

December 30, 2022

Aesculap Inc. Tim Stoudt Associate Director- Regulatory Affairs 3773 Corporate Parkway Center Valley, Pennsylvania 18034

Re: K214041

Trade/Device Name: Aesculap AICON[™] Container Regulation Number: 21 CFR 880.6850 Regulation Name: Sterilization Wrap Regulatory Class: Class II Product Code: KCT Dated: November 30, 2022 Received: December 2, 2022

Dear Tim Stoudt:

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 <u>Federal Register</u>.

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 <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). 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 (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray III -S

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)* K214041

Device Name AESCULAP Aicon™ Container

Indications for Use (Describe)

The AESCULAP AiconTM 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
- STERRAD 100NX: Standard, Express, Flex, Duo
- STERRAD NX: Standard, Advanced
- STERRAD 100S
- STERIZONE VP4
- PreVac Steam

The AESCULAP AiconTM consists of two different container styles: a solid bottom container and enhanced drying system (EDS) container.

The following tables identify the load configurations.

Sterilization Cycle	Container Sizes	Compatible
		Lumens
Ethylene Oxide (EtO)	Full Size	(2) Stainless Steel Lumens (\geq 3.0mm ID x \leq 400mm L)
(130°F, 60 minute exposure 50-70% RH, concentration 735mg/L)	Three-Quarter Size	(2) Stainless Steel Lumens (\geq 3.0mm ID x \leq 400mm L)
50-70% KH, concentration 755mg/L)	Half Size	(2) Stainless Steel Lumens (\geq 3.0mm ID x \leq 400mm L)
	Full Size	(6) Stainless Steel Lumens (\geq 1mm ID x \leq 400mm L) (6) Stainless Steel Lumens (\geq 0.77mm ID x \leq 250mm L)
STERIS V-PRO maX /maX 2 Lumen Cycle	Three-Quarter Size	(6) Stainless Steel Lumens (\geq 1mm ID x \leq 400mm L) (6) Stainless Steel Lumens (\geq 0.77mm ID x \leq 250mm L)
	Half Size	(12) Stainless Steel Lumens (\geq 1mm ID x \leq 150mm L)
STERIS V-PRO Max/ Max 2	Full Size	Non lumened stainless steel instruments
Non-Lumen Cycle	Three-Quarter Size	Non lumened stainless steel instruments
	Half Size	Non lumened stainless steel instruments
	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 $\geq 1 \text{ mm ID } x \leq 1050 \text{ mm L}$
STERIS V-PRO maX / maX 2 Flex Cycle	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 ≥ 1 mm ID x ≤ 1050 mm L
	Half Size	(2) Flexible endoscopes with a light cord (if not integral to

Table 1. AESCULAP Aicon[™] Container Lumen Configurations

		endoscope) without any additional load. The flexible endoscope may be single lumen
		that is $\geq 1 \text{ mm ID } x \leq 1050 \text{ mm L}$ or two lumens with one $\geq 1 \text{ mm ID } and \leq 990 \text{ mm L}$
		and the other $\ge 1 \text{ mm ID}$ and $\le 850 \text{ mm L}$ 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 $\geq 1 \text{ mm ID}$ and $\leq 1050 \text{ L}$ or two lumens with one $\geq 1 \text{ mm ID}$ and
		\leq 990 L and the other \geq 1 mm ID and \leq 850 mm L
	Full Size	(6) Stainless Steel Lumens ($\geq 1 \text{ mm ID } x \leq 400 \text{ mm L}$)
STERIS VPRO 60		(6) Stainless Steel Lumens (≥ 0.77 mm ID x ≤ 250 mm L)
Lumen Cycle	Three-Quarter Size	(6) Stainless Steel Lumens (≥ 1 mm ID x ≤ 400 mm L)
Lumen Cycle		(6) Stainless Steel Lumens (≥ 0.77 mm ID x ≤ 250 mm L)
	Half Size	(12) Stainless Steel Lumens (≥ 1 mm ID x ≤ 150 mm L)
STERIS VPRO 60	Full Size	Non lumened stainless steel instruments
Non-Lumen Cycle	Three-Quarter Size	Non lumened stainless steel instruments
	Half Size	Non lumened stainless steel instruments
	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)
STERIS VPRO 60	Three-Quarter Size	(1) flexible surgical endoscope or bronchoscope with a
Flex Cycle	TT 10 01	light cord (if not integral to scope) and single lumen (≥ 1 mm ID x ≤ 990 mm L)
-	Half Size	(1) flexible surgical endoscope or bronchoscope with a
		light cord (if not integral to scope) and single lumen or dual lumens
	Full Size	(≥1mm ID x ≤990mm L) (5) Stainless-Steel Lumens (≥1.0mm ID x ≤500mm L)
	r'un size	(5) Stainless-Steel Lumens (≥ 0.7 mm ID x ≤ 400 mm L)
STERRAD 100NX	Three-Quarter Size	(5) Stainless-Steel Lumens (\geq 0.7 mm ID x \leq 400 mm L)
Standard Cycle	Three-Quarter Size	(5) Stainless-Steel Lumens (\geq 0.7mm ID x \leq 400mm L)
	Half Size	(5) Stainless Steel Lumens (≥ 0.7 mm ID x ≤ 250 mm L)
		(5) Stainless-Steel Lumens (≥ 0.7 mm ID x ≤ 200 mm L)
	Full Size	(5) Stainless Steel Lumens (\geq 3.0mm 1.D. x \leq 400mm L)
STERRAD 100S	Three-Quarter Size	(5) Stainless Steel Lumens (\geq 3.0mm 1.D. x \leq 400mm L)
STERATE TOOS	Half Size	(5) Stainless Steel Lumens (\geq 2.0mm ID x \leq 250mm L)
	Full Size	(10)Stainless steel luments (\geq 2.5mm ID x \leq 400mm L)
STERRAD NX		
Standard Cycle	Three-Quarter Size	(10)Stainless-steel lumens (\geq 2.5mm ID x \leq 400mm L)
-	Half Size	(10) Stainless-steel lumens ($\geq 2mm$ ID x $\leq 200mm$ L)
	Full Size	(5) Stainless-steel lumens (≥2.5mm ID x ≤500mm L)
		(5) Flexible Lumens (≥1mm ID x ≤850mm L)
STERRAD NX	Three-Quarter Size	(5) Stainless-steel lumen (\geq 2.5mm ID x \leq 500mm L)
Advanced Cycle	TT 10 C	(5) Flexible Lumens (≥ 1 mm ID x ≤ 850 mm L)
	Half Size	(10) Stainless-steel lumens ($\geq 2mm$ ID x $\leq 200mm$ L)
STERRAD 100NX	Eull Size	Non lumened stainless steel instruments
Express Cycle	Full Size Three-Quarter Size	Non lumened stainless steel instruments
Express Cycle		
	Full Size	Non lumened stainless steel instruments
STERRAD 100NX	Full Size	(1) Flexible Lumen ($\geq 1 \text{ mm ID } x \leq 850 \text{ mm L}$)
DUO Cycle	Three-Quarter Size	(1) Flexible Lumen (\geq 1mm ID x \leq 850mm L)
	Half Size	(1) Flexible Lumen ($\geq 1.$ mm ID x ≤ 650 mm L)
	Full Size	(1) Flexible Lumen(≥ 1.5 mm ID x ≤ 650 mm L)
CTEDDAD 100NIX		
STERRAD 100NX	Three-Quarter Size	(1) Flexible Lumen (≥ 1.5 mm ID x ≤ 650 mm L)
Flex Cycle	Half Size	(1) Flexible lumen (\geq 1.mm ID x \leq 650mm L)
DraVac Staam with dry time	Full Size	(4) Stainless Steel Lumens (≥1.mm ID x ≤200mm L)
PreVac Steam with dry time (270°F, 4 min Exposure)	Three-Quarter	(4) Stainless Steel Lumens (≥1.0mm ID x ≤200mm L)
	Half Size	(4) Stainless Steel Lumens (≥1.0mm ID x ≤200mm L)
Der Voo Stoom 4 4		
PreVac Steam without dry time	Full Size	(4) Stainless Steel Lumens (\geq 1mm ID x \leq 125 mm L) (4) Stainless Steel Lumens (\geq 1mm ID x \leq 125 mm L)
(270°F, 4 min Exposure) Porous	Three-Quarter Size	(4) Stainless Steel Lumens (\geq 1mm ID x \leq 125 mm L) (4) Stainless Steel Lumens (\geq 1mm ID x \leq 125 mm L)
101005	Half Size	(4) Stainless Steel Lumens (≥ 1 mm ID x ≤ 125 mm L)
Prevac cycles without dry times are		
Immediate Use Sterilization Cycles		
(IUSS).		
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(270°F, 3 min Exposure)	Full Size	Non-lumened instruments
Non-Porous	Three-Quarter Size	Non-lumened instruments
	Half Size	Non-lumened instruments
Prevac cycles without dry times are		
Immediate Use Sterilization Cycles		
(IUSS).		
STERIZONE VP4	Full Size	(1) Dual channel flexible scope (≥ 1.5 mm ID x ≤ 850 mm L) and
Load 8		$(\geq 1.5 \text{mm ID } x \leq 989 \text{mm L})$
	Thurse Orienter Circ	 (1) Single channel flexible scope (≥1.5mm ID x ≤850mm L) (1) Dual channel flexible scope (≥1.5mm ID x ≤850mm L) and
(Aicon Validated Load 1)	Three-Quarter Size	(1) Dual channel flexible scope (≥ 1.5 mm ID x ≤ 850 mm L) and (≥ 1.5 mm ID x ≤ 989 mm L)
		(1) Single channel flexible scope (≥ 1.5 mm ID x ≤ 850 mm L)
	Half Size	(1) Dual channel flexible scope (\geq 1.5mm ID x \leq 850mm L) and
		$(\geq 1.5 \text{mm ID x} \leq 989 \text{mm L})$
		(1) Single channel flexible scope (≥ 1.5 mm ID x ≤ 850 mm L)
STERIZONE VP4	Full Size	(1) Dual channel semi rigid scope (≥ 0.7 mm ID x 500mm L; ≥ 1.1 mm ID x ≤ 500 mm L)
Load 4		(1) Dual channel semi rigid scope ($\geq 1.1 \text{ mm ID x 500mm L}$; $\geq 1.1 \text{ mm ID x } \leq 500 \text{ mm L}$)
		(2) Stainless Steel Lumens (≥2mm ID x ≤250mm L)
(Aicon Validated Load 2)		(2) Stainless Steel Lumens (≥3mm ID x ≤400mm L)
	Three-Quarter Size	(1) Dual channel semi rigid scope (≥ 0.7 mm ID x 500mm L; ≥ 1.1 mm ID x ≤ 500 mm L)
		(1) Dual channel semi rigid scope ($\geq 1.1 \text{ mm ID x 500mm L}$; $\geq 1.1 \text{ mm ID x} \leq 500 \text{mm L}$)
		(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 (\geq 3.0 mm ID x \leq 300mm L)
STERIZONE VP4	Full Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
Load 7	Three-Quarter Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
	Half Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
(Aicon Validated Load 3)		

Table 2. AESCULAP Aicon™ Container Configurations

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

	Half Size 8"	JJ230	JJ231			
	Half Size 10"	JJ240	JJ241	-		
	Full Size 4"	JJ110	JJ111			
-	Full Size 6"	JJ120	JJ121	4		
	Full Size 8"	JJ130	JJ131	JJ410	25	
	Full Size 10"	JJ140	JJ141	-		
	Three-Quarter Size 4"	JJ310	JJ311			
STERIS VPRO	Three-Quarter Size 6"	JJ320	JJ321	-		
maX / maX 2 Non-Lumen	Three-Quarter Size 8"	JJ330	JJ331	JJ430	25	
	Three-Quarter Size 10"	JJ340	JJ341	-		
	Half Size 4"	JJ210	JJ211			
	Half Size 6"	JJ220	JJ221	-		
	Half Size 8"	JJ230	JJ231	JJ420	18.7	
	Half Size 10"	JJ240	JJ241	-		
	Full Size 4"	JJ110	JJ111		(1) Flexible endoscope with	
	Full Size 6"	JJ120	JJ121	1	a light cord (if not integral to	
	Full Size 8"	JJ130	JJ131	JJ410	endoscope) without any additional load. The flexible endoscope may be single lumen that is ≥ 1 mm ID x ≤ 1050 mm L	
	Three-Quarter Size 4"	JJ310	JJ311		(1) Flexible endoscope with	
	Three-Quarter Size 6"	JJ320	JJ321		a light cord (if not integral to	
	Three-Quarter Size 8"	JJ330	JJ331	JJ430	endoscope) without any additional load. The flexible	
STERIS VPRO maX / maX 2 Flex	Three-Quarter Size 10"	JJ340	JJ341		endoscope may be single lumen that is \geq 1mm ID x \leq 1050mm L	
	Half Size 4"	JJ210	JJ211		(2) Flexible endoscopes with a light cord (if not integral to endoscope) without any additional load. The flexible endoscope may be	
	Half Size 6"	JJ220	JJ221	JJ420	single lumen that is $\geq 1 \text{ mr}$ ID x $\leq 1050 \text{ mm}$ L or two lumens with one $\geq 1 \text{ mm}$ ID and $\leq 990 \text{ mm}$ L and the other $\geq 1 \text{ mm}$ ID and $\leq 850 \text{ mm}$ L OR (1) flexible endoscope	
	Half Size 8"	JJ230	JJ231		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 $\geq 1 \text{ mm ID}$ and $\leq 1050 \text{ L or}$	
	Half Size 10"	JJ240	JJ241		two lumens with one $\geq 1 \text{ mm ID and } \leq 990 \text{ L}$ and the other $\geq 1 \text{ mm ID}$ and $\leq 850 \text{ mm L}$	
STERIS VPRO 60 Lumen	+	+				

			1			
	Full Size 6"	JJ120	JJ121			
	Full Size 8"	JJ130	JJ131			
	Three-Quarter Size 4"	JJ310	JJ311			
	Three-Quarter Size 6"	JJ320	JJ321	JJ430	11	
	Three-Quarter Size 8"	JJ330	JJ331	33430	11	
	Three-Quarter Size 10"	JJ340	JJ341			
	Half Size 4"	JJ210	JJ211	_		
	Half Size 6"	JJ220	JJ221	JJ420	11	
	Half Size 8"	JJ230	JJ231	_		
STERIS VPRO 60 Non-Lumen	Half Size 10" Full Size 4"	JJ240	JJ241			
STERIS VI RO 00 Non-Eunen		JJ110	JJ111			
	Full Size 6"	JJ120	JJ121	JJ410	12	
	Full Size 8"	JJ130	JJ131			
	Three-Quarter Size 4"	JJ310	JJ311			
	Three-Quarter Size 6"	JJ320	JJ321			
	Three-Quarter Size 8"	JJ330	JJ331	JJ430	12	
	Three-Quarter Size 10"	JJ340	JJ341			
	Half Size 4"	JJ210	JJ211			
	Half Size 6"	JJ220	JJ221			
	Half Size 8"	JJ230	JJ231	JJ420	12	
	Half Size 10"	JJ240	JJ241			
	Full Size 4"	JJ110	JJ111		(1) flexible surgical	
	Full Size 6"	JJ120	JJ121	JJ410	endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)	
	Full Size 8"	JJ130	JJ131			
	Three-Quarter Size 4"	JJ310	JJ311			
STERIS VPRO 60 Flex	Three-Quarter Size 6"	JJ320	JJ321	JJ430	(1) flexible surgical endoscope or bronchoscope with a light cord (if not	
	Three-Quarter Size 8"	JJ330	JJ331		integral to scope) and single lumen (≥1mm ID x ≤990mm L)	
	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
	Half Size 6"	11220	11221		≤990mm L)
	Half Size 6"	JJ220	JJ221		
				_	
	Half Size 8"	JJ230	JJ231		
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	21.4
	Full Size 8"	JJ130	JJ131	33410	21.4
	Full Size 10"	JJ140	JJ141		
STERRAD 100NX Standard	Three-Quarter Size 4"	JJ310	JJ311		
	Three-Quarter Size 6"	JJ320	JJ321	11420	21.4
	Three-Quarter Size 8"	JJ330	JJ331	JJ430	21.4
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221	-	
			JJ231	JJ420	13.8
	Half Size 8"	JJ230	JJ241	_	
	Half Size 10"	JJ240			
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	13.9
	Full Size 8"	JJ130	JJ131		
	Full Size 10"	JJ140	JJ141		
STERRAD 100S	Three-Quarter Size 4"	JJ310	JJ311		
	Three-Quarter Size 6"	JJ320	JJ321	JJ430	13.9
	Three-Quarter Size 8"	JJ330	JJ331		15.7
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221	JJ420	13.9
	Half Size 8"	JJ230	JJ231		
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	10.7
	Full Size 8"	JJ130	JJ131		
	Full Size 10"	JJ140	JJ141		
STERRAD NX Standard	Three-Quarter Size 4"	JJ310	JJ311	_	
	Three-Quarter Size 6" Three-Quarter Size 8"	JJ320 JJ330	JJ321 JJ331	JJ430	10.7
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221	-	
	Half Size 8"	JJ230	JJ231	JJ420	10.7
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111	JJ410	10.7
	Full Size 6"	JJ120	JJ121	JJ+10	10./

	Three-Quarter Size 6"	JJ320	JJ321		
	Three-Quarter Size 8"	JJ330	JJ331	_	
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221		
	Half Size 8"	JJ230	JJ231	JJ420	10.7
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	10.7
	Full Size 8"	JJ120	JJ131		10.7
STERRAD 100NX Express	Three-Quarter Size 4"	JJ310	JJ311		
1	Three-Quarter Size 6"	JJ320	JJ321		
	Three-Quarter Size 8"	JJ330	JJ331	JJ430	10.7
	Three-Quarter Size 10"	JJ340	JJ341	-	
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221	-	
	Half Size 8"	JJ220 JJ230	JJ231	JJ420	10.7
		JJ230 JJ240	JJ241		
	Half Size 10"		JJ111		
	Full Size 4"	JJ110	JJ121	_	13.2
STERRAD 100NX DUO	Full Size 6"	JJ120	JJ131	JJ410	
STERRAD IOUNA DOO	Full Size 8"	JJ130	JJ141	4	
	Full Size 10"	JJ140	JJ3141 JJ311		
	Three-Quarter Size 4"	JJ310	JJ311 JJ321	_	
	Three-Quarter Size 6"	JJ320		JJ430	13.2
	Three-Quarter Size 8"	JJ330	JJ331		
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211	_	
	Half Size 6"	JJ220	JJ221	JJ420	6.0
	Half Size 8"	JJ230	JJ231	_	
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	14.7
	Full Size 8"	JJ130	JJ131		,
	Full Size 10"	JJ140	JJ141		
	Three-Quarter Size 4"	JJ310	JJ311		
STERRAD 100NX Flex	Three-Quarter Size 6"	JJ320	JJ321	JJ430	14.7
	Three-Quarter Size 8"	JJ330	JJ331		11.7
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221	JJ420	10.7
	Half Size 8"	JJ230	JJ231	33420	10.7
	Half Size 10"	JJ240	JJ241		
D 0	Full Size 4"	JJ110	JJ111		25
Prevac Steam 270°F, 4 min exposure	Full Size 6"	JJ120	JJ121		24
	Full Size 8"	JJ130	JJ131	JJ410	23
With silicone mat and lid cover* 30 minute dry time	Full Size 10"	JJ140	JJ141	┥ ┝	22
-	Three-Quarter Size 4"	JJ310	JJ311		23
Without silicone mat and lid	Three-Quarter Size 6"	JJ320	JJ321	JJ430	22

20 minute dry time	Three-Quarter Size 8"	JJ330	JJ331		20
	Three-Quarter Size 10"	JJ340	JJ341		18
	Half Size 4"	JJ210	JJ211		18
	Half Size 6"	JJ220	JJ221		18
	Half Size 8"	JJ230	JJ231	JJ420	15
	Half Size 10"	JJ240	JJ241		13
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121		
	Full Size 8"	JJ130	JJ131	JJ410	25
PreVac Steam without dry time	Full Size 10"	JJ140	JJ141		
270°F	Three-Quarter Size 4"	JJ310	JJ311		
3 min Exposure (Non-porous)	Three-Quarter Size 6"	JJ320	JJ321		
(Non-porous)	Three-Quarter Size 8"	JJ330	JJ331	JJ430	25
AND	Three-Quarter Size 10"	JJ340	JJ341		
Duran - Star	Half Size 4"	JJ210	JJ211		
Prevac Steam without dry time 270°F	Half Size 6"	JJ220	JJ221		
4 min Exposure	Half Size 8"	JJ230	JJ231	JJ420	25
(Porous)	Half Size 10"	JJ240	JJ241		
Prevac cycles without dry time are Immediate Use Sterilization Cycles (IUSS).	s				
	Full Size 4"	JJ110	JJ111	JJ410	Based on Load Configuration
	Full Size 6"	JJ120	JJ121		in Table 1
	Full Size 8"	JJ130	JJ131		13.8lbs
STERIZONE VP4	Three-Quarter Size 4"	JJ310	JJ311	JJ430	
Based on Sterizone Validated Load 8	Three-Quarter Size 6"	JJ320	JJ321		Based on Load Configuration
	Three-Quarter Size 8"	JJ330	JJ331		in Table 1
(Aicon Validated Load 1)	Three-Quarter Size 10"	JJ340	JJ341		13.8lbs
	Half Size 4"	JJ210	JJ211	JJ420	
	Half Size 6"	JJ220	JJ221		Based on Load Configuration
	Half Size 8"	JJ230	JJ231		in Table 1
	Half Size 10"	JJ240	JJ241		5.8lbs
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121		Based on Load Configuration in Table 1
	Full Size 8"	JJ120	JJ131	JJ410	in rable r
	T ull Size 8	33130	55151		11.7lbs
	Three-Quarter Size 4"	JJ310	JJ311		
STERIZONE VP4	Three-Quarter Size 6"	JJ320	JJ321		Based on Load Configuration
Based on Sterizone Validated	Three-Quarter Size 8"	JJ330	JJ331	JJ430	in Table 1
Load 4	Three-Quarter Size 10"	JJ340	JJ341		11.7lbs
(Aicon Validated Load 2)	Half Size 4"	JJ210	JJ211		
(110011 + 11111100 2000 2)	Half Size 6"	JJ220	JJ221		Based on Load Configuration
	Half Size 8"	JJ230	JJ231	JJ420	in Table 1
	Half Size 10"	JJ230 JJ240	JJ231 JJ241		5.8lbs
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	11410	25
CTEDIZONE VD4	Full Size 8"	JJ120	JJ131	JJ410	25
STERIZONE VP4 Based on Sterizone Validated	Three-Quarter Size 4"	JJ310	JJ311		
Load 7	Three-Quarter Size 6"	JJ320	JJ321		
2000 /	Three-Quarter Size 8"	JJ320 JJ330	JJ321	JJ430	25
(Aicon Validated Load 3)	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		

Aesculap AICON Containers ma	y be used with commercially	y available Aescular	o accessories according	g to the table below:

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 (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	No Silicone Pieces	No Silicone Pieces	No Silicone Pieces	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.

Silicone mats and lid covers are compatible with PreVac steam only. Silicone pieces should not be used with Ethylene Oxide, Steris V-Pro Systems, STERRAD Systems, or STERIZONE VP4 Systems.

Healthcare Facilities should follow steam sterilization cycle guidelines as stated in AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

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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510(k) SUMMARY K214041

Aesculap Aicon[™] Container November 30, 2022

COMPANY: CONTACT:	Aesculap, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714 Tim Stoudt tim.stoudt@bbraunusa.com (484) 523-4581 610-791-6882 (fax)
TRADE NAME:	Aesculap Aicon TM Container
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	
TRADE NAME:	Aesculap JJ Series Container System
510(k) NUMBER:	K192056
COMMON NAME:	Sterilization Container Wrap
CLASSIFICATION NAME:	Wrap, Sterilization
REGULATION NUMBER:	880.6850
PRODUCT CODE:	КСТ
DEVICE CLASS:	Class II per 21 CFR 880.6850

DEVICE DESCRIPTION

The AESCULAP Aicon Container is a reusable container system intended for sterilization and storage of other medical devices. This container system is compatible for use in the following sterilization modalities:

- Ethylene Oxide
- STERIS VPRO maX/ maX 2: Lumen, Non- Lumen, Flex,
- STERIS VPRO 60: Lumen, Non-Lumen, Flex
- STERRAD 100NX: Standard, Express, Flex, Duo

- STERRAD NX: Standard, Advanced
- STERRAD 100S
- STERIZONE VP4
- PreVac Steam

The containers are perforated and made from anodized aluminum and utilize a single-use filter.

INDICATIONS FOR USE

The AESCULAP AiconTM 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
- STERRAD 100NX: Standard, Express, Flex, Duo
- STERRAD NX: Standard, Advanced
- STERRAD 100S
- STERIZONE VP4
- PreVac Steam

The AESCULAP AiconTM consists of two different container styles: a solid bottom container and enhanced drying system (EDS) container.

The following tables identify the load configurations.

Table 1. AESCULA	P Aicon [™] Container	Lumen Configura	tions

Sterilization Cycle	Container	Compatible Lumens				
	Sizes					
Ethylene Oxide (EtO)	Full Size	(2) Stainless Steel Lumens (\geq 3.0mm ID x \leq 400mm L)				
(130°F, 60 minute exposure	Three-Quarter	(2) Stainless Steel Lumens (\geq 3.0mm ID x \leq 400mm L)				
50-70% RH, concentration	Size					
735mg/L)	Half Size	(2) Stainless Steel Lumens (≥3.0mm ID x ≤ 400mm L)				
	Full Size	(6) Stainless Steel Lumens (≥ 1 mm ID x ≤ 400 mm L)				
		(6) Stainless Steel Lumens (≥ 0.77 mm ID x ≤ 250 mm L)				
STERIS V-PRO maX /maX 2	Three-Quarter	(6) Stainless Steel Lumens ($\geq 1 \text{ mm ID } x \leq 400 \text{ mm L}$)				
Lumen Cycle	Size	(6) Stainless Steel Lumens (≥ 0.77 mm ID x ≤ 250 mm L)				
	Half Size	(12) Stainless Steel Lumens ($\geq 1 \text{ mm ID } x \leq 150 \text{ mm L}$)				
	Full Size					
		Non lumened stainless steel instruments				
STERIS V-PRO Max/ Max 2	Three-Quarter	Non lumened stainless steel instruments				
Non-Lumen Cycle	Size					
	Half Size	Non lumened stainless steel instruments				
	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				
STERIS V-PRO maX / maX 2	T1 0 /	$\geq 1 \text{ mm ID } x \leq 1050 \text{ mm L}$				
Flex Cycle	Three-Quarter	(1) Flexible endoscope with a light cord (if not integral to				
	Size	endoscope) without any additional load. The flexible endoscope may be single lumen that 10×10^{-1050} Jump ID $x < 10^{-500}$ Jump ID $x < 10^{-5$				
	Half Size	is $\geq 1 \text{ mm ID } x \leq 1050 \text{ mm L}$ (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				
		\geq 1mm ID x \leq 1050mm L or two lumens with one \geq 1 mm ID and \leq 990 mm L and the other \geq				
		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 $\geq 1 \text{ mm ID}$ and $\leq 1050 \text{ L}$ or two lumens with one $\geq 1 \text{ mm ID}$ and $\leq 990 \text{ L}$ and the other $\geq 1 \text{ mm ID}$ and $\leq 850 \text{ mm L}$
	Full Size	(6) Stainless Steel Lumens ($\geq 1 \text{ mm ID } x \leq 400 \text{ mm L}$)
STERIS VPRO 60	T 1 0 ((6) Stainless Steel Lumens (≥ 0.77 mm ID x ≤ 250 mm L)
Lumen Cycle	Three-Quarter Size	(6) Stainless Steel Lumens (≥ 1 mm ID x ≤ 400 mm L) (6) Stainless Steel Lumens (≥ 0.77 mm ID y ≤ 250 mm L)
	Half Size	(6) Stainless Steel Lumens (\geq 0.77mm ID x \leq 250mm L) (12) Stainless Steel Lumens (\geq 1mm ID x \leq 150mm L)
STERIS VPRO 60	Full Size	Non lumened stainless steel instruments
Non-Lumen Cycle	Three-Quarter Size	Non lumened stainless steel instruments
	Half Size	Non lumened stainless steel instruments
	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)
STERIS VPRO 60	Three-Quarter	(1) flexible surgical endoscope or bronchoscope with a
Flex Cycle	Size	light cord (if not integral to scope) and single lumen (≥1mm ID x ≤990mm L)
Thex Cycle	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)
	Full Size	(5) Stainless-Steel Lumens (≥1.0mm ID x ≤500mm L)
CTERRAR 1000 IV		(5) Stainless-Steel Lumens (≥0.7mm ID x ≤400mm L)
STERRAD 100NX	Three-Quarter	(5) Stainless-Steel Lumens (\geq 1.0mm ID x \leq 500mm L)
Standard Cycle	Size	(5) Stainless-Steel Lumens (≥ 0.7 mm ID x ≤ 400 mm L)
	Half Size	(5) Stainless-Steel Lumens (≥ 0.7 mm ID x ≤ 250 mm L)
	Full Size	(5) Stainless-Steel Lumens (≥0.7mm ID x ≤200mm L) (5) Stainless Steel Lumens (≥3.0mm 1.D. x ≤ 400mm L)
STERRAD 100S	Three-Quarter Size	(5) Stainless Steel Lumens (\geq 3.0mm 1.D. x \leq 400mm L)
	Half Size	(5) Stainless Steel Lumens (\geq 2.0mm ID x \leq 250mm L)
	Full Size	(10)Stainless-steel lumens (\geq 2.5mm ID x \leq 400mm L)
STERRAD NX Standard Cycle	Three-Quarter Size	(10)Stainless-steel lumens (\geq 2.5mm ID x \leq 400mm L)
	Half Size	(10) Stainless-steel lumens ($\geq 2mm$ ID x $\leq 200mm$ L)
	Full Size	 (5) Stainless-steel lumens (≥2.5mm ID x ≤500mm L) (5) Flexible Lumens (≥1mm ID x ≤850mm L)
STERRAD NX	Three-Quarter	(5) Stainless-steel lumen (≥2.5mm ID x ≤500mm L)
Advanced Cycle	Size	(5) Flexible Lumens (≥1mm ID x ≤850mm L)
	Half Size	(10) Stainless-steel lumens ($\geq 2mm$ ID x $\leq 200mm$ L)
STERRAD 100NX	Full Size	Non lumened stainless steel instruments
Express Cycle	Three-Quarter Size	Non lumened stainless steel instruments
	Full Size	Non lumened stainless steel instruments
STERRAD 100NX	Full Size	(1) Flexible Lumen (≥ 1 mm ID x ≤ 850 mm L)
		(1) Flexible Lumen (≥ 1 mm ID x ≤ 850 mm L)
DUO Cycle	Three-Quarter	(1) Flexible Lumen (\geq 1mm ID x \geq 830mm L)
DUO Cycle	Three-Quarter Size	(1) Mexible Lumen (\geq min iD x \leq 850min L)
DUO Cycle		(1) Flexible Lumen (\geq 1.mm ID x \leq 650mm L)
DUO Cycle	Size	
STERRAD 100NX	Size Half Size	(1) Flexible Lumen (\geq 1.mm ID x \leq 650mm L)
	Size Half Size Full Size Three-Quarter Size	(1) Flexible Lumen ($\geq 1.mm$ ID x $\leq 650mm$ L)(1) Flexible Lumen($\geq 1.5mm$ ID x $\leq 650mm$ L)(1) Flexible Lumen ($\geq 1.5mm$ ID x $\leq 650mm$ L)
STERRAD 100NX Flex Cycle	Size Half Size Full Size Three-Quarter	(1) Flexible Lumen (\geq 1.mm ID x \leq 650mm L) (1) Flexible Lumen(\geq 1.5mm ID x \leq 650mm L)
STERRAD 100NX	Size Half Size Full Size Three-Quarter Size Half Size	(1) Flexible Lumen ($\geq 1.mm$ ID x $\leq 650mm$ L)(1) Flexible Lumen($\geq 1.5mm$ ID x $\leq 650mm$ L)(1) Flexible Lumen ($\geq 1.5mm$ ID x $\leq 650mm$ L)(1) Flexible lumen ($\geq 1.mm$ ID x $\leq 650mm$ L)

PreVac Steam	Full Size	(4) Stainless Steel Lumens ($\geq 1 \text{ mm ID } x \leq 125 \text{ mm L}$)
without dry time	Three-Quarter	(4) Stainless Steel Lumens (≥ 1 mm ID x ≤ 125 mm L)
(270°F, 4 min	Size	
Exposure) Porous	Half Size	(4) Stainless Steel Lumens (≥ 1 mm ID x ≤ 125 mm L)
• •		
Prevac cycles without dry time		
are Immediate Use Sterilization		
Cycles (IUSS).		
Prevac Steam	Full Size	Non-lumened instruments
without dry time	Three-Quarter	Non-lumened instruments
(270°F, 3 min	Size	
Exposure)	Half Size	Non-lumened instruments
Non-Porous		
Prevac cycles without dry time		
are Immediate Use Sterilization		
Cycles (IUSS).		
STERIZONE VP4	Full Size	(1) Dual channel flexible scope (\geq 1.5mm ID x \leq 850mm L) and (\geq 1.5mm
Load 8		ID x ≤989mm L)
		(1) Single channel flexible scope (\geq 1.5mm ID x \leq 850mm L)
(Aicon Validated Load 1)	Three-Quarter	(1) Dual channel flexible scope (≥ 1.5 mm ID x ≤ 850 mm L) and (≥ 1.5 mm
,	Size	ID x ≤989mm L)
		(1) Single channel flexible scope (\geq 1.5mm ID x \leq 850mm L)
	Half Size	(1) Dual channel flexible scope (≥ 1.5 mm ID x ≤ 850 mm L) and (≥ 1.5 mm
		ID x ≤989mm L)
		(1) Single channel flexible scope (\geq 1.5mm ID x \leq 850mm L)
STERIZONE VP4	Full Size	(1) Dual channel semi rigid scope (≥0.7mm ID x 500mm L; ≥1.1mm ID x ≤500mm L)
Load 4		(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)
(Aicon Validated Load 2)		(2) Stainless Steel Lumens (≥3mm ID x ≤400mm L)
	Three-Quarter	(1) Dual channel semi rigid scope (≥0.7mm ID x 500mm L; ≥1.1mm ID x ≤500mm L)
	Size	(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 ($\geq 0.7 \text{ mm ID x} \leq 300 \text{ mm L}$)
		(1) Stainless Steel Lumen ($\geq 1.0 \text{ mm ID x} \leq 300 \text{ mm L}$)
		(2) Stainless Steel Lumens ($\geq 2.0 \text{ mm ID x} \leq 250 \text{mm L}$)
		(2) Stainless Steel Lumens (\geq 3.0 mm ID x \leq 300mm L)
STERIZONE VP4	Full Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
Load 7	Three-Quarter	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)
	Size	
(Aicon Validated Load 3)	Half Size	Non-Lumened Stainless Steel Instruments (including hinges, luerlocks)

Sterilization Method	Container Size	Standard Container	EDS Container	Container Lid Part #	Total Loaded Container (lbs)
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121		
	Full Size 8"	JJ130	JJ131	JJ410	25
	Full Size 10"	JJ140	JJ141		
	Three-Quarter Size 4"	JJ310	JJ311		
	Three-Quarter Size 6"	JJ320	JJ321		
EtO	Three-Quarter Size 8"	JJ330	JJ331	JJ430	25
(130°F, 60 minute exposure 50-70% RH, concentration 735mg/L)	Three-Quarter Size 10"	JJ340	JJ341		
50-70% KH, concentration 755mg/L)	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221		
	Half Size 8"	JJ230	JJ231	JJ420	25
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		

STERIS VPRO	Full Size 6"	JJ120	JJ121		
maX/ maX 2 Lumen	Full Size 8"	JJ130	JJ131	JJ410	19.65
	Full Size 10"	JJ140	JJ141		
	Three-Quarter Size 4"	JJ310	JJ311	_	
	Three-Quarter Size 6"	JJ320	JJ321 JJ331	11420	19.65
	Three-Quarter Size 8"	JJ330	JJ331 JJ341	JJ430	19.05
	Three-Quarter Size 10"	JJ340	33341		
	Half Size 4"	JJ210	JJ211	JJ420	13.8
	Half Size 6"	JJ220	JJ221		15.0
	Half Size 8"	JJ230	JJ231		
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	25
	Full Size 8"	JJ130	JJ131	JJ410	25
	Full Size 10"	JJ140	JJ141		
	Three-Quarter Size 4"	JJ310	JJ311		
STERIS VPRO	Three-Quarter Size 6"	JJ320	JJ321	11420	25
maX / maX 2 Non-Lumen	Three-Quarter Size 8"	JJ330	JJ331	JJ430	25
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221		
	Half Size 8"	JJ230	JJ231	JJ420	18.7
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		(1) Flexible endoscope w
	Full Size 6"	JJ120	JJ121	_	a light cord (if not integra
	Full Size 8"	JJ130	JJ131	JJ410	endoscope) without any additional load. The flexi endoscope may be single lumen that is ≥1mm ID y ≤1050mm L
	Three-Quarter Size 4"	JJ310	JJ311		(1) Flexible endoscope w
STERIS VPRO	Three-Quarter Size 6"	JJ320	JJ321		a light cord (if not integra
maX / maX 2 Flex	Three-Quarter Size 8"	JJ330	JJ331	JJ430	endoscope) without any additional load. The flexi
	Three-Quarter Size 10"	JJ340	JJ341		endoscope may be single lumen that is ≥1mm ID x ≤1050mm L
	Half Size 4"	JJ210	JJ211	JJ420	(2) Flexible endoscopes with a light cord (if no integral to endoscope) without any additional load. The

	Half Size 6" Half Size 8"	JJ220 JJ230	JJ221 JJ231		flexible endoscope may be single lumen that is ≥ 1 mm ID x ≤ 1050 mm 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 (24lbs). The flexible endoscope can have: a single lumen that is
	Half Size 10"	JJ240	JJ241	_	\geq 1mm ID and \leq 1050 L or two lumens with one \geq 1 mm ID and \leq 990 L and the other \geq 1 mm ID and \leq 850 mm L
STERIS VPRO 60 Lumen	Full Size 4"	JJ110	JJ111	JJ410	11
	Full Size 6"	JJ120	JJ121		
	Full Size 8"	JJ120	JJ121 JJ131	-	
	Three-Quarter Size 4"	JJ310	JJ311 JJ311		
	Three-Quarter Size 6"	JJ320	JJ321	-	
	Three-Quarter Size 8"	JJ3320	JJ331	JJ430	11
	Three-Quarter Size 10"	JJ340	JJ341	-	
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221	-	
	Half Size 8"	JJ230	JJ231	JJ420	11
	Half Size 10"	JJ240	JJ241	-	
STERIS VPRO 60 Non-Lumen	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	12
	Full Size 8"			JJ410	12
		JJ130	JJ131		
	Three-Quarter Size 4"	JJ310	JJ311		
	Three-Quarter Size 6"	JJ320	JJ321	11420	12
	Three-Quarter Size 8"	JJ330	JJ331	JJ430	12
	Three-Quarter Size 10"	JJ340	JJ341	_	
	Half Size 4"	JJ210	JJ211	JJ420	
	Half Size 6"	JJ220	JJ221		
	Half Size 8"	JJ230	JJ231		12
	Half Size 10"	JJ240	JJ241	1	
	Full Size 4"	JJ110	JJ111		

Full Size 6" J1120 J121 J410 (1) flexible signed integrat to scool of data integrat to scool or branchoscope integrat to					-	
Full Size 8" JJ130 JJ131 Jummin (2-Imm ID x symmet) Three-Quarter Size 4" JJ310 JJ311 (1) Acade arrival protection of the optimum of the optimum of the optimum protection of the optimum of the optimum of the optimum of the optimum protection of the optimum of the o		Full Size 6"	JJ120	JJ121	JJ410	endoscope or bronchoscope with a light cord (if not
STERIS VPRO 60 Flex Image: Construction of the start of		Full Size 8"	JJ130	JJ131		lumen (≥1mm ID x
Intro-Quarter Size 6" JJ320 JJ321 JJ400 [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes (if not integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes (if not integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope integral to scop-3 and single langes) [1] flexible surgical endoscope or bronchoscope endoscope endoracter endos		Three-Quarter Size 4"	JJ310	JJ311		
Three-Quarter Size 8" JJ330 JJ331 June (2 mm ID x \$\$90mm I.) Three-Quarter Size 10" JJ340 JJ341 [1] flexible surgical endoscope or bronchoscope with a light cord (if not ninegral to scope) and single borne (2 mm ID x \$\$90mm I.) Haif Size 4" JJ210 JJ211 JJ420 [1] flexible surgical endoscope or bronchoscope with a light cord (if not ninegral to scope) and single borne (2 mm ID x \$\$90mm I.) Haif Size 6" JJ220 JJ221 JJ420 [1] flexible surgical endoscope or bronchoscope with a light cord (if not ninegral to scope) and single borne (2 mm ID x \$\$90mm I.) Haif Size 6" JJ220 JJ221 JJ420 [1] flexible surgical endoscope or bronchoscope with a light cord (if not ninegral to scope) and single borne (2 mm ID x \$\$90mm I.) Haif Size 6" JJ230 JJ221 JJ420 [1] flexible surgical endoscope or bronchoscope with a light cord (if not ninegral to scope) and single borne (2 mm ID x \$\$90mm I.) Haif Size 6" JJ230 JJ221 JJ410 [1] flexible surgical endoscope or bronchoscope with a light cord (if not ninegral to scope) and single borne (2 mm ID x \$\$90mm I.) STERRAD 1000NX Standard Full Size 4" JJ120 JJ121 JJ410 21.4 Three-Quarter Size 6" JJ310 JJ310 JJ310 <	STERIS VPRO 60 Flex	Three-Quarter Size 6"	JJ320	JJ321	JJ430	endoscope or bronchoscope with a light cord (if not
Half Size 4" JJ210 JJ211 JJ420 (1) flexible surgical endoscope or bronchoscope with a light coscope or br		Three-Quarter Size 8"	JJ330	JJ331		lumen (≥1mm ID x
Half Size 4"JJ210JJ211JJ420endoscope or bronchoscope with a light cod (if not integral to scope) and single humen (2 lmm ID x 5990mm L.)Half Size 6"JJ220JJ221Image: Comparison of the code of th		Three-Quarter Size 10"	JJ340	JJ341		
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$		Half Size 4"	JJ210	JJ211	JJ420	endoscope or bronchoscope with a light cord (if not
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$		Half Size 6"	JJ220	JJ221		lumen (≥1mm ID x ≤990mm L)
Full Size 4" JJ110 JJ111 Full Size 6" JJ120 JJ121 Full Size 6" JJ130 JJ131 Full Size 6" JJ140 JJ140 Full Size 10" JJ140 JJ141 Three-Quarter Size 4" JJ310 JJ311 Three-Quarter Size 6" JJ320 JJ321 Three-Quarter Size 6" JJ330 JJ331 Three-Quarter Size 8" JJ330 JJ331 Three-Quarter Size 10" JJ340 JJ341 Half Size 6" JJ220 JJ221 Half Size 6" JJ230 JJ221 Half Size 6" JJ230 JJ240		Half Size 8"	JJ230	JJ231		
Full Size 6" JJ120 JJ121 Full Size 6" JJ130 JJ131 JJ40 21.4 STERRAD 100NX Standard Full Size 10" JJ140 JJ141 1 STERRAD 100NX Standard Three-Quarter Size 4" JJ310 JJ311 1 Three-Quarter Size 6" JJ320 JJ321 1 1 Three-Quarter Size 6" JJ330 JJ331 1 1 Three-Quarter Size 8" JJ330 JJ331 1 1 Half Size 4" JJ210 JJ211 1 1 Half Size 6" JJ220 JJ221 1 1 Half Size 8" JJ230 JJ231 1 13.8		Half Size 10"	JJ240	JJ241		
Full Size 0 3/120 JJ130 JJ131 JJ410 21.4 Full Size 8" JJ130 JJ140 JJ141 21.4 STERRAD 100NX Standard Three-Quarter Size 4" JJ310 JJ311 JJ430 21.4 Three-Quarter Size 6" JJ320 JJ321 JJ430 21.4 Three-Quarter Size 6" JJ320 JJ331 JJ430 21.4 Three-Quarter Size 8" JJ330 JJ331 JJ430 21.4 Half Size 4" JJ210 JJ211 JJ430 21.4 Half Size 6" JJ220 JJ221 JJ420 13.8		Full Size 4"	JJ110			
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STERRAD 100NX StandardThree-Quarter Size 4"JJ310JJ311Three-Quarter Size 6"JJ320JJ321Three-Quarter Size 6"JJ330JJ331Three-Quarter Size 8"JJ330JJ331Three-Quarter Size 10"JJ340JJ341Half Size 4"JJ210JJ211Half Size 6"JJ220JJ221JHALF Size 8"JJ230JJ231JJ420I3.8		Full Size 8"	JJ130		JJ410	21.4
Three-Quarter Size 6" JJ320 JJ321 Three-Quarter Size 6" JJ330 JJ331 Three-Quarter Size 8" JJ330 JJ341 Three-Quarter Size 10" JJ340 JJ341 Half Size 4" JJ210 JJ211 Half Size 6" JJ220 JJ221 Half Size 8" JJ230 JJ231		Full Size 10"	JJ140			
Three-Quarter Size 8"JJ330JJ331JJ43021.4Three-Quarter Size 10"JJ340JJ3411Half Size 4"JJ210JJ211Half Size 6"JJ220JJ221Half Size 8"JJ230JJ231	STERRAD 100NX Standard	Three-Quarter Size 4"	JJ310			
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Half Size 4" JJ210 JJ211 Half Size 6" JJ220 JJ221 Half Size 8" JJ230 JJ231		Three-Quarter Size 8"	JJ330		JJ420	21.4
Half Size 6" JJ220 JJ221 Half Size 8" JJ230 JJ231		Three-Quarter Size 10"	JJ340			
Half Size 8" JJ230 JJ231 JJ420 13.8		Half Size 4"	JJ210	JJ211		
Half Size 8" JJ230 JJ241		Half Size 6"	JJ220	JJ221		
Italf Size 10" JJ241		Half Size 8"	JJ230	JJ231	JJ420	13.8
Hall Size IU JJ240		Half Size 10"	JJ240	JJ241	1	

			JJ111		
	Full Size 4"	JJ110		_	
	Full Size 6"	JJ120	JJ121	JJ410	13.9
	Full Size 8"	JJ130	JJ131		1010
	Full Size 10"	JJ140	JJ141		
STERRAD 100S	Three-Quarter Size 4"	JJ310	JJ311		
	Three-Quarter Size 6"	JJ320	JJ321		
	Three-Quarter Size 8"	JJ330	JJ331	JJ430	13.9
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
			JJ221	_	
	Half Size 6"	JJ220	JJ231	JJ420	13.9
	Half Size 8"	JJ230	JJ231 JJ241	_	
	Half Size 10"	JJ240			
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	10.7
	Full Size 8"	JJ130	JJ131	JJ410	10.7
	Full Size 10"	JJ140	JJ141		
STERRAD NX Standard	Three-Quarter Size 4"	JJ310	JJ311		
	Three-Quarter Size 6"	JJ320	JJ321		10.7
	Three-Quarter Size 8"	JJ330	JJ331	JJ430	10.7
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221		10 5
	Half Size 8"	JJ230	JJ231	JJ420	10.7
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		10.5
	Full Size 6"	JJ120	JJ121	JJ410	10.7
STERRAD NX Advanced	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		
	Half Size 6"	JJ220	JJ221		
	Half Size 8"	JJ230	JJ231	JJ420	10.7
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	10.7
	Full Size 8"	JJ130	JJ131	-	
STERRAD 100NX Express	Three-Quarter Size 4"	JJ310	JJ311		
*	Three-Quarter Size 6"	JJ320	JJ321		
	Three-Quarter Size 8"	JJ320 JJ330	JJ331	JJ430	10.7
			JJ341		
	Three-Quarter Size 10"	JJ340			
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221		

	Half Size 8"	JJ230	JJ231	JJ420	10.7
	Half Size 10"	JJ240	JJ241	-	
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	-	
STERRAD 100NX DUO	Full Size 8"	JJ120	JJ131	JJ410	13.2
			JJ141	<u> </u>	
	Full Size 10"	JJ140	JJ311		
	Three-Quarter Size 4"	JJ310		_	
	Three-Quarter Size 6"	JJ320	JJ321	JJ430	13.2
	Three-Quarter Size 8"	JJ330	JJ331		10.2
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221		<i>.</i>
	Half Size 8"	JJ230	JJ231	JJ420	6.0
	Half Size 10"	JJ240	JJ241	-	
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	-	
	Full Size 8"	JJ130	JJ131	JJ410	14.7
	Full Size 10"	JJ140	JJ141	_	
			JJ311		
	Three-Quarter Size 4"	JJ310	JJ321	_	
STERRAD 100NX Flex	Three-Quarter Size 6"	JJ320		JJ430	14.7
	Three-Quarter Size 8"	JJ330	JJ331		
	Three-Quarter Size 10"	JJ340	JJ341		
	Half Size 4"	JJ210	JJ211		
	Half Size 6"	JJ220	JJ221	11420	10.7
	Half Size 8"	JJ230	JJ231	JJ420	10.7
	Half Size 10"	JJ240	JJ241		
	Full Size 4"	JJ110	JJ111		25
Prevac Steam 270°F, 4 min exposure	Full Size 6"	JJ120	JJ121		24
270 F, 4 min exposure	Full Size 8"	JJ130	JJ131	JJ410	23
With silicone mat and lid cover*	Full Size 10"	JJ140	JJ141		22
30 minute dry time	Three-Quarter Size 4"	JJ310	JJ311		23
Without silicone mat and lid cover*			JJ321	JJ430	
20 minute dry time	Three-Quarter Size 6"	JJ320	JJ331		22
	Three-Quarter Size 8"	JJ330	JJ341		20
	Three-Quarter Size 10" Half Size 4"	JJ340 JJ210	JJ211		18
	Half Size 6"	JJ220	JJ221		18
	Half Size 8"	JJ230	JJ231	JJ420	15
	Half Size 10"	JJ240	JJ241		13
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121		
	Full Size 8"	JJ130	JJ131	JJ410	25
PreVac Steam without dry time 270°F	Full Size 10"	JJ140	JJ141		
3 min Exposure	Three-Quarter Size 4"	JJ310	JJ311		
(Non-porous)	Three-Quarter Size 6"	JJ320	JJ321 JJ331		25
AND	Three-Quarter Size 8"	JJ330	JJ331 JJ341	JJ430	25
AIND	Three-Quarter Size 10" Half Size 4"	JJ340 JJ210	JJ211		

Prevac Steam without dry time	Half Size 6"	JJ220	JJ221		
270°F 4 min Exposure	Half Size 8"	JJ230	JJ231	JJ420	25
(Porous)	Half Size 10"	JJ240	JJ241		
Prevac cycles without dry times are Immediate Use Sterilization Cycles (IUSS).					
	Full Size 4"	JJ110	JJ111	JJ410	Based on Load Configuration
	Full Size 6"	JJ120	JJ121		in Table 1
	Full Size 8"	JJ130	JJ131		13.8lbs
STERIZONE VP4	Three-Quarter Size 4"	JJ310	JJ311	JJ430	
Based on Sterizone Validated	Three-Quarter Size 6"	JJ320	JJ321		Based on Load Configuration
Load 8	Three-Quarter Size 8"	JJ330	JJ331		in Table 1
(Aicon Validated Load 1)	Three-Quarter Size 10"	JJ340	JJ341		13.8lbs
	Half Size 4"	JJ210	JJ211	JJ420	
	Half Size 6"	JJ220	JJ221		Based on Load Configuration
	Half Size 8"	JJ230	JJ231		in Table 1
	Half Size 10"	JJ240	JJ241		5.8lbs
	Full Size 4"	JJ110	JJ111		Based on Load Configuration
	Full Size 6"	JJ120	JJ121	JJ410	in Table 1
	Full Size 8"	JJ130	JJ131	33110	11.711
	Three-Quarter Size 4"	JJ310	JJ311		11.7lbs
STERIZONE VP4	Three-Quarter Size 6"	JJ320	JJ321		Based on Load Configuration
Based on Sterizone Validated	Three-Quarter Size 8"	JJ330	JJ331	JJ430	in Table 1
Load 4	Three-Quarter Size 10"	JJ340	JJ341		11.7lbs
(Aicon Validated Load 2)	Half Size 4"	JJ210	JJ211		
(Half Size 6"	JJ220	JJ221	-	Based on Load Configuration in Table 1
	Half Size 8"	JJ230	JJ231	JJ420	in Table I
	Half Size 10"	JJ230	JJ231 JJ241	-	5.8lbs
	Full Size 4"	JJ110	JJ111		
	Full Size 6"	JJ120	JJ121	JJ410	25
STERIZONE VP4	Full Size 8"	JJ130	JJ131		25
Based on Sterizone Validated	Three-Quarter Size 4"	JJ310	JJ311		
Load 7	Three-Quarter Size 6"	JJ320	JJ321		
	Three-Quarter Size 8"	JJ330	JJ331	JJ430	25
(Aicon Validated Load 3)	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	1	

Aesculap AICON Containers may be used with commercially available Aesculap accessories according to the table below:

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 (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	No Silicone Pieces	No Silicone Pieces	No Silicone Pieces	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.

Silicone mats and lid covers are compatible with PreVac steam only. Silicone pieces should not be used with Ethylene Oxide, Steris V-Pro Systems, STERRAD Systems, or STERIZONE VP4 Systems.

Healthcare Facilities should follow steam sterilization cycle guidelines as laid out in AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

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.

	Subject Device -		Reference Device-	Reference Device-	
	Aesculap Aicon			Aesculap SterilContainer	
Characteristi	Container (JJ Series)		S2 System	S2 System	Discussio
c	(K214041)	(K192056)	(K193582)	(K182414)	n
-	Product Code: KCT		Product Code: KCT	Product Code: KCT	
Intended Use	A device intended to be	Same			
	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	enclosed medical device	enclosed medical device	enclosed medical device	
	and also to maintain				
	sterility of the enclosed				
	device until used.	device until used.	device until used.	device until used.	
Sterilization	PreVac Steam with dry		• EtO	Prevac Steam	Similar
Modalities	time	time	• STERIZONE VP4	Gravity Steam	
	PreVac Steam without	Prevac Steam without	• STERRAD 100NX DUO	• STERIS VPRO maX:	
	dry time	dry time		Lumen, Non-Lumen, Flex	
	Ethylene Oxide			• STERIS VPRO 60:	
	• STERIS VPRO maX/maX			Lumen,	
	2: Lumen, Non-Lumen,			Non-Lumen, Flex	
	Flex,			• STERRAD: 100S, NX	
	• STERIS VPRO 60:			Standard, NX	
	Lumen,			Advanced, 100NX	
	Non- Lumen, Flex			Standard, 100NX Flex	
	• STERRAD: 100S, NX				
	Standard, NX Advanced,				
	100NX Standard, 100NX				
	Flex, 100 NX Express,				
Material	100NX Duo	Cantainan	Containan	Cantainan	Same
wiaterial	Container: Anodized	Container: Anodized	Container: Anodized	Container: Anodized	Same
	aluminum	aluminum	aluminum	aluminum	
	Lid: Anodized aluminum		Lid: Anodized aluminum	Lid: Anodized aluminum	
	Gasket: Silicone	Gasket: Silicone	Gasket: Silicone	Gasket: Silicone	
Filter Type &		Single use (Paper)	Single use (Paper or	Single use (Paper	Similar
Material	Single use (1 olyptopytelle)	Single use (1 aper)	polypropylene)	or polypropylene)	Similar
171attiai			porypropyrene)	Reusable (PTFE)	
Container	Solid bottom or	Solid bottom or	Perforated bottom with	Perforated bottom with	Similar
Design	Solid bottom with enhanced	Solid bottom with enhanced	perforated lid	perforated lid	
-	drying system with	drying system with			

	Perforated Lid	Perforated Lid			
Vent to	0.04mm ⁻¹ * 10 ⁻³	0.04mm ⁻¹ * 10 ⁻³	$0.50 \text{mm}^{-1} * 10^{-3}$	0.50mm ⁻¹ * 10 ⁻³	Similar
volume	to		to	to	
ratios	0.26 mm ⁻¹ * 10 ⁻³	0.26 mm ⁻¹ * 10 ⁻³	3.43 mm ⁻¹ * 10 ⁻³	3.43mm ⁻¹ * 10 ⁻³	
Maintenance	365 days	365 days	360 days	360 days	Similar
of sterility					

PERFORMANCE DATA

Testing was conducted in accordance with applicable FDA guidance and standards. The table below outlines the testing which was performed on the subject 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. 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.	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. No presence of growth after incubation period.	Pass
Simulated Use	To determine the effective sterilization of flexible scopes when used with the test device.	A minimum of $1.0 \ge 10^6$ spores contained within organic soil representative of actual use conditions are killed during defined sterilization cycle.	Pass
Material Compatibility	To assess effects of full use cycles on device components and their intended functionality.	No impact to functionality at the completion multiple sterilization cycles.	Pass
Cytotoxicity	To determine the potential of a test device to cause cytotoxicity.	Testing completed in accordance with ISO 10993-5: 2009 to demonstrate no significant cytotoxic reaction after exposure to sterilant. Using the ISO Elution Method, the response to the article is not greater than 2 (mild reactivity).	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 after processing for 365 days under conditions which simulate hospital sterile package handling and storage conditions. 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 Aesculap Aicon Container is as safe, as effective, and performs as well as or better than the legally marketed predicate device K192056.