicate except for the modification to replace an obsolete control chip.

**13. Description of Devices**

The AMSCO 400 Steam Sterilizers are the same as the predicate devices except for the specific modifications described in this submission. There are no differences in the indications for use or technology (including features and principles of operation) between the proposed and predicate devices. Therefore, the differences between the proposed and predicate devices are limited to the described modifications, and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

**14. Intended Use / Indications for Use**

The AMSCO 400 Medium Steam Sterilizers (Models 36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL and 60CSL) are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in the following configuration:

- *Prevacuum* – equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles

The Amsco 400 Small *Prevacuum* Steam Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 4.8):

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Modifications to AMSCO 400 Steam Sterilizers**

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**Table 4.8.**

Amsco 400 Medium *Prevacuum* Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. <i>Refer to Table 4.9 for recommended quantities.</i>
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. <i>Refer to Table 4.9 for recommended quantities.</i>
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4.9 for recommended quantities.</i>
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. <i>Refer to Table 4.9 for recommended quantities.</i>
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4.9 for recommended quantities.</i>
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 4.9 for recommended quantities.</i>
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. <i>Refer to Table 4.9 for recommended quantities.</i>
Liquid*	250°F (121°C)	45 minutes	N/A	<i>Validated with 3 1000ml bottles. Refer to Table 4.10 for recommended full load quantities.</i>
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

\*The liquid cycle is for non-patient contact use only.

The following table lists STERIS's recommended loads by sterilizer size:

**Table 4.9**

Amsco 400 Medium Steam Sterilizer recommended loads per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 37.5" x 36"	9	18
26" x 37.5" x 48"	12	30
26" x 37.5" x 60"	15	36

The following table is a guideline for liquid cycle processing:

**STERIS Corporation Special Premarket Notification [510(k)]  
Modifications to AMSCO 400 Steam Sterilizers**

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**Table 4.10**  
AMSCO 400 Medium Steam Sterilizer Liquid Cycle Guideline

Sterilizer Size	Number of Containers for full load	Number of Containers for validation	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
26" x 37.5" x 36"	112	3	1000 ml	45 minutes
26" x 37.5" x 48"	154	3	1000 ml	45 minutes
26" x 37.5" x 60"	196	3	1000 ml	45 minutes

\*The liquid cycle is for non-patient contact use only.

The AMSCO 400 Medium Steam Sterilizer is offered in the following chamber sizes:

- 26" x 37.5" x 36" (Models 36H, 36CH, 36SL, 36CSL)
- 26" x 37.5" x 48" (Models 48H, 48CH, 48SL, 48CSL)
- 26" x 37.5" x 60" (Models 60H, 48CH, 48SL, 48CSL)

**15. Summary of Nonclinical Tests**

The modified sterilizers have the same indications for use, intended use and same technological characteristics as the predicate devices. Performance testing to demonstrate substantial equivalence to the predicate, using the same methods as were used to validate the original design, is summarized below.

Test	Result	Conclusion
Software validation per IEC 62304	All safety and functional tests pass	PASS

**6. Conclusion**

Based on the intended use, technological characteristics and non-clinical performance data, the AMSCO 400 Medium Steam Sterilizer is as safe, as effective and performs as well or better than the legally marketed predicate device K112055, Class II (21 CFR 880.6880), product code FLE.