



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 Federal Register.

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

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

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

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

Sincerely,

  
**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 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
- 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 enhanced drying system (EDS) container.

The following tables identify the load configurations.

Table 1. AESCULAP Aicon™ Container Lumen Configurations

| Sterilization Cycle   | Container Sizes    | Compatible Lumens  |
|---|--------------------|--|
| Ethylene Oxide (EtO)<br>(130°F, 60 minute exposure<br>50-70% RH, concentration 735mg/L) | Full Size          | (2) Stainless Steel Lumens ( $\geq 3.0\text{mm ID x } \leq 400\text{mm L}$ )   |
|   | Three-Quarter Size | (2) Stainless Steel Lumens ( $\geq 3.0\text{mm ID x } \leq 400\text{mm L}$ )   |
|   | Half Size          | (2) Stainless Steel Lumens ( $\geq 3.0\text{mm ID x } \leq 400\text{mm L}$ )   |
| STERIS V-PRO maX /maX 2<br>Lumen Cycle  | Full Size          | (6) Stainless Steel Lumens ( $\geq 1\text{mm ID x } \leq 400\text{mm L}$ )<br>(6) Stainless Steel Lumens ( $\geq 0.77\text{mm ID x } \leq 250\text{mm L}$ )  |
|   | Three-Quarter Size | (6) Stainless Steel Lumens ( $\geq 1\text{mm ID x } \leq 400\text{mm L}$ )<br>(6) Stainless Steel Lumens ( $\geq 0.77\text{mm ID x } \leq 250\text{mm L}$ )  |
|   | Half Size          | (12) Stainless Steel Lumens ( $\geq 1\text{mm ID x } \leq 150\text{mm L}$ )  |
| STERIS V-PRO Max/ Max 2<br>Non-Lumen Cycle  | 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<br>Flex Cycle  | 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 $\geq 1\text{mm ID x } \leq 1050\text{mm L}$ |
|   | 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 $\geq 1\text{mm ID x } \leq 1050\text{mm L}$ |
|   | 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 $\geq 1\text{mm ID} \times \leq 1050\text{mm L}$ 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 $\leq 850\text{ mm L}$<br>OR<br>(1) flexible endoscope with a light cord (if not integral to endoscope) and additional non-lumened instruments. The flexible endoscope can have:<br>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 $\leq 850\text{ mm L}$ |
| STERIS VPRO 60<br>Lumen Cycle  | Full Size          | (6) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 400\text{mm L}$ )<br>(6) Stainless Steel Lumens ( $\geq 0.77\text{mm ID} \times \leq 250\text{mm L}$ )  |
|  | Three-Quarter Size | (6) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 400\text{mm L}$ )<br>(6) Stainless Steel Lumens ( $\geq 0.77\text{mm ID} \times \leq 250\text{mm L}$ )  |
|  | Half Size          | (12) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 150\text{mm L}$ )  |
| STERIS VPRO 60<br>Non-Lumen Cycle  | 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<br>Flex Cycle   | Full Size          | (1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen ( $\geq 1\text{mm ID} \times \leq 990\text{mm L}$ )  |
|  | Three-Quarter Size | (1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen ( $\geq 1\text{mm ID} \times \leq 990\text{mm L}$ )  |
|  | Half Size          | (1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen or dual lumens ( $\geq 1\text{mm ID} \times \leq 990\text{mm L}$ )   |
| STERRAD 100NX<br>Standard Cycle  | Full Size          | (5) Stainless-Steel Lumens ( $\geq 1.0\text{mm ID} \times \leq 500\text{mm L}$ )<br>(5) Stainless-Steel Lumens ( $\geq 0.7\text{mm ID} \times \leq 400\text{mm L}$ )   |
|  | Three-Quarter Size | (5) Stainless-Steel Lumens ( $\geq 1.0\text{mm ID} \times \leq 500\text{mm L}$ )<br>(5) Stainless-Steel Lumens ( $\geq 0.7\text{mm ID} \times \leq 400\text{mm L}$ )   |
|  | Half Size          | (5) Stainless-Steel Lumens ( $\geq 0.7\text{mm ID} \times \leq 250\text{mm L}$ )<br>(5) Stainless-Steel Lumens ( $\geq 0.7\text{mm ID} \times \leq 200\text{mm L}$ )   |
| STERRAD 100S   | Full Size          | (5) Stainless Steel Lumens ( $\geq 3.0\text{mm I.D.} \times \leq 400\text{mm L}$ )   |
|  | Three-Quarter Size | (5) Stainless Steel Lumens ( $\geq 3.0\text{mm I.D.} \times \leq 400\text{mm L}$ )   |
|  | Half Size          | (5) Stainless Steel Lumens ( $\geq 2.0\text{mm ID} \times \leq 250\text{mm L}$ )   |
| STERRAD NX<br>Standard Cycle   | Full Size          | (10)Stainless-steel lumens ( $\geq 2.5\text{mm ID} \times \leq 400\text{mm L}$ )   |
|  | Three-Quarter Size | (10)Stainless-steel lumens ( $\geq 2.5\text{mm ID} \times \leq 400\text{mm L}$ )   |
|  | Half Size          | (10) Stainless-steel lumens ( $\geq 2\text{mm ID} \times \leq 200\text{mm L}$ )  |
| STERRAD NX<br>Advanced Cycle   | Full Size          | (5) Stainless-steel lumens ( $\geq 2.5\text{mm ID} \times \leq 500\text{mm L}$ )<br>(5) Flexible Lumens ( $\geq 1\text{mm ID} \times \leq 850\text{mm L}$ )  |
|  | Three-Quarter Size | (5) Stainless-steel lumen ( $\geq 2.5\text{mm ID} \times \leq 500\text{mm L}$ )<br>(5) Flexible Lumens ( $\geq 1\text{mm ID} \times \leq 850\text{mm L}$ )   |
|  | Half Size          | (10) Stainless-steel lumens ( $\geq 2\text{mm ID} \times \leq 200\text{mm L}$ )  |
| STERRAD 100NX<br>Express Cycle   | Full Size          | Non lumened stainless steel instruments  |
|  | Three-Quarter Size | Non lumened stainless steel instruments  |
|  | Full Size          | Non lumened stainless steel instruments  |
| STERRAD 100NX<br>DUO Cycle   | Full Size          | (1) Flexible Lumen ( $\geq 1\text{mm ID} \times \leq 850\text{mm L}$ )   |
|  | Three-Quarter Size | (1) Flexible Lumen ( $\geq 1\text{mm ID} \times \leq 850\text{mm L}$ )   |
|  | Half Size          | (1) Flexible Lumen ( $\geq 1.\text{mm ID} \times \leq 650\text{mm L}$ )  |
| STERRAD 100NX<br>Flex Cycle  | Full Size          | (1) Flexible Lumen( $\geq 1.5\text{mm ID} \times \leq 650\text{mm L}$ )  |
|  | Three-Quarter Size | (1) Flexible Lumen ( $\geq 1.5\text{mm ID} \times \leq 650\text{mm L}$ )   |
|  | Half Size          | (1) Flexible lumen ( $\geq 1.\text{mm ID} \times \leq 650\text{mm L}$ )  |
| PreVac Steam with dry time<br>(270°F, 4 min Exposure)                          | Full Size          | (4) Stainless Steel Lumens ( $\geq 1.\text{mm ID} \times \leq 200\text{mm L}$ )  |
|  | Three-Quarter      | (4) Stainless Steel Lumens ( $\geq 1.0\text{mm ID} \times \leq 200\text{mm L}$ )   |
|  | Half Size          | (4) Stainless Steel Lumens ( $\geq 1.0\text{mm ID} \times \leq 200\text{mm L}$ )   |
| PreVac Steam without dry time<br>(270°F, 4 min Exposure)<br>Porous             | Full Size          | (4) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 125\text{ mm L}$ )  |
|  | Three-Quarter Size | (4) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 125\text{ mm L}$ )  |
|  | Half Size          | (4) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 125\text{ mm L}$ )  |
| Prevac cycles without dry times are Immediate Use Sterilization Cycles (IUSS). |                    |  |

|   |                    |  |
|---|--------------------|--|
| (270°F, 3 min Exposure)<br>Non-Porous<br><br>Prevac cycles without dry times are<br>Immediate Use Sterilization Cycles<br>(IUSS). | Full Size          | Non-lumened instruments  |
|   | Three-Quarter Size | Non-lumened instruments  |
|   | Half Size          | Non-lumened instruments  |
| STERIZONE VP4<br>Load 8<br><br>(Aicon Validated Load 1)   | Full Size          | (1) Dual channel flexible scope ( $\geq 1.5$ mm ID x $\leq 850$ mm L) and ( $\geq 1.5$ mm ID x $\leq 989$ mm L)<br>(1) Single channel flexible scope ( $\geq 1.5$ mm ID x $\leq 850$ mm L)   |
|   | Three-Quarter Size | (1) Dual channel flexible scope ( $\geq 1.5$ mm ID x $\leq 850$ mm L) and ( $\geq 1.5$ mm ID x $\leq 989$ mm L)<br>(1) Single channel flexible scope ( $\geq 1.5$ mm ID x $\leq 850$ mm L)   |
|   | Half Size          | (1) Dual channel flexible scope ( $\geq 1.5$ mm ID x $\leq 850$ mm L) and ( $\geq 1.5$ mm ID x $\leq 989$ mm L)<br>(1) Single channel flexible scope ( $\geq 1.5$ mm ID x $\leq 850$ mm L)   |
| STERIZONE VP4<br>Load 4<br><br>(Aicon Validated Load 2)   | Full Size          | (1) Dual channel semi rigid scope ( $\geq 0.7$ mm ID x 500mm L; $\geq 1.1$ mm ID x $\leq 500$ mm L)<br>(1) Dual channel semi rigid scope ( $\geq 1.1$ mm ID x 500mm L; $\geq 1.1$ mm ID x $\leq 500$ mm L)<br>(2) Stainless Steel Lumens ( $\geq 2$ mm ID x $\leq 250$ mm L)<br>(2) Stainless Steel Lumens ( $\geq 3$ mm ID x $\leq 400$ mm L) |
|   | Three-Quarter Size | (1) Dual channel semi rigid scope ( $\geq 0.7$ mm ID x 500mm L; $\geq 1.1$ mm ID x $\leq 500$ mm L)<br>(1) Dual channel semi rigid scope ( $\geq 1.1$ mm ID x 500mm L; $\geq 1.1$ mm ID x $\leq 500$ mm L)<br>(2) Stainless Steel Lumens ( $\geq 2$ mm ID x $\leq 250$ mm L)<br>(2) Stainless Steel Lumens ( $\geq 3$ mm ID x $\leq 400$ mm L) |
|   | Half Size          | (1) Stainless Steel Lumen ( $\geq 0.7$ mm ID x $\leq 300$ mm L)<br>(1) Stainless Steel Lumen ( $\geq 1.0$ mm ID x $\leq 300$ mm L)<br>(2) Stainless Steel Lumens ( $\geq 2.0$ mm ID x $\leq 250$ mm L)<br>(2) Stainless Steel Lumens ( $\geq 3.0$ mm ID x $\leq 300$ mm L)   |
| STERIZONE VP4<br>Load 7<br><br>(Aicon Validated Load 3)   | 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) |
|--|------------------------|--------------------|---------------|----------------------|------------------------------|
| EtO<br>(130°F, 60 minute exposure<br>50-70% RH, concentration 735mg/L) | Full Size 4"           | JJ110              | JJ111         | JJ410                | 25                           |
|  | 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<br>maX/ maX 2 Lumen  | Full Size 4"           | JJ110              | JJ111         | JJ410                | 19.65                        |
|  | 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<br>maX / maX 2 Non-Lumen | Full Size 4"           | JJ110        | JJ111 | JJ410 | 25  |
|                                      | 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 | 18.7  |
|                                      | Half Size 6"           | JJ220        | JJ221 |       |   |
|                                      | Half Size 8"           | JJ230        | JJ231 |       |   |
|                                      | Half Size 10"          | JJ240        | JJ241 |       |   |
| STERIS VPRO<br>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 $\geq 1$ mm ID x $\leq 1050$ mm L   |
|                                      | 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 $\geq 1$ mm ID x $\leq 1050$ mm 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 $\geq 1$ mm ID x $\leq 1050$ mm L or two lumens with one $\geq 1$ mm ID and $\leq 990$ mm L and the other $\geq 1$ mm ID and $\leq 850$ mm L<br>OR<br>(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 $\geq 1$ mm 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 |
|                                      | Half Size 6"           | JJ220        | JJ221 |       |   |
|                                      | Half Size 8"           | JJ230        | JJ231 |       |   |
|                                      | Half Size 10"          | JJ240        | JJ241 |       |   |
|                                      | STERIS VPRO 60 Lumen   | Full Size 4" | JJ110 | JJ111 | JJ410   |

|                          |                        |              |       |       |   |
|--------------------------|------------------------|--------------|-------|-------|---|
|                          | 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 |       |   |
|                          | 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  |
|                          | 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 |       |   |
|                          | STERIS VPRO 60 Flex    | Full Size 4" | JJ110 | JJ111 | JJ410   |
| 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 ( $\geq 1\text{mm ID x } \leq 990\text{mm L}$ ) |
| 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   |

|                        |                        |       |       |       |   |
|------------------------|------------------------|-------|-------|-------|---|
|                        | Half Size 6"           | JJ220 | JJ221 |       | lumen ( $\geq 1\text{mm ID x}$<br>$\leq 990\text{mm L}$ ) |
|                        | Half Size 8"           | JJ230 | JJ231 |       |   |
|                        | Half Size 10"          | JJ240 | JJ241 |       |   |
| STERRAD 100NX Standard | Full Size 4"           | JJ110 | JJ111 | JJ410 | 21.4  |
|                        | 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  |
|                        | 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  |
|                        | 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  |
|                        | Full Size 6"           | JJ120 | JJ121 |       |   |
|                        | Three-Quarter Size 4"  | JJ310 | JJ311 | JJ430 | 10.7  |



|   |                        |       |       |       |      |
|---|------------------------|-------|-------|-------|------|
|   | Three-Quarter Size 6"  | JJ320 | JJ321 | JJ420 | 10.7 |
|   | Three-Quarter Size 8"  | JJ330 | JJ331 |       |      |
|   | Half Size 4"           | JJ210 | JJ211 |       |      |
|   | 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 |
|   | 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 |
|   | 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 | JJ420 | 6.0  |
|   | Half Size 4"           | JJ210 | JJ211 |       |      |
|   | 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 |
|   | 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 | JJ420 | 10.7 |
|   | Half Size 4"           | JJ210 | JJ211 |       |      |
|   | Half Size 6"           | JJ220 | JJ221 |       |      |
|   | Half Size 8"           | JJ230 | JJ231 |       |      |
|   | Half Size 10"          | JJ240 | JJ241 |       |      |
| Prevac Steam<br>270°F, 4 min exposure<br><br><b>With</b> silicone mat and lid cover*<br>30 minute dry time<br><br><b>Without</b> silicone mat and lid<br>cover* | Full Size 4"           | JJ110 | JJ111 | JJ410 | 25   |
|   | 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   |

|   |                        |       |       |       |  |
|---|------------------------|-------|-------|-------|--|
| 20 minute dry time  | Three-Quarter Size 8"  | JJ330 | JJ331 | JJ420 | 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 |       | 15   |
|   | Half Size 10"          | JJ240 | JJ241 |       | 13   |
| PreVac Steam without dry time<br>270°F<br>3 min Exposure<br>(Non-porous)<br><br>AND<br>Prevac Steam without dry time<br>270°F<br>4 min Exposure<br>(Porous)<br><br>Prevac cycles without dry times<br>are Immediate Use Sterilization<br>Cycles (IUSS). | Full Size 4"           | JJ110 | JJ111 | JJ410 | 25   |
|   | Full Size 6"           | JJ120 | JJ121 |       |  |
|   | Full Size 8"           | JJ130 | JJ131 |       |  |
|   | Full Size 10"          | JJ140 | JJ141 | JJ430 | 25   |
|   | Three-Quarter Size 4"  | JJ310 | JJ311 |       |  |
|   | Three-Quarter Size 6"  | JJ320 | JJ321 |       |  |
|   | Three-Quarter Size 8"  | JJ330 | JJ331 | JJ420 | 25   |
|   | Three-Quarter Size 10" | JJ340 | JJ341 |       |  |
|   | Half Size 4"           | JJ210 | JJ211 |       |  |
|   | Half Size 6"           | JJ220 | JJ221 | JJ420 | 25   |
|   | Half Size 8"           | JJ230 | JJ231 |       |  |
|   | Half Size 10"          | JJ240 | JJ241 |       |  |
| STERIZONE VP4<br>Based on Sterizone Validated<br>Load 8<br><br>(Aicon Validated Load 1)   | Full Size 4"           | JJ110 | JJ111 | JJ410 | Based on Load Configuration<br>in Table 1<br><br>13.8lbs |
|   | Full Size 6"           | JJ120 | JJ121 |       |  |
|   | Full Size 8"           | JJ130 | JJ131 |       |  |
|   | Three-Quarter Size 4"  | JJ310 | JJ311 | JJ430 | Based on Load Configuration<br>in Table 1<br><br>13.8lbs |
|   | Three-Quarter Size 6"  | JJ320 | JJ321 |       |  |
|   | Three-Quarter Size 8"  | JJ330 | JJ331 |       |  |
|   | Three-Quarter Size 10" | JJ340 | JJ341 | JJ420 | Based on Load Configuration<br>in Table 1<br><br>5.8lbs  |
|   | Half Size 4"           | JJ210 | JJ211 |       |  |
|   | Half Size 6"           | JJ220 | JJ221 |       |  |
|   | Half Size 8"           | JJ230 | JJ231 |       |  |
| Half Size 10"   | JJ240                  | JJ241 |       |       |  |
| STERIZONE VP4<br>Based on Sterizone Validated<br>Load 4<br><br>(Aicon Validated Load 2)   | Full Size 4"           | JJ110 | JJ111 | JJ410 | Based on Load Configuration<br>in Table 1<br><br>11.7lbs |
|   | Full Size 6"           | JJ120 | JJ121 |       |  |
|   | Full Size 8"           | JJ130 | JJ131 |       |  |
|   | Three-Quarter Size 4"  | JJ310 | JJ311 | JJ430 | Based on Load Configuration<br>in Table 1<br><br>11.7lbs |
|   | Three-Quarter Size 6"  | JJ320 | JJ321 |       |  |
|   | Three-Quarter Size 8"  | JJ330 | JJ331 |       |  |
|   | Three-Quarter Size 10" | JJ340 | JJ341 | JJ420 | Based on Load Configuration<br>in Table 1<br><br>5.8lbs  |
|   | Half Size 4"           | JJ210 | JJ211 |       |  |
|   | Half Size 6"           | JJ220 | JJ221 |       |  |
|   | Half Size 8"           | JJ230 | JJ231 |       |  |
| Half Size 10"   | JJ240                  | JJ241 |       |       |  |
| STERIZONE VP4<br>Based on Sterizone Validated<br>Load 7<br><br>(Aicon Validated Load 3)   | Full Size 4"           | JJ110 | JJ111 | JJ410 | 25   |
|   | 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 | JJ420 | 25   |
|   | Half Size 4"           | JJ210 | JJ211 |       |  |
|   | Half Size 6"           | JJ220 | JJ221 |       |  |
|   | Half Size 8"           | JJ230 | JJ231 |       |  |
| Half Size 10"   | JJ240                  | JJ241 |       |       |  |

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

**CONTACT:** Tim Stoudt tim.stoudt@bbraunusa.com  
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610-791-6882 (fax)

**TRADE NAME:** Aesculap Aicon™ 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:** KCT

**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 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
- 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 enhanced drying system (EDS) container.

The following tables identify the load configurations.

Table 1. AESCULAP Aicon™ Container Lumen Configurations

| <b>Sterilization Cycle</b>   | <b>Container Sizes</b> | <b>Compatible Lumens</b>  |
|--|------------------------|---|
| Ethylene Oxide (EtO)<br>(130°F, 60 minute exposure<br>50-70% RH, concentration<br>735mg/L) | Full Size              | (2) Stainless Steel Lumens ( $\geq 3.0\text{mm ID} \times \leq 400\text{mm L}$ )  |
|  | Three-Quarter Size     | (2) Stainless Steel Lumens ( $\geq 3.0\text{mm ID} \times \leq 400\text{mm L}$ )  |
|  | Half Size              | (2) Stainless Steel Lumens ( $\geq 3.0\text{mm ID} \times \leq 400\text{mm L}$ )  |
| STERIS V-PRO maX /maX 2<br>Lumen Cycle   | Full Size              | (6) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 400\text{mm L}$ )<br>(6) Stainless Steel Lumens ( $\geq 0.77\text{mm ID} \times \leq 250\text{mm L}$ )   |
|  | Three-Quarter Size     | (6) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 400\text{mm L}$ )<br>(6) Stainless Steel Lumens ( $\geq 0.77\text{mm ID} \times \leq 250\text{mm L}$ )   |
|  | Half Size              | (12) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 150\text{mm L}$ )   |
| STERIS V-PRO Max/ Max 2<br>Non-Lumen Cycle   | 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<br>Flex Cycle   | 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 $\geq 1\text{mm ID} \times \leq 1050\text{mm L}$  |
|  | 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 $\geq 1\text{mm ID} \times \leq 1050\text{mm L}$  |
|  | 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 $\geq 1\text{mm ID} \times \leq 1050\text{mm L}$ 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 $\leq 850\text{mm L}$<br>OR<br>(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 $\geq 1$ mm 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 Cycle                         | Full Size          | (6) Stainless Steel Lumens ( $\geq 1$ mm ID x $\leq 400$ mm L)<br>(6) Stainless Steel Lumens ( $\geq 0.77$ mm ID x $\leq 250$ mm L)  |
|  | Three-Quarter Size | (6) Stainless Steel Lumens ( $\geq 1$ mm ID x $\leq 400$ mm L)<br>(6) Stainless Steel Lumens ( $\geq 0.77$ mm ID x $\leq 250$ mm L)  |
|  | Half Size          | (12) Stainless Steel Lumens ( $\geq 1$ mm ID x $\leq 150$ mm L)  |
| STERIS VPRO 60 Non-Lumen Cycle                     | 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                          | Full Size          | (1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen ( $\geq 1$ mm ID x $\leq 990$ mm L)  |
|  | Three-Quarter Size | (1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen ( $\geq 1$ mm ID x $\leq 990$ 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 ( $\geq 1$ mm ID x $\leq 990$ mm L)   |
| STERRAD 100NX Standard Cycle                       | Full Size          | (5) Stainless-Steel Lumens ( $\geq 1.0$ mm ID x $\leq 500$ mm L)<br>(5) Stainless-Steel Lumens ( $\geq 0.7$ mm ID x $\leq 400$ mm L)   |
|  | Three-Quarter Size | (5) Stainless-Steel Lumens ( $\geq 1.0$ mm ID x $\leq 500$ mm L)<br>(5) Stainless-Steel Lumens ( $\geq 0.7$ mm ID x $\leq 400$ mm L)   |
|  | Half Size          | (5) Stainless-Steel Lumens ( $\geq 0.7$ mm ID x $\leq 250$ mm L)<br>(5) Stainless-Steel Lumens ( $\geq 0.7$ mm ID x $\leq 200$ mm L)   |
| STERRAD 100S                                       | Full Size          | (5) Stainless Steel Lumens ( $\geq 3.0$ mm I.D. x $\leq 400$ mm L)   |
|  | Three-Quarter Size | (5) Stainless Steel Lumens ( $\geq 3.0$ mm I.D. x $\leq 400$ mm L)   |
|  | Half Size          | (5) Stainless Steel Lumens ( $\geq 2.0$ mm ID x $\leq 250$ mm L)   |
| STERRAD NX Standard Cycle                          | Full Size          | (10)Stainless-steel lumens ( $\geq 2.5$ mm ID x $\leq 400$ mm L)   |
|  | Three-Quarter Size | (10)Stainless-steel lumens ( $\geq 2.5$ mm ID x $\leq 400$ mm L)   |
|  | Half Size          | (10) Stainless-steel lumens ( $\geq 2$ mm ID x $\leq 200$ mm L)  |
| STERRAD NX Advanced Cycle                          | Full Size          | (5) Stainless-steel lumens ( $\geq 2.5$ mm ID x $\leq 500$ mm L)<br>(5) Flexible Lumens ( $\geq 1$ mm ID x $\leq 850$ mm L)  |
|  | Three-Quarter Size | (5) Stainless-steel lumen ( $\geq 2.5$ mm ID x $\leq 500$ mm L)<br>(5) Flexible Lumens ( $\geq 1$ mm ID x $\leq 850$ mm L)   |
|  | Half Size          | (10) Stainless-steel lumens ( $\geq 2$ mm ID x $\leq 200$ mm L)  |
| STERRAD 100NX Express Cycle                        | Full Size          | Non lumened stainless steel instruments  |
|  | Three-Quarter Size | Non lumened stainless steel instruments  |
|  | Half Size          | Non lumened stainless steel instruments  |
| STERRAD 100NX DUO Cycle                            | Full Size          | (1) Flexible Lumen ( $\geq 1$ mm ID x $\leq 850$ mm L)   |
|  | Three-Quarter Size | (1) Flexible Lumen ( $\geq 1$ mm ID x $\leq 850$ mm L)   |
|  | Half Size          | (1) Flexible Lumen ( $\geq 1.0$ mm ID x $\leq 650$ mm L)   |
| STERRAD 100NX Flex Cycle                           | Full Size          | (1) Flexible Lumen( $\geq 1.5$ mm ID x $\leq 650$ mm L)  |
|  | Three-Quarter Size | (1) Flexible Lumen ( $\geq 1.5$ mm ID x $\leq 650$ mm L)   |
|  | Half Size          | (1) Flexible lumen ( $\geq 1.0$ mm ID x $\leq 650$ mm L)   |
| PreVac Steam with dry time (270°F, 4 min Exposure) | Full Size          | (4) Stainless Steel Lumens ( $\geq 1.0$ mm ID x $\leq 200$ mm L)   |
|  | Three-Quarter      | (4) Stainless Steel Lumens ( $\geq 1.0$ mm ID x $\leq 200$ mm L)   |
|  | Half Size          | (4) Stainless Steel Lumens ( $\geq 1.0$ mm ID x $\leq 200$ mm L)   |

|   |                    |  |
|---|--------------------|--|
| PreVac Steam without dry time (270°F, 4 min Exposure) Porous<br><br>Prevac cycles without dry time are Immediate Use Sterilization Cycles (IUSS).     | Full Size          | (4) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 125\text{ mm L}$ )  |
|   | Three-Quarter Size | (4) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 125\text{ mm L}$ )  |
|   | Half Size          | (4) Stainless Steel Lumens ( $\geq 1\text{mm ID} \times \leq 125\text{ mm L}$ )  |
| Prevac Steam without dry time (270°F, 3 min Exposure) Non-Porous<br><br>Prevac cycles without dry time are Immediate Use Sterilization Cycles (IUSS). | Full Size          | Non-lumened instruments  |
|   | Three-Quarter Size | Non-lumened instruments  |
|   | Half Size          | Non-lumened instruments  |
| STERIZONE VP4 Load 8<br><br>(Aicon Validated Load 1)  | Full Size          | (1) Dual channel flexible scope ( $\geq 1.5\text{mm ID} \times \leq 850\text{mm L}$ ) and ( $\geq 1.5\text{mm ID} \times \leq 989\text{mm L}$ )<br>(1) Single channel flexible scope ( $\geq 1.5\text{mm ID} \times \leq 850\text{mm L}$ )   |
|   | Three-Quarter Size | (1) Dual channel flexible scope ( $\geq 1.5\text{mm ID} \times \leq 850\text{mm L}$ ) and ( $\geq 1.5\text{mm ID} \times \leq 989\text{mm L}$ )<br>(1) Single channel flexible scope ( $\geq 1.5\text{mm ID} \times \leq 850\text{mm L}$ )   |
|   | Half Size          | (1) Dual channel flexible scope ( $\geq 1.5\text{mm ID} \times \leq 850\text{mm L}$ ) and ( $\geq 1.5\text{mm ID} \times \leq 989\text{mm L}$ )<br>(1) Single channel flexible scope ( $\geq 1.5\text{mm ID} \times \leq 850\text{mm L}$ )   |
| STERIZONE VP4 Load 4<br><br>(Aicon Validated Load 2)  | Full Size          | (1) Dual channel semi rigid scope ( $\geq 0.7\text{mm ID} \times 500\text{mm L}$ ; $\geq 1.1\text{mm ID} \times \leq 500\text{mm L}$ )<br>(1) Dual channel semi rigid scope ( $\geq 1.1\text{ mm ID} \times 500\text{mm L}$ ; $\geq 1.1\text{ mm ID} \times \leq 500\text{mm L}$ )<br>(2) Stainless Steel Lumens ( $\geq 2\text{mm ID} \times \leq 250\text{mm L}$ )<br>(2) Stainless Steel Lumens ( $\geq 3\text{mm ID} \times \leq 400\text{mm L}$ ) |
|   | Three-Quarter Size | (1) Dual channel semi rigid scope ( $\geq 0.7\text{mm ID} \times 500\text{mm L}$ ; $\geq 1.1\text{mm ID} \times \leq 500\text{mm L}$ )<br>(1) Dual channel semi rigid scope ( $\geq 1.1\text{ mm ID} \times 500\text{mm L}$ ; $\geq 1.1\text{ mm ID} \times \leq 500\text{mm L}$ )<br>(2) Stainless Steel Lumens ( $\geq 2\text{mm ID} \times \leq 250\text{mm L}$ )<br>(2) Stainless Steel Lumens ( $\geq 3\text{mm ID} \times \leq 400\text{mm L}$ ) |
|   | Half Size          | (1) Stainless Steel Lumen ( $\geq 0.7\text{ mm ID} \times \leq 300\text{mm L}$ )<br>(1) Stainless Steel Lumen ( $\geq 1.0\text{ mm ID} \times \leq 300\text{mm L}$ )<br>(2) Stainless Steel Lumens ( $\geq 2.0\text{ mm ID} \times \leq 250\text{mm L}$ )<br>(2) Stainless Steel Lumens ( $\geq 3.0\text{ mm ID} \times \leq 300\text{mm L}$ )   |
| STERIZONE VP4 Load 7<br><br>(Aicon Validated Load 3)  | 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) |
|--|------------------------|--------------------|---------------|----------------------|------------------------------|
| EtO<br>(130°F, 60 minute exposure<br>50-70% RH, concentration 735mg/L) | Full Size 4"           | JJ110              | JJ111         | JJ410                | 25                           |
|  | 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         |                      |                              |
|  | Full Size 4"           | JJ110              | JJ111         |                      |                              |

|                                      |                        |       |       |       |   |
|--------------------------------------|------------------------|-------|-------|-------|---|
| STERIS VPRO<br>maX/ maX 2 Lumen      | Full Size 6"           | JJ120 | JJ121 | JJ410 | 19.65   |
|                                      | 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<br>maX / maX 2 Non-Lumen | Full Size 4"           | JJ110 | JJ111 | JJ410 | 25  |
|                                      | 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 | 18.7  |
|                                      | Half Size 6"           | JJ220 | JJ221 |       |   |
|                                      | Half Size 8"           | JJ230 | JJ231 |       |   |
|                                      | Half Size 10"          | JJ240 | JJ241 |       |   |
| STERIS VPRO<br>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 $\geq 1\text{mm ID}$ x $\leq 1050\text{mm L}$ |
|                                      | 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 $\geq 1\text{mm ID}$ x $\leq 1050\text{mm L}$ |
|                                      | 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   |



|                          |                        |       |       |       |   |
|--------------------------|------------------------|-------|-------|-------|---|
|                          | Half Size 6"           | JJ220 | JJ221 |       | flexible endoscope may be single lumen that is $\geq 1$ mm ID x $\leq 1050$ mm L or two lumens with one $\geq 1$ mm ID and $\leq 990$ mm L and the other $\geq 1$ mm ID and $\leq 850$ mm L<br>OR<br>(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 $\geq 1$ mm 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 |
|                          | Half Size 8"           | JJ230 | JJ231 |       |   |
|                          | Half Size 10"          | JJ240 | JJ241 |       |   |
| STERIS VPRO 60 Lumen     | Full Size 4"           | JJ110 | JJ111 | JJ410 | 11  |
|                          | 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  |
|                          | 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 |       |       |   |
|                          | Full Size 4"           | JJ110 | JJ111 |       |   |

|                        |                        |       |       |       |  |
|------------------------|------------------------|-------|-------|-------|--|
| STERIS VPRO 60 Flex    | Full Size 6"           | JJ120 | JJ121 | JJ410 | (1) flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and single lumen ( $\geq 1$ mm ID x $\leq 990$ mm L ) |
|                        | 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 ( $\geq 1$ mm ID x $\leq 990$ mm 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 ( $\geq 1$ mm ID x $\leq 990$ mm L ) |
|                        | 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   |
|                        | 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 |
|                       | 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 |
|                       | 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 |
|                       | 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 |
|                       | 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 |       |      |
|                       | Half Size 6"           | JJ220 | JJ221 |       |      |

|  |  |              |       |       |       |    |
|--|--|--------------|-------|-------|-------|----|
|  | Half Size 8"   | JJ230        | JJ231 | JJ420 | 10.7  |    |
|  | Half Size 10"  | JJ240        | JJ241 |       |       |    |
| STERRAD 100NX DUO  | Full Size 4"   | JJ110        | JJ111 | JJ410 | 13.2  |    |
|  | 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  |    |
|  | 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<br>270°F, 4 min exposure<br><br><b>With</b> silicone mat and lid cover*<br>30 minute dry time<br><br><b>Without</b> silicone mat and lid cover*<br>20 minute dry time | Full Size 4"   | JJ110        | JJ111 | JJ410 | 25    |    |
|  | 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    |    |
|  | Pre Vac Steam without dry time<br>270°F<br>3 min Exposure<br>(Non-porous)<br><br>AND | Full Size 4" | JJ110 | JJ111 | JJ410 | 25 |
|  |  | 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 |       |       |    |

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

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.

| <b>Characteristic</b>             | <b>Subject Device - Aesculap Aicon Container (JJ Series) (K214041)<br/>Product Code: KCT</b>   | <b>Primary Predicate Device - Aesculap JJ Series Container System (K192056)<br/>Product Code: KCT</b>   | <b>Reference Device– Aesculap SterilContainer S2 System (K193582)<br/>Product Code: KCT</b>   | <b>Reference Device– Aesculap SterilContainer S2 System (K182414 )<br/>Product Code: KCT</b>  | <b>Discussion</b> |
|-----------------------------------|--|---|---|---|-------------------|
| <b>Intended Use</b>               | 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. | 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              |
| <b>Sterilization Modalities</b>   | <ul style="list-style-type: none"> <li>• PreVac Steam with dry time</li> <li>• PreVac Steam without dry time</li> <li>• Ethylene Oxide</li> <li>• STERIS VPRO maX/maX 2: Lumen, Non-Lumen, Flex,</li> <li>• STERIS VPRO 60: Lumen, Non- Lumen, Flex</li> <li>• STERRAD: 100S, NX Standard, NX Advanced, 100NX Standard, 100NX Flex, 100 NX Express, 100NX Duo</li> </ul> | <ul style="list-style-type: none"> <li>• PreVac Steam with dry time</li> <li>• Prevac Steam without dry time</li> </ul>   | <ul style="list-style-type: none"> <li>• EtO</li> <li>• STERIZONE VP4</li> <li>• STERRAD 100NX DUO</li> </ul>   | <ul style="list-style-type: none"> <li>• Prevac Steam</li> <li>• Gravity Steam</li> <li>• STERIS VPRO maX: Lumen, Non-Lumen, Flex</li> <li>• STERIS VPRO 60: Lumen, Non-Lumen, Flex</li> <li>• STERRAD: 100S, NX Standard, NX Advanced, 100NX Standard, 100NX Flex</li> </ul> | Similar           |
| <b>Material</b>                   | Container: Anodized aluminum<br>Lid: Anodized aluminum<br>Gasket: Silicone   | Container: Anodized aluminum<br>Lid: Anodized aluminum<br>Gasket: Silicone  | Container: Anodized aluminum<br>Lid: Anodized aluminum<br>Gasket: Silicone  | Container: Anodized aluminum<br>Lid: Anodized aluminum<br>Gasket: Silicone  | Same              |
| <b>Filter Type &amp; Material</b> | Single use (Polypropylene)   | Single use (Paper)  | Single use (Paper or polypropylene)   | Single use (Paper or polypropylene)<br>Reusable (PTFE)  | Similar           |
| <b>Container Design</b>           | Solid bottom or Solid bottom with enhanced drying system with  | Solid bottom or Solid bottom with enhanced drying system with   | Perforated bottom with perforated lid   | Perforated bottom with perforated lid   | Similar           |

|                                 |  |  |  |  |         |
|---------------------------------|--|--|--|--|---------|
|                                 | Perforated Lid   | Perforated Lid   |  |  |         |
| <b>Vent to volume ratios</b>    | 0.04mm <sup>-1</sup> * 10 <sup>-3</sup><br>to<br>0.26mm <sup>-1</sup> * 10 <sup>-3</sup> | 0.04mm <sup>-1</sup> * 10 <sup>-3</sup><br>to<br>0.26mm <sup>-1</sup> * 10 <sup>-3</sup> | 0.50mm <sup>-1</sup> * 10 <sup>-3</sup><br>to<br>3.43mm <sup>-1</sup> * 10 <sup>-3</sup> | 0.50mm <sup>-1</sup> * 10 <sup>-3</sup><br>to<br>3.43mm <sup>-1</sup> * 10 <sup>-3</sup> | Similar |
| <b>Maintenance of sterility</b> | 365 days   | 365 days   | 360 days   | 360 days   | Similar |

### **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.

| <b>Performance Testing</b>  | <b>Purpose</b>   | <b>Acceptance Criteria</b>   | <b>Results</b> |
|-----------------------------|--|--|----------------|
| Sterilization Efficacy      | To determine sterilization effectiveness of test device after processing in a sterilization cycle.       | A sterility assurance level (SAL) of 10 <sup>-6</sup> 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 x 10 <sup>6</sup> 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.