

October 29, 2020

OsteoMed LLC Andrew Johnson Senior Regulatory Affairs Specialist 3885 Arapaho Road Addison, Texas 75001

Re: K202105

Trade/Device Name: OsteoMed ExtremiFix Mini & Small System Tray

Regulation Number: 21 CFR 880.6850 Regulation Name: Sterilization Wrap

Regulatory Class: Class II Product Code: KCT Dated: July 28, 2020 Received: July 31, 2020

#### Dear Andrew Johnson:

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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); 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 <a href="https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems">https://www.fda.gov/medical-device-problems</a>.

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

Sincerely,

For Kapil Panguluri, PhD
Acting 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

# DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

# **Indications for Use**

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020 See PRA Statement below.

510(k) Number <i>(if known)</i>		
K202105		
Device Name OsteoMed ExtremiFix Mini & Small System Tray		

#### Indications for Use (Describe)

The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.

Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.

Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:

Method: Steam Cycle

Pre-Vacuum Temperature: 270°F (132°C)

Exposure Time: 4 minutes Minimum Dry Time: 50 minutes

Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a rigid container configuration:

Method: Steam Cycle

Pre-Vacuum Temperature: 270°F (132°C)

Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes

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."



# **K202105 510(k) SUMMARY**

#### I. SUBMITTER

OsteoMed

3885 Arapaho Rd.

Addison, TX 75001 USA

Phone: 972-677-4795 Fax: 972-677-4601

Email: djohnson@osteomed.com Contact Person: Drew Johnson

Date Prepared: 7/28/2020

#### II. DEVICE

Name of the Device: OsteoMed ExtremiFix Mini & Small System Tray

Common or Usual Name: Sterilization Tray

Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other

Accessories

Regulation: 880.6850 Regulatory Class: II Product Code: KCT

#### III. PREDICATE DEVICE

Predicate Device: OsteoMed MMF Sterilization Tray (K173391)

Reference Device: NuVasive Sterilization Tray (K143579)

#### IV. DEVICE DESCRIPTION

The OsteoMed ExtremiFix Mini & Small System Tray is composed of anodized and non-anodized aluminum, stainless steel, silicone, polyethylene terephthalate (Mylar), polyphenylsulfone (Radel), polyamide 11 (nylon), and ZEUS Perfluoroalkoxy (PFA), which are common tray materials, and is used to enclose, protect, and organize OsteoMed ExtremiFix Mini & Small System implants and surgical instruments. This is a product specific sterilization storage system tray (only for use with the OsteoMed ExtremiFix Mini & Small System) that is intended to provide storage for the OsteoMed ExtremiFix screws and accessories during sterilization, storage, and transportation within the hospital environment.

The OsteoMed ExtremiFix Mini & Small System Tray is a single sterilization storage system that is comprised of one outer case (base + lid), two screw modules



(any two of the four sizes), and two trays (handle tray + instrument tray). The trays are perforated to allow for steam sterilization. An FDA-cleared wrap or FDA-cleared rigid sterilization container must be used for sterilization and to maintain the sterility of the contents. The OsteoMed ExtremiFix Mini & Small SystemTray is designed to be used with standard autoclaves used in hospitals and healthcare facilities. As such, the OsteoMed ExtremiFix Mini & Small System Tray is effective for containing the system devices during sterilization and have been designed to withstand repeated steam sterilization cycles.

#### V. INDICATIONS FOR USE

The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.

Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.

Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:

Method: Steam Cycle

Pre-Vacuum Temperature: 270°F (132°C)

Exposure Time: 4 minutes

Minimum Dry Time: 50 minutes

 $Validated\ sterilization\ parameters\ for\ OsteoMed\ ExtremiFix\ Mini\ \&\ Small$ 

System Tray in a rigid container configuration:

Method: Steam Cycle

Pre-Vacuum Temperature: 270°F (132°C)

Exposure Time: 4 minutes

Minimum Dry Time: 30 minutes



# VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Provided in the table below is the OsteoMed ExtremiFix Mini & Small System Tray and the comparison with the predicate.

Characteristics	Subject Device: OsteoMed ExtremiFix Mini & Small System Tray	Predicate Device: OsteoMed QuickFix Hybrid MMF Sterilization Tray (K173391)	Comparison
Product Code	KCT	KCT	Same
21 CFR	888.685	888.685	Same
System Components	Base, lid, screw modules, instrument trays	Base, lid, locking latch	Similar
<b>Material Composition</b>	Aluminum, stainless steel, silicone, polyethylene terephthalate, nylon, polyphenylsulfone, ZEUS Perfluoroalkoxy	Aluminum	Similar
Physical Properties	Evenly distributed perforated hole pattern	Evenly distributed perforated hole pattern	Same
Configurations/Dimensions (L x W x H) in.	Outer case: 17.6 x 9.5 x 4.1 Screw modules: 8.1 x 6.1 x 3.3 Instrument trays: 9.2 x 3.3 x 1.6	Rectangle base with lid: 9.5 x 5.0 x 1.5	Similar
Sterilant Penetration	Sterilant (steam) penetration through perforations in tray	Sterilant (steam) penetration through perforations in tray	Same
Sterilization method	Steam	Steam	Same
Sterilization cycle	Pre-vacuum	Pre-vacuum	Same
Exposure temperature	270°F (132°C)	270°F (132°C)	Same
Exposure time	4 minutes	4 minutes	Same
Dry time	30 minutes (rigid container) 50 minutes (wrapped)	30 minutes	Similar
Reusable	Yes	Yes	Same
Vent to Volume Ratio	Outer case: 0.231 in <sup>2</sup> /in <sup>3</sup> Module: 0.260 in <sup>2</sup> /in <sup>3</sup>	Base/lid: 0.050 in <sup>2</sup> /in <sup>3</sup>	Similar
Worse Case Lumen	T7 driver long: Ø0.038, L = 0.371" (1 ea.) T10 driver long: Ø0.050, length 5" (1	Base steam hole: Ø0.094, length 1.075" (1 ea.) Driver sleeve: Ø0.115, length	Similar
Wolse Case Lumen	ea.)  2.0mm module screw hole: Ø0.092, length 0.325" (126 ea.)	0.680"  Driver handle: blind hole Ø0.111, depth 1.173"	



2.4mm module screw hole: 00.135, length 0.325" (150 ea.)  3.0mm module screw hole: 00.150, length 0.325" (108 ea.)  4.0mm module screw hole: 00.165, length 0.325" (108 ea.)  The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid to be used in conjunction with a validated to be used in conjunction with a validated with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication fray is intended to maintain sterility; they are intended to maintain sterility in the enclosed devices. The sterilization wrap in order to maintain sterility of the enclosed devices. The sterilizat				
3.0mm module screw hole: 00.130, length 0.325" (160 e.a.)  4.0mm module screw hole: 00.165, length 0.325" (108 e.a.)  The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilizy; it is intended to maintain sterilizy; it is intended to maintain sterilizy; it is intended to maintain sterilizy; it is intended to be used in conjunction with a validated, FDA-cleared sterilization warp in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  I		2.4mm module screw		
3.0mm module screw hole: 00.130, length 0.325" (160 e.a.)  4.0mm module screw hole: 00.165, length 0.325" (108 e.a.)  The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilizy; it is intended to maintain sterilizy; it is intended to maintain sterilizy; it is intended to maintain sterilizy; it is intended to be used in conjunction with a validated, FDA-cleared sterilization warp in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  I		hole: Ø0.105, length		
3.0mm module screw hole: Ø0.130, length 0.325" (108 ca.)  4.0mm module screw hole: Ø0.165, length 0.325" (108 ca.)  The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication for Use  Indications for Use  Indications for Use  Indication for Use  Indications for Use  Indications for Use  Indication for Use on Indication for Use of Everification for Use of Use				
4.0mm module screw hole: 60.155, length 0.325" (108 ca.)  The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; of its intended to be used in conjunction with a validated, FDA-cleared sterilization warp in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization  Tray is intended to contain  Sterilization, storage and handling. The OsteoMed QuickFix Hybrid MMF sterilization vary is more to maintain sterility of the enclosed devices. The sterilization rays may also be used in conjunction with a legally marketed rigid container. Sterilization vary maximum load of 2.3 lbs. in the sterilization vary may show the validated sterilization parameters for OsteoMed QuickFix Hybrid MMF sterilization vary may may may may may may may may may ma		0.323 (130 cu.)		
4.0mm module screw hole: 60.155, length 0.325" (108 ca.)  The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; of its intended to be used in conjunction with a validated, FDA-cleared sterilization warp in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization  Tray is intended to contain  Sterilization, storage and handling. The OsteoMed QuickFix Hybrid MMF sterilization vary is more to maintain sterility of the enclosed devices. The sterilization rays may also be used in conjunction with a legally marketed rigid container. Sterilization vary maximum load of 2.3 lbs. in the sterilization vary may show the validated sterilization parameters for OsteoMed QuickFix Hybrid MMF sterilization vary may may may may may may may may may ma		2 0		
4.0mm module screw hole: 60.165, length 0.325" (108 ca.)  The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Ind				
4.0mm module screw hole: 90.165, length 0.325" (108 ea.)  The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indications for Use  1 The OsteoMed QuickFix Hybrid MMF in Indicated to maintain sterility; it is intended to be used in conjunction with a legally marketed rigid container.  Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validation parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization tray:  Validated sterilization validation parameters for OsteoMed QuickFix Hybrid MMF Sterilization tray:  Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Method: Steam Cycle Pre-Vacuum  Validated sterilization:  The OsteoMed QuickFix Hybrid MMF Sterilization tray:  Walidated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Method: Steam Cycle Pre-Vacuum  Temperature:				
Indications for Use    To StecoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Tray may also be used in conjunction with a validated, was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation.  Do not exceed a maximum load of 14.1 lbs, in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validation vas done for the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs, in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validation vas done for the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs, in the sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Welfold: Steam Cycle Pre-Vacuum  Tray is intended to contain Tray is intende		0.325" (96 ea.)		
Indications for Use    To StecoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Tray may also be used in conjunction with a validated, was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation.  Do not exceed a maximum load of 14.1 lbs, in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validation vas done for the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs, in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validation vas done for the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs, in the sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Welfold: Steam Cycle Pre-Vacuum  Tray is intended to contain Tray is intende				
Indications for Use    Social Search   Contain   Contain		4.0mm module screw		
The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility; of the enclosed devices. The System Tray may also be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility; of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication Sterilization wrap in order to maintain sterilization wrap in order				
The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility; it is intended to maintain sterility it is intended to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication for Yie Use Indication for Yie Use Indication for Yie Use Indication for Yie Use Indication for Yie Use Indication for Yie				
Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility: it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication fray is not intended to maintain sterility; they are intended to be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication fray is not intended to maintain sterility; they are intended to be used in			The Oster Med Ossiel-Eise	
intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility: it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication for Use  Indications for Use  Indication for Use  Indications for Use			_	
and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization		•		
surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication fray is autiable for dynamic air removal (pre-vacuum) steam sterilization methods. The tray is not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility; they are intended to be used in conjunction with a legally marketed rigid container. Sterilization validation was one for the OsteoMed Quick-Fix Hybrid MMF Sterilization Tray:  Indication Fray is a v				
sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication Vialidated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The sterilization valid		and Small implants and	Tray is intended to	
sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication Vialidated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The sterilization valid		surgical instruments for	contain	
handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication fray is an usualidated, FDA-cleared sterilization was done for the OsteoMed QuickFix Hybrid MMF device and accessories be used in conjunction with a legally marketed rigid container. Sterilization validation was done for the OsteoMed QuickFix Hybrid MMF Sterilization for dynamic air receivance in the devices. The System on intended to maintain sterility; they are intended to with a validated, FDA-cleared sterilization was done for the OsteoMed QuickFix Hybrid MMF Sterilization for a validation was done for the OsteoMed QuickF				
Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA- cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instruments for sterilization tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The tray is not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization vrap in order to maintain sterility of the enclosed devices. The System in conjunction with a legally marketed rigid container.  Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instruments for sterilization or methods. The System Guickie, Thybrid MMF Similated, FDA- cleared sterilization methods. The tray is not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA- cleared sterilization wrap in order to maintain sterility of the enclosed devices. The sterilization trays may also be used in conjunction with a legally marketed rigid container. Sterilization validation, was done for the OsteoMed QuickFix Hybrid MMF Similated to be used in conjunction with a legally marketed rigid container. Sterilization validated, FDA- cleared sterilization validated, validated, FDA- cleared sterilization on the volume tran			-	
Indications for Use  Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization was performed utilizing the ExtremiFix Mini & Small System tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization		<u> </u>		
dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The tray is not intended to maintain sterility; they are intended to maintain sterility for be enclosed devices. The sterilization ware promabled to be used in conjunction with a legally marketed rigid container. Sterilization vary and walso be used in conjunction ware promabled to be used in conjunction ware for Use of the Color				
sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication Fix Hybrid MmF  Indication Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The tray is not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization ward pin order to maintain sterilization ward accessories. The Sterilization variation accessories such as accessories. Do not exceed a maximum load of 14.1 lbs. in the sterilization validation ward pin order to maintain sterilization variation ward for the OsteoMed QuickFix Hybrid MMF Sterilization Tray in ward pin order to maintain steri			_	
Sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indications for Use  Indications for Use  Indications for Use  OuickFix Hybrid MMF Sterilization Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The tray is not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation.  Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Validated vomanicair removal (pre-vacuum) Steam sterilization Tray is suitable for dynamic air removal (pre-vacuum) Steam sterilization Tray is suitable for dynamic air removal (pre-vacuum) Steam sterilization Tray is suitable for dynamic air removal (pre-vacuum) Steam sterilization Tray is suitable for dynamic air removal (pre-vacuum) Steam sterilization Tray is suitable for dynamic air removal (pre-vacuum) Steam sterilization Tray is suitable for dynamic air removal (pre-vacuum) Steam sterilization Tray is suit			_	
The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication fray is suitable for dynamic air removal (pre-vacuum)  Intended to maintain sterility; they are intended to be used in conjunction with a legally marketed rigid container.  Indications for Use  Indications for Use  Indications for Use  Indications for Use  Indication Tray is suitable for dynamic air removal (pre-vacuum)  Intended to be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication Tray is suitable for dynamic air removal (pre-vacuum)  Intended to be use		<b>1</b>		
intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication wrap in order to maintain sterility; they are intended to be used in conjunction with a legally are intended to be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indications for Us				
sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization warp in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication for Use  Indications for Use  Indication for Use used in conjunction with a validated, FDAcleared sterilization was a validated, FDAcleared sterilization tray smay also be used in conjunction with a validated, FDAcleared sterilization tray in order to maintain sterility; they are intended to wointained to be used in conjunction with a validated, FDAcleared sterilization was a validated, FDAcleared sterilization tray in order to maintain sterility; they are intended to to be used in conjunction with a validated, FDAcleared sterilization tray in order to maintain sterility; they are intended to be used in conjunction with a legally marketed rigid container. Sterilization validation, FDAcleared sterilization validated, FDAcleared sterilization validated, FDAcleared validated, FDAcleared validated, FDAcleared validated, FDAcleared validated, FDAcleared val		The system tray is not	Sterilization Tray is	
sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization warp in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication for Use  Indications for Use  Indication for Use used in conjunction with a validated, FDAcleared sterilization was a validated, FDAcleared sterilization tray smay also be used in conjunction with a validated, FDAcleared sterilization tray in order to maintain sterility; they are intended to wointained to be used in conjunction with a validated, FDAcleared sterilization was a validated, FDAcleared sterilization tray in order to maintain sterility; they are intended to to be used in conjunction with a validated, FDAcleared sterilization tray in order to maintain sterility; they are intended to be used in conjunction with a legally marketed rigid container. Sterilization validation, FDAcleared sterilization validated, FDAcleared sterilization validated, FDAcleared validated, FDAcleared validated, FDAcleared validated, FDAcleared validated, FDAcleared val		intended to maintain	suitable for dynamic air	
be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a container.  Indications for Use  Indication wand in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conju				
with a validated, FDA- cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Temperature:			-	
cleared sterilization wrap in order to maintain sterility; they are intended devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indication wall a validated, FDAcleared sterilization warp in order to maintain sterility; they are intended to be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a validated, FDAcleared sterilization trays may also be used in conjunction with a legally marketed rigid devices. The sterilization trays may also be used in conjunction with a legally marketed rigid devices. The sterilization validation was done for the OsteoMed QuickFix Hybrid MMF Sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Indications avalidated, FDAcleared sterilization tray was also be used in conjunction with a legally marketed rigid container. Sterilization validation was done for the OsteoMed QuickFix Hybrid MMF Sterilization tray.  Indications avalidated, FDAcleared sterilization tray saw also be used in conjunction with a legally marketed rigid container. Sterilization validation was done fo				
in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.  Indications for Use  Indications variation wrap  In order to maintain  Indication wrap  In order to maintain  Indication wrap  In order to maintain  Indications variation wrap  In order to maintain  Indications variation wrap  In order to maintain  Indications variation wrap  In order to maintain  Indications for Use  Indications variation  Indications variation variation wrap  Indications variation wrap  Indications variation variation wrap  Indications variation wrap  Indications variation variation wrap  Indications variation wrap  Indications variation variation  Indications variation variation variation  Indications variation wrap  Indications variation variation variation  Indications variations  Indications variation variation variation  Indications		· ·	•	
Indications for Use  Indication for Use  Indications for Use  Indication wrap in order to maintain sterilization wrap also be used in conjunction with a validated, FDAcleared sterilization wrap in order to maintain sterilized for trays may also be used in conjunction wrap in order to maintain sterilization wrap devices. The sterilization validation was done for the OsteoMed QuickFix Hybrid MMF MMF device and accessories. Do not exceed a maximum load of 2.3 lbs. in the sterilization parameters for OsteoMed QuickFix Hybrid MMF Steril		-		
Indications for Use  Indication wrap  In order to maintain  Indication wrap  In order to maintain  Indication wrap  In order to maintain  Indication wrap  Indication be used in conjunction with a legally marketed rigid  It was may also be used in conjunction with a legally marketed rigid  Indication wrap  Indication wr				
Indications for Use  Tray may also be used in conjunction with a legally marketed rigid container.  Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization Validated StermiPix Mini & Small System Tray in a wrapped configuration: Validated sterilization Validated sterilization Validated sterilization Validated sterilization Validated StermiPix Mini & Sterilization Tray: Method: Steam Cycle Pre-Vacuum Validated sterilization: Temperature:		sterility of the enclosed	intended	
Indications for Use    Conjunction with a legally marketed rigid container.		devices. The System	to be used in conjunction	
Indications for Use    Conjunction with a legally marketed rigid container.		Tray may also be used in	with a validated,	
Indications for Use    legally marketed rigid container.   sterilization wrap in order to maintain sterility of the enclosed devices. The sterilization trays may also be used in conjunction with a Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:    Validated sterilization validation wrap in order to maintain sterilized devices. The sterilization trays may also be used in conjunction with a legally marketed rigid container. Sterilization validation was done for the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs. in the sterilization tray.    Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Validated sterilization    Validated sterilization Temperature:   Validated sterilization   Validated sterilization   Temperature:   Validated sterilization   Validated   Validated			FDAcleared	
container.  Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization Validated Sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Walidated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Walidated sterilization Tray:  Walidated sterilization Tray:  Method: Steam Cycle Pre-Vacuum Temperature:	Indications for Use			Similar
sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Validated sterilization Validated sterilization Validated sterilization Temperature:	marcations for esc		_	Similar
Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation.  Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization		Container.		
was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization the ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization tray:  Validated sterilization Temperature:  Trays may also be used in conjunction with a legally marketed rigid container. Sterilization validation was done for the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs. in the sterilization tray.  Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Method: Steam Cycle Pre-Vacuum  Temperature:			•	
the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization Validated rigid container. Sterilization Validation was done for the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs. in the sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Temperature:				
Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Validated sterilization Validated sterilization Validated sterilization Tray: Method: Steam Cycle Pre-Vacuum Validated sterilization Temperature:				
System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Temperature:				
accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a Wrapped configuration: Validated sterilization Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Temperature:		Small Cannulated Screw	legally marketed rigid	
accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a Wrapped configuration: Validated sterilization Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Temperature:		System implants and	container. Sterilization	
as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Validated sterilization Temperature:  the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs. in the sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Temperature:		=	validation was done for	
instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization  Validated sterilization  parameters for OsteoMed QuickFix Hybrid MMF  Sterilization Tray:  Method: Steam Cycle  Pre-Vacuum  Validated sterilization  Temperature:				
Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization  Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Wethod: Steam Cycle Pre-Vacuum Validated sterilization Temperature:		_	_	
maximum load of 14.1 lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Validated sterilization Temperature:			•	
lbs. in the sterilization system tray.  Validated sterilization parameters for OsteoMed ExtremiFix Mini & QuickFix Hybrid MMF Small System Tray in a wrapped configuration:  Validated sterilization of 2.3 lbs. in the sterilization tray.  Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray:  Method: Steam Cycle Pre-Vacuum  Validated sterilization Temperature:				
validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization tray.  Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Validated sterilization Temperature:				
Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:  Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Validated sterilization Temperature:				
parameters for OsteoMed ExtremiFix Mini & QuickFix Hybrid MMF Small System Tray in a wrapped configuration: Walidated sterilization  parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Temperature:		system tray.	sterilization tray.	
parameters for OsteoMed ExtremiFix Mini & QuickFix Hybrid MMF Small System Tray in a wrapped configuration: Walidated sterilization  parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Temperature:				
ExtremiFix Mini & QuickFix Hybrid MMF Small System Tray in a wrapped configuration:  Wethod: Steam Cycle Pre-Vacuum  Validated sterilization  Temperature:		Validated sterilization	Validated sterilization	
ExtremiFix Mini & QuickFix Hybrid MMF Small System Tray in a wrapped configuration:  Wethod: Steam Cycle Pre-Vacuum  Validated sterilization  Temperature:		parameters for OsteoMed	parameters for OsteoMed	
Small System Tray in a wrapped configuration:  Wethod: Steam Cycle Pre-Vacuum  Validated sterilization  Temperature:				
wrapped configuration:  Method: Steam Cycle Pre-Vacuum  Validated sterilization  Temperature:				
Validated sterilization Pre-Vacuum Temperature:		•		
Validated sterilization Temperature:		wrapped configuration:		
		XX 1: 1		
parameters for OsteoMed   270°F (132°C)				
		I paramatara for Octoo Mad	∟ <i>771</i> 0°F (132°C)	İ



		1
ExtremiFix Mini &	Exposure Time: 4	
Small System Tray in a	minutes	
wrapped configuration:	Minimum Dry Time: 30	
Method: Steam Cycle	minutes	
Pre-Vacuum		
Temperature: 270°F		
(132°C)		
Exposure Time: 4		
minutes		
Minimum Dry Time: 50		
minutes		
Validated sterilization		
parameters for OsteoMed		
ExtremiFix Mini &		
Small System Tray in a		
rigid container		
configuration:		
Method: Steam Cycle		
Pre-Vacuum		
Temperature:		
270°F (132°C)		
Minimum Dry Time: 30		
minutes		
1	1	1

#### SUMMARY OF NON-CLINICAL TESTING

The testing provided below was performed to demonstrate whether the subject device met the performance acceptance criteria of the respective standard listed below:

## **Biocompatibility Testing**

A biocompatibility evaluation was conducted according to FDA guidance document "Use of International Standard ISO-10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process," Guidance for Industry and Food and Drug Administration Staff, dated June 16, 2016. The subject device does not have direct contact with patients. The implants and instruments to be sterilized in the subject device will have contact with the subject device's surfaces; therefore, the subject device's case, trays, and modules have indirect contact with the patient. The subject device indirect patient contact materials are similar materials that were previous cleared with the predicate device, K173391, and the reference device, K143579.

The subject device met testing requirements for:

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogen testing



# **Bench Testing**

The following table provides a summary of the bench testing conducted.

Test	Purpose	Acceptance	Summary of Test
Description		Criteria	Results
Design Validation	To validate the design and performance of the ExtremiFix Mini & Small System.	Surgeons evaluated the functionalit y of the tray.	Pass; met all requirements



Test Description	Purpose	Acceptance Criteria	Summary of Test Results
Ship Testing	To establish that the ExtremiFix Mini & Small System, and associated packaging, protects and retains the implants and instruments during normal shipping and handling.	Ship packaged plate per ASTM D-4169 and evaluate package contents for damage upon return.	Pass
Cleaning Validation (reusable instruments)	To validate the prescribed manual cleaning process for the ExtremiFix Mini & Small System.	Use the T7 cannulated long driver as worst- case device to verify that re- useable instruments can be cleaned per instructions to achieve standard requirements for reusable devices per AAMI TIR 12 and AAMI TIR 30.	Pass
Sterilization Validation	To validate the steam sterilization parameters for the ExtremiFix Mini & Small System to ensure that the fully-populated system can be sterilized.	Validate sterilization parameters with 3 consecutive tests. Conducted test for both systems wrapped in polypropylene sterile wrap and system enclosed in rigid container.	Passed for both sterile wrap and rigid container configurati ons
Reliability Verification (Sterilization Cycles Validation)	To assess the reliability, via repeated use and sterilization, of the ExtremiFix Mini & Small System.	Verify functionality and graphics legibility after the system tray is steam sterilized for 100 cycles with the sterilization parameters described in the IFU.	Passed functional and visual criteria after 100 cycles
Cytotoxicity	The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances.	The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade	Pass



		greater than 2 is considered cytotoxic effect, or a failing score.	
Sensitization	To determine the potential sensitization effects of subject device indirect contact materials.	The test is considered negative for signs of sensitization if the positive response observed is in less than 10% of the test animals.	Pass
Irritation	To determine the potential irritation effects of subject device indirect contact materials.	The requirements of the test will be met if the difference between the test article mean score and control mean score is 1.0 or less.	Pass
Pyrogen testing	The Bacterial Endotoxins Test, or Limulus Amebocyte Lysate (LAL) test, is an in vitro assay to detect and quantify bacterial endotoxin, a component of the cell wall of Gram negative bacteria.	For medical devices, the endotoxin limit is not more than 20.0 EU/device.	Pass

The results on the non-clinical testing demonstrated that the subject device met the acceptance criteria of the standard.

## **Animal Study**

No animal studies were performed to demonstrate safety and efficacy.

## **Clinical Studies**

No clinical studies were performed to demonstrate safety and efficacy.

#### VII. CONCLUSIONS

The conclusions drawn from the nonclinical tests demonstrate that the OsteoMed ExtremiFix Mini & Small System Tray is as safe, as effective, and performs as well as or better than the legally marketed device OsteoMed MMF Sterilization Tray (K173391) under regulation 21 CFR 880.6850, product code KCT.