May 13, 2025

Aesculap Inc.
Hamza Ahmed
Regulatory Affairs Specialist
3773 Corporate Pkwy
Center Valley, Pennsylvania 18034

Re: K242762
Trade/Device Name: Aesculap Aicon® Series Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: September 12, 2024
Received: April 10, 2025

Dear Hamza Ahmed:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.05.13 16:20:02 -04'00'

for: Christopher K. Dugard, M.S.
Director
DHT4C: Division of Infection Control 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

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K242762

Device Name
Aesculap Aicon® Series Container System

Indications for Use *(Describe)*

The AESCULAP Aicon® Container is a reusable rigid sterilization container intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device during transport and until used. This container is compatible for use in the following sterilization modalities in the configurations listed below:

- Ethylene Oxide (EtO)
- STERIS V-PRO maX/maX 2: Lumen, Non-Lumen, Flex
- STERIS V-PRO 60: Lumen, Non- Lumen, Flex
- STERIS V-PRO S2 Non-Lumen
- STERRAD 100NX: Standard, Express, Flex, Duo
- STERRAD NX: Standard, Advanced
- STERRAD 100S
- STERIZONE VP4
- PreVac Steam

The AESCULAP Aicon® consists of two different container styles: a solid bottom container and enhance drying system (EDS) container.

The AESCULAP Aicon® Container is compatible with accessories such as baskets, trays, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders, and tags. Prevac cycles without dry times are Immediate Use Sterilization Cycles (IUSS).

The following tables identify the load configurations.

Table 1. AESCULAP Aicon® Container Lumen Configurations

Sterilization Cycle	IOS Configuration	Container Sizes	Compatible Lumens
Ethylene Oxide (EtO) (130°F, 60 minute exposure 50-70% RH, concentration 735mg/L)	If including silicone, stainless steel, or no IOS:	Full Size	(2) Stainless Steel Lumens (≥3.0mm ID x ≤ 400mm L)
		Three-Quarter Size	(2) Stainless Steel Lumens (≥3.0mm ID x ≤ 400mm L)
		Half Size	(2) Stainless Steel Lumens (≥3.0mm ID x ≤ 400mm L)
STERIS V-PRO maX /maX 2 Lumen Cycle	Only stainless steel or no IOS:	Full Size	(6) Stainless Steel Lumens (≥1mm ID x ≤ 400mm L) (6) Stainless Steel Lumens (≥0.77mm ID x ≤ 250mm L)
		Three-Quarter Size	(6) Stainless Steel Lumens (≥1mm ID x ≤ 400mm L) (6) Stainless Steel Lumens (≥0.77mm ID x ≤ 250mm L)
		Half Size	(12) Stainless Steel Lumens (≥1mm ID x ≤ 150mm L)
STERIS V-PRO Max/ Max 2 Non-Lumen Cycle	If including silicone, stainless steel, or no IOS:	Full Size	Non lumened stainless steel instruments
		Three-Quarter Size	Non lumened stainless steel instruments
		Half Size	Non lumened stainless steel instruments
STERIS V-PRO maX / maX 2 Flex Cycle	Only stainless steel or no IOS:	Full Size	(1) Flexible endoscope with a light cord (if not integral to endoscope) without any additional load. The flexible

Sterilization Cycle	IOS Configuration	Container Sizes	Compatible Lumens
			endoscope may be single lumen that is ≥1mm ID x ≤1050mm L
		Three-Quarter Size	(1) Flexible endoscope with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L
		Half Size	(2) Flexible endoscopes with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L OR (1) flexible endoscope with a light cord (if not integral to endoscope) and additional non-lumened instruments. The flexible endoscope can have: a single lumen that is ≥ 1mm ID and ≤ 1050 L or two lumens with one ≥ 1 mm ID and ≤ 990 L and the other ≥ 1 mm ID and ≤ 850 mm L
STERIS VPRO 60 Lumen Cycle	Only stainless steel or no IOS:	Full Size	(6) Stainless Steel Lumens (≥1mm ID x ≤ 400mm L) (6) Stainless Steel Lumens (≥0.77mm ID x ≤ 250mm L)
		Three-Quarter Size	(6) Stainless Steel Lumens (≥1mm ID x ≤ 400mm L) (6) Stainless Steel Lumens (≥0.77mm ID x ≤ 250mm L)
		Half Size	(12) Stainless Steel Lumens (≥1mm ID x ≤ 150mm L)
STERIS VPRO 60 Non-Lumen Cycle	If including silicone, stainless steel, or no IOS:	Full Size	Non lumened stainless steel instruments
		Three-Quarter Size	Non lumened stainless steel instruments
		Half Size	Non lumened stainless steel instruments
STERIS VPRO 60 Flex Cycle	Only stainless steel or no IOS:	Full Size	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)
		Three-Quarter Size	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)
		Half Size	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen or dual lumens (≥1mm ID x ≤990mm L)
STERIS VPRO S2 Non-Lumen Cycle	If including silicone, stainless steel, or no IOS:	Full Size	Non lumened stainless steel instruments
		Three-Quarter Size	Non lumened stainless steel instruments
		Half Size	Non lumened stainless steel instruments
STERRAD 100NX Standard Cycle	Only stainless steel or no IOS:	Full Size	(5) Stainless-Steel Lumens (≥1.0mm ID x ≤500mm L) (5) Stainless-Steel Lumens (≥0.7mm ID x ≤400mm L)
		Three-Quarter Size	(5) Stainless-Steel Lumens (≥1.0mm ID x ≤500mm L) (5) Stainless-Steel Lumens (≥0.7mm ID x ≤400mm L)
		Half Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤250mm L) (5) Stainless-Steel Lumens (≥0.7mm ID x ≤200mm L)
	If including silicone IOS:	Full Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤500mm L)
		Three-Quarter Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤500mm L)
		Half Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤250mm L)
STERRAD 100S	Only stainless steel or no IOS:	Full Size	(5) Stainless Steel Lumens (≥3.0mm 1.D. x ≤ 400mm L)
		Three-Quarter Size	(5) Stainless Steel Lumens (≥3.0mm 1.D. x ≤ 400mm L)
		Half Size	(5) Stainless Steel Lumens (≥2.0mm ID x ≤ 250mm L)
	If including silicone IOS:	Full Size	(5) Stainless Steel Lumens (≥3mm 1.D. x ≤ 400mm L)
		Three-Quarter Size	(5) Stainless Steel Lumens (≥3mm 1.D. x ≤ 400mm L)
		Half Size	(5) Stainless Steel Lumens (≥3mm ID x ≤ 250mm L)

Sterilization Cycle	IOS Configuration	Container Sizes	Compatible Lumens
STERRAD NX Standard Cycle	Only stainless steel or no IOS:	Full Size	(10) Stainless-steel lumens (≥2.5mm ID x ≤ 400mm L)
		Three-Quarter Size	(10) Stainless-steel lumens (≥2.5mm ID x ≤ 400mm L)
		Half Size	(10) Stainless-steel lumens (≥2mm ID x ≤ 200mm L)
	If including silicone IOS:	Full Size	(5) Stainless-Steel Lumens (≥2mm ID x ≤400mm L)
		Three-Quarter Size	(5) Stainless-Steel Lumens (≥2mm ID x ≤400mm L)
		Half Size	(5) Stainless-Steel Lumens (≥2mm ID x ≤250mm L)
STERRAD NX Advanced Cycle	Only stainless steel or no IOS:	Full Size	(5) Stainless-steel lumens (≥2.5mm ID x ≤500mm L) (5) Flexible Lumens (≥1mm ID x ≤850mm L)
		Three-Quarter Size	(5) Stainless-steel lumen (≥2.5mm ID x ≤500mm L) (5) Flexible Lumens (≥1mm ID x ≤850mm L)
		Half Size	(10) Stainless-steel lumens (≥2mm ID x ≤ 200mm L)
STERRAD 100NX Express Cycle	Only stainless steel or no IOS:	Full Size	Non lumened stainless steel instruments
		Three-Quarter Size	Non lumened stainless steel instruments
		Full Size	Non lumened stainless steel instruments
STERRAD 100NX DUO Cycle	Only stainless steel or no IOS:	Full Size	(1) Flexible Lumen (≥1mm ID x ≤ 850mm L)
		Three-Quarter Size	(1) Flexible Lumen (≥1mm ID x ≤ 850mm L)
		Half Size	(1) Flexible Lumen (≥1.mm ID x ≤ 650mm L)
STERRAD 100NX Flex Cycle	Only stainless steel or no IOS:	Full Size	(1) Flexible Lumen(≥1.5mm ID x ≤ 650mm L)
		Three-Quarter Size	(1) Flexible Lumen (≥1.5mm ID x ≤ 650mm L)
		Half Size	(1) Flexible lumen (≥1.mm ID x ≤ 650mm L)
PreVac Steam with dry time (270°F, 4 min Exposure)	If including silicone, stainless steel, or no IOS:	Full Size	(4) Stainless Steel Lumens (≥1.mm ID x ≤200mm L)
		Three-Quarter	(4) Stainless Steel Lumens (≥1.0mm ID x ≤200mm L)
		Half Size	(4) Stainless Steel Lumens (≥1.0mm ID x ≤200mm L)
PreVac Steam without dry time (270°F, 4 min Exposure) Porous	If including silicone, stainless steel, or no IOS:	Full Size	(4) Stainless Steel Lumens (≥1mm ID x ≤ 125 mm L)
		Three-Quarter Size	(4) Stainless Steel Lumens (≥1mm ID x ≤ 125 mm L)
		Half Size	(4) Stainless Steel Lumens (≥1mm ID x ≤ 125 mm L)
Prevac Steam without dry time (270°F, 3 min Exposure) Non-Porous	If including silicone, stainless steel, or no IOS:	Full Size	Non-lumened instruments
		Three-Quarter Size	Non-lumened instruments
		Half Size	Non-lumened instruments
STERIZONE VP4 Load 8 (Aicon Validated Load 1)	Only stainless steel or no IOS:	Full Size	(1) Dual channel flexible scope (≥1.5mm ID x ≤850mm L) and (≥1.5mm ID x ≤989mm L) (1) Single channel flexible scope (≥1.5mm ID x ≤850mm L)
		Three-Quarter Size	(1) Dual channel flexible scope (≥1.5mm ID x ≤850mm L) and (≥1.5mm ID x ≤989mm L) (1) Single channel flexible scope (≥1.5mm ID x ≤850mm L)
		Half Size	(1) Dual channel flexible scope (≥1.5mm ID x ≤850mm L) and (≥1.5mm ID x ≤989mm L) (1) Single channel flexible scope (≥1.5mm ID x ≤850mm L)
STERIZONE VP4 Load 4 (Aicon Validated Load 2)	Only stainless steel or no IOS:	Full Size	(1) Dual channel semi rigid scope (≥0.7mm ID x 500mm L; ≥1.1mm ID x ≤500mm L) (1) Dual channel semi rigid scope (≥1.1 mm ID x 500mm L; ≥1.1 mm ID x ≤500mm L) (2) Stainless Steel Lumens (≥2mm ID x ≤250mm L) (2) Stainless Steel Lumens (≥3mm ID x ≤400mm L)
		Three-Quarter Size	(1) Dual channel semi rigid scope (≥0.7mm ID x 500mm L; ≥1.1mm ID x ≤500mm L) (1) Dual channel semi rigid scope (≥1.1 mm ID x

Sterilization Cycle	IOS Configuration	Container Sizes	Compatible Lumens
			500mm L; ≥1.1 mm ID x ≤500mm L) (2) Stainless Steel Lumens (≥2mm ID x ≤250mm L) (2) Stainless Steel Lumens (≥3mm ID x ≤400mm L)
		Half Size	(1) Stainless Steel Lumen (≥0.7 mm ID x ≤300mm L) (1) Stainless Steel Lumen (≥1.0 mm ID x ≤300mm L) (2) Stainless Steel Lumens (≥2.0 mm ID x ≤250mm L) (2) Stainless Steel Lumens (≥3.0 mm ID x ≤300mm L)
STERIZONE VP4 Load 7 (Aicon Validated Load 3)	Only stainless steel or no IOS:	Full Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
		Three-Quarter Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
		Half Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)

Table 2. AESCULAP Aicon® Container Configurations

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
EtO (130°F, 60 minute exposure 50-70% RH, concentration 735mg/L)	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	25	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	25	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO maX / maX 2 Lumen	Full Size 4”	JJ110	JJ111	JJ410	19.65	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	19.65	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	13.8	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO maX / maX 2 Non-Lumen	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	18.72	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	13.92	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO maX / maX 2 Flex	Full Size 4”	JJ110	JJ111	JJ410	(1) Flexible endoscope with a light cord (if not integral to	Only Stainless Steel IOS Compatible

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Full Size 6”	JJ120	JJ121		endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L	
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	(1) Flexible endoscope with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	(2) Flexible endoscopes with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L OR (1) flexible	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Half Size 10”	JJ240	JJ241		endoscope with a light cord (if not integral to endoscope) and additional non-lumened instruments (24lbs). The flexible endoscope can have: a single lumen that is ≥ 1mm ID and ≤ 1050 L or two lumens with one ≥ 1 mm ID and ≤ 990 L and the other ≥ 1 mm ID and ≤ 850 mm L	
STERIS VPRO 60 Lumen	Full Size 4”	JJ110	JJ111	JJ410	11	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	11	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	11	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO 60 Non-Lumen	Full Size 4”	JJ110	JJ111	JJ410	12	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	12	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	12	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
STERIS VPRO 60 Flex	Full Size 4”	JJ110	JJ111	JJ410	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO S2 Non-Lumen	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	18.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	25	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100NX Standard	Full Size 4”	JJ110	JJ111	JJ410	21.4	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	21.4	
	Three-Quarter Size 6”	JJ320	JJ321			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	13.8	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100S	Full Size 4”	JJ110	JJ111	JJ410	13.9	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	13.9	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	13.9	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD NX Standard	Full Size 4”	JJ110	JJ111	JJ410	10.7	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	10.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	10.7	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD NX Advanced	Full Size 4”	JJ110	JJ111	JJ410	10.7	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	10.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Half Size 4”	JJ210	JJ211	JJ420	10.7	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100NX Express	Full Size 4”	JJ110	JJ111	JJ410	10.7	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	10.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	10.7	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100NX DUO	Full Size 4”	JJ110	JJ111	JJ410	13.2	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	13.2	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	6.0	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100NX Flex	Full Size 4”	JJ110	JJ111	JJ410	14.7	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	14.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	10.7	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
Prevac Steam 270°F, 4 min exposure **With** silicone mat and lid cover* 30 minute dry time **Without** silicone mat and lid cover* 20 minute dry time	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121		24	
	Full Size 8”	JJ130	JJ131		23	
	Full Size 10”	JJ140	JJ141		22	
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	23	
	Three-Quarter Size 6”	JJ320	JJ321		22	
	Three-Quarter Size 8”	JJ330	JJ331		20	
	Three-Quarter Size 10”	JJ340	JJ341		18	
	Half Size 4”	JJ210	JJ211	JJ420	18	
	Half Size 6”	JJ220	JJ221		18	
	Half Size 8”	JJ230	JJ231		15	
	Half Size 10”	JJ240	JJ241		13	
PreVac Steam without dry time	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel
	Full Size 6”	JJ120	JJ121			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
270°F 3 min Exposure (Non-porous) AND Prevac Steam without dry time	Full Size 8”	JJ130	JJ131			IOS Compatible
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	25	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
270°F 4 min Exposure (Porous)	Half Size 4”	JJ210	JJ211	JJ420	25	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIZONE VP4 Based on Sterizone Validated Load 8 (Aicon Validated Load 1)	Full Size 4”	JJ110	JJ111	JJ410	Based on Load Configuration in Table 1 13.8lbs	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	Based on Load Configuration in Table 1 13.8lbs	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	Based on Load Configuration in Table 1 5.8lbs	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIZONE VP4 Based on Sterizone Validated Load 4 (Aicon Validated Load 2)	Full Size 4”	JJ110	JJ111	JJ410	Based on Load Configuration in Table 1 11.7lbs	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	Based on Load Configuration in Table 1 11.7lbs	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	Based on Load Configuration in Table 1 5.8lbs	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIZONE VP4 Based on Sterizone Validated Load 7 (Aicon Validated Load 3)	Full Size 4”	JJ110	JJ111	JJ410	25	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	25	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	25	
	Half Size 6”	JJ220	JJ221			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			

*Silicone mats and/or lid covers may require a longer drying time when used in PreVac Steam Sterilization.

Table 3: AESCULAP Aicon® Container Sterilization Cycle Compatible Accessories

Accessories		EtO	Steris V-PRO Systems	STERRAD Systems	STERIZONE VP4	PREVAC STEAM
Baskets, trays, indicator cards, tamper evident locks, faceplate holders, and tags.		Yes	Yes	Yes	Yes	Yes
Instrument Organization System (IOS) (Stainless Steel racks, brackets, holders, and clamps)	Without Silicone	Yes	Yes	Yes	Yes	Yes
	With Silicone	Yes	See Table 2	See Table 2	No	Yes
Silicone mats		No	No	No	No	Yes*
Lid Covers		No	No	No	No	Yes*

* Use of silicone mats and/or lid covers may require a longer drying time.

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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510(k) SUMMARY (as required by 21 CFR 807.92)

COMPANY: Aesculap, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Hamza Ahmed
hamza.ahmed@bbraunusa.com
(610) 737-3900
(901) 832-7486
610-791-6882 (fax)

Date Prepared: May 6, 2025

TRADE NAME: Aesculap Aicon® Series Container System

COMMON NAME: Sterilization Container Wrap

CLASSIFICATION NAME: Wrap, Sterilization

REGULATION NUMBER: 880.6850

PRODUCT CODE: KCT

DEVICE CLASS: Class II per 21 CFR 880.6850

PREDICATE DEVICE

- Primary predicate: Aicon® JJ Series Container for low temperature sterilization (K214041).
- Reference Device: Aicon® JJ Series Container for PreVac Steam sterilization (K192056)

DEVICE DESCRIPTION

The AESCULAP Aicon® Container System is a reusable rigid container system used for the packaging, transportation, and storage of instruments prior to, during, and after sterilization. It consists of the various sizes of container bottoms, container lid, and basket options, and should only be used with designated Aesculap® filters, locks and indicator cards identified in this IFU.

The AESCULAP Aicon® Container System is provided non-sterile and will undergo sterilization by the end user. The AESCULAP Aicon® Container System can be identified by its JJ Series part number.

• The first digit of the model number designates the container length.
• The second digit designates the height.
• The last digit identifies the model and features.
  o Standard solid bottom container, designated by the “0” at the end of the product number.
  o Enhanced Drying System (EDS) solid bottom container, designated by the “1” at the end of the product number. The EDS container can also be identified by the Enhanced Drying Module, item 14 in the Product Component Diagram.

• The JJ Series uses the same lids for the Standard and the EDS container bottoms.

Container Size	Standard Container	EDS Container	Lid
Full Size 4”	JJ110	JJ111	JJ410
Full Size 6”	JJ120	JJ121	
Full Size 8”	JJ130	JJ131	
Full Size 10”	JJ140	JJ141	
Three-Quarter Size 4”	JJ310	JJ311	JJ430
Three-Quarter Size 6”	JJ320	JJ321	
Three-Quarter Size 8”	JJ330	JJ331	
Three-Quarter Size 10”	JJ340	JJ341	
Half Size 4”	JJ210	JJ211	JJ420
Half Size 6”	JJ220	JJ221	
Half Size 8”	JJ230	JJ231	
Half Size 10”	JJ240	JJ241	

The AESCULAP Aicon® Container System lid latches should remain in the closed position at all times except when installing on and removing the lid from the container bottom.

The JJ Series can be used with the perforated baskets and trays of both the AESCULAP Aicon® Container System and Aesculap® SterilContainer™ System. Non-Aesculap® pre-configured baskets that meet the clearance requirements, and can be properly aseptically presented may also be used. Medical device and container IFUs parameters (time and temperature) should be reconciled. Steam sterilization dry time performance may vary by facility based on water and steam quality and/or sterilization performance. Ensure you can achieve the same end result as identified in the instrument IFU. Follow facilities policies and procedures.

Notes:

- *Thoroughly clean all Aesculap® container products, baskets, accessories and replacement parts prior to first use and after container repair service has been performed.*
- *Aesculap® baskets and accessories can be cleaned and sterilized following accepted industry guidelines and by using the same processes as Aesculap® sterile container bottoms.*
- *AESCULAP Aicon® Container System has ONLY been validated with Aesculap® filters, locks and indicator cards.*
- *Aesculap® only performed container testing with baskets and does not recommend using containers without baskets or with only mats.*

INDICATIONS FOR USE

The AESCULAP Aicon® Container is a reusable rigid sterilization container intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device during transport and until used. This container is compatible for use in the following sterilization modalities in the configurations listed below:

- Ethylene Oxide (EtO)
- STERIS V-PRO maX/maX 2: Lumen, Non-Lumen, Flex
- STERIS V-PRO 60: Lumen, Non- Lumen, Flex
- STERIS V-PRO S2 Non-Lumen
- STERRAD 100NX: Standard, Express, Flex, Duo
- STERRAD NX: Standard, Advanced
- STERRAD 100S
- STERIZONE VP4
- PreVac Steam

The AESCULAP Aicon® consists of two different container styles: a solid bottom container and enhance drying system (EDS) container.

The AESCULAP Aicon® Container is compatible with accessories such as baskets, trays, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders, and tags. Prevac cycles without dry times are Immediate Use Sterilization Cycles (IUSS).

The following tables identify the load configurations.

Table 1. AESCULAP Aicon® Container Lumen Configurations

Sterilization Cycle	IOS Configuration	Container Sizes	Compatible Lumens
Ethylene Oxide (EtO) (130°F, 60 minute exposure 50-70% RH, concentration 735mg/L)	If including silicone, stainless steel, or no IOS:	Full Size	(2) Stainless Steel Lumens (≥3.0mm ID x ≤ 400mm L)
		Three-Quarter Size	(2) Stainless Steel Lumens (≥3.0mm ID x ≤ 400mm L)
		Half Size	(2) Stainless Steel Lumens (≥3.0mm ID x ≤ 400mm L)
STERIS V-PRO maX /maX 2 Lumen Cycle	Only stainless steel or no IOS:	Full Size	(6) Stainless Steel Lumens (≥1mm ID x ≤ 400mm L) (6) Stainless Steel Lumens (≥0.77mm ID x ≤ 250mm L)
		Three-Quarter Size	(6) Stainless Steel Lumens (≥1mm ID x ≤ 400mm L) (6) Stainless Steel Lumens (≥0.77mm ID x ≤ 250mm L)
		Half Size	(12) Stainless Steel Lumens (≥1mm ID x ≤ 150mm L)
STERIS V-PRO Max/ Max 2 Non-Lumen Cycle	If including silicone, stainless steel, or no IOS:	Full Size	Non lumened stainless steel instruments
		Three-Quarter Size	Non lumened stainless steel instruments
		Half Size	Non lumened stainless steel instruments
STERIS V-PRO maX / maX 2 Flex Cycle	Only stainless steel or no IOS:	Full Size	(1) Flexible endoscope with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L

Sterilization Cycle	IOS Configuration	Container Sizes	Compatible Lumens
		Three-Quarter Size	(1) Flexible endoscope with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L
		Half Size	(2) Flexible endoscopes with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L OR (1) flexible endoscope with a light cord (if not integral to endoscope) and additional non-lumened instruments. The flexible endoscope can have: a single lumen that is ≥ 1mm ID and ≤ 1050 L or two lumens with one ≥ 1 mm ID and ≤ 990 L and the other ≥ 1 mm ID and ≤ 850 mm L
STERIS VPRO 60 Lumen Cycle	Only stainless steel or no IOS:	Full Size	(6) Stainless Steel Lumens (≥1mm ID x ≤ 400mm L) (6) Stainless Steel Lumens (≥0.77mm ID x ≤ 250mm L)
		Three-Quarter Size	(6) Stainless Steel Lumens (≥1mm ID x ≤ 400mm L) (6) Stainless Steel Lumens (≥0.77mm ID x ≤ 250mm L)
		Half Size	(12) Stainless Steel Lumens (≥1mm ID x ≤ 150mm L)
STERIS VPRO 60 Non-Lumen Cycle	If including silicone, stainless steel, or no IOS:	Full Size	Non lumened stainless steel instruments
		Three-Quarter Size	Non lumened stainless steel instruments
		Half Size	Non lumened stainless steel instruments
STERIS VPRO 60 Flex Cycle	Only stainless steel or no IOS:	Full Size	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)
		Three-Quarter Size	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)
		Half Size	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen or dual lumens (≥1mm ID x ≤990mm L)
STERIS VPRO S2 Non-Lumen Cycle	If including silicone, stainless steel, or no IOS:	Full Size	Non lumened stainless steel instruments
		Three-Quarter Size	Non lumened stainless steel instruments
		Half Size	Non lumened stainless steel instruments
STERRAD 100NX Standard Cycle	Only stainless steel or no IOS:	Full Size	(5) Stainless-Steel Lumens (≥1.0mm ID x ≤500mm L) (5) Stainless-Steel Lumens (≥0.7mm ID x ≤400mm L)
		Three-Quarter Size	(5) Stainless-Steel Lumens (≥1.0mm ID x ≤500mm L) (5) Stainless-Steel Lumens (≥0.7mm ID x ≤400mm L)
		Half Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤250mm L) (5) Stainless-Steel Lumens (≥0.7mm ID x ≤200mm L)
		Full Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤500mm L)

Sterilization Cycle	IOS Configuration	Container Sizes	Compatible Lumens
	If including silicone IOS:	Three-Quarter Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤500mm L)
		Half Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤250mm L)
STERRAD 100S	Only stainless steel or no IOS:	Full Size	(5) Stainless Steel Lumens (≥3.0mm 1.D. x ≤ 400mm L)
		Three-Quarter Size	(5) Stainless Steel Lumens (≥3.0mm 1.D. x ≤ 400mm L)
		Half Size	(5) Stainless Steel Lumens (≥2.0mm ID x ≤ 250mm L)
	If including silicone IOS:	Full Size	(5) Stainless Steel Lumens (≥3mm 1.D. x ≤ 400mm L)
		Three-Quarter Size	(5) Stainless Steel Lumens (≥3mm 1.D. x ≤ 400mm L)
		Half Size	(5) Stainless Steel Lumens (≥3mm ID x ≤ 250mm L)
STERRAD NX Standard Cycle	Only stainless steel or no IOS:	Full Size	(10) Stainless-steel lumens (≥2.5mm ID x ≤ 400mm L)
		Three-Quarter Size	(10) Stainless-steel lumens (≥2.5mm ID x ≤ 400mm L)
		Half Size	(10) Stainless-steel lumens (≥2mm ID x ≤ 200mm L)
	If including silicone IOS:	Full Size	(5) Stainless-Steel Lumens (≥2mm ID x ≤400mm L)
		Three-Quarter Size	(5) Stainless-Steel Lumens (≥2mm ID x ≤400mm L)
		Half Size	(5) Stainless-Steel Lumens (≥2mm ID x ≤250mm L)
STERRAD NX Advanced Cycle	Only stainless steel or no IOS:	Full Size	(5) Stainless-steel lumens (≥2.5mm ID x ≤500mm L) (5) Flexible Lumens (≥1mm ID x ≤850mm L)
		Three-Quarter Size	(5) Stainless-steel lumen (≥2.5mm ID x ≤500mm L) (5) Flexible Lumens (≥1mm ID x ≤850mm L)
		Half Size	(10) Stainless-steel lumens (≥2mm ID x ≤ 200mm L)
STERRAD 100NX Express Cycle	Only stainless steel or no IOS:	Full Size	Non lumened stainless steel instruments
		Three-Quarter Size	Non lumened stainless steel instruments
		Full Size	Non lumened stainless steel instruments
STERRAD 100NX DUO Cycle	Only stainless steel or no IOS:	Full Size	(1) Flexible Lumen (≥1mm ID x ≤ 850mm L)
		Three-Quarter Size	(1) Flexible Lumen (≥1mm ID x ≤ 850mm L)
		Half Size	(1) Flexible Lumen (≥1.mm ID x ≤ 650mm L)
STERRAD 100NX Flex Cycle	Only stainless steel or no IOS:	Full Size	(1) Flexible Lumen(≥1.5mm ID x ≤ 650mm L)
		Three-Quarter Size	(1) Flexible Lumen (≥1.5mm ID x ≤ 650mm L)
		Half Size	(1) Flexible lumen (≥1.mm ID x ≤ 650mm L)
PreVac Steam with dry time (270°F, 4 min Exposure)	If including silicone, stainless steel, or no IOS:	Full Size	(4) Stainless Steel Lumens (≥1.mm ID x ≤200mm L)
		Three-Quarter	(4) Stainless Steel Lumens (≥1.0mm ID x ≤200mm L)
		Half Size	(4) Stainless Steel Lumens (≥1.0mm ID x ≤200mm L)
PreVac Steam without dry time (270°F, 4 min Exposure) Porous	If including silicone, stainless steel, or no IOS:	Full Size	(4) Stainless Steel Lumens (≥1mm ID x ≤ 125 mm L)
		Three-Quarter Size	(4) Stainless Steel Lumens (≥1mm ID x ≤ 125 mm L)
		Half Size	(4) Stainless Steel Lumens (≥1mm ID x ≤ 125 mm L)
Prevac Steam without dry time (270°F, 3 min Exposure) Non-Porous	If including silicone, stainless steel, or no IOS:	Full Size	Non-lumened instruments
		Three-Quarter Size	Non-lumened instruments
		Half Size	Non-lumened instruments
STERIZONE VP4 Load 8	Only stainless steel or no IOS:	Full Size	(1) Dual channel flexible scope (≥1.5mm ID x ≤850mm L) and (≥1.5mm ID x ≤989mm L)

Sterilization Cycle	IOS Configuration	Container Sizes	Compatible Lumens
(Aicon Validated Load 1)			(1) Single channel flexible scope (≥1.5mm ID x ≤850mm L)
		Three-Quarter Size	(1) Dual channel flexible scope (≥1.5mm ID x ≤850mm L) and (≥1.5mm ID x ≤989mm L) (1) Single channel flexible scope (≥1.5mm ID x ≤850mm L)
		Half Size	(1) Dual channel flexible scope (≥1.5mm ID x ≤850mm L) and (≥1.5mm ID x ≤989mm L) (1) Single channel flexible scope (≥1.5mm ID x ≤850mm L)
STERIZONE VP4 Load 4 (Aicon Validated Load 2)	Only stainless steel or no IOS:	Full Size	(1) Dual channel semi rigid scope (≥0.7mm ID x 500mm L; ≥1.1mm ID x ≤500mm L) (1) Dual channel semi rigid scope (≥1.1 mm ID x 500mm L; ≥1.1 mm ID x ≤500mm L) (2) Stainless Steel Lumens (≥2mm ID x ≤250mm L) (2) Stainless Steel Lumens (≥3mm ID x ≤400mm L)
		Three-Quarter Size	(1) Dual channel semi rigid scope (≥0.7mm ID x 500mm L; ≥1.1mm ID x ≤500mm L) (1) Dual channel semi rigid scope (≥1.1 mm ID x 500mm L; ≥1.1 mm ID x ≤500mm L) (2) Stainless Steel Lumens (≥2mm ID x ≤250mm L) (2) Stainless Steel Lumens (≥3mm ID x ≤400mm L)
		Half Size	(1) Stainless Steel Lumen (≥0.7 mm ID x ≤300mm L) (1) Stainless Steel Lumen (≥1.0 mm ID x ≤300mm L) (2) Stainless Steel Lumens (≥2.0 mm ID x ≤250mm L) (2) Stainless Steel Lumens (≥3.0 mm ID x ≤300mm L)
STERIZONE VP4 Load 7 (Aicon Validated Load 3)	Only stainless steel or no IOS:	Full Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
		Three-Quarter Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
		Half Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)

Table 2. AESCULAP Aicon® Container Configurations

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
EtO (130°F, 60 minute exposure 50-70% RH, concentration 735mg/L)	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	25	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	25	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO maX / maX 2 Lumen	Full Size 4”	JJ110	JJ111	JJ410	19.65	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	19.65	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	13.8	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO maX / maX 2 Non-Lumen	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	18.72	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	13.92	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
STERIS VPRO maX / maX 2 Flex	Full Size 4”	JJ110	JJ111	JJ410	(1) Flexible endoscope with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	(1) Flexible endoscope with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	(2) Flexible endoscopes with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥1mm ID x ≤1050mm L or two lumens	
	Half Size 6”	JJ220	JJ221			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Half Size 8”	JJ230	JJ231		with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L OR (1) flexible endoscope with a light cord (if not integral to endoscope) and additional non-lumened instruments (24lbs). The flexible endoscope can have: a single lumen that is ≥ 1mm ID and ≤ 1050 L or two lumens with one ≥ 1 mm ID and ≤ 990 L and the other ≥ 1 mm ID and ≤ 850 mm L	
	Half Size 10”	JJ240	JJ241			
STERIS VPRO 60 Lumen	Full Size 4”	JJ110	JJ111	JJ410	11	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	11	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	11	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO 60 Non-Lumen	Full Size 4”	JJ110	JJ111	JJ410	12	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	12	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	12	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO 60 Flex	Full Size 4”	JJ110	JJ111	JJ410	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	(1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIS VPRO S2 Non-Lumen	Full Size 4”	JJ110	JJ111	JJ410	25	
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	18.7	Silicone and Stainless Steel IOS Compatible
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	25	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100NX Standard	Full Size 4”	JJ110	JJ111	JJ410	21.4	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	21.4	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	13.8	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100S	Full Size 4”	JJ110	JJ111	JJ410	13.9	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	13.9	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	13.9	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD NX Standard	Full Size 4”	JJ110	JJ111	JJ410	10.7	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	10.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Half Size 6”	JJ220	JJ221	JJ420	10.7	
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD NX Advanced	Full Size 4”	JJ110	JJ111	JJ410	10.7	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	10.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Half Size 4”	JJ210	JJ211	JJ420	10.7	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100NX Express	Full Size 4”	JJ110	JJ111	JJ410	10.7	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	10.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	10.7	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100NX DUO	Full Size 4”	JJ110	JJ111	JJ410	13.2	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	13.2	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	6.0	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERRAD 100NX Flex	Full Size 4”	JJ110	JJ111	JJ410	14.7	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	14.7	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	10.7	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
Prevac Steam 270°F, 4 min exposure **With** silicone mat and lid cover* 30 minute dry time **Without** silicone mat and lid cover* 20 minute dry time	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121		24	
	Full Size 8”	JJ130	JJ131		23	
	Full Size 10”	JJ140	JJ141		22	
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	23	
	Three-Quarter Size 6”	JJ320	JJ321		22	
	Three-Quarter Size 8”	JJ330	JJ331		20	
	Three-Quarter Size 10”	JJ340	JJ341		18	
	Half Size 4”	JJ210	JJ211	JJ420	18	
	Half Size 6”	JJ220	JJ221		18	
	Half Size 8”	JJ230	JJ231		15	
	Half Size 10”	JJ240	JJ241		13	
PreVac Steam without dry time 270°F 3 min Exposure (Non-porous) AND Prevac Steam without dry time 270°F 4 min Exposure (Porous)	Full Size 4”	JJ110	JJ111	JJ410	25	Silicone and Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Full Size 10”	JJ140	JJ141			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	25	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	25	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIZONE VP4 Based on Sterizone Validated Load 8 (Aicon Validated Load 1)	Full Size 4”	JJ110	JJ111	JJ410	Based on Load Configuration in Table 1 13.8lbs	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	Based on Load Configuration in Table 1	
	Three-Quarter Size 6”	JJ320	JJ321			

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)	IOS Compatibility
	Three-Quarter Size 8”	JJ330	JJ331		13.8lbs	
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	Based on Load Configuration in Table 1 5.8lbs	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIZONE VP4 Based on Sterizone Validated Load 4 (Aicon Validated Load 2)	Full Size 4”	JJ110	JJ111	JJ410	Based on Load Configuration in Table 1 11 7lbs	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	Based on Load Configuration in Table 1 11 7lbs	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	Based on Load Configuration in Table 1 5.8lbs	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			
STERIZONE VP4 Based on Sterizone Validated Load 7 (Aicon Validated Load 3)	Full Size 4”	JJ110	JJ111	JJ410	25	Only Stainless Steel IOS Compatible
	Full Size 6”	JJ120	JJ121			
	Full Size 8”	JJ130	JJ131			
	Three-Quarter Size 4”	JJ310	JJ311	JJ430	25	
	Three-Quarter Size 6”	JJ320	JJ321			
	Three-Quarter Size 8”	JJ330	JJ331			
	Three-Quarter Size 10”	JJ340	JJ341			
	Half Size 4”	JJ210	JJ211	JJ420	25	
	Half Size 6”	JJ220	JJ221			
	Half Size 8”	JJ230	JJ231			
	Half Size 10”	JJ240	JJ241			

*Silicone mats and/or lid covers may require a longer drying time when used in PreVac Steam Sterilization.

Table 3: AESCULAP Aicon® Container Sterilization Cycle Compatible Accessories

Accessories		EtO	Steris V-PRO Systems	STERRAD Systems	STERIZONE VP4	PREVAC STEAM
Baskets, trays, indicator cards, tamper evident locks, faceplate holders, and tags.		Yes	Yes	Yes	Yes	Yes
Instrument Organization System (IOS) (Stainless Steel racks, brackets, holders, and clamps)	Without Silicone	Yes	Yes	Yes	Yes	Yes
	With Silicone	Yes	See Table 2	See Table 2	No	Yes
Silicone mats		No	No	No	No	Yes*
Lid Covers		No	No	No	No	Yes*

* Use of silicone mats and/or lid covers may require a longer drying time.

TECHNOLOGICAL CHARACTERISTICS (compared to predicate device)

The table below provides a summary of the device technological characteristics comparing the subject device and predicate device. The subject device is offered in similar sizes and is comprised of similar materials of construction as the predicate device. The AESCULAP Aicon® Container has the same intended use as the Aesculap predicate device.

Characteristic	Subject Device Aesculap AICON® Series Container System (K242762) Product Code: KCT	Predicate Device - Aesculap JJ Series Container System (K214041) Product Code: KCT	Reference Device - Aesculap JJ Series Container System (K192056) Product Code: KCT	Discussion of similarities and differences
Indications for Use	See indications for use section provided in eSTAR	Reference form 3881 in K214041	Reference form 3881 in K192056	Change to indications for use to allow usage of silicone instrument organization systems for some VHP modalities and designated Stainless Steel IOS for modalities which were already cleared in K214041. Revised table 1 and table 2 in the indications for use and added columns for filter compatibility and silicone accessories compatibility for a given modality.

				Added additional line items for Sterrad 100S, Sterrad NX Standard, Sterrad 100 NX standard, Steris V-Pro max 2 Non-Lumen, V-PRO max Non-Lumen, V-PRO 60 Non-Lumen, and V-PRO S2 Non-Lumen for modified load configurations which incorporate usage of silicone IOS. Reduced lumen sizes were designated for modalities with Silicone IOS allowance in lumen cycles.
Intended Use	A device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	A device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	A device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	Same
Sterilization Modalities	Sterrad 100S Sterrad NX Standard Sterrad 100 NX Standard Steris V-Pro max 2 Non-Lumen V-PRO max Non-Lumen V-PRO 60 Non-Lumen V-PRO S2 Non-Lumen	Ethylene Oxide STERIS VPRO: 60 Lumen, 60 Non-Lumen, 60 Flex, maX Lumen, maX Non-Lumen, maX Flex STERRAD 100NX STERRAD 100NX FLEX STERRAD 100NX DUO cycle STERRAD 100NX EXPRESS cycle STERIZONE VP4 PreVac Steam with dry time	PreVac Steam with dry time Prevac Steam without dry time	Similar; Sterilization modalities of the subject device are comparable to the predicate device sterilization modalities

		PreVac Steam without dry time		
Material	Container: Anodized aluminum Lid: Anodized aluminum Gasket: Silicone	Container: Anodized aluminum Lid: Anodized aluminum Gasket: Silicone	Container: Anodized aluminum Lid: Anodized aluminum Gasket: Silicone	Same
Filter Type	Single use (Polypropylene)	Single use (Polypropylene)	Single use (Paper)	Same
Container Design	Solid bottom or Solid bottom with enhanced drying system with Perforated Lid	Solid bottom or Solid bottom with enhanced drying system with Perforated Lid	Solid bottom or Solid bottom with enhanced drying system with Perforated Lid	Same
Sizes	Full size Three-Quarter Size Half Size	Full size Three-Quarter Size Half Size	Full size Three-Quarter Size Half Size	Same
Accessories	Baskets, trays, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders and tags.	Baskets, trays, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders and tags (No Silicone Pieces)	Baskets, trays, silicone mats, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders and tags.	Same
Sterility Shelf Life	365 days	365 days	365 days	Same

PERFORMANCE DATA AS REQUIRED BY 21 CFR 807.92

The table below provides a brief discussion of the non-clinical tests submitted, referenced, or relied on in the premarket notification submission to demonstrate device performance. Clinical testing is not required for this device.

Performance Testing	Purpose	Acceptance Criteria	Results
Sterilization Efficacy	To determine sterilization effectiveness of test device after processing in a sterilization cycle.	A sterility assurance level (SAL) of 10^{-6} will be achieved post sterilization using the BI overkill method and half cycle validation indicated in section 5.6 of AAMI ST-77. Biological indicators must be negative for growth after incubation period	Pass
Dry Time	To determine the proper drying time required for the Aesculap Aicon Container.	Per AAMI ST-77 section 4.4.2, (in association with EN868-8 section G.3/G.4 and EN 285 section G20.3), the system shall demonstrate an average pre and post sterilization weight difference of less than 0.2% within five 5 minutes of cycle completion using final validated parameters and be free of visible moisture following a cooling period.	Pass
Microbial Aerosol Challenge	To analyze the package integrity and microbial barrier properties of the test device.	The container load maintains sterility after exposure to a defined amount of aerosol microorganisms per ST-77 sections 5.9.1.1 & 5.9.1.2. No presence of growth after incubation period.	Pass
Cytotoxicity	To determine the potential of a test device to cause cytotoxicity.	Testing completed in accordance with ISO 10993-5:2009. Using the ISO Elution Method, the response to the article must not be greater than 2 (mild reactivity).	Pass
Simulated Use	To determine the effective sterilization of flexible scopes when used with the test device.	A minimum of 1.0×10^6 spores contained within organic soil representative of actual use conditions are killed during defined sterilization cycle.	Pass
Cleaning Validation	To verify the effectiveness of the device cleaning procedure.	In accordance with Annex A and section 7.5 of TIR30, test samples shall show no visible soil after cleaning and shall have protein or hemoglobin levels less than the predetermined amounts.	Pass
Material Compatibility	To assess effects of full use cycles on device components and their intended functionality.	No degradation or impact to functionality at the completion multiple sterilization cycles according to section 5.0 of TIR17.	Pass

Sterility Maintenance	To demonstrate that a processed test device can maintain a sterile barrier for a defined period of time.	Sterility of container contents is maintained under conditions which simulate hospital sterile package handling and storage conditions and were tested per ISO 11167-1 section 6.4. Test articles stored for their post processing shelf life. Biological indicators must be negative for growth after incubation period.	Pass

Results of the testing demonstrates that the proposed device met the acceptance criteria for each performance test.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K242762, Aesculap Aicon® Container system, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared in K214041.