

TRADEMARK ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

ETAS ID: TM462372

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT OF THE ENTIRE INTEREST AND THE GOODWILL
SEQUENCE:	1

CONVEYING PARTY DATA

Name	Formerly	Execution Date	Entity Type
Sterile Containment Technology, LLC		02/13/2018	Corporation: CALIFORNIA
Sterile Containment Technology, LLC		02/13/2018	Corporation: NEVADA

RECEIVING PARTY DATA

Name:	Innovative Sterilization Technologies, LLC
Street Address:	7625 Paragon Rd.
City:	Dayton
State/Country:	OHIO
Postal Code:	45459
Entity Type:	Limited Liability Company: OHIO

PROPERTY NUMBERS Total: 2

Property Type	Number	Word Mark
Registration Number:	2772642	ONE TRAY
Serial Number:	75950207	ONE TRAY

CORRESPONDENCE DATA

Fax Number: 4154333883

Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.

Phone: 4157729655

Email: scorreia@weintraub.com

Correspondent Name: Shauna Correia

Address Line 1: 475 Sansome Street, Suite 1800

Address Line 4: San Francisco, CALIFORNIA 94111

NAME OF SUBMITTER:	Shauna N. Correia
SIGNATURE:	/s/ Shauna N. Correia
DATE SIGNED:	02/15/2018

Total Attachments: 33

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INTELLECTUAL PROPERTY RIGHTS PURCHASE AND TRANSFER AGREEMENT

This Intellectual Property Rights Purchase and Transfer Agreement (this "Agreement") is made as of February 12, 2018 ("Effective Date"), by and between Innovative Sterilization Technologies, LLC, a limited liability company organized and existing under the laws of the State of Ohio and having a principal place of business at 7625 Paragon Rd, Dayton, OH 45459 (hereinafter referred to as "IST" or "Buyer"), on the one hand, and Sterile Containment Technology, LLC, a limited liability company organized and existing under the laws of the State of California, with an address at Suite 204, 1301 Quarry Court, Richmond, CA 94801 ("SCT-CA"), Sterile Containment Technology, LLC, a limited liability company organized and existing under the laws of the State of Nevada, with an address at 5605 Riggins Court, Suite 200, Reno, NV 89502 ("SCT-Nevada"), and Percival Banks, an individual residing at 66 Hardie Drive, Moraga, CA 94556 (SCT-CA, SCT-Nevada, and Percival Banks are herein after collectively referred to as "SCT" or "Seller"), on the other hand.

RECITALS:

A. Seller currently owns or has the right to certain intellectual property rights identified without limitation on Exhibit A hereto, including but not limited to the Patents, Trademarks, Copyrights, FDA Approvals and 510(k) clearance, and all associated Intellectual Property Rights for what is commonly known as the "ONE TRAY Rapid Processing System" and its components, including but not limited to containers, processing kits, filters and solutions (hereinafter referred to as "ONE TRAY").

B. On or about February 22, 2013, IST entered into an on-going, exclusive, transferrable, world-wide, royalty-bearing right and license with SCT to make, use, sell, offer for sale, and have made products or components covered by the ONE TRAY "Intellectual Property Rights", as that term is defined below (hereinafter referred to as the ONE TRAY Exclusive License Agreement"). A copy of the ONE TRAY Exclusive License Agreement and any and all amendments thereto is attached as Exhibit B hereto.

C. On or about February 22, 2013, Innovative Interventions-SCT, LLC entered into an Exclusive Distributor Agreement with SCT granting IST the exclusive right to market and sell the ONE TRAY products in Illinois, Indiana, Kentucky, Ohio, Michigan, Tennessee, Western Pennsylvania and West Virginia. Subsequently, Innovative Interventions-SCT, LLC assigned its interest in the exclusive distributor agreement to IST. Thereafter, IST purchased the exclusive distribution rights from all other third parties with whom SCT had entered into distributor agreements for the territories of: New York, Connecticut, Rhode Island, Massachusetts, Maine, New Hampshire, Vermont, Maryland, Virginia, Delaware, Washington D.C., Eastern Pennsylvania, North Carolina, South Carolina, Missouri, Kansas, Nebraska, Iowa, Colorado, Minnesota, Montana, North Dakota, South Dakota, Utah, Wisconsin, Wyoming, Georgia, Texas, Oklahoma, and the Veterans Administration and other U.S. Government Agencies (collectively, the "Distribution Rights").

D. IST now wishes to purchase in full from SCT all rights, title, and interests in the ONE TRAY intellectual property and all attendant Intellectual Property Rights for the Purchase Price set forth in Section 3.

E. On or about January 26, 2015, Don Jay Hegwer, an individual (“Hegwer”), a Third-Party to this Agreement, sued IST and SCT for claims unrelated to the ONE TRAY Intellectual Property Rights (Contra Costa Superior Court Case No. C-15-00143, referred to as “the Action”). IST and Hegwer reached a settlement, the terms of which were satisfied in full, and obtained a good faith settlement determination from the Court. IST and SCT reached a settlement of IST’s cross-claim against SCT, the terms of which were satisfied in full. Hegwer and SCT then reached a settlement, pursuant to which the Court entered a money judgment against SCT in favor of Hegwer in the amount of \$500,000.00 (inclusive of attorney’s fees), plus costs and accrued interest. In turn, Hegwer’s attorneys of record, Loren Schwartz of Dunn & Panagotacos LLP, filed an attorney’s fee lien against Hegwer’s recovery from SCT in the Action. Hegwer obtained an Order from the Court in the Action on December 7, 2017, assigning to him all of SCT’s rights to any payments under the IST License Agreement, and to any of SCT’s “interest” in IST, until the judgment lien has been satisfied. Hegwer has recorded notices of his judgment lien against the ONE TRAY Intellectual Property Rights, in the U.S. Patent and Trademark Office and with the FDA. The Parties desire to extinguish and satisfy Hegwer’s lien in full, in conjunction with the sale of the ONE TRAY Intellectual Property Rights and payment from IST to SCT therefor. Hegwer has agreed to accept \$500,000.00 in full satisfaction of his judgment lien against SCT, as set forth in the Release of Monetary Interest attached hereto as Exhibit C.

It is therefore agreed as follows:

1. Definitions. As used herein, the following terms shall have the following meanings:

1.1 Intellectual Property Rights. The term “Intellectual Property Rights” means all (i) patents, patent applications, provisionals, continuations, divisionals, foreign patent applications, patent disclosures and inventions, any application claiming priority from any of these, any patents that have issued or in the future issue therefrom, and any and all extensions or restorations by existing or future extension or restoration mechanisms including reissues and post-grant proceedings of the foregoing patents or patent applications, (ii) Internet Domain names, trademarks, service marks, trade dress, trade names, logos and corporate names and registrations and applications for registration thereof together with all of the goodwill associated therewith, (iii) copyrights (registered or unregistered) and copyrightable works and registrations and applications for registration thereof, (iv) mask works and registrations and applications thereof, (v) computer software, data, databases and documentation thereof, (vi) trade secrets and other confidential information (including ideas, formulas, compositions, inventions (whether patentable or unpatentable and whether or not reduced to practice), know-how, manufacturing and production processes and techniques, research and development information, drawings, specifications, designs, plans, proposals, technical data, and copyrightable works, financial and marketing plans and customer and supplier lists and information, (vii) copies and tangible

embodiments thereof (in whatever form or medium), and (viii) all FDA approvals and 510(k) clearances.

1.2 Affiliate. The term "Affiliate" shall mean (i) any individual, partnership, corporation, or other entity or person which is owned or controlled directly or indirectly by a Party; (ii) any other individual, partnership, corporation, or other entity or person which controls or is controlled by or under common control with Seller; and (iii) any officer, director, partner, or owner of 10 percent or greater equity or voting interest in any such other corporation, partnership, or other entity or person.

1.3 Agreement. The term "Agreement" shall mean this instrument and all Schedules and Exhibits attached hereto.

1.4 Party. "Party" means Buyer or Seller, and "Parties" means Buyer and Seller together.

1.5 Third Party. "Third Party" means any entity other than Buyer or Seller and their respective Affiliates.

2. Sale, Purchase and Transfer of Intellectual Property Rights.

2.1 Assignment of Intellectual Property Rights. Subject to the terms and conditions of this Agreement, and as of the Effective Date, Seller hereby sells, assigns, transfers, conveys and delivers to Buyer, and Buyer hereby purchases and acquires from Seller, all of Seller's right, title and interest in and to the ONE TRAY Intellectual Property Rights, free and clear of any security interest, lien, charge, option, claim or other encumbrance except as specifically disclosed in this Agreement.

3. Payment Obligations.

3.1 Purchase Price. The total purchase price ("Purchase Price") for the ONE TRAY Intellectual Property Rights and assets shall be six-hundred and one thousand U.S dollars (\$601,000), a portion of which will be paid directly by Buyer to Don Jay Hegwer and his attorneys (Dunn & Panagotacos LLP) in full satisfaction of Mr. Hegwer's judgment lien and the Dunn & Panagotacos LLP attorney fee lien. Payment to Mr. Hegwer and his attorneys will be made to release of all of Mr. Hegwer's liens and any other alleged claims to any and all right, title or interest to any and all of the ONE TRAY Intellectual Property Rights. Payments to SCT, Mr. Davis, Mr. Hegwer and his attorneys will be made only if and only after the Effective date and only after Mr. Banks has executed this Agreement and only if and only after Mr. Hegwer has executed the Release of Monetary Interest in Intellectual Property, a copy of which is attached as Exhibit C hereto, and the Full Satisfaction of Judgment, a copy of which is attached to that agreement as Exhibit 2, and after Loren Schwartz has delivered an executed pleading providing that the Dunn & Panagotacos LLP lien has been satisfied in full.

3.2 Payment Distribution. Payment of the Purchase Price by Buyer shall be made only as follow, and all payments from Buyer are contingent upon execution of the Agreements as set forth in 3.1:

3.2.1 One-hundred and one thousand U.S. dollars (\$101,000) to Percival C. Banks within five (5) business days after the Effective Date, provided that Mr. Banks has executed this Agreement. Payment will be made via wire transfer to:

Jefford C. Davis (client trust account)
Chase Bank
Transit/ABA/routing no.: 322271627
Account no.: 8790025429

270 S. State College Blvd.
Brea, CA 92821

3.2.2 Three-hundred and seventy-five thousand U.S. dollars (\$375,000) to Don Jay Hegwer. Payment is contingent upon, and will be made only after the Effective Date and after Mr. Hegwer has executed the Release of Monetary Interest in Intellectual Property and Satisfaction of Judgment, and be made via wire transfer as set forth in the Release of Monetary Interest in Intellectual Property (Exhibit C hereto).

3.2.3 One-hundred and twenty-five thousand U.S. dollars (\$125,000) to Dunn & Panagotacos LLP. Payment is contingent upon, and will be made only after the Effective Date and only after Mr. Hegwer has executed the Release of Monetary Interest in Intellectual Property and Satisfaction of Judgment, and be made via wire transfer as set forth in the Release of Monetary Interest in Intellectual Property (Exhibit C hereto).

4. No License Back to Seller. For the avoidance of doubt, the Parties expressly agree Buyer does not grant back to Seller any license or other rights to the ONE TRAY Intellectual Property Rights on or after the Effective Date. Without limitation, Seller therefore expressly agrees as of the Effective Date to the removal of the ONE TRAY section of the SCT website (<http://www.sctus.com>), removal of any mention of ONE TRAY on the SCT website, and removal of any documentation on the SCT website related to ONE TRAY.
5. Transfer Fees. Any recording fees or related ONE TRAY Intellectual Property Rights transfer fees shall be paid by Buyer.
6. Representations and Warranties of Seller.

6.1 Seller represents and warrants to Buyer that:

(a) Seller owns all right, title and interest in and to the ONE TRAY Intellectual Property Rights and has not transferred its interest in the ONE TRAY Exclusive License Agreement.

(b) There are no assignments, transfers, conveyances, distribution agreements, or liens affecting his right, title and interest in or to the ONE TRAY Intellectual Property Rights that are currently in force or currently existing that will in the future come into force except those specifically disclosed in this Agreement.

(c) Seller has the sole right to grant the rights hereunder and has not granted any right or license to any Third Party to use the ONE TRAY Intellectual Property Rights, including any rights of first or last refusal or other options to negotiate rights in the ONE TRAY Intellectual Property Rights.

(d) No royalties, honoraria or other fees are payable to any Third Party for the use of or right to use any ONE TRAY Intellectual Property Rights.

(e) To Seller's Knowledge, the ONE TRAY Intellectual Property Rights do not infringe any patent, copyright, trademark, or other Intellectual Property Rights of any Third Party or otherwise violate the rights of any Third Party and no claim has been made or threatened alleging any such violation.

(f) To Seller's knowledge, no Third Party has violated any right of Seller in the ONE TRAY Intellectual Property Rights.

(g) No Third Party is challenging the ownership, use, validity or enforceability of the ONE TRAY Intellectual Property Rights.

(h) Seller shall not engage in any act or conduct, or omit to perform any necessary act, the result of which would invalidate any portion of any of the ONE TRAY Intellectual Property Rights or render any portion of them unenforceable.

(i) Seller certifies that the 510(k) clearance for the ONE TRAY Sealed Sterilization Container is current and legal.

7. Representations and Warranties of Buyer.

7.1 IST has not transferred or sold its interests in the ONE TRAY Exclusive License Agreement or the Distribution Rights.

8. Mutual Representations and Warranties.

8.1 Each Party represents and warrants to the other Party that:

(a) Such Party has the full power and authority to enter into and perform this Agreement.

(b) This Agreement constitutes the valid and binding obligations of such Party, enforceable against it or him in accordance with its terms, except as may be limited by bankruptcy, insolvency, moratorium or other similar laws affecting creditors' rights generally, and subject to general principles of equity (regardless of whether enforcement is considered in a proceeding in equity or at law).

(c) The execution, delivery and performance by such Party of this Agreement will not (i) conflict with or result in the breach or termination of, or constitute a default under, any lease, agreement, commitment or other instrument, or any order, judgment or decree to which such Party is a party or by which such Party is bound or (ii) constitute a violation by such Party of any law, regulation, ordinance, order, writ, judgment, injunction, decree or other requirement of any governmental body or court applicable to such Party.

(d) No consent, approval or authorization of, or designation, declaration or filing with, any person, entity or governmental authority is required on the part of such Party in connection with the execution, delivery and performance of this Agreement.

(e) There is no claim, litigation, proceeding or governmental investigation pending or, to such Party's knowledge, threatened, or any order, injunction or decree outstanding, against such Party that would prevent or have a material adverse effect on the rights, duties or obligations of the Parties as set forth in this Agreement.

(f) Both Parties agree that this Agreement terminates the ONE TRAY Exclusive License Agreement, and all rights, duties, or obligations, including as set forth in any addenda thereto.

9. Further Agreements of the Parties.

9.1 Notice of Changes and Events. Each Party shall promptly notify the other Party in writing, and furnish to such Party any information that such Party may reasonably request, with respect to the occurrence of any event or the existence of any state of facts that would (i) result in the Party's representations and warranties not being true or (ii) impair the Party's ability to perform its obligations under this Agreement.

9.2 Expenses. Except as otherwise specifically provided in this Agreement, Buyer and Seller shall bear their own respective expenses incurred in connection with this Agreement and in connection with all obligations required to be performed by each of them under this Agreement.

9.3 Publicity. Buyer shall have the right to issue a public announcement or press release or otherwise inform any Third-Party concerning the transactions contemplated by this Agreement, or provide a Third-Party with a copy of the

Agreement. Seller shall not issue a public announcement or press release or otherwise inform any Third-Party concerning the transactions contemplated by this Agreement, or provide a Third-Party with a copy of the Agreement, except with the express written consent of Buyer and/or as may be required by applicable law or regulation or rule of any stock exchange or organized securities market on which the securities of Buyer or Seller's securities are listed or traded.

- 9.4 Indemnification. Seller shall indemnify and hold harmless Buyer, and its Affiliates, directors, officers, employees, agents and other representatives (collectively, the "Buyer Indemnified Parties"), against all loss, liability, claims, damage, expense, fines, or penalties (including reasonable fees and expenses of counsel in any matter, whether involving a third party or between the Seller and Buyer Indemnified Parties) (collectively "Losses") that any Buyer Indemnified Party may suffer, sustain or become subject to as a result of, arising out of, or in connection with: (i) any breach by Seller of any representations or warranties contained in this Agreement; and (ii) any breach by Seller of his covenants or other agreements contained in this Agreement.
- 9.5 Governing Law. This Agreement shall be governed by and construed in accordance with the law of the State of California, without giving effect to principles governing conflicts of law that would cause the law of any other jurisdiction to apply.
- 9.6 Venue and Jurisdiction. In the event of a cause of action arising under or in connection with this Agreement, the Parties agree to have their disputes or controversies decided in the Superior Court in and for the County of Contra Costa, State of California and/or the United States District Court for the Northern District of California shall have exclusive jurisdiction over the Parties with respect to such dispute or controversy. Each of the Parties submits to the venue and jurisdiction of those courts, including the *in personam* and subject matter jurisdiction of those courts, waives any objection to such jurisdiction on the grounds of venue or *forum non conveniens*, the absence of *in personam* or subject matter jurisdiction and any similar grounds, consents to service of process by mail or any other manner permitted by law, and irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement. These consents to jurisdiction shall not be deemed to confer rights on any person other than the Parties.
- 9.7 Assignment. No Party may assign any of its rights or delegate any of its duties under this Agreement without the prior written consent of the other Party, which may be withheld for any reason or for no reason, except that either Party may assign its rights and delegate its duties to a successor to such Party's entire business and Buyer may, without the consent of Seller, (a) assign its rights under this Agreement to any Affiliate of Buyer, and (b) collaterally assign any or all of its rights and interests hereunder to one or more lenders of Buyer.

- 9.8 Counterparts. This Agreement may be executed in multiple counterparts, which together shall constitute a single instrument. E-mail or other electronic delivery of an executed counterpart shall be valid and binding for all purposes.
- 9.9 Entire Agreement. This Agreement, including the schedules and exhibits hereto, contains a complete statement of all the arrangements between the Parties with respect to its subject matter, supersedes any previous agreements between them relating to that subject matter, and cannot be amended, modified or terminated except in a written document executed by the Parties.
- 9.10 Severability. The invalidity of any provision or portion of a provision of this Agreement shall not affect the validity of any other provision of this Agreement or the remaining portion of the applicable provision.
- 9.11 No Third-Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person other than the Parties and their respective successors and permitted assigns.
- 9.12 Amendments and Waivers. No amendment of any provision of this Agreement shall be valid unless the same shall be in writing and signed by Buyer and Seller. No waiver by either Party of any default, misrepresentation or breach of warranty or covenant hereunder, whether intentional or not, shall be deemed to extend to any prior or subsequent default, misrepresentation or breach of warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence.
- 9.13 Construction. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring either Party by virtue of the authorship of any of the provisions of this Agreement. Any reference to any federal, state or local statute or law shall be deemed also to refer to all rules and regulations promulgated thereunder, unless the context requires otherwise. The word "including" shall mean including without limitation. If any Party has breached any representation, warranty or covenant contained herein in any respect, the fact that there exists another representation, warranty or covenant relating to the same subject matter (regardless of the relative levels of specificity) which the Party has not breached shall not detract from or mitigate the fact that the Party is in breach of the first representation, warranty or covenant.
- 9.14 Specific Performance. Each of the Parties acknowledges and agrees that the other Parties would be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached. Accordingly, each of the Parties agrees that the other Parties shall be entitled to an injunction or injunctions to prevent breaches of the provisions of this Agreement.


9.15 Cooperation. Each of the Parties hereto will fully cooperate with the other, and will execute all such other documents as may be necessary to effectuate a full and complete transfer of ownership including, without limitation, SCT's notice to the Food and Drug Administration of the change of ownership of the application and 510k Clearance and Approvals to IST, attached hereto as Exhibit E.

IN WITNESS WHEREOF, The parties have executed this Agreement as of the Effective Date.

By: _____ Date: _____
Sterile Containment Technology, LLC (California)
Percival Banks
Managing Member/CEO

By: _____ Date: _____
Sterile Containment Technology, LLC (Nevada)
Percival Banks
Managing Member/CEO


By: _____ Date: _____
Percival Banks
Individually


By:  _____ Date: 2/12/2018
Innovative Sterilization Technologies
Scott Cohen
President/CEO

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By:  Date: 2/13/2018
Sterile Containment Technology, LLC (California)
Percival Banks
Managing Member/CEO

By:  Date: 2/13/2018
Sterile Containment Technology, LLC (Nevada)
Percival Banks
Managing Member/CEO

By:  Date: 2/13/2018
Percival Banks
Individually

By: _____ Date: _____
Innovative Sterilization Technologies
Scott Cohen
President/CEO

PLEASE SEE ATTACHED
FOR NOTARIZATION

CERTIFICATE OF ACKNOWLEDGMENT

California All-Purpose Acknowledgment

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Contra Costa

On 2.13.18 before me, M. MARCUCCI, Notary Public,
Date Name of Officer

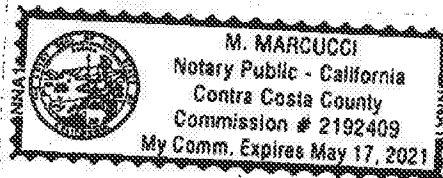
personally appeared Percival Banks
Name of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

M. Marcucci
Signature of Notary Public



Place Notary Seal Above

Description of Attached Document

Title or Type of Document: Purchase & Transfer Agreement

Document Date: 2.13.18 Number of Pages: _____

Signers(s) other than named above: _____

Exhibit A

ONE TRAY Intellectual Property Rights (without limitation)

- U.S. Patent No. 6,319,481, entitled “Sterilization Container”
- U.S. Patent No. 7,595,032, entitled “Protected seal for a filtered vent in a sterilization container”
- * U.S. Trademark Reg. No. 2772642 (Serial Number 78108889) for “ONE TRAY”
- * U.S. Trademark Serial Number 75950207 for “ONE TRAY”
- * U.S. Copyright for “ONE TRAY”
- * FDA 510(K) No. K052567 for the ONE TRAY Sealed Sterilization Container
- Device description from original 510k approval:
 - ONE TRAY® is a sealed rigid container with a rectangular patterned group of perforations forming vented areas in the lid and base. Disposable hydrophobic SMS filters cover each vented area and are held firmly in place by a perforated stainless steel filter cover. This assembly permits the penetration of steam during the sterilization process and serves as a bacterial and fluid barrier at the conclusion of the sterilization cycle.

Exhibit B
(ONE TRAY Exclusive License Agreement)

{SF094685.DOCX;3}

LICENSE AGREEMENT

This Agreement is made to become effective on the 22nd day of February 2013 ("Effective Date") between STERILE CONTAINMENT TECHNOLOGIES, LLC AND PERCIVAL BANKS, individually and in his capacity as a member/CEO of Sterile Containment Technologies, LLC a limited liability company organized and existing under the laws of the State of California, whose address is Suite 204, 1301 Quarry Court, Richmond, CA 94801 (hereinafter referred to collectively as "Licensor"), and INNOVATIVE STERILIZATION TECHNOLOGIES, a company organized and existing under the laws of the State of Ohio and having its principal place of business at 10881 Yankee Street, Centerville, Ohio 45458 (hereinafter referred to as "Licensee").

WHEREAS, Licensor has been assigned the rights to the following patents ("The Patents", Copyrights, ("The Copyrights") Trademarks ("The Trademark") and FDA Approvals ("The Approvals) for what is commonly known as the "ONE TRAY Rapid Processing System" and its components, including but not limited to containers, processing kits, filters and solutions (hereinafter referred to as ONE TRAY). This is a medical device used for sterilization.

- * U.S. Patent #6,319,481 B1 Sterilization Container
- * U.S. Patent #7,595,032 B2 Protected Seal for Filtered Vent in a Sterilization Container
- * U.S. Trademark Registration # 78108889 and 75950207
- * U.S. Copyright # "ONE TRAY"
- * FDA Approval # K052567

WHEREAS, Licensee is in the business of marketing and selling various types of medical products; and

WHEREAS, it is acknowledged, by both Licensor and Licensee that in order to produce the ONE TRAY product in quantities sufficient for commercial distribution and sale that significant capital and labor is required to bring the product to market.

WHEREAS, Licensee is ready, willing and able to make the significant capital and labor investments to manufacture, market and sell the ONE TRAY family of products.

WHEREAS, the parties hereto desire to enter into the present license agreement whereby, during the term hereof, Licensor agrees to grant to Licensee certain rights and privileges with respect to said patents, trademarks, copyrights and FDA approvals trademarks to market and sell the ONE TRAY products.

NOW, THEREFORE, in consideration of the above premises, the parties hereto agree as follows:

1. Definitions

- (a). The term "Licensed Product" shall mean and include but is not limited to the "ONE TRAY Rapid Processing System" and its components, including but not limited to containers, processing kits, filters and solutions covered by the claims of a The Patents, The Trademarks, The Copyrights and The Approvals which is designed for sale directly to the end user thereof and is capable of being used by said end user without any modification thereof or addition thereto.
- (ii) any product which utilizes a partially constructed or modified sterilization system covered by the claims of The Patents, The Trademarks, The Copyrights and The Approvals as a major and integral component in either the final construction thereof or in the operation thereof, such as a non-standard size tray or modified tray, and the like.
- (iii) any product that does use the same or similar, packaging, filter set and/or solution covered by the claims of The Patents, The Trademarks, The Copyrights and The Approvals.
- (iv). The term "The Patents" shall mean the Patent, together with all reissues, continuations, continuation-in-parts and divisions subsequently filed and any patents issued thereon, together with all foreign counterpart patents, applications for patents, registrations, and the like, which are filed thereon.
- (v). The term "Licensed Technology" shall mean and include Licensor's proprietary and confidential specifications of Licensed Products and any component therefor or thereof.
- (vi). The "Term" of this Agreement shall commence on the Effective Date hereof and shall continue in effect for the life or lives of said Licensed Patents, The Trademarks, The Copyrights and The Approvals, and any extensions thereof, unless otherwise terminated in accordance with the terms hereinafter set forth.

2. Licenses and Other Rights and Obligations

- (a). During the Term and subject to the terms and conditions hereinafter set forth, Licensor hereby grants to Licensee an exclusive, transferable, worldwide, royalty-bearing right and license under the Licensed Patents, the Trademarks, the Copyrights, the Approvals and Licensed Technology to make, use, sell and to have made any Licensed Products, or any component thereof or therefor.

3. Payment and Other Rights Granted To Licensor

- (a). Licensee shall pay to Licensor(s), jointly and severally, the sum of \$22,250.00 USD on the Effective Date hereof. Receipt of which is hereby specifically acknowledged by

- (b) Licensor shall have the right to purchase certain Licensed Products, when available,

from Licensee for resale to other distributors who may market and sell the Licensed Products, only outside of the states of Illinois, Indiana, Kentucky, Ohio, Michigan, Tennessee, West Virginia and Western Pennsylvania (Licensee is and remains the exclusive distributor in these states), as follows:

- (i) Licensors may purchase, when available, all ONE TRAY Containers and filter sets from Licensee for the sum of the total tray manufacturing cost (to be determined and set after assembly from the actual manufacturer) plus 20%. These costs may fluctuate from the supplier and cause purchase amounts to change. Licensors will require 75% of total container costs up front before manufacturing begins on those trays. The remaining 25% of total cost and an additional 20% will be paid to Licensee in 30 days following delivery.
- (ii) Licensors may purchase, when available, the ONE TRAY filter sets from Licensee for the total sum of filter manufacturing cost (to be determined and set after assembly from the actual manufacturer/suppliers) plus 20%. These costs may fluctuate from manufacturers/suppliers and cause purchase amounts to change. Licensors will require 75% of total filter set costs up front before manufacturing begins on those filter sets. The remaining 25% of total cost and additional 20% will be paid to Licensee in 30 days following delivery.
- (c) Licensors may acquire the initial tooling used for manufacturing the Licensed Products for the sum of Licensors' total manufacturing costs (To be determined at time of purchase from Licensee) plus 20% interest plus \$500,000 for compensation of previous work completed. Licensors may execute this tooling purchase option at any time the Licensors has the ability to pay for all of the above sums in cash in a single payment.
- (d) The Licensors will automatically acquire from Licensee the initial tooling used to manufacture the Licensed Products when Licensee's net profits from tray sales equals Licensee's total investment for manufacturing the Licensed Products plus 20% interest plus \$500,000 for compensation of previous work completed. Licensee agrees to update Licensors on progress each quarter regarding the net profits compared to total investment for manufacturing the Licensed Products.
- (e) In the event that the Licensors acquires the tooling from Licensee used to manufacture the Licensed Products and in fact manufactures some or all of the Licensed Products then the Licensee shall have the right of first refusal to purchase all Licensed Products produced by the Licensors at a price of cost of plus 20% which will be paid to Licensors 30 days following delivery. The failure of Licensors to have available quantities of licensed products in quantities sufficient to fulfill orders placed by the Licensee shall be deemed a material breach of this agreement.
- (f) In the event that the Licensors acquires the tooling from Licensee for the manufacturing of the Licensed Products and manufactures the ONE TRAY filter sets, and the Licensee stops manufacturing the filter sets, then Licensors agrees to stock filter sets in verifiable inventory in the sum of no less than 200,000 units for every 1,000 tray units

manufactured by the Licensee so that the Licensee may continue to supply customers and other end users of the Licensed Product without risk of shortage or disruption to the normal course of business.

4. Obligations of Licensor.

(a) It is acknowledged by the Licensor that he has particular technical expertise in the design, function and operation of the Licensed Products and will be required to participate in the set-up, tooling and manufacturing process to ensure that the Licensed Products will meet or exceed designed performance specifications. Licensor shall timely assist in supplying technical support and expertise in the manufacturing of the trays, filter set configuration and sourcing.

(b) In light of Licensor's superior technical expertise regarding the Licensed Products, the Licensor will be required to timely respond to any product complaints and/or requests for technical information. If the requested information constitutes a trade secret or confidential information no right of privilege shall be asserted against the Licensee its agents, representatives or employees, but may be asserted against any third parties requesting assistance or information regarding the Licensed Products.

(c) Due to the fact that the Licensed Products only have FDA Approval for a shelf life of Forty-Eight (48) hours it is necessary to increase the shelf life of the Licensed Products to no less than thirty (30) days so that the product will be competitive in the marketplace. Licensor agrees to immediately focus on extending the shelf life of the existing Licensed Products to no less than thirty (30) days by conducting new testing and submitting appropriate applications and material to the FDA for approval within one year from the date of the execution of this agreement.

(d) Licensor is required to attend and participate in national trade shows, meetings and conferences in order to promote the Licensed Products in a manner that is consistent with the best practices of the industry.

(e) Licensor shall provide promotional and sales assistance.

5. Representations and Warranties; Limitation of Liability; Indemnification

(a). Licensor hereby represents that it has independently developed the Licensed Technology and that, to the best of its knowledge and belief, the manufacture, use and/or sale of any Licensed Product according to the Licensed Technology will not infringe upon any patent right of any third party and that it has no present knowledge that such a Licensed Product will infringe upon any patent right of any third party.

(b). The warranties provided by Licensor in this Section 8 are in addition to all statutory and implied warranties, including but not limited to warranties of non-infringement, merchantability and fitness for a particular purpose.

(c). Licensor shall defend, indemnify and hold Licensee harmless from and against all claims, damages, losses, liabilities and expenses, including reasonable fees and expenses of attorneys and other professionals arising out of or resulting from claims that the Licensed Products are defective in design, defectively manufactured and/or that there was a failure to warn of dangerous conditions regarding the use of the Licensed Products and/or warn of the risks associated with the Licensed Product. Licensor agrees to obtain sufficient amounts of liability insurance to cover any claims for damages, losses, liabilities and expenses, including reasonable fees and expenses of attorneys and other professionals which may be caused by or related to the Licensed Products.

(d). Licensor shall defend, indemnify and hold Licensee harmless from and against all claims, damages, losses, liabilities and expenses, including reasonable fees and expenses of attorneys and other professionals arising out of or resulting from the following: (a), any action by a third party against Licensee that is based upon or alleges any claim that any Licensed Product infringes any right of any third party; and (ii) any action by a third party that is based upon or alleges that any product sold or manufactured by Licensee is defective in any way; and (iii) any other claim caused in whole or in part due to the breach of this Agreement by Licensor and/or any negligent act or omission of Licensor or any of its officers, agents, contractors or employees.

6. General Provisions

(a). All notices required by this Agreement shall be in writing and sent by certified mail, return receipt requested, by hand or overnight courier, to the following addresses:

If to Licensor: Sterile Containment Technologies
 Attn. Percival Banks
 1301 Quarry Ct.
 Suite #204
 Richmond, California 94801

If to Licensee: Innovative Sterilization Technologies
 Attn. Scott Cohen
 10881 Yankee Street
 Centerville, OH 45458

Unless either party shall at any time by notice in writing designate a different address. Notice shall be effective (i) three (3) days after the date officially recorded as having been deposited in the mails, or (ii) upon receipt by hand delivery or (ii) the next day if by overnight courier.

(b). If any provision (or any portion thereof) of this Agreement is for any reason declared to be invalid or unenforceable, the validity of the remaining provisions (or remaining portions thereof) shall not be affected.

(c). No waiver by either party, whether express or implied, of any provision of this Agreement, or of any default hereunder including, but not limited to, the provisions relating to timely payment, shall constitute a continuing waiver or a waiver of any other provision or default, and no waiver shall prevent the other party from enforcing any and all provisions of this Agreement upon subsequent or continuing breach or default.

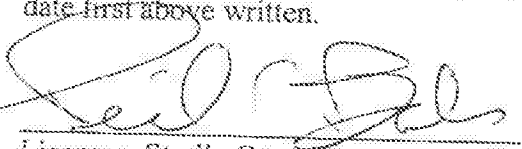
(d). The relationship established between the parties by this Agreement is that of independent contractors, i.e., Licensee and Licensor. No provision of this Agreement shall be deemed to place the parties in the relationship of partners or joint ventures, or constitute one party the agent of the other.

(e). This Agreement represents the entire agreement of the parties replacing any earlier agreements concerning the same matters. It may only be modified by a subsequent writing signed by the parties.

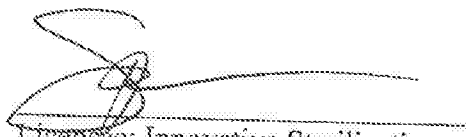
(f). This Agreement shall be governed by and shall be construed in accordance with the laws of the State of Ohio, U.S.A. excluding any conflicts of law provisions.

(g). Time is of the essence in this agreement.

IN WITNESS WHEREOF, the parties hereto have set their signatures as of the date first above written.



Licensor: Sterile Containment
Technologies LLC.



Licensee: Innovative Sterilization
Technologies



Licensor: Percival Banks, individually



Licensee: Scott Cohen

Date: 2/22/13

Date: 2/22/2013

ADDENDUM TO LICENSE AGREEMENT

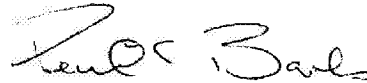
This Addendum to License Agreement (this "Addendum") is made to become effective on the 28th day of February, 2013 (the "Effective Date") between Sterile Containment Technologies, LLC, a limited liability company organized and existing under the laws of the State of California and Percival Banks, individually and in his capacity as a Member/CEO of Sterile Containment Technologies, LLC (hereinafter referred to collectively as "Licensor") and Innovative Sterilization Technologies, LLC, a limited liability company organized and existing under the laws of the State of Ohio (the "Licensee") who agree as follows:

1. Recitals. Pursuant to a License Agreement dated February 22, 2013 (the "License Agreement"), Licensor granted certain license rights to Licensee. The Licensor and Licensee have entered into this Addendum to modify the License Agreement in certain respects.

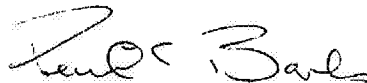
2. Addendum. The License Agreement identified the Licensee as "Innovative Sterilization Technologies, a company organized and existing under the laws of the State of Ohio". The License Agreement is hereby modified to identify the Licensee as "Innovative Sterilization Technologies, LLC, a limited liability company organized and existing under the laws of the State of Ohio". The Effective Date of this Addendum shall be the Effective Date of the License Agreement.

3. Confirmation. In all other respects the License Agreement is hereby ratified, confirmed and approved.

STERILE CONTAINMENT TECHNOLOGIES, LLC



By: Percival C. Banks
Its: President

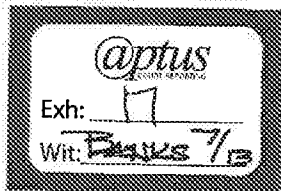


Percival Banks, Individually

INNOVATIVE STERILIZATION TECHNOLOGIES, LLC

By: _____
Its: Scott Cohen, President

KTBH: 4819-1166-9011, v. 1



IST_000596

TRADEMARK
REEL: 006274 FRAME: 0216

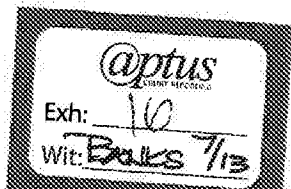
ADDENDUM TO LICENSE AGREEMENT

This Addendum to License Agreement (this "Addendum") is made to become effective on the 29th day of March, 2013 (the "Effective Date") between Sterile Containment Technologies, LLC a limited liability company organized and existing under the laws of the State of California and Percival Banks, individually and in his capacity as a Member/CEO of Sterile Containment Technologies, LLC (herein referred to collectively as "Licensor") and Innovative Sterilization Technologies, LLC, a limited liability company organized and existing under the laws of the State of Ohio (the "Licensee") who agrees as follows:

- 1. Recitals.** Pursuant to a License Agreement dated February 22, 2013 (the "License Agreement"), Licensor granted certain license rights to Licensee. The Licensor and Licensee have entered into this Addendum to modify the License Agreement in certain respects.
- 2. Addendum.** In the event of the untimely death of Percival Banks, in his capacity as a Member/CEO of Sterile Containment Technologies LLC, he agrees to transfer ownership of all ONE TRAY® intellectual property including but not limited to U.S. Patent #6,319,481 and #7,595,032, all Trademark Registrations including but not limited to U.S. Trademark Registration #78108889 and #75950207, all U.S. Copyrights including but not limited to U.S. Copyright # "ONE TRAY®", and all U.S. FDA Approvals including but not limited to FDA Approval # K05267.

In exchange for the transfers of ownership to the above items, Innovative Sterilization Technologies LLC will pay Sterile Containment Technologies, LLC, an amount equal to 5% of the net sales for the previous 12 month period. This payment will be sent following the completion of the transference of ownership to all of the above items and in one lump sum payment. Innovative Sterilization Technologies, LLC, reserves the rights to execute this Addendum.
- 3. Confirmation.** In all other respects the License Agreement is hereby ratified, confirmed, and approved.

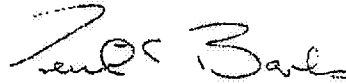
Innovative Sterilization Technologies, LLC
10881 Yankee Street
Dayton, OH 45458
O: (937) 619-0138 F: (937) 630-4346



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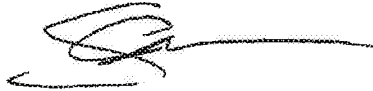
TRADEMARK
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STERILE CONTAINMENT TECHNOLOGIES, LLC



By: Percival C. Banks
Its: President/Individually

INNOVATIVE STERILIZATION TECHNOLOGIES,
LLC



By: Scott E. Cohen
Its: President/CEO

Innovative Sterilization Technologies, LLC
10881 Yankee Street
Dayton, OH 45458
O: (937) 619-0138 F: (937) 630-4346

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TRADEMARK
REEL: 006274 FRAME: 0218

Exhibit C
(Release of Monetary Interest in Intellectual Property)

{SF094685.DOCX;3}

Exhibit D

(Transfer of Ownership of Applications for FDA Approval)

{SF094685.DOCX;3}

February 12, 2018

Food and Drug Administration
Center for Devices & Radiological Health, HFZ-308
9200 Corporate Blvd.
Rockville, MD 20850-4015

Re: Transfer of 510(k) No. K052567

To whom it may concern:

Pursuant to Section 314.72 of Title 21 of the Code of Federal Regulations, subsection (a), please allow this to serve as notice that 510(k) submitter/holder Sterile Containment Technology, LLC (FDA Establishment Registration No. 3003793526) is no longer in the business of marketing, distributing, selling or developing the One Tray Sealed Sterilization container or associated products related to the FDA 510(k) number K052567.

Ownership and all rights to the below-referenced application, 510(k) clearance, and medical device, including the rights to use the medical device's 510(k) number, have been transferred effective as of February 12, 2018 to Innovative Sterilization Technologies, LLC (FDA Owner/Operator Number 10046120, Establishment Registration Number 3010772758).

Please update your files to reflect that Innovative Sterilization Technologies, LLC is the new the 510(k) holder of the following medical device:


Device Name and Classification

510(k) Number:	K052567
Trade Name:	One Tray Sealed Sterilization container
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Common Name:	One Tray Sealed Sterilization Container
Proprietary Names:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories - M2104 ONE TRAY; M2106 ONE TRAY; M2108 ONE TRAY; M2404 ONE TRAY; M2406 ONE TRAY; M2408 ONE TRAY; ONE TRAY Sterilization Container; OTK 210 One Tray Processing Kit
Device Classification:	General Hospital, Class II, Regulation No. 880.8650
Product Code:	KCT

Attached hereto as Exhibit I, for reference, is a true and correct copy of the FDA 510(k) approval letter dated March 13, 2006.

{SF094703.DOCX;}

Should you have any questions, please do not hesitate to contact me.

By: 

Sterile Containment Technology, LLC
Percival Banks
Managing Member/CEO

Percival Banks
Sterile Containment Technology, LLC
1301 Quarry Court, Suite 204
Point Richmond, CA 94801
510-412-6383 (phone)
perc@sectus.com
FDA Establishment Registration No.: 3003793526

PLEASE SEE ATTACHED
FOR NOTARIZATION

{SF094703.DOCX;}

CERTIFICATE OF ACKNOWLEDGMENT California All-Purpose Acknowledgment

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Contra Costa

On 2.13.18 before me, M. Marcucci, Notary Public,
Date Name of Officer

personally appeared Percival Banks
Name of Signer(s)

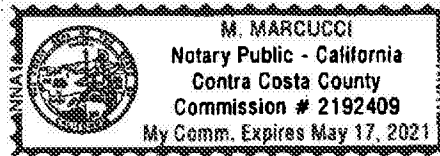
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

M. Marcucci

Signature of Notary Public



Place Notary Seal Above

Description of Attached Document

Title or Type of Document: Transfer of 510 (K)

Document Date: 2-13-18 Number of Pages: _____

Signer(s) other than named above: _____



MAR 13 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gage Garman
Sterile Containment Technology, Limited Liability Company
1301 Quarry Court, Suite 204
Point Richmond, California 94801

Re: K052567
Trade/Device Name: ONE TRAY® Sealed Sterilization Container
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: February 11, 2006
Received: February 16, 2006

Dear Mr. Garman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

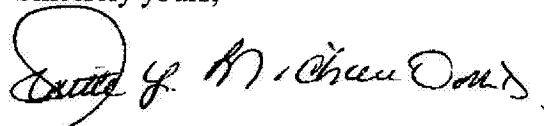
Page 2 – Mr. Gage Garman

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Summary of
Safety and Effectiveness

MAR 13 2006

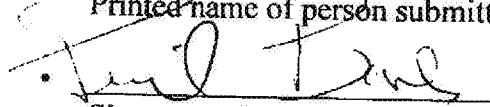
K052567

Submitter: Sterile Containment Technology, LLC

1301 Quarry Court
Suit 204
Point Richmond, CA 94801
510-412-6383 (phone)
510-588-4699 (fax)

- Establishment FDA Registration No.: 3003793526
- Date Summary was prepared August 30th, 2005

- Percival Banks
Printed name of person submitting for 510(k)

- 
Signature of person submitting for 510(k)

- President
Title of person submitting for 510(k)

Device Name and Classification

Trade Name: ONE TRAY[®] Sealed Sterilization Container
Classification Name: Sterilization Wrap
Common Name: Sterilization, Rigid Reusable Case
Device Classification: General Hospital, Class II, Regulation No. 880.6850
Product Code: 80FRG

Predicate Device

Case Medical SteriTite[®] K960738 and K022978

Additional Predicate Devices

Medin K833343 and FlashPak K871202

Device Description

ONE TRAY[®] is a sealed rigid container with a rectangular patterned group of perforations forming vented areas in the lid and base. Disposable hydrophobic SMS filters cover each vented area and are held firmly in place by a perforated stainless steel filter cover. This assembly permits the penetration of steam during the sterilization process and serves as a bacterial and fluid barrier at the conclusion of the sterilization cycle.

Intended Use

The ONE TRAY[®] Sealed Sterilization Containers are intended to be used for rapid sterilization of instruments or instrument sets in flash cycles. The containers are intended to be used to hold medical devices during steam sterilization. The complete line of ONE TRAY[®] Sealed Sterilization Containers can be processed in both flash steam pre-vacuum and gravity cycles.

After sterilization, ONE TRAY[®] provides for the safe transport and assured delivery of the enclosed devices in a sealed container with tamper evident protection according to AAMI and AORN guidelines.

Technical Characteristics

The ONE TRAY[®] design is rectangular in shape and has vents in the lid and floor. The ONE TRAY[®] design/performance concept takes advantage of the thermodynamic behavior of steam to facilitate the expeditious and complete introduction of the sterilant throughout the container. This is accomplished by incorporating a specific number of proportionate size vents in strategic locations in both the lid and base. As the sterilizing media (steam) fills up the chamber of the sterilizer, it is introduced into the container through the dedicated entry vent in the lid of ONE TRAY[®]. This dedicated entry port provides for displacement of the atmosphere within the container from the top to the bottom.

The vents located in the extreme lateral portions of the floor provide two dedicated exit ports that offer twice the vapor exchange capacity of the single entry vent in the lid. This relationship facilitates the complete, consistent and expeditious displacement of the atmosphere by the sterilant throughout the ONE TRAY[®] container.

Performance Testing

Testing was performed in order to determine the functional equivalency between the ONE TRAY[®] and the predicate device. Performance testing of the ONE TRAY[®] included, steam penetration, half cycle validation, package integrity, shelf life, material compatibility and biocompatibility studies. Based on the results of laboratory tests; the ONE TRAY[®] is substantially equivalent to the predicate container.

Conclusion

Supportive data has demonstrated that the ONE TRAY[®] is substantially equivalent to the predicate device in that they have the same intended uses and the performance attributes are the same. The use of the ONE TRAY[®] raises no issues related to its safety or effectiveness and therefore the ONE TRAY[®] should be allowed for market in the United States.

INDICATIONS for USE

510(k) Number: K052567

Device Name: ONE TRAY® Sealed Sterilization Container

Indications For Use:

ONE TRAY® Sealed Sterilization Containers are intended to be used to hold temperature tolerant medical devices, surgical supplies, single instruments, multiple instruments or an instrument set for immediate use following flash sterilization. This includes sterilization of lumens 3 mm in diameter or larger with lengths of up to 400 mm.

ONE TRAY® Sealed Sterilization Containers are available in the following sizes:

ONE TRAY System Components		
Product No.	Product Name	Description
ONE 20 Model		
OTS-MB2000	ONE 20ML Base	ONE 20ML Base - 20" Low Profile Base (Metal, Blue, 11.5"x20.5"x3")
OTS-MB2001	ONE 20MH Base	ONE 20MH Base - 20" High Profile Base (Metal, Blue, 11.5"x20.5"x5")
OTS-MB2010	ONE 20ML Cover	ONE 20ML Cover - 20" Low Profile Cover (Metal, Blue, 11.5"x20.5"x1")
OTS-MB2011	ONE 20MH Cover	ONE 20MH Cover - 20" High Profile Cover (Metal, Blue, 11.5"x20.5"x2.5")
OTS-MB2020	ONE 20M Deck	ONE 20M Deck -20" Deck Plate (Metal, Blue, 11.5"x20.5")
ONE 23 Model		
OTS-MB2300	ONE 23ML Base	ONE 23ML Base - 23" Low Profile Base (Metal, Blue, 11.5"x23.5"x3")
OTS-MB2301	ONE 23MH Base	ONE 23MH Base - 23" High Profile Base (Metal, Blue, 11.5"x23.5"x5")
OTS-MB2310	ONE 23ML Cover	ONE 23ML Cover - 23" Low Profile Cover (Metal, Blue, 11.5"x23.5"x1")
OTS-MB2311	ONE 23MH Cover	ONE 23MH Cover - 23" High Profile Cover (Metal, Blue, 11.5"x23.5"x2.5")
OTS-MB2320	ONE 23M Deck	ONE 23M Deck -23" Deck Plate (Metal, Blue, 11.5"x23.5")

The ONE TRAY® components listed in the preceding table have been validated in all of the various size configurations listed in the following table to process a twenty five pound (25 lb) gross weight load (single container plus contents) in a steam pre-vacuum cycle at 132°C for 4 minutes exposure time; or in a steam gravity cycle at 132°C for 34 minutes exposure time.

Shirley A. Mungley 3/4/06
Page 1 of 2

Shirley A. Mungley, General Hospital
K052567

K052567

ONE 20 Model			ONE 23 Model		
Name	Description	Product No.	Name	Description	Product No.
ONE 20MH	① High Profile Base	OTS-MB2001	ONE 23MH	① High Profile Base	OTS-MB2301
	② High Profile Cover	OTS-MB2011		② High Profile Cover	OTS-MB2311
	③ Deck Plate	OTS-MB2020		③ Deck Plate	OTS-MB2320
ONE 20MHL	① High Profile Base	OTS-MB2001	ONE 23MHL	① High Profile Base	OTS-MB2301
	② Low Cover	OTS-MB2010		② Low Cover	OTS-MB2310
	③ Deck Plate	OTS-MB2020		③ Deck Plate	OTS-MB2320
ONE 20MLH	④ Low Profile Base	OTS-MB2000	ONE 23MLH	④ Low Profile Base	OTS-MB2300
	② High Profile Cover	OTS-MB2011		② High Profile Cover	OTS-MB2311
	③ Deck Plate	OTS-MB2020		③ Deck Plate	OTS-MB2320
ONE 20ML	④ Low Profile Base	OTS-MB2000	ONE 23ML	④ Low Profile Base	OTS-MB2300
	⑤ Low Profile Cover	OTS-MB2010		⑤ Low Profile Cover	OTS-MB2310
	③ Deck Plate	OTS-MB2020		③ Deck Plate	OTS-MB2320

After sterilization, ONE TRAY provides for the safe transport and assured delivery for immediate use of the enclosed devices in a sealed container with tamper evident security and load record documentation according to AAMI and AORN guidelines.

The performance and intended use of ONE TRAY Sealed Sterilization Containers should comply at all times with the methods of use and flash sterilization guidelines as recommended by the manufacturer of the devices being sterilized, AAMI (Association for the Advance of Medical Instrumentation), AORN (Association of periOperative Nurses), ASHCSP (American Society of Healthcare Central Service Professionals), NIHSPPO (National Institute for the Certification of Healthcare Sterile Processing and Distribution Personnel) and IAHCMM (International Association of Healthcare Central Service Materiel Management)

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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