510K Summary of S&E K101653 p1of3

Miltex.

AUG 0 2 2010

Miltex® Thompson™ Cassettes

DEVICE DESCRIPTION

Miltex® Thompson™ Cassettes are sterilization cassettes made of surgical-grade passivated stainless steel to provide protection, storage and organization for all types of instruments. Miltex® Thompson™ Cassettes may be used in dental, surgical or veterinary procedures. Cassettes are available in a variety of configurations and are designed to fit standard autoclaves.

INDICATIONS FOR USE

Miltex® Thompson™ Cassettes are general dental/surgical instrument cassettes indicated to hold instruments and accessories in place during storage and the sterilization cycle. Suitable for gravity steam and pre-vacuum steam, the cassettes are intended to be used in conjunction with sterilization wrap in order to maintain sterility.

CONTRAINDICATIONS

- None

WARNINGS

- Do not stack or overfill instruments in cassette; ensure that each instrument is correctly placed into slots provided.
- Close cassette lid to avoid injury caused by instruments protruding from cassette.
- Do not stack cassettes in sterilization unit.
- Do not use any unused instruments in the cassette once soiled instruments have been placed back into the cassette.

PRECAUTIONS

- Wrap instrument cassette only with legally marketed FDA-cleared sterilization wrap.
- Use of nonabsorbent tray liners, such as plastic/silicone-fingered organizing mats, can cause condensate to pool inside cassette.
- Small baskets, trays, and other types of accessories, especially those with covers or lids, should be used with cassettes only if cassettes have been specifically designed and tested for such purpose.
- Complex instruments should be prepared and sterilized according to instrument manufacturer's instructions.
- For effective sterilization and drying, the weight of the wrapped surgical cassette and its contents should not exceed 4.4 lbs per the validated sterilization study.

INSTRUCTIONS FOR USE

Cassette Cleaning

1. Cassettes should be cleaned with an instrument brush and surfactant or detergent and water to remove visible debris from all crevices prior to use.
2. Cassettes may be cleaned in an ultrasonic cleaner with an enzymatic solution, such as Miltex EZ-Zyme All Purpose Enzyme Cleaner.
3. Submerge cassette fully into ultrasonic unit and place lid on unit.
4. Process single layer cassettes for 15 minutes and double layer cassettes for 30 minutes in ultrasonic unit.
5. Following ultrasonic cleaning procedure, remove cassettes and thoroughly rinse with warm water to remove cleaning solution; allow cassette to dry before placing instruments in cassettes for processing.

Manual Cleaning - Instruments

1. Open instrument cassette by pressing push button to release lid. Fold lid under cassette or lay lid flat on a table or work station.

2. Remove visible debris from each reusable instrument by scrubbing instrument manually with an instrument brush and surfactant or detergent and water.
3. Rinse with water to remove chemical or detergent residue.
4. Dry instruments and place them into cassette. Hand instruments fit into grooves on racks inside cassette; additional instruments can be placed in accessory area of cassette.
5. Close cassette lid tightly after placing instruments in cassette.

Sterilization

1. Wrap cassette in FDA-cleared sterilization wrap; seal wrap with autoclave tape.
2. Date and code cassette on autoclave tape or label on outside of wrapped cassette.
3. Place wrapped cassette into sterilization unit and follow sterilizer's recommended sterilization procedures and an approved National/International Standard.

   Miltex® Thompson™ cassettes have been tested with no adverse effects under the following sterilization parameters:

Gravity Steam:	**Pre-Vacuum Steam:**
Temperature: 250°F (121°C)	Temperature: 270° F (132°C)
Exposure Time: 30 minutes	Exposure Time: 4 minutes
Dry Time: 20 minutes	Dry Time: 20 minutes

4. After sterilization, remove cassette from sterilization unit and place in a storage location. Cassettes wrapped in FDA-cleared sterilization wrap maintain sterility of enclosed instruments for 30 days as long as sterile barrier is not compromised.

MAINTENANCE OF CASSETTE

- Miltex® Thompson™ cassettes have been validated to withstand up to 50 sterilization cycles with no evidence of deterioration.
- For best and lengthy service life, instrument cassettes should be allowed to properly dry before the sterilization procedure.
- Use Miltex® Instrument Stain Remover to remove water marks or stains if they appear on cassette.

HOW SUPPLIED

Miltex® Thompson™ Cassettes are supplied one per package in a variety of configurations.

Part #	Model	Part #	Model
3-083005	Thompson™ 5 Utility	STDORTHO	Thompson™ Orthodontic Cassette
3-083105	Thompson™ 5 Single Rack	STDORTHOS	Thompson™ Orthodontic Cassette - Small
3-083210	Thompson™ 5 Double Rack	STDBOS	Thompson™ Surgical Cassette – Small
3-084007	Thompson™ 7 Utility	STDBOM	Thompson™ Surgical Cassette – Medium
3-084107	Thompson™ 7 Single Rack	STDBOL	Thompson™ Surgical Cassette – Large
3-084214	Thompson™ 7 Double Rack	3-080205	Handpiece/Accessory Cassette
3-085009	Thompson™ 9 Utility	4-6835	Universal Surgical Cassette, Small
3-085109	Thompson™ 9 Single Rack	4-083000	Universal Surgical Cassette #5
3-085218	Thompson™ 9 Double Rack	4-084000	Universal Surgical Cassette #7
3-089110	Thompson™ 10	4-085000	Universal Surgical Cassette #9
3-118114	Thompson™ 14	4-089100	Universal Surgical Cassette #10
3-118116	Thompson™ 16	4-008122	Universal Surgical Cassette #22
3-118122	Thompson™ 22	4-008115	Universal Surgical Cassette
3-139126	Thompson™ 26	4-009126	Universal Surgical Cassette #26
3-072007	Thompson™ Slimline 7	4-6815	Universal Surgical Cassette, X-Long
3-082008	Thompson™ Slimline 7 Extended	STDBH	Bur Holder – 12-Hole
STDSL27	Thompson™ Slimline 7 Deep	STDBH6	Bur Holder – 6-Hole
3-072014	Thompson™ Slimline 14	STDBHS	Surgical Bur Holder – 6-Hole
STD222	Standard Cassette - Oral Surgical Double	STDBB2	Bur Box #2 - 40-Hole
STD209	Standard Cassette - Double Nine	STDPB	Small Parts Box
STDSTAT	Standard Cassette	STDES48	Endo File Stand – 48-Hole
STDSTAT8	Standard Cassette 8	STDES60	Endo File Stand – 60-Hole
STDSTAT814	Standard Cassette 814	STDES72	Endo File Stand – 72-Hole

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SYMBOLS USED ON LABELING

 Manufacturer

 Authorized Representative in European Community

 Catalog number

 Lot number

 CAUTION: See warnings or precautions

 Consult instructions for use

 Complies with EU Directive 93/42/EEC

Miltex, Inc.
589 Davies Drive
York, PA 17402
800-645-8000
www.miltex.com

Miltex GmbH
78604 Rietheim-Weilheim
Germany

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Jennifer Bosley, MBA, RAC
Regulatory Affairs Manager
Miltex, Incorporated
589 Davies Drive
York, Pennsylvania 17402

AUG 0 2 2010

Re: K101653
Trade/Device Name: Miltex® Sterilization Cassettes
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: June 10, 2010
Received: June 11, 2010

Dear Ms. Bosley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K101653

AUG 0 2 2010

Device Name: Miltex® Sterilization Cassettes

Indications for Use:
Miltex Sterilization Cassettes (Miltex®, Thompson™) are general dental/surgical instrument cassettes indicated to hold instruments and accessories in place during storage and the sterilization cycle. Suitable for Gravity Steam and Pre-Vacuum Steam, the cassettes are intended to be used in conjunction with sterilization wrap in order to maintain sterility.

Validated Sterilization Parameters:

Method	Temperature	Exposure Time	Drying Time
Gravity Steam	250°F (121°C)	30 minutes	20 minutes
Pre-Vacuum Steam	270°F (132°C)	4 minutes	20 minutes

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Prescription Use_____ AND/OR Over-The-Counter-Use ✓
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101653