For Part Code: IMS-1241

INFECTION PREVENTION

HU-FRIEDY
STEAM STERILIZATION INTEGRATOR

CLASS 5 INTEGRATING INDICATOR
AS CLASSIFIED BY ANSI/AAMI/ISO 11140-1:2005

TECHNICAL BULLETIN

DEVICE DESCRIPTION

The Hu-Friedy Steam Sterilization Integrator is a single use class 5 Integrating Chemical Indicator as classified by ANSI/AAMI/ISO 11140-1:2005. It integrates three essential criteria for proper steam sterilization: time, temperature, and steam. When processed along with a load it indicates, with a margin of safety, whether the proper steam sterilization criteria have been achieved.

INDICATIONS FOR USE

Use Hu-Friedy Class 5 Integrators in 250-275°F (121-135°C) gravity, pre vacuum or flash cycles.

CONTRAINDICATIONS

None.

PRECAUTIONS

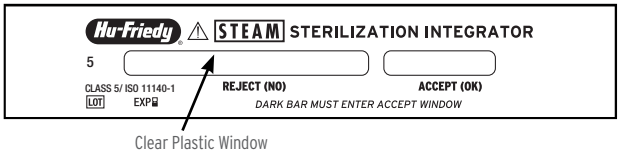
Do not use Hu-Friedy Class 5 Integrators to monitor dry heat, ethylene oxide, or other low temperature sterilization processes.

PRODUCT DESIGN

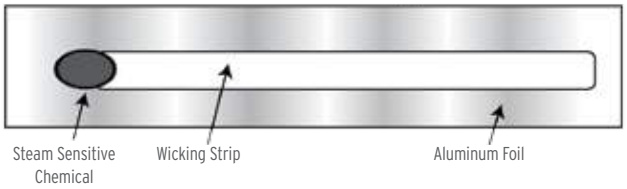
The Hu-Friedy Integrator consists of aluminum foil coated with a pressure sensitive adhesive. The aluminum foil has an embossed cavity at one end filled with a steam sensitive chemical. The dry heat melting point of the chemical is higher than the normal steam sterilization temperature. The presence of steam lowers the melting point of the chemical. A wicking strip is attached to the foil. One end of the wicking strip is in contact with the chemical and the rest runs along the length of the foil. The whole assembly is covered with steam sensitive plastic laminated to paper with printed graphics and cut out windows. The window overlies the wicking strip while the laminated graphics and the foil completely seal the chemical and the wicking strip inside.

During the sterilization process the steam penetrates the plastic cover, lowering the melting point of the chemical. The rate at which the chemical melts is determined by the vapor transmission rate of the plastic cover and the temperature. When the chemical melts, the wicking paper soaks up the chemical. With time, the chemical moves up the wicking strip, turning it dark. When the dark bar enters the accept window the sterilization criteria are satisfied.

TOP VIEW



WITHOUT TOP COVER



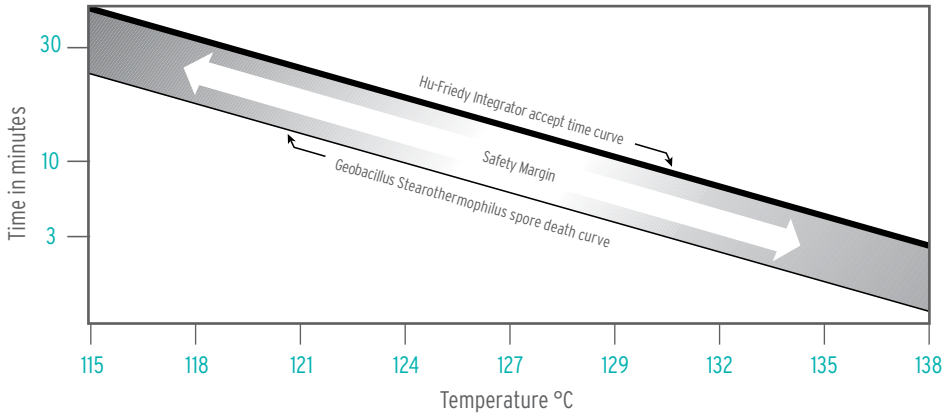
How the best perform Hu-Friedy®

PERFORMANCE OF HU-FRIEDY INTEGRATORS

Hu-Friedy integrators were tested in a BIER (Biological Indicator Evaluator Resistometer) vessel at various time and temperature intervals in order to estimate the time required at each temperature to reach the accept window. The following are the mean times (calculated from the test results) required at each temperature for the integrators to reach the accept window:

TEMPERATURE	TIME IN MINUTES FOR HU-FRIEDY INTEGRATOR TO REACH SAFE MARK	THERMAL DEATH TIME IN MINUTES OF GEOBACILLUS STEAROTHERMOPHILUS SPORES
250°F (121°C)	23.58	11.8
262°F (128°C)	5.5	2.39
275°F (135°C)	1.8	0.48

The performance (time required to reach the accept mark at various temperatures) of the Hu-Friedy Integrator and the thermal death time of Geobacillus stearothermophilus spores are plotted in the graph shown below. It is evident from the graph that the Hu-Friedy Integrator parallels the spore death curve in the normal sterilization range with a margin of safety. It is clear from the data contained in the table and the graph that the Hu-Friedy Integrator provides additional safety in ensuring proper sterilization. The Hu-Friedy Steam Sterilization Integrator provides an instant evaluation of the Sterilization process with the accuracy of a biological indicator.



DIRECTIONS FOR USE

1. Place a Hu-Friedy Integrator Strip in the center of each pack or load and process according to sterilizer manufacturer's directions.
2. Adequate sterilization conditions are reached when the dark bar has completely travelled through the REJECT window and has entered the ACCEPT window.
3. If the dark bar does not reach the ACCEPT window, reprocessing of the pack is required.

For Use in Steam Sterilizers 250°-275°F (121-135°C).

Processed and unprocessed strips should be stored at room temperature away from sources of steam, moisture and heat.

See attached label on back of package for Stated Values. The chart lists the time in minutes and the corresponding temperature at which the indicated lot of integrators reach their endpoint when tested in a steam resistometer.

INTERPRETING RESULTS

Unprocessed



Processed - REJECT



Processed - ACCEPT



If the dark bar has not reached the ACCEPT window adequate sterilization conditions are not satisfied. Material should be reprocessed.

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