

etréma® sterilization pouches 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 pouches should be washed and dried prior to sterilization. ONLY place CLEAN and DRY pouches into autoclave.

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

DO NOT use soiled or dirty pouches 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

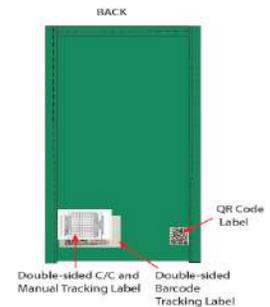
Store in clean and dry area, limiting the UV light exposure. Storage temperature should be between 20-23°C (68-73°F).

USAGE TRACKING

All etréma pouches are tested and approved for 75 cycles (**1 cycle = x1 wash, x1dry, x1 sterilization, x1 use**)

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

- 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 pouches as required to ensure contents and sterilization information is tracked.

Stickers should include the following information:

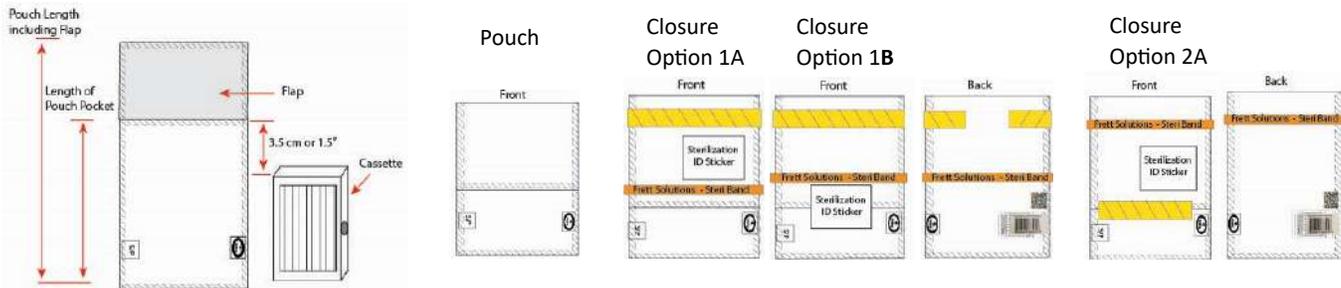
- a. Package code or name if applicable
- b. Name of person who assembled the pouch or autoclave technician name
- c. Sterilization load or batch number
- d. Sterilization date

SPECIFIC POUCH UTILIZATION INSTRUCTIONS

STERILIZATION POUCHES FOR USE WITH CASSETTES

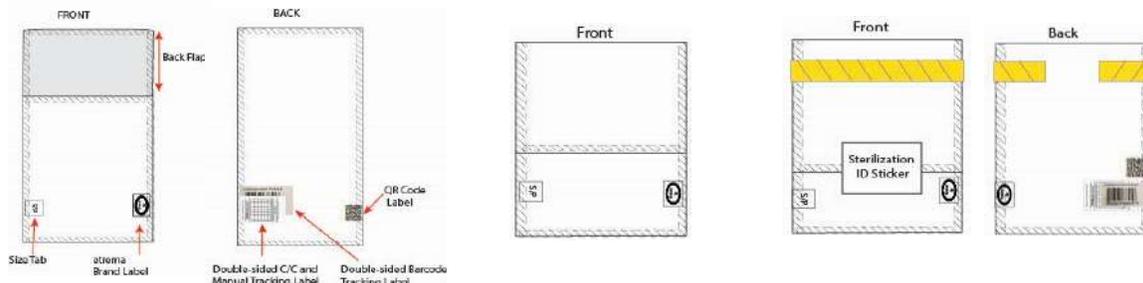
1. Cassettes, tools and pouches should be clean and dry. Never use dirty or soiled devices in an autoclave.
2. Select a pouch size where the total length of the pocket is at least 3.5 cm or 1.5" longer than the cassette.
3. Inspect pouch for holes and/or tears. Do not use damaged pouches.
4. Place tools for sterilization inside the cassette and include a sterilization chemical indicator inside of the cassette.
5. Close and secure the cassette lid then gently place cassette inside of pouch. Do not drop or force cassette into pouch.

6. **Fold** the pouch such that the fold is flush against the edge of the cassette. The fold should be **AT LEAST 10 cm/4"** below the top of the flap (or 3.5 cm/1.5" below the pocket opening). The **fold MUST be flat and have no gaps**.
7. Use autoclave tape to secure the pouch flap in place, creating a barrier integrity seal.
8. Place your Sterilization ID sticker onto the pouch. **Do NOT put tape or stickers over labels**.
9. Wrap a Frëtt Solutions Steri-Band ë LSTK around the pouch for final security.



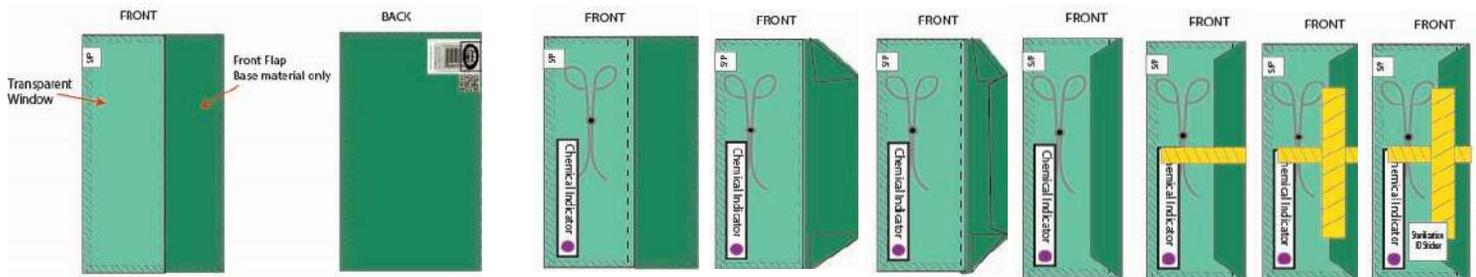
STERILIZATION POUCHES FOR USE WITH LOOSE TOOLS (NO TRANSPARENT WINDOW)

1. Follow your regional (Federal or Provincial) or governing body (i.e. medical, dental, veterinary, hygienist colleges) standards and requirements regarding sterilization of loose tools and devices; contact, number of tools, disassembly, or separators.
2. Tools and pouches should be clean and dry. Never use dirty or soiled devices in an autoclave.
3. Select a pouch size where the pocket is at least 3.5 cm or 1.5" longer and wider than the device(s) you want to sterilize. Do not overfill a pouch and follow your industry or regional requirements regarding loose tools in sterilization.
4. Inspect pouch for holes and/or tears. Do not use damaged pouches.
5. Place tool(s) gently inside of pouch. Do not drop sharp or heavy tools into pouch as they may damage the material.
6. Insert your sterilization chemical indicator into the pouch.
7. Fold the material (both the back and front of the pouch) 3.5" or 1.5" below the top stitched pocket edge, ensuring that both the front and back of the pouch are pressed tightly together without wrinkles or gaps.
8. Attach sterilization tape approximately 2.0 cm below the top fold of the pouch to create your barrier integrity seal.
9. Place your Sterilization ID sticker onto the pouch. **Do NOT put tape or stickers over labels**.
10. **DO NOT** use Frëtt Solution Steri-Bands or other elasticized bands with loose tools and pouches as it wrinkles and distorts the material excessively. You can apply sterilization tape or the sterilization ID sticker to the pouch to help the flap edge lay flat.



STERILIZATION POUCHES WITH TRANSPARENT WINDOW FOR USE WITH LOOSE TOOLS

1. Follow your regional (Federal or Provincial) or governing body (i.e. medical, dental, veterinary, hygienist colleges) standards and requirements regarding sterilization of tools and devices; contact, number of tools, disassembly, or separators.
2. Tools and pouches should be clean and dry. Never use dirty or soiled devices in an autoclave.
3. Select a pouch size where the transparent (clear) window is 2.0 cm longer and 2.0 cm wider than the device(s) you want to sterilize. Do not overfill a pouch and follow your industry or regional requirements regarding loose tools in sterilization.
4. Inspect pouch for holes and/or tears. Do not use damaged pouches.
5. Place tool(s) gently inside of pouch. Do not drop sharp tools into pouch as they may damage the material.
6. Insert your sterilization chemical indicator so that the color change marker is visible through the transparent window.
7. On the front side, fold both corners of the pouch flap towards each other creating 2 small triangles.
8. **DO NOT fold the transparent window** (that should remain flat and unfolded always).
9. Keeping the corners folded, turn and fold the opening once and then turn and fold again (turned twice), preventing gaps.
10. Use autoclave sterilization tape perpendicular (across) the folded pouch, then apply a second piece parallel, along the folded edge to create your barrier integrity seal.
11. Place your Sterilization ID sticker onto the front or back of pouch. **Do NOT put tape or stickers over labels.**
12. **DO NOT** use Frëtt Solution Steri-Bands or other elasticized bands with loose tools and pouches as it wrinkles and distorts the material excessively.



****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