

etrëma® sterilization wraps are tested for up to x75 wash, dry and sterilization cycles

GENERAL INFORMATION

REPROCESSING AND CYCLE INFORMATION

Laundering: Machine wash, regular cycle, hot water (50-71°)

Tumble Dry: High heat (50- 90° C)

Steam Autoclave Sterilization: Sterilization cycle at 134°C for 4 minutes (warm-up, sterilization, drying, cool down)

STERILIZATION PREPARATION

All wraps should be washed and dried prior to sterilization. ONLY place CLEAN and DRY wrappers into autoclave.

Ensure your preparation area is clean and that the contact surface areas are dry.

DO NOT use soiled or dirty wraps in an autoclave. This can damage the pouches and your autoclave.

Please follow the maximum fill instructions for your particular autoclave in relation to maximum weight, capacity, and spacing.

STORAGE

Store in clean and dry area, limiting the UV light exposure. Storage temperature should be between 20-23°C (68-73°F).

USAGE TRACKING

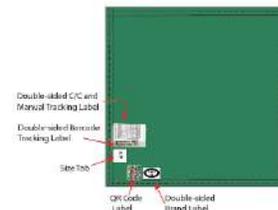
All etrëma® wrappers are tested and approved for 75 cycles (**1 cycle = x1 wash, x1dry, x1 sterilization, x1 use**).

Tracking should be done either a) after laundering and during inspection, or b) in preparation of wrapping a device or cassette.

It is important to select one approach to tracking so that wrappers are not mistakenly scanned/marked multiple times for only one usage or tracking is accidentally omitted.

Tracking can be done using one of the options available on your wrap:

- Manual tracking label using an autoclave safe marker
- Barcode label which can be connected to your organization's database
- QR code label using your smart device



STERILIZATION IDENTIFICATION (ID) STICKERS

Sterilization ID stickers must be applied to all wraps to ensure contents and sterilization information is tracked.

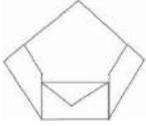
Stickers should include the following information:

- a. Package code or name if applicable
- b. Name of person who assembled the pouch or autoclave technician name
- c. Sterilization load or batch number
- d. Sterilization date

SPECIFIC WRAPPER UTILIZATION INSTRUCTIONS

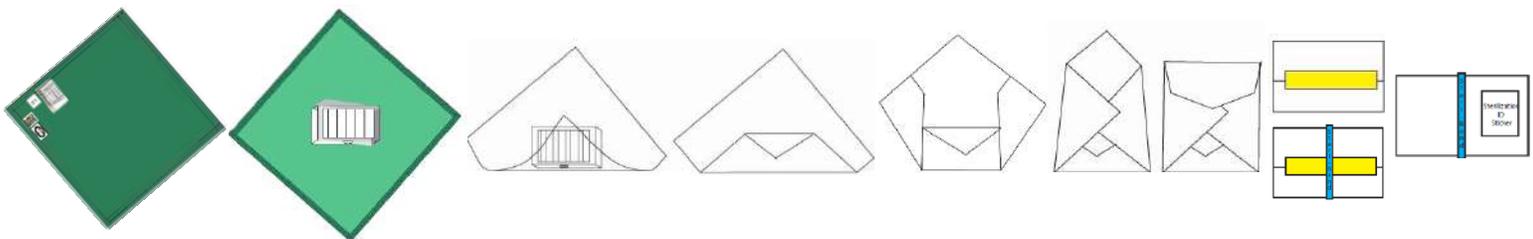
STERILIZATION WRAPPERS FOR USE WITH CASSETTES

1. Follow your regional (Federal or Provincial) or governing body (i.e. medical, dental, veterinary, hygienist) standards and requirements regarding sterilization of loose instruments and devices; contact, number of tools, and separators.
2. Cassettes, tools and wrappers should be clean and dry. Never use dirty or soiled devices in an autoclave.
3. Select a wrapper size where the wrapper area is approximately 50% larger than the cassette being sterilized. When the wrapper is folded around the cassette, there should be at least 2.5 cm/ 1" overlap at all folds and corners to ensure there are no gaps.

4. Inspect wrap for holes and/or tears. Do not use damaged wrappers.
5. On a clean and flat surface, place the wrapper in a diamond position in front of you with one point, pointing towards your chest. The cotton material (lining) should be facing upwards.
6. Place tools for sterilization inside the cassette and include a sterilization chemical indicator inside of the cassette. Close and secure the cassette lid.
7. Place the prepared cassette in the centre of the wrapper.
8. Fold the wrapper corner pointing towards your chest up to the centre of the diamond and over top of the cassette, slightly turn back the point so that it is facing you again.
9. There should now be a flat edge of the wrapper that is flush against the bottom edge of the cassette.
10. Press the material down along both the left and right sides of the cassette.
11. Turn and fold both the side corners upwards. Your wrap will now look like a pentagon with an envelope where material is flush against 3 sides of the cassette. 
12. Fold the new side corners of the wrapper towards the centre, over the cassette, so that they overlap. Your wrapper now looks like an envelope. Material should be flush against the cassette on the bottom and both side edges.
13. Keeping the wrapper sides flush against the sides of the cassette, bring the top corner towards you so that the material is now also flush against the top edge of the cassette. The top point should extend beyond the cassette.
14. Fold the point inwards or around to the backside of the wrapper and secure in place with autoclave sterilization tape. This piece of tape creates the barrier integrity seal to secure the wrapper and indicates if the sterile barrier has been tampered with.
15. There should be no gaps or open corners of the wrapper, or any part of the cassette exposed.
16. Place either a Frëtt Solutions Steri-Band ð LSTK around the wrap or an additional piece of autoclave tape, to fully secure the wrapper.
17. Apply your Sterilization ID sticker to the wrap. **Do NOT put tape or stickers over labels.**

Front of Wrapper
with Labels

Back of Wrapper
with Cotton Lining

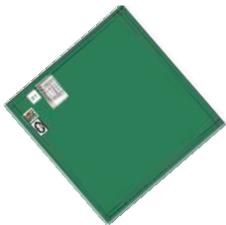


STERILIZATION WRAPPERS FOR USE WITH LOOSE DEVICES/TOOLS

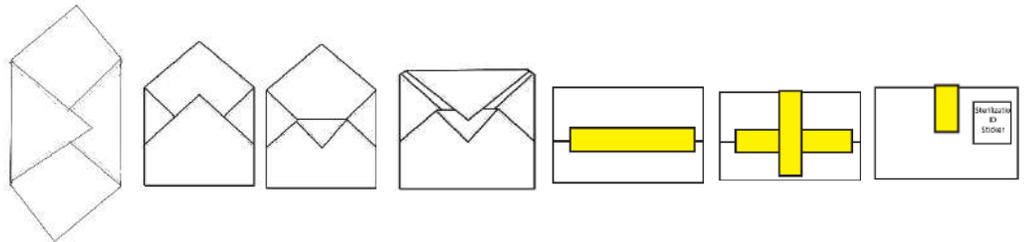
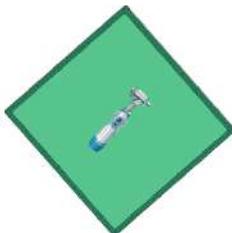
1. Follow your regional (Federal or Provincial) or governing body (i.e. medical, dental, veterinary, hygienist) standards and requirements regarding sterilization of loose instruments and devices; contact, number of tools, and separators.
2. Select a wrapper size whose area is approximately 50% larger than the device being sterilized. When the wrapper is folded around the device/tool, there should be at least 2.5 cm/ 1" overlap at all folds to ensure there are no gaps.
3. Inspect wrapper for holes and/or tears. Do not use damaged wrappers.

4. On a clean and flat surface, place the wrapper in a diamond position in front of you with one point, pointing towards your chest. The cotton material (lining) should be facing upwards.
5. Place the device or tool to be sterilized in the centre of the wrapper. Put a sterilization indicator CI (chemical indicator) beside or on top of the device.
6. Fold the two side corners of the wrapper towards the centre. The corners should overlap.
7. Fold the wrapper corner pointing towards your chest up to the centre of the diamond and over top of the device, slightly turn back the point so that it is facing you again.
8. Take the pointed corner at the top and fold it down towards the middle so that your wrapper now looks more like a square or rectangle.
9. You do not need to have the wrapper edges flush with all the edges of the device being sterilized. **Do not fold tightly over sharp or pointed objects, as this might result in the device perforating the wrapper.**
10. Take the top flat edge and fold it over once more creating a fully enclosed envelope. Your wrap should now resemble a rectangle or square.
11. **DO NOT use Frëtt Steri-Band or any other elasticized band** to close or secure the wrap with loose instruments as it will create folds, gaps, or distort the material.
12. Using 1-2 pieces of autoclave sterilization tape, secure the wrapper so that all folds stay in place. You should NOT use more than 2 pieces of autoclave tape. Your autoclave tape will act as a barrier integrity seal, indicating if someone has tampered with your wrapper.
13. Place your Sterilization ID sticker onto the wrap. **Do NOT put tape or stickers over labels.**

Front of Wrapper
with Labels



Back of Wrapper
with Cotton Lining



****IMPORTANT NOTE****

Pouch and wrapper sterilization instructions are based on product characteristics, 3rd party laboratory testing, and requirements from Health Canada and from the National Standards of Canada: CSA Z314:23, Canadian Medical Device Reprocessing in all Health Care Settings. If there is a discrepancy between these instructions and your local/provincial requirements, please follow the directions of your local/provincial governing body.

Health Canada Class 1 Medical Device Establishment License: no°22723