Talladium España, SL
% Rebecca Kattan
Regulatory Specialist
Paxmed International, LLC
1925 Palomar Oaks Way
Suite 210
Calarsbad, California 92008

January 29, 2026

Re: K243732
Trade/Device Name: Multi-Unit DAS System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 9, 2026
Received: January 9, 2026

Dear Rebecca Kattan:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

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

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K243732

Device Name

Multi-Unit DAS System

Indications for Use (Describe)

Multi-Unit DAS System is intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

Compatible Implant Systems

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform Diameter, mm or Name
Astra Tech EV (Internal Taper)	3.6	3.6
	4.2	4.2
	4.8	4.8
Osstem® TS Hiossen® ET (Internal Taper)	3.5	Mini
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular
Neodent GM (Morse taper)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB/WB

All digitally designed custom abutments for use with Multi-Unit DAS System are to be sent to a Talladium validated milling center for manufacture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K243732
Talladium España, SL
Multi-Unit DAS System

January 28, 2026

ADMINISTRATIVE INFORMATION

Manufacturer Name	Talladium España, SL Virginia Woolf, 17 Lleida, Lleida, ES 25005 Telephone +34 973-289-580
Official Contact	Xavier Soca Filella, General Manager
Representative/Consultant	Rebecca E, Kattan, PhD Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone +1 858-792-1235 Email rkattan@paxmed.com kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Multi-Unit DAS System
Common Names	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K231559, Multi-Unit DAS System, Talladium España, SL

Reference Devices
K212108, Dynamic TiBase, Talladium España, SL
K241170, Dynamic TiBase; TRI Screws, Talladium España, SL

Reference Devices for OEM implant body clearances:
K120414, OsseoSpeed™ Plus, Astra Tech AB
K161604, OSSTEM Implant System, OSSTEM Implant Co., Ltd.
K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários SA
K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
K201225, Neodent Implant System – GM Helix Implants 7.0, JJGC Indústria e Comércio de Materiais Dentários S.A.

K140878, Straumann® Bone Level Tapered Implants, Straumann USA, LLC
K173961, Straumann® BLX Implant System, Institut Straumann AG
K181703, Straumann® BLX Line Extension – Implants, SRAs and Anatomic Abutments, Institut Straumann AG
K191256, Straumann BLX Ø3.5 mm Implants, Institut Straumann AG
K210855, Straumann BLX Implant System, Institut Straumann AG
K212533, Straumann BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implant, Institut Straumann AG
K213609, NOVA RESIN dual cure, self adhesive resin cement, Imicryl Dis Malzemeleri Sanayi Ve Ticaret A.S.

INDICATIONS FOR USE STATEMENT

Multi-Unit DAS System is intended for use with dental implants as a support for single unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

Compatible Implant Systems

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform Diameter, mm or Name
Astra Tech EV (Internal Taper)	3.6	3.6
	4.2	4.2
	4.8	4.8
Osstem® TS Hiossen® ET (Internal Taper)	3.5	Mini
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular
Neodent GM (Morse taper)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB/WB

All digitally designed custom abutments for use with Multi-Unit DAS System are to be sent to a Talladium validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

Multi-Unit DAS System abutments are two-piece abutments composed of a CAD-CAM fabricated zirconia superstructure and a prefabricated titanium base component where the final two-piece abutment (base and cemented superstructure) is the finished device used for the prosthetic restoration

Multi-Unit DAS system abutments are designed for retention of multi-unit or single-unit restorations. The multi-unit abutments are provided in a straight design (no angulation in the base portion) that threads directly to the OEM implant. For all compatible OEM implant lines, the multi-unit abutment components are provided with gingival heights ranging from 1 mm to 4 mm, a prosthetic platform diameter of 4 mm, and a prosthetic post height of 1.4 mm.

This submission includes one (1) abutment level Ti-Base (coping) Engaging Interface for use with the subject multi-unit abutments. The subject Ti-Base (coping) Engaging Interface is a straight prepable design with an additional gingival height of 1.5 mm and a prepable 10.5 mm prosthetic post. This Ti-Base (coping) Engaging Interface has an engaging interface to the multi-unit abutments and is to be used to fabricate a straight final abutment and a straight final restoration. The subject device is identical to the previously cleared abutment level Ti-base (Part 35.312.209.21-2, K231559), except the current subject device has an engaging interface. The previously cleared abutment level Ti-base (Part 35.312.209.21-2, K231559) is to be used to fabricate a straight final abutment and a straight final restoration.

The subject device multi-unit abutments may be used with the following components, all previously cleared in K231559: Straight Ti-base, non-engaging, part number 35.312.209.21-2; DAS Multi-Unit Engaging Dynamic Ti-Base, part number 31.312.209.01-2; DAS Multi-Unit Non-Engaging Dynamic Ti-Base, part number 31.322.209.01-2; DAS Multi-Unit Non-Engaging Dynamic Ti-Base, part number 31.322.209.21-2;

DAS Multi-Unit Healing Cap Regular, part number 40.320.003.88-2; DAS Multi-Unit Healing Cap Wide, part number 40.320.003.89-2; DAS Multi-Unit Dynamic Screw 3.0, part number 41.320.040.01-2; DAS Multi-Unit Provisional Dynamic Screw, part number 41.320.050.02-2; and DAS Multi-Unit Straight Screw, part number 40.320.003.06-2.

No new DAS Multi-Unit Dynamic Ti-Bases are included in this submission. The previously cleared DAS Multi-Unit Dynamic Ti-Base (coping) components (K231599), part numbers 31.312.209.01-2, 31.322.209.01-2, and 31.322.209.21-2 may be used with the subject device Angled Multi-Unit abutments to fabricate a final angled abutment.

A summary of the subject device Multi-Unit DAS System abutment compatibilities with the OEM implants is provided in the following Table 1 *Summary of Compatibilities.*

Table 1 Summary of Compatibilities

Compatible Dental Implant Connections			**Subject Device: Multi-Unit DAS System**		
Compatible Implant System (Connection)	**Implant Body Diameter, mm**	**Implant Platform, mm**	**Gingival Height, mm**	**Prosthetic Platform, mm**	**Prosthetic Post Height**
Astra Tech EV (Internal Taper)	3.6	3.6	1-4	4	1.4
	4.2	4.2	1-4	4	1.4
	4.8	4.8	1-4	4	1.4
Osstem® TS Hiossen® ET (Internal Taper)	3.5	Mini	1-4	4	1.4
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular	1-4	4	1.4
Neodent (Morse taper GM)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM	1-4	4	1.4
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC	1-4	4	1.4
	4.1, 4.8	RC	1-4	4	1.4
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB/WB	1-4	4	1.4

All zirconia superstructures for use with the subject device Multi-Unit DAS system will be made at a Talladium España, SL validated milling center under FDA quality system regulations, and the material will conform to ISO 13356.

The design parameters for the CAD-CAM zirconia superstructure for the subject Multi-Unit DAS Dynamic Ti-base are:

Minimum wall thickness – 0.25 mm
Minimum post height for single-unit restorations – 4.0 mm
(post height measured above the gingival height of the final patient-matched design)
Maximum gingival height – 4.90 mm
Minimum gingival height – 3.89 mm
Maximum angulation – 15°

The design parameters for the CAD-CAM zirconia superstructure for the subject device Multi-Unit DAS Ti-Base (coping) Engaging Interface are:

Minimum wall thickness – 0.25 mm
Minimum post height for single-unit restorations – 4.0 mm
(post height measured above the gingival height of the final patient-matched design)
Maximum gingival height – 4.90 mm
Minimum gingival height – 3.89 mm
Maximum angulation – 0°

The required cement for bonding the zirconia superstructure to the abutment base is Nova Resin Cement cleared in K213609.

PERFORMANCE DATA

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- provided in this submission was a non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods, J.G. Delfino, and S. Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation Volume 49, No. 2 (March/April 2021): 783–795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition, and the rationale addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, including magnetically induced displacement force and torque*;
- referenced from K231559 (provided in K212108) was moist heat sterilization for subject devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2;
- referenced from K231559 (provided in K212108) was biocompatibility testing according to ISO 10993-5 (cytotoxicity) for the abutment materials ASTM F136 and ISO 13356;
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device abutments in conjunction with the compatible OEM implants; and
- provided in this submission was compatibility analysis (of OEM implant bodies, OEM abutments, and OEM abutment screws) to demonstrate that the subject device abutments are compatible with Astra Tech EV, Osstem® TS/ Hiossen® ET, Neodent GM, Straumann Bone Level, and Straumann BLX Implant Systems.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

All subject device abutments are similar in design, materials, and technological characteristics to the abutments cleared in the primary predicate device K231559.

The subject multi-unit abutments are used with a prosthetic coping (Ti-base), either the subject coping or a previously cleared coping. A patient specific zirconia superstructure is bonded to the component to complete the abutment. The subject multi-unit abutments may be used for multi-unit restorations (same as the primary predicate K231559) or single-unit restorations (same as the reference device K241170).

The subject device abutments and the subject device prosthetic coping are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for Talladium España, SL abutments and prosthetic components previously cleared in the primary predicate device K231559.

The subject device abutments and the subject device prosthetic Ti-Base (coping) Engaging Interface have very similar or identical ranges of prosthetic platform diameter and gingival height as compared to the primary predicate device K231559.

The subject device abutments are to be used with a zirconia superstructure (bonded to a prosthetic coping) with similar design parameters as the primary predicate K231559. The zirconia material and required cement to bond the superstructure to the prosthetic coping component are the same as the primary predicate K231559.

The subject device components are provided non-sterile and are to be sterilized by the same moist heat cycle as in the primary predicate K231559. The subject devices are provided in pouches manufactured from a polyethylene terephthalate (PET) and cast polypropylene (CPP) laminate, identical to the primary predicate K231559.

The subject device abutments are to be used with a prosthetic coping and a zirconia superstructure to create the final abutment. The risks associated with the use of angled abutments were mitigated by the mechanical testing performed according to ISO 14801.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device and the primary predicate device encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate device listed above.

The basis for the belief of Talladium España, SL that the subject device is substantially equivalent to the predicate devices is summarized in the following *Table of Substantial Equivalence.*

Table of Substantial Equivalence

Comparison	Subject Device	Predicate Device
	K243732 Multi-Unit DAS System Talladium España, SL	K231559 Multi-Unit DAS System Talladium España, SL
Indications for Use Statements	Multi-Unit DAS System is intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient. *<complete list of OEM compatible implants is provided in the Indications for Use Statement>* All digitally designed custom abutments for use with Multi-Unit DAS System are to be sent to a Talladium validated milling center for manufacture.	Multi-Unit DAS System are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient. *<complete list of OEM compatible implants is provided in the Indications for Use Statement of K231559>* All digitally designed custom abutments for use with Multi-Unit DAS System are to be sent to a Talladium validated milling center for manufacture.
Reason for Predicate Device	Not Applicable	IFUS; abutment designs; materials; manufacturing; biocompatibility; sterilization
Product Codes	NHA	NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Multi-unit Abutment Component Designs		
Prosthesis Attachment	Screw-retained	Screw-retained
Restoration	Multi-unit or single-unit	Multi-unit
Prosthetic Interface Connections	Internal	Internal
Prosthetic Platform Diameter	4.0 mm, Multi-unit Abutments 4.0 mm, Ti-Base Coping for Multi-unit Abutments	4.0 mm, Multi-unit Abutments 4.0 mm, 4.15 mm Ti-Base Copings for Multi-unit Abutments
Gingival Height	1 mm – 4 mm	1 mm – 4 mm
Coping for Multi-Unit Abutment		
Multi-Unit DAS Ti-Base (coping) Engaging Interface	Gingival height – 1.5 mm Prosthetic post height – 10.5 mm Engaging interface Angulation of finished abutment – 0°	Gingival height – 1.5 mm Prosthetic post height – 10.5 mm Non-engaging interface Angulation of finished abutment – 0°
DAS Multi-Unit Ti-Base Coping for Multi-Unit Abutment	Gingival height – 0.5 mm, 1.5 mm Prosthetic post height – 4.5 mm/3.0 mm, 9.0 mm/3.0 mm (maximum/cut-down) Engaging, and Non-engaging interface Angulation of finished abutment – per zirconia superstructure parameters	Gingival height – 0.5 mm, 1.5 mm Prosthetic post height – 4.5 mm/3.0 mm, 9.0 mm/3.0 mm (maximum/cut-down) Engaging, and Non-engaging interface Angulation of finished abutment – per zirconia superstructure parameters

Comparison	Subject Device	Predicate Device
	K243732 Multi-Unit DAS System Talladium España, SL	K231559 Multi-Unit DAS System Talladium España, SL
Zirconia Superstructure Design Parameters		
Configuration for Straight Final Abutment	Subject device Multi-Unit DAS Ti-Base (coping) Engaging Interface (part number 35.322.209.21-2), on subject device Multi-Unit Abutments, with straight zirconia superstructure: Minimum wall thickness – 0.25 mm Minimum post height for single-unit restorations – 4.0 mm (post height measured above the gingival height of the final patient-matched design) Maximum gingival height – 4.90 mm Minimum gingival height – 3.89 mm Maximum angulation – 0°	Minimum wall thickness – 0.25 mm Minimum post height for single-unit restorations – 4.0 mm (post height measured above the gingival height of the final patient-matched design) Maximum gingival height – 5.24 mm Minimum gingival height – 0 mm Maximum angulation – 30°
Configuration for Angled Final Abutment	Subject device Multi-Unit Abutments with previously cleared Dynamic Ti-Base (part number 35.312.209.21-2), with an angled zirconia superstructure: Minimum wall thickness – 0.25 mm Minimum post height for single-unit restorations – 4.0 mm (post height measured above the gingival height of the final patient-matched design) Maximum gingival height – 4.90 mm Minimum gingival height – 3.89 mm Maximum angulation – 15°	Minimum wall thickness – 0.25 mm Minimum post height for single-unit restorations – 4.0 mm (post height measured above the gingival height of the final patient-matched design) Maximum gingival height – 5.24 mm Minimum gingival height – 0 mm Maximum angulation – 30°
Materials		
Multi-Unit Abutments	Titanium alloy, ASTM F136 / ISO 5832-3, anodized	Titanium alloy, ASTM F136/ ISO 5832-3, anodized
Coping for Multi-Unit Abutments Multi-Unit DAS Ti-Base (coping) Engaging Interface DAS Multi-Unit Dynamic Ti-Base	Titanium alloy, ASTM F136 / ISO 5832-3, anodized	Titanium alloy, ASTM F136 / ISO 5832-3, anodized
Superstructure Material	Zirconia, ISO 13356	Zirconia, ISO 13356
Required cement to bond zirconia superstructure to the abutment base	Nova Resin Cement (cleared in K213609)	G-CEM LinkAce™ (cleared as GAM-200 in K120243)
How Provided		
Sterilization	Provided non-sterile; to be moist heat sterilized by the end user	Provided non-sterile; to be moist heat sterilized by the end user
Usage – All Components	Single patient, single use	Single patient, single use