



June 20, 2018

Paragon Medical
% Dave Yungvirt
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K173615

Trade/Device Name: Stryker Universal Select Sterilization Tray System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 5, 2018
Received: April 9, 2018

Dear Dave Yungvirt:

This letter corrects our substantially equivalent letter of April 18, 2018.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known)

K173615

Device Name

Stryker Universal Select Sterilization Tray System

Indications for Use (Describe)

The Stryker Universal Select Sterilization Tray System is intended to organize, enclose, sterilize, transport and store Stryker implantable devices and surgical instruments within a healthcare facility when used in conjunction with a validated, FDA cleared rigid sterilization container in order to maintain sterility of the enclosed devices. The Stryker Universal Select Sterilization Tray System has been validated for use in the following sterilization cycles:

| | Pre-vacuum Steam | |
|--------------------|------------------------------|------------------------------|
| Enclosure | Rigid Container ¹ | Rigid Container ¹ |
| Temperature | 132°C (270°F) | 135°C (275°F) |
| Sterilization Time | 4 minutes | 3 minutes |
| Minimum Dry Time | 30 minutes | 30 minutes |
| Maximum Weight | 25 lbs / 11.36 kg | 25 lbs / 11.36 kg |

¹ Tray System has been validated in the following Aesculap SterilContainer cleared for pre-vacuum steam sterilization under K792558: Full DIN JK444 (base) and JK489 (lid) and ½ DIN JK346 (base) and JK389 (lid).

The maximum validated product loads for the trays in containers are as follows:

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Indications for Use

510(k) Number (if known)

K173615

Device Name

Stryker Universal Select Sterilization Tray System

Indications for Use (Describe)

| Configuration ¹ | Maximum Validated Load Set Contents ^{2,5} |
|---|---|
| 3-Level Rack – Qty. 2 (29-13910) in a Full DIN Rigid Sterilization Container ³ | 29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941) |
| | 29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941) |
| | 29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941) |
| | 29-17901 1.7 Mid-Face Plates Module with Lid (29-13941) |
| | 29-17903 1.7 Orthognathic Plates Inlay |
| | 29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921) |
| | 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) |
| | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) |
| | 29-23901 2.0/2.3 Mandible Plates Module with Lid (29-13941) |
| | 29-23905 2.0/2.3 Mini Plates Inlay, Large |
| 3-Level Rack – Qty. 1 (29-13910) in a ½ DIN Rigid Sterilization Container ⁴ | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) |
| | 29-23903 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941) |
| | 29-23904 2.0/2.3 Mandible Recon Primary Plates Inlay |
| | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) |
| | 29-13905 Trocar Instrument Tray with Lid (29-13921) |
| | 29-13906 Mandible Reconstruction Instrument Tray with Lid (29-13921) |
| | 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) |

¹ Model numbers shown in table are Stryker® model numbers

² Contents in the validated Tray System included: Single-use implants (plates, meshes, bone screws, etc.), single-use instruments (drills), and reusable surgical instruments (benders, forceps, handles, depth gauges, trocars, etc.)

³ Tray system components part of the worst-case configuration in a full DIN Rigid Sterilization Container validation in an Aesculap SterilContainer Base (JK446) and Lid (JK489) cleared under K792558

⁴ Tray system components part of the worst-case configuration in a 1/2 DIN Rigid Sterilization Container validation in an Aesculap SterilContainer Base (JK346) and Lid (JK389) cleared under K792558

⁵ No lumened devices were validated within the tray system as part of the product load. The Stryker Universal Select Sterilization Tray System does not have any lumen claims.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”



510(k) Summary for Stryker Universal Select Sterilization Tray System

In accordance with 21 CFR 807.92, the following 510(k) summary is provided:

- 1. Applicant Information:**

Paragon Medical
8 Matchett Drive
Pierceton, IN 46562 USA
Phone: 574-594-2140
Fax: 574-594-2154
- 2. Correspondent Contact Information:**

Rebecca Walker
Regulatory Affairs Manager
Rebecca.walker@paragonmedical.com
Phone: 574-594-2140 ext. 10384
- 3. Date Prepared:** April 16, 2018
- 4. Trade Name:** Stryker Universal Select Sterilization Tray System
- 5. Common Name:** Sterilization Tray
- 6. Classification Name:** Sterilization wrap (21 CFR 880.6850, Product Code KCT)
- 7. Predicate Device:** The Stryker Universal Select Sterilization Tray System is substantially equivalent to the following 510(k) cleared device:
 - Medtronic Transportation/Sterilization Cassettes, K163279
- 8. Device Description:** The Stryker Universal Select Sterilization Tray System consists of anodized aluminum implant modules and inlays to store single-use titanium implants and stainless steel instrument and accessory trays for surgical instrumentation. The implant modules and trays have stainless steel lids which have a slide latch feature. Instrument trays are specific to a set configuration and have stainless steel and silicone brackets, removable screw caddy (for the 90° screwdriver instrument tray), and silkscreened artwork to assist the end user in correct placement of the instruments. Accessory trays are not specific to a set configuration, and have an open area designed for placement of commonly used instruments such as cutters, benders and forceps. The individual components of the system can be organized and stored in a 2-level or a 3-level stainless steel rack. The rack is designed to fit in an Aesculap rigid sterilization container (K792558). The tray system is reusable and provided in a non-sterile condition.



9. Indications for Use: The Stryker Universal Select Sterilization Tray System is intended to organize, enclose, sterilize, transport and store Stryker implantable devices and surgical instruments within a healthcare facility when used in conjunction with a validated, FDA cleared rigid sterilization container in order to maintain sterility of the enclosed devices. The Stryker Universal Select Sterilization Tray System has been validated for use in the following sterilization cycles:

| | Pre-Vacuum Steam | |
|-----------------------------|------------------------------|------------------------------|
| Enclosure | Rigid Container ² | Rigid Container ² |
| Temperature | 132°C (270°F) | 135°C (275°F) |
| Sterilization Time | 4 minutes | 3 minutes |
| Minimum Dry Time | 30 minutes | 30 minutes |
| Maximum Weight ¹ | 25 lbs / 11.36 kgs | 25 lbs / 11.36 kgs |

¹ Tray System has been validated in the following Aesculap SterilContainer cleared for pre-vacuum steam sterilization under K792558: Full DIN JK444 (base) and JK489 (lid) and ½ DIN JK346 (base) and JK389 (lid)

The maximum validated product loads for the trays in containers are as follows:

| Configuration ¹ | Maximum Validated Load Set Contents ^{2,5} |
|---|--|
| 3-Level Rack – Qty. 2 (29-13910) in a Full DIN Rigid Sterilization Container ³ | 29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941) 29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941) 29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941) 29-17901 1.7 Mid-Face Plates Module with Lid (29-13941) 29-17903 1.7 Orthognathic Plates Inlay 29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921) 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) 29-23901 2.0/2.3 Mandible Plates Module with Lid (29-13941) 29-23905 2.0/2.3 Mini Plates Inlay, Large 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) 29-13905 Trocar Instrument Tray with Lid (29-13921) |
| 3-Level Rack – Qty. 1 (29-13910) in a ½ DIN Rigid Sterilization Container ⁴ | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) 29-23903 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941) 29-23904 2.0/2.3 Mandible Recon Primary Plates Inlay 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) 29-13905 Trocar Instrument Tray with Lid (29-13921) 29-13906 Mandible Reconstruction Instrument Tray with Lid (29-13921) 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) |

¹ Model numbers shown in table are Stryker® model numbers

² Contents in the validated Tray System included: Single-use implants (plates, meshes, bone screws, etc.), single-use instruments (drills), and reusable surgical instruments (benders, forceps, handles, depth gauges, trocars, etc.)

³ Tray system components part of the worst-case configuration in a full DIN Rigid Sterilization Container validation in an Aesculap SterilContainer Base (JK446) and Lid (JK489) cleared under K792558

⁴ Tray system components part of the worst-case configuration in a 1/2 DIN Rigid Sterilization Container validation in an Aesculap SterilContainer Base (JK346) and Lid (JK389) cleared under K792558

⁵ No lumened devices were validated within the tray system as part of the product load. The Stryker Universal Select Sterilization Tray System does have any lumen claims.



10. Technological Comparison: A detailed comparison of the subject device to the predicate device demonstrates the similarities and differences in intended use, design, principles of operation, and materials of composition. The following pages contain a comparison of the technological (Table 1) and performance (Table 2) characteristics of the subject and predicate device.

Table 1: Comparison of Technological Characteristics

| | Predicate Device | Subject Device |
|----------------------|--|--|
| Device Name | Medtronic Transportation/Sterilization Cassettes | Stryker Universal Select Sterilization Tray System |
| 510(k) Number | K163279 | K173615 |
| Product Code | KCT | KCT |



**Indications
for Use**

The Medtronic Transportation/Sterilization Cassettes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The Medtronic Transportation/Sterilization Cassettes are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap. Sterilization validations for the worst case Medtronic Transportation/Sterilization Cassette (22.75 x 11.26 x 5.5 inches) included implants and common surgical instruments such as rasps, drivers, trials, handles, inserters, probes, drills, etc. The validated total weight was 28.4lbs. The validated worst case loading configurations of the Medtronic Transportation/Sterilization Cassette included the following worst case lumen dimensions:

- 363 x 1.575 mm
- 247.5 x 4.1 mm

| Cycle | Temp. | Exposure Time (min) | Dry Time (min) |
|------------|--------|---------------------|----------------|
| Gravity | 121°C | 30 | 30 |
| Gravity | 132 °C | 15 | 30 |
| Gravity | 135 °C | 10 | 30 |
| Pre-vacuum | 132 °C | 4 | 30 |
| Pre-vacuum | 135 °C | 3 | 30 |

The Stryker Universal Select Sterilization Tray System is intended to organize, enclose, sterilize, transport and store Stryker implantable devices and surgical instruments within a healthcare facility when used in conjunction with a validated, FDA cleared rigid sterilization container in order to maintain sterility of the enclosed devices.

The Stryker Universal Select Sterilization Tray System has been validated for use in the following sterilization cycles:

| | Pre-vacuum Steam Cycles | |
|--------------------|------------------------------|------------------------------|
| Enclosure | Rigid Container ¹ | Rigid Container ¹ |
| Temperature | 132°C (270°F) | 135°C (275°F) |
| Sterilization Time | 4 minutes | 3 minutes |
| Minimum Dry Time | 30 minutes | 30 minutes |
| Maximum Weight | 25 lbs / 11.36 kg | 25 lbs / 11.36 kg |

¹Tray System has been validated in the following Aesculap SterilContainer cleared for pre-vacuum steam sterilization under K792558: Full DIN JK444 (base) and JK489 (lid) and ½ DIN JK346 (base) and JK389 (lid).



| Indications for Use (continued) | | <p>The maximum validated product loads for the tray system in containers are as follows:</p> <table border="1"> <thead> <tr> <th style="text-align: center;">Configuration¹</th> <th style="text-align: center;">Maximum Validated Load Set Contents^{2,5}</th> </tr> </thead> <tbody> <tr> <td rowspan="10"> 3-Level Rack – Qty. 2 (29-13910) in a Full DIN Rigid Sterilization Container³ </td> <td>29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941)</td> </tr> <tr> <td>29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941)</td> </tr> <tr> <td>29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941)</td> </tr> <tr> <td>29-17901 1.7 Mid-Face Plates Module with Lid (29-13941)</td> </tr> <tr> <td>29-17903 1.7 Orthognathic Plates Inlay</td> </tr> <tr> <td>29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921)</td> </tr> <tr> <td>29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941)</td> </tr> <tr> <td>29-23901 2.0/2.3 Mandible Plates Module with Lid (29-13941)</td> </tr> <tr> <td>29-23905 2.0/2.3 Mini Plates Inlay, Large</td> </tr> <tr> <td rowspan="7"> 3-Level Rack – Qty. 1 (29-13910) in a ½ DIN Rigid Sterilization Container⁴ </td> <td>29-13904 Mandible Fracture Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13905 Trocar Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941)</td> </tr> <tr> <td>29-23903 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941)</td> </tr> <tr> <td>29-23904 2.0/2.3 Mandible Recon Primary Plates Inlay</td> </tr> <tr> <td>29-13904 Mandible Fracture Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13905 Trocar Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13906 Mandible Reconstruction Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921)</td> </tr> </tbody> </table> | Configuration ¹ | Maximum Validated Load Set Contents ^{2,5} | 3-Level Rack – Qty. 2 (29-13910) in a Full DIN Rigid Sterilization Container³ | 29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941) | 29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941) | 29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941) | 29-17901 1.7 Mid-Face Plates Module with Lid (29-13941) | 29-17903 1.7 Orthognathic Plates Inlay | 29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921) | 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) | 29-23901 2.0/2.3 Mandible Plates Module with Lid (29-13941) | 29-23905 2.0/2.3 Mini Plates Inlay, Large | 3-Level Rack – Qty. 1 (29-13910) in a ½ DIN Rigid Sterilization Container⁴ | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) | 29-13905 Trocar Instrument Tray with Lid (29-13921) | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) | 29-23903 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941) | 29-23904 2.0/2.3 Mandible Recon Primary Plates Inlay | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) | 29-13905 Trocar Instrument Tray with Lid (29-13921) | 29-13906 Mandible Reconstruction Instrument Tray with Lid (29-13921) | 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) |
|--|--|--|----------------------------|--|---|---|--|---|--|---|---|---|--|--|--|--|---|--|--|--|---|---|--|---|---|
| | Configuration ¹ | Maximum Validated Load Set Contents ^{2,5} | | | | | | | | | | | | | | | | | | | | | | | |
| | 3-Level Rack – Qty. 2 (29-13910) in a Full DIN Rigid Sterilization Container³ | 29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | |
| 29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-17901 1.7 Mid-Face Plates Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-17903 1.7 Orthognathic Plates Inlay | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-23901 2.0/2.3 Mandible Plates Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-23905 2.0/2.3 Mini Plates Inlay, Large | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3-Level Rack – Qty. 1 (29-13910) in a ½ DIN Rigid Sterilization Container⁴ | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13905 Trocar Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-23903 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-23904 2.0/2.3 Mandible Recon Primary Plates Inlay | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13905 Trocar Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-13906 Mandible Reconstruction Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <p>¹ Model numbers shown in table are Stryker® model numbers</p> <p>² Contents in the validated Tray System included: Single-use implants (plates, meshes, bone screws, etc.), single-use instruments (drills), and reusable surgical instruments (benders, forceps, handles, depth gauges, trocars, etc.)</p> <p>³ Tray system components part of the worst-case configuration in a full DIN Rigid Sterilization Container validation in an Aesculap SterilContainer Base (JK446) and Lid (JK489) cleared under K792558</p> <p>⁴ Tray system components part of the worst-case configuration in a 1/2 DIN Rigid Sterilization Container validation in an Aesculap SterilContainer Base (JK346) and Lid (JK389) cleared under K792558</p> <p>⁵ No lumened devices were validated within the tray system as part of the product load. The Stryker Universal Select Sterilization Tray System does have any lumen claims.</p> | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |



**PARAGON
MEDICAL**

8 Matchett Drive • Pierceton, IN 46562 • 800.225-6975 • Fax: 574.594.2154 • paragonmedical.com

| Design | Base, Lid with a locking latch, Individual Inserts | <p>The Stryker Universal Select Sterilization Tray System platform is designed to be compatible with Stryker implantable devices and surgical instrumentation.</p> <p>Individual components were designed to slide in to 2- and 3-level storage racks. Racks have handles on the side to facilitate carrying. Module and tray lids have sliding latch mechanism to facilitate containment.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--------------|---------------------------|--------------|---------------------------|---------------------------------|---------------------------|-------------------------------------|---------------------------|---------------------------------|---------------------------|--|---------------------------|-----------------------------|---------------------------|--------------------|---------------------------|--------------------------|---------------------------|--------|---------------------------|--------------|---------------------------|-------------|---------------------------|--|---------------------------|--|---------------------------|
| Materials of Construction | Thermoplastic Polymers, Aluminum, Stainless Steel | Stainless Steel, Anodized Aluminum, USP Class VI Silicone, PPSU, Polypropylux | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Configuration and Dimensions | <p>Perforated Bases, Lids, Inserts</p> <p>Case - Triple Generic Outer Base 22.74 x 11.260 x 5.040 inches</p> <p>Lid - Generic Outer Lid 22.75 x 11.260 x 0.470 inches</p> <p>Tray Lid 21 x 10.13 x 0.075 inches</p> <p>Tray 1 20.75 x 9.79 x 1.32 inches</p> <p>Tray 2 21 x 10.13 x 1.69 inches</p> <p>Tray 3 21 x 10.13 x 1.38 inches</p> <p>Large Caddy 9.47 x 6.37 x 1.3 inches</p> <p>Small Caddy 5.85 x 4.725 x 0.095 inches</p> <p>Small Lid 2 x 1.5 x 1.025 inches</p> <p>2 x 1.29 x 0.095 inches</p> | <p>Perforated 2-level and 3-level Racks that house the following tray components:</p> <table border="0"> <tr> <td>2-level Rack</td> <td>9.80 x 9.70 x 5.27 inches</td> </tr> <tr> <td>3-level Rack</td> <td>9.80 x 9.70 x 7.57 inches</td> </tr> <tr> <td>¼ DIN Instrument/Accessory Tray</td> <td>9.31 x 4.09 x 1.54 inches</td> </tr> <tr> <td>¼ DIN Instrument/Accessory Tray Lid</td> <td>9.29 x 4.30 x 0.51 inches</td> </tr> <tr> <td>½ DIN Instrument/Accessory Tray</td> <td>9.31 x 8.55 x 1.54 inches</td> </tr> <tr> <td>½ DIN Instrument/Accessory Tray Lid</td> <td>9.29 x 8.71 x 0.55 inches</td> </tr> <tr> <td>¼ DIN Implant/Screw Modules</td> <td>9.31 x 4.25 x 1.05 inches</td> </tr> <tr> <td>¼ DIN Screw Module</td> <td>9.31 x 4.25 x 1.75 inches</td> </tr> <tr> <td>¼ DIN Implant Module Lid</td> <td>9.33 x 4.23 x 0.44 inches</td> </tr> <tr> <td>Inlay</td> <td>4.34 x 3.85 x 0.53 inches</td> </tr> <tr> <td>Inlay, large</td> <td>8.91 x 3.85 x 0.34 inches</td> </tr> <tr> <td>Drill Caddy</td> <td>3.30 x 1.33 x 1.47 inches</td> </tr> <tr> <td>¼ DIN Instrument/Accessory Tray Silicone Mat</td> <td>8.95 x 3.67 x 0.63 inches</td> </tr> <tr> <td>½ DIN Instrument/Accessory Tray Silicone Mat</td> <td>8.95 x 8.14 x 0.63 inches</td> </tr> </table> | 2-level Rack | 9.80 x 9.70 x 5.27 inches | 3-level Rack | 9.80 x 9.70 x 7.57 inches | ¼ DIN Instrument/Accessory Tray | 9.31 x 4.09 x 1.54 inches | ¼ DIN Instrument/Accessory Tray Lid | 9.29 x 4.30 x 0.51 inches | ½ DIN Instrument/Accessory Tray | 9.31 x 8.55 x 1.54 inches | ½ DIN Instrument/Accessory Tray Lid | 9.29 x 8.71 x 0.55 inches | ¼ DIN Implant/Screw Modules | 9.31 x 4.25 x 1.05 inches | ¼ DIN Screw Module | 9.31 x 4.25 x 1.75 inches | ¼ DIN Implant Module Lid | 9.33 x 4.23 x 0.44 inches | Inlay | 4.34 x 3.85 x 0.53 inches | Inlay, large | 8.91 x 3.85 x 0.34 inches | Drill Caddy | 3.30 x 1.33 x 1.47 inches | ¼ DIN Instrument/Accessory Tray Silicone Mat | 8.95 x 3.67 x 0.63 inches | ½ DIN Instrument/Accessory Tray Silicone Mat | 8.95 x 8.14 x 0.63 inches |
| 2-level Rack | 9.80 x 9.70 x 5.27 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3-level Rack | 9.80 x 9.70 x 7.57 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ¼ DIN Instrument/Accessory Tray | 9.31 x 4.09 x 1.54 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ¼ DIN Instrument/Accessory Tray Lid | 9.29 x 4.30 x 0.51 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ½ DIN Instrument/Accessory Tray | 9.31 x 8.55 x 1.54 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ½ DIN Instrument/Accessory Tray Lid | 9.29 x 8.71 x 0.55 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ¼ DIN Implant/Screw Modules | 9.31 x 4.25 x 1.05 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ¼ DIN Screw Module | 9.31 x 4.25 x 1.75 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ¼ DIN Implant Module Lid | 9.33 x 4.23 x 0.44 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inlay | 4.34 x 3.85 x 0.53 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inlay, large | 8.91 x 3.85 x 0.34 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Drill Caddy | 3.30 x 1.33 x 1.47 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ¼ DIN Instrument/Accessory Tray Silicone Mat | 8.95 x 3.67 x 0.63 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ½ DIN Instrument/Accessory Tray Silicone Mat | 8.95 x 8.14 x 0.63 inches | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sterilization Parameters (Pre-Vacuum) | <table border="1"> <thead> <tr> <th>Cycle</th> <th>Temp</th> <th>Exposure</th> <th>Min Dry Time</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Pre-Vacuum</td> <td>132° C (270°F)</td> <td>4 Min</td> <td>30 Min</td> </tr> <tr> <td>135°C (275°F)</td> <td>3 Min</td> <td>30 Min</td> </tr> </tbody> </table> | Cycle | Temp | Exposure | Min Dry Time | Pre-Vacuum | 132° C (270°F) | 4 Min | 30 Min | 135°C (275°F) | 3 Min | 30 Min | <table border="1"> <thead> <tr> <th>Cycle</th> <th>Temp</th> <th>Exposure</th> <th>Min Dry Time</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Pre-Vacuum</td> <td>132° C (270°F)</td> <td>4 Min</td> <td>30 Min</td> </tr> <tr> <td>135°C (275°F)</td> <td>3 Min</td> <td>30 Min</td> </tr> </tbody> </table> | Cycle | Temp | Exposure | Min Dry Time | Pre-Vacuum | 132° C (270°F) | 4 Min | 30 Min | 135°C (275°F) | 3 Min | 30 Min | | | | | | |
| Cycle | Temp | Exposure | Min Dry Time | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pre-Vacuum | 132° C (270°F) | 4 Min | 30 Min | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 135°C (275°F) | 3 Min | 30 Min | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cycle | Temp | Exposure | Min Dry Time | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pre-Vacuum | 132° C (270°F) | 4 Min | 30 Min | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 135°C (275°F) | 3 Min | 30 Min | | | | | | | | | | | | | | | | | | | | | | | | | | | |



| Validated Worst Case Configuration | <p>Cassette: 22.75 x 11.26 x 5.5 inches</p> <p>Contents: Implants, Common Surgical Instruments such as rasps, drivers, trials, handles, inserters, probes, drills, etc.</p> <p>Lumen Dimensions:</p> <ul style="list-style-type: none"> • 363 x 1.575 mm • 247.5 x 4.1 mm | <p>The following set configurations were validated as the worst-case configuration in a full DIN rigid sterilization container:</p> <table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: left;">Configuration</th> <th style="text-align: left;">Maximum Validated Load Set Contents</th> </tr> </thead> <tbody> <tr> <td rowspan="12" style="vertical-align: top;"> 3-Level Rack – Qty. 2 (29-13910) in a Full DIN Rigid Sterilization Container </td> <td>29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941)</td> </tr> <tr> <td>29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941)</td> </tr> <tr> <td>29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941)</td> </tr> <tr> <td>29-17901 1.7 Mid-Face Plates Module with Lid (29-13941)</td> </tr> <tr> <td>29-17903 1.7 Orthognathic Plates Inlay</td> </tr> <tr> <td>29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921)</td> </tr> <tr> <td>29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941)</td> </tr> <tr> <td>29-23901 2.0/2.3 Mandible Plates Module with Lid (29-13941)</td> </tr> <tr> <td>29-23905 2.0/2.3 Mini Plates Inlay, Large</td> </tr> <tr> <td>29-13904 Mandible Fracture Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13905 Trocar Instrument Tray with Lid (29-13921)</td> </tr> </tbody> </table> <p>The following set configurations were validated as the worst-case configuration in a ½ DIN rigid sterilization container:</p> <table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: left;">Configuration</th> <th style="text-align: left;">Maximum Validated Load Set Contents</th> </tr> </thead> <tbody> <tr> <td rowspan="6" style="vertical-align: top;"> 3-Level Rack – Qty. 1 (29-13910) in a ½ DIN Rigid Sterilization Container </td> <td>29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941)</td> </tr> <tr> <td>29-23903 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941)</td> </tr> <tr> <td>29-23904 2.0/2.3 Mandible Recon Primary Plates Inlay</td> </tr> <tr> <td>29-13904 Mandible Fracture Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13905 Trocar Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13906 Mandible Reconstruction Instrument Tray with Lid (29-13921)</td> </tr> <tr> <td>29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921)</td> </tr> </tbody> </table> <p>Contents include Stryker single-use implants (plates, meshes, bone screws, etc.) single-use reprocessed instruments (drills), and reusable instruments (Such as benders, forceps, handles, depth gauge, trocar, etc.)</p> | Configuration | Maximum Validated Load Set Contents | 3-Level Rack – Qty. 2 (29-13910) in a Full DIN Rigid Sterilization Container | 29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941) | 29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941) | 29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941) | 29-17901 1.7 Mid-Face Plates Module with Lid (29-13941) | 29-17903 1.7 Orthognathic Plates Inlay | 29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921) | 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) | 29-23901 2.0/2.3 Mandible Plates Module with Lid (29-13941) | 29-23905 2.0/2.3 Mini Plates Inlay, Large | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) | 29-13905 Trocar Instrument Tray with Lid (29-13921) | Configuration | Maximum Validated Load Set Contents | 3-Level Rack – Qty. 1 (29-13910) in a ½ DIN Rigid Sterilization Container | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) | 29-23903 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941) | 29-23904 2.0/2.3 Mandible Recon Primary Plates Inlay | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) | 29-13905 Trocar Instrument Tray with Lid (29-13921) | 29-13906 Mandible Reconstruction Instrument Tray with Lid (29-13921) | 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) |
|--|---|--|---------------|-------------------------------------|---|---|--|---|--|---|---|---|--|--|--|---|--|---------------|-------------------------------------|---|--|--|---|---|--|---|---|
| | Configuration | Maximum Validated Load Set Contents | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3-Level Rack – Qty. 2 (29-13910) in a Full DIN Rigid Sterilization Container | 29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-17901 1.7 Mid-Face Plates Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-17903 1.7 Orthognathic Plates Inlay | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-23901 2.0/2.3 Mandible Plates Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-23905 2.0/2.3 Mini Plates Inlay, Large | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13905 Trocar Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Configuration | Maximum Validated Load Set Contents | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3-Level Rack – Qty. 1 (29-13910) in a ½ DIN Rigid Sterilization Container | 29-23900 2.0/2.3 Mandible Screws Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-23903 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-23904 2.0/2.3 Mandible Recon Primary Plates Inlay | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13904 Mandible Fracture Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13905 Trocar Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 29-13906 Mandible Reconstruction Instrument Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Percent Perforation</p> <p>Evenly distributed perforated steam hole pattern.</p> | <p>Evenly distributed perforated steam hole pattern.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Sterilization Method</p> <ul style="list-style-type: none"> • Pre-vacuum • Gravity | <ul style="list-style-type: none"> • Pre-vacuum | | | | | | | | | | | | | | | | | | | | | | | | | | |



| | | |
|------------------------|---------------------------|---------------------------|
| Reusable | Yes | Yes |
| Patient Contact | No direct patient contact | No direct patient contact |
| Air Permeance | Yes | Yes |

Table 2: Comparison of Performance Characteristics

| | Predicate Device (Medtronic Transportation/Sterilization Cassettes) | Subject Device (Stryker Universal Select Sterilization Tray System) |
|--|--|---|
| Material Compatibility with Sterilization Process | Materials are compatible with sterilization method | Materials are compatible with steam sterilization. Performance testing demonstrated that the materials of construction are compatible with repeated steam sterilization cycles. |
| Toxicological Properties | Materials are biocompatible | Cytotoxicity testing demonstrated that the materials are non-cytotoxic. |



11. Performance Testing: The following non-clinical performance testing was conducted on the Stryker Universal Select Sterilization Tray System:

- **Sterilization and Dry Time Validation**

Sterilization validations were performed to verify the effectiveness of steam sterilization of a fully loaded Stryker Universal Select Sterilization Tray System sterilized in a rigid sterilization container using an autoclave cycle with pre-vacuum air removal. The study evaluated the resistance of biological indicators (BIs) in the form of paper spore strips inoculated with 10^{-6} *Geobacillus stearothermophilus* spores to 132°C pre-vacuum steam autoclave half cycle exposures. Dry time was evaluated after sterilization. Both full size and ½ size rigid sterilization containers were validated per ANSI/AAMI/ISO 17665-1:2006.

- **Cleaning Validation**

A manual and automated cleaning validation was performed on the worst case configured tray system per AAMI TIR 30:2011 to validate the cleaning instructions. The results indicate that the recommended cleaning methods, using a neutral pH detergent were effective in removing soil from all designated surfaces of the Stryker Universal Select Sterilization Tray System that might be accessible to the end user.

- **Design Verification**

Design verification testing included containment verification during transport and simulated use, handle strength testing per AAMI ST77:2013 and EN 868-8:2009, verification of the tray system to stack, edge sharpness and verification of the maximum weight.

- **Life Cycle Testing**

Lifecycle testing was performed to verify that the Stryker Universal Select Sterilization Tray System maintained functional quality requirements, material integrity, and traceability (artwork and UDI legibility) after exposure to repeated pre-vacuum steam sterilization cycles and automated washing cycles, and simulated functional use of the components (latch and handle actuation).

- **Biocompatibility**

Biocompatibility testing was conducted on all materials used in construction of the Stryker Universal Select Sterilization Tray System per ISO 10993-5 using the MEM Elution method. Test article extracts showed grade 2 or less cell lysis and reactivity, indicating the materials met acceptable cytotoxicity levels post-sterilization.

All results of design verification testing met acceptance criteria.

12. Conclusion: The Stryker Universal Select Sterilization Tray System has been validated to meet the established performance criteria. Based on the intended use, technological characteristics, performance data, and nonclinical testing performed; the subject device is substantially equivalent to the legally marketed predicate device.