SUPER RAPID 5 STEAM - CHALLENGE PACK

TYPE: LPCD21

VERSION: 2024.09.01

PRODUCT DESCRIPTION

The LISTER Super Rapid 5 Steam - Challenge Pack LPCD21 is specifically designed to qualify and monitor vacuum-assisted steam sterilization processes at 132°C to 135°C in healthcare facilities. The challenge pack consists of multiple layers of medical index cards, some of which are die-cut to contain the monitoring products. The stacked cards are wrapped with a sterilization wrap. Each challenge pack has a process indicator on the pack label that changes from yellow to grey or black when exposed to steam. This convenient disposable challenge pack presents a challenge to the sterilization process equivalent to the user-assembled biological indicator (BI) challenge test pack (towel PCD) recommended by the Association for the Advancement of Medical Instrumentation (AAMI). The challenge pack is a single use device.

Each challenge pack contains a LISTER Super Rapid Biological Indicators (Dark blue cap, hereinafter referred to as a LBS060), a LISTER Steam Chemical Integrator, and a record keeping sheet. LISTER Steam Chemical Integrators are Type 5 Integrating Indicators as categorized by ISO 11140-1:2014. LISTER Steam Chemical Integrators are single-use chemical indicators consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/Film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked ACCEPT or a window marked REJECT; the extent of migration depends on steam, time, and temperature.The LBS060 is a self-contained dual readout biological indicator specifically designed for rapid and reliable monitoring of the steam sterilization process when used in conjunction with the LISTER Auto-reader (hereinafter referred to as the BIOPT2), or a LISTER Mini Auto-reader (hereinafter referred to as the BIOPT1).

INDICATIONS FOR USE

Use the LISTER Super Rapid 5 Steam - Challenge Pack LPCD21 in conjunction with the LISTER Auto-reader BIOPT2,or the LISTER Mini Auto-reader BIOPT1 to qualify or monitor 132°C to 135°C vacuum-assisted steam sterilization cycles.

READOUT TIMES

The super rapid readout and the optional 48-hour visual pH color change incubation times have been correlated with a 7-day incubation period following ISO 11138-8.

Processed indicators were examined at 48 hours and 7 days for detection of a visual pH color change. The fluorescent result and the 48-hour visual pH color change readings were compared to the 7-day visual pH color change readings to determine the readout time of the indicator.

60-minute Fluorescent Result

LBS060 BIs incubated in a BIOPT1 or BIOPT2 Auto-reader have a 60-minute reduced incubation time result that correlates to the 7-day (168 hours) visual readout result with an accuracy ≥ 97%.

48-hour Visual pH Color Change Result

LBS060 BIs incubated in a BIOPT1 or BIOPT2 Auto-reader have 48 hour reduced incubation time results that correlate to the 7-day (168 hours) visual readout result with an accuracy ≥ 97%.

Due to the high reliability of the fluorescent result there is no advantage to incubating LBS060 BIs after the fluorescent result has been determined by the Auto-reader and recorded.

PRECAUTIONS

1. DO NOT OPEN challenge pack prior to sterilization.
2. DO NOT incubate a LBS060 if, after processing and before BI activation, it is observed to have a broken media ampoule. Retest the sterilizer with a new challenge pack.
3. DO NOT re-incubate LBS060 BIs for which the Auto-reader has already determined a result.

MONITORING FREQUENCY

Follow facility Policies and Procedures which should specify a biological indicator monitoring frequency compliant with professional association recommended practices and/or national guidelines and Standards. As a best practice and to provide optimal patient safety, LISTER recommends that every steam Sterilization load be monitored with a biological indicator in an appropriate Process Challenge Device (i.e.,BI challenge test pack).

DIRECTIONS FOR USE

1. Place a LISTER Super Rapid 5 Steam - Challenge Pack LPCD21, with the label side up, in the most challenging area for the sterilant to reach. This is generally on the bottom shelf, over the drain. Do not place objects (e.g. another pack) on top of the challenge pack. This will create too great a challenge for air removal and steam penetration.
2. Process the load according to established procedures.
3. After completion of the cycle, retrieve the challenge pack.Check to see that the external process indicator on the outside of the challenge pack has changed from yellow to grey or black. Open the challenge pack and allow the LBS060 BI to cool for 5 minutes.
4. Check the LISTER Steam Chemical Integrator. The dark color should have entered the ACCEPT window. If the dark color has not entered the ACCEPT window, this indicates a REJECT result which means the load was not exposed to sufficient steam sterilization conditions. This load should not be released for use but reprocessed. Record integrator result.
5. Check the process indicator on the outside of the LBS060 BI pipe. A color change from pink to grey or black confirms that the biological indicator has been exposed to the steam process. This color change does not indicate that the steam process was sufficient to achieve sterility.
6. Identify the processed LBS060 BI by writing the sterilizer, load number, and processing date on the indicator label. It is best practice to activate and incubate the LBS060 BI as soon as it has cooled.
7. Place the LBS060 BI in an upright position, compress the plastic pipe in the crushing cavity of the reader to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.
8. After a certain incubation time (LBS060-60 minute), the automatic reader will display the fluorescence test result. The automatic reader displays "**—**", indicating a negative result for the BI, and "**+**" indicates a positive result for the BI. If necessary, continue to incubate for 48 hours to observe the biological culture results. If the color of the culture medium changes from purple to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (purple), the BI is negative.
9. If utilized, fill out the required information on the record keeping card. Record the LBS060 BI result when available. Discard the challenge pack. Using the challenge pack more than once will invalidate subsequent test results.
10. Act immediately on any positive results for processed biological indicators. Determine the cause of the positive biological indicator following facility policies and procedures. Always retest the sterilizer and do not use sterilizer for processing loads until qualification testing yields satisfactory results (typically three consecutive cycles with negative biological indicator results and three consecutive cycles with passing Bowie-Dick test results).

STORAGE

Store at normal room temperature 15-30°C and 40-60% RH.

Store away from direct sunlight. Do not store challenge packs near sterilants or other chemicals.

DISPOSAL

Dispose of used LBS060 BIs according to your health care facility policy. You may wish to steam sterilize any positive biological indicators at 132°C to 135°C for 3 minutes in a dynamic-air-removal steam sterilizer prior to disposal.

For further information, please contact your local LISTER representative.

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