

Indications for Use

510(k) Number (if known)

K220345

Device Name

STERLINK mini Sterilizer with STERLOAD™ mini Cassette

Indications for Use (Describe)

The STERLINK mini sterilizer with STERLOAD™ mini cassette is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture.

The STERLINK mini can sterilize*:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless-steel lumen with:
 - o An inside diameter of 1.6 mm or larger and a length of 200 mm or shorter

*The validation testing was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load with a total weight of 1.54 lbs.

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)

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Device Name

Tyvek® Roll with CI for STERLINK™ Sterilizer

Indications for Use (Describe)

Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK™ sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization.

The materials compatible for use in the Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in Chamber mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HDPE), Polypropylene (PP), Polytetrafluoroethylene (PTFE) and Silicone (Hardness 50).

The maximum load weight that can be placed in the Tyvek® roll is:

- 3.97 pounds (1.8 kg) for CHAMBER mode of FPS-15s Plus sterilizer
- 1.54 pounds (0.7 kg) for CHAMBER mode of STERLINK mini sterilizer

The roll is printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer.

The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in the follow 1 type:

- Sterilization roll, Flat

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)

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Device Name

Sterilization Process Indicator for STERLINK™ Sterilizer

Terragene Bionova® SCBI (BT96), Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye® (CD42), Terragene Cintape® (CT40)

Indications for Use (Describe)

Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60°C.

Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60°C and 37°C and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met.

Terragene Cintape® (CT40) is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with:

- CHAMBER mode of FPS-15s Plus sterilizer
- CHAMBER mode of STERLINK mini sterilizer

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

Prescription Use (Part 21 CFR 801 Subpart D)

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