HOLLOW TUBE PROCESS CHALLENGE DEVICE

TYPE: LPCD11

VERSION: 2024.09.01

PRODUCT DESCRIPTION

The Hollow Tube Process Challenge Device is used to test for successful air removal and steam penetration from high-vacuum hollow-load sterilizers used in the sterilization of health care products. The presence of air within the device, due to an inefficient air removal stage, an air leak during this stage or non-condensable gases in the steam supply, is a circumstance which can lead to failure of the test. The result of the test may also be affected by other factors which inhibit steam penetration. A Hollow Tube Process Challenge Device consist of three components: tube which used to simulate hollow load, holder which used to place chemical strip, chemical strip which used to evaluate air removal and steam penetration.

Indicators 100% free of toxic heavy metals.

Metal free

INDICATIONS FOR USE

To evaluate air removal and Steam penetration in hollow Loads.

INSTRUCTIONS FOR USE

1. Insert chemical indicator according to the selected process conditions into the holder (metal capsule or plastic capsule) of the screw cap; settle the reactive indicating ink towards the gas inlet, avoiding folding those areas printed with reactive indicating ink.
LPCD11-3.5 3.5 min. 134°C
LPCD11-5.0 4.0 min. 134°C, 16.5 min. 121°C
IMPORTANT: avoid contact between chemical indicator and capsule interior surface.
2. Put the capsule cap with moderate pressure.
3. Settle the system into the sterilization bag.
4. The entire system should be sterilized in a vacuum chamber.
5. Retrieve the indicator and evaluate the result. If the 4 bars reach the final color, the result can be considered successful, which means the sterilizer is working correctly. If one bar doesn't reach the final color, it means that residual air is present in the sterilizer, therefore a malfunction of the equipment. The reasons for the failure can be insufficient air removal, leakages and noncondensable gases in steam.
NOTE: If any serious incident occurs in relation to the device, it should be reported to LISTER.

STORAGE

Store in a dry place, protected from light, at a temperature between 10-30°C, and at a relative humidity between 30-80%. Do not wet. Do not store near sterilizing agents.

SHELF LIFE

LPCD11 chemical indicators have an expiration date of 2 years from the date of manufacture when stored under recommended storage conditions. Both, the expiration date and batch number of the product, are specified on the package label.
Do not use LPCD11 chemical indicators after their expiration date.
Do not reuse.
Endpoint stability reaction: chemical indicator endpoint shall remain unchanged for a period of not less than 6 months when stored at previously indicated conditions.

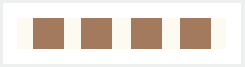
DISPOSAL

Discard used chemical indicators along with paper waste, according to your country's healthcare and safety regulations.

RESULT REFERENCE GUIDE

Sufficient temperature, time and steam penetration

Insufficient air removal and steam penetration



Temperature achieved, but no air removal and no steam penetration

Insufficient temperature and no air removal and no steam penetration

NOTE: Reference colors exhibited in printed prospects and boxes, do not necessarily represent the real color as shown in the actual indicators.

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5 STEAM CHALLENGE PACK

TYPE: LPCD12

VERSION: 2024.09.01

PRODUCT DESCRIPTION

LISTER 5 Steam Challenge Pack is specifically designed to routinely challenge the steam sterilization process in healthcare facilities. This convenient disposable process challenge device presents a challenge to the sterilization process equivalent to the 16-towel process challenge device (PCD) recommended by the Association for the Advancement of Medical Instrumentation (AAMI). Each test pack contains a process indicator on the outside that changes from yellow to grey or black when steam processed.Each pack contains a LISTER Steam Chemical Integrator and a record keeping sheet.

INDICATIONS FOR USE

Use the LISTER 5 Steam Challenge Pack to monitor:

- 121°C gravity displacement steam sterilization cycles at 30 minutes
- 132°C dynamic-air-removal steam sterilization cycles at 4 minutes
- 135°C dynamic-air-removal steam sterilization cycles at 3 minutes

PRECAUTION

Guidance on routine load release is split into two subcategories: nonimplant loads and implant loads. Release based on result LISTER 5 Steam Challenge Pack without placing BI is only applicable to nonimplant loads.

INSTRUCTIONS FOR USE

1. Place a LISTER 5 Steam Challenge Pack LPCD12, 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. Allow the challenge pack to cool for 5 minutes.
4. Open the challenge pack and 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.

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.

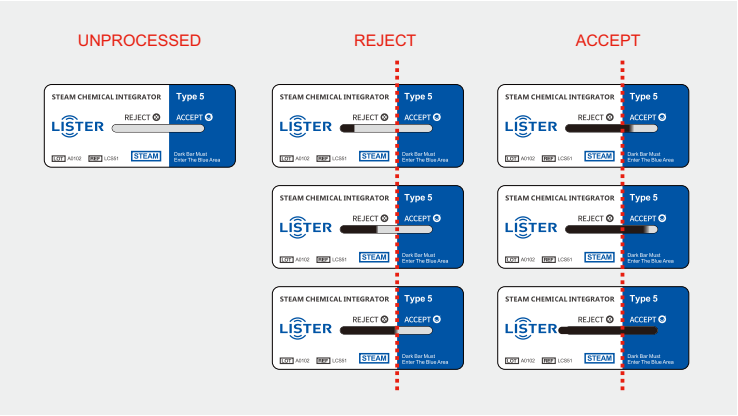
SHELF LIFE

The expiration date is printed on the package.

DISPOSAL

Discard chemical indicators after use along with paper waste, according to your country's healthcare and safety regulations.

RESULT REFERENCE GUIDE



NOTE: Reference colors exhibited in printed prospects and boxes, do not necessarily represent the real color as shown in the actual indicators.

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ULTRA SUPER RAPID 5 STEAM - CHALLENGE PACK

TYPE: LPCD20

VERSION: 2024.09.01

PRODUCT DESCRIPTION

The LISTER Ultra Super Rapid 5 Steam - Challenge Pack LPCD20 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 Ultra Super Rapid Biological Indicators (blue cap, hereinafter referred to as a LBS020), 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 LBS020 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 Ultra Super Rapid 5 Steam - Challenge Pack LPCD20 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 ultra 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.

20-minute Fluorescent Result

LBS020 BIs incubated in a BIOPT1 or BIOPT2 Auto-reader have a 20-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

LBS020 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 LBS020 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 LBS020 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 LBS020 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 Ultra Super Rapid 5 Steam - Challenge Pack LPCD20, 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 LBS020 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 LBS020 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 LBS020 BI by writing the sterilizer, load number, and processing date on the indicator label. It is best practice to activate and incubate the LBS020 BI as soon as it has cooled.
7. Place the LBS020 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 (LBS020-20 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 LBS020 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 LBS020 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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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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RAPID 5 STEAM - CHALLENGE PACK

TYPE: LPCD22

VERSION: 2024.09.01

PRODUCT DESCRIPTION

The LISTER Rapid 5 Steam - Challenge Pack LPCD22 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 Rapid Biological Indicators (brown cap, hereinafter referred to as a LBS180), 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 LBS180 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 Rapid 5 Steam - Challenge Pack LPCD22 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 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.

<u>180-minute Fluorescent Result</u>

LBS180 BIs incubated in a BIOPT1 or BIOPT2 Auto-reader have a 180-minute reduced incubation time result that correlates to the 7-day (168 hours) visual readout result with an accuracy ≥ 97%.

<u>48-hour Visual pH Color Change Result</u>

LBS180 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 LBS180 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 LBS180 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 LBS180 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 Rapid 5 Steam - Challenge Pack LPCD22, 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 LBS180 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 LBS180 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 LBS180 BI by writing the sterilizer, load number, and processing date on the indicator label. It is best practice to activate and incubate the LBS180 BI as soon as it has cooled.
7. Place the LBS180 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 (LBS180-180 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 LBS180 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 LBS180 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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ULTRA SUPER RAPID CHALLENGE PACK

TYPE: LPCD23

VERSION: 2024.09.01

PRODUCT DESCRIPTION

The LISTER Ultra Super Rapid Challenge Pack 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 biological indicators. 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 Rapid Readout Biological Indicator(LBS020), and a record keeping sheet.

INDICATIONS FOR USE

Use the LISTER Ultra Super Rapid 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 ultra 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.
20-minute Fluorescent Result
LBS020 BIs incubated in a BIOPT1 or BIOPT2 Auto-reader have a 20-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
LBS020 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 LBS020 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 LBS020 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 LBS020 Bis for which the Auto-reader has already determined a result.

INSTRUCTIONS FOR USE

1. Place a LISTER ultra super rapid Challenge Pack LPCD23, 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 BI to cool for 5 minutes.
4. Check the process indicator on the outside of the 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.
5. Identify the processed BI by writing the sterilizer, load number, and processing date on the indicator label. It is best practice to activate and incubate the BI as soon as it has cooled.
6. Place the 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.
7. After a certain incubation time, 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.
8. If utilized, fill out the required information on the record keeping card. Record the BI result when available. Discard the challenge pack. Using the challenge pack more than once will invalidate subsequent test results.
9. 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 10-40°C and 10-80% RH.
Store away from direct sunlight. Do not store challenge packs near sterilants or other chemicals.

SHELF LIFE

The expiration date is printed on the package.

DISPOSAL

Dispose of used BIs according to your health care facility policy. You may wish to steam sterilize any positive biological indicators at 132°C for 4 minutes or at 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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SUPER RAPID CHALLENGE PACK

TYPE: LPCD24

VERSION: 2024.09.01

PRODUCT DESCRIPTION

The LISTER Super Rapid Challenge Pack 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 biological indicators. 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 Rapid Readout Biological Indicator(LBS060), and a record keeping sheet.

INDICATIONS FOR USE

Use the LISTER Super Rapid 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.

INSTRUCTIONS FOR USE

1. Place a LISTER super rapid Challenge Pack LPCD24, 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 BI to cool for 5 minutes.
4. Check the process indicator on the outside of the 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.
5. Identify the processed BI by writing the sterilizer, load number, and processing date on the indicator label. It is best practice to activate and incubate the BI as soon as it has cooled.
6. Place the 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.
7. After a certain incubation time, 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.
8. If utilized, fill out the required information on the record keeping card. Record the BI result when available. Discard the challenge pack. Using the challenge pack more than once will invalidate subsequent test results.
9. 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 10-40°C and 10-80% RH.
Store away from direct sunlight. Do not store challenge packs near sterilants or other chemicals.

SHELF LIFE

The expiration date is printed on the package.

DISPOSAL

Dispose of used BIs according to your health care facility policy. You may wish to steam sterilize any positive biological indicators at 132°C for 4 minutes or at 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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RAPID CHALLENGE PACK

TYPE: LPCD25

VERSION: 2024.09.01

PRODUCT DESCRIPTION

The LISTER Rapid Challenge Pack 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 biological indicators. 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 Rapid Readout Biological Indicator(LBS180), and a record keeping sheet.

INDICATIONS FOR USE

Use the LISTER Rapid 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 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.
180-minute Fluorescent Result
LBS180 BIs incubated in a BIOPT1 or BIOPT2 Auto-reader have a 180-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
LBS180 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 LBS180 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 LBS180 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 LBS180 BIs for which the Auto-reader has already determined a result.

INSTRUCTIONS FOR USE

1. Place a LISTER rapid Challenge Pack LPCD25, 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 BI to cool for 5 minutes.
4. Check the process indicator on the outside of the 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.
5. Identify the processed BI by writing the sterilizer, load number, and processing date on the indicator label. It is best practice to activate and incubate the BI as soon as it has cooled.
6. Place the 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.
7. After a certain incubation time, 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.
8. If utilized, fill out the required information on the record keeping card. Record the BI result when available. Discard the challenge pack. Using the challenge pack more than once will invalidate subsequent test results.
9. 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 10-40°C and 10-80% RH.
Store away from direct sunlight. Do not store challenge packs near sterilants or other chemicals.

SHELF LIFE

The expiration date is printed on the package.

DISPOSAL

Dispose of used BIs according to your health care facility policy. You may wish to steam sterilize any positive biological indicators at 132°C for 4 minutes or at 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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BOWIE-DICK TEST PACK

TYPE: LBD10

VERSION: 2024.09.01

PRODUCT DESCRIPTION

The LISTER Bowie-Dick Type Test Pack consists of a lead-free steam-sensitive chemical indicator test sheet positioned in a package of layered porous materials. The porous materials are paperboard sheets that have moisture impervious plastic layers at the top and bottom. These materials are wrapped in a non-woven, disposable wrap secured with a lead-free steam indicator label. The test sheet consists of a lead-free chemical indicator printed on paper as a yellow-colored diagonal pattern and is positioned near the center of the porous pack. The primary test sheet will turn a uniform grey/black color, except when air removal failures such as air leaks occur. An air removal failure is indicated as a lighter-colored area near the center of an otherwise dark-colored test sheet.

INDICATIONS FOR USE

The LISTER Bowie-Dick Type Test Pack is designed for testing air removal efficiency of 132-134°C vacuum-assisted steam sterilizers.

INSTRUCTIONS FOR USE

1. Test sterilizer once a day.
2. Test at the beginning of each day. A shortened cycle should be used to preheat the system (i.e. omit the drying phase). If the sterilizer is in continual use, then testing can be performed at any time, but it should be tested at the same time every day.
3. Place the pack on the bottom rack in the front section of the sterilizer, near the door and over the drain.
4. The test is most accurate when nothing else is in the chamber, so do not use this cycle to sterilize items or packs. Other items in this cycle may invalidate the test.
5. Run a pre-vacuum cycle following the parameters (121°C, larger than 10mins; 132°C or 134°C, large than 3mins). You may eliminate the drying phase to save time without affecting the test.
6. After the cycle is complete, remove the pack and open to examine the indicator sheet.
CAUTION! Test pack may still be hot so use caution when handling to avoid injury.
7. Record the necessary information on the sheet (or in a log book) and store for your records.
8. The filter paper pack can be discarded into a paper recycle bin.

STORAGE

Store at normal room temperature 10-40°C and 10-80% RH.
Store exposed indicator sheet away from light sources.

SHELF LIFE

The expiration date is printed on the package.

DISPOSAL

Discard chemical indicators after use along with paper waste, according to your country's healthcare and safety regulations.

RESULT REFERENCE GUIDE

UNPROCESSED | FAILURES | PROCESSED AND SATISFACTORY

NOTE: Reference colors exhibited in printed prospects and boxes, do not necessarily represent the real color as shown in the actual indicators.

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