Instructions for use (en) - ULTRA

INDICATIONS FOR USE:
ULTRA Pouches and Reels with STEAM Chemical Indicator are intended to be used for the packaging of medical devices that are to be terminally sterilized in Sterile Barrier Systems and compatible with the intended sterilization process(es).
Color change of the chemical indicator ensures that the pouch has been exposed to sterilant.
The printed chemical indicator which is a process indicator changes from pink to brown (dark brown or lighter) when exposed to STEAM during sterilization process.
ULTRA Pouches and Reels are compatible with the following sterilization processes: steam, vH2O2 (Hydrogen Peroxide vapor) and ethylene oxide (EO).
After the sterilization process, pouches and reels are intended to maintain sterility of the packaged device until used.

PRINTED SYMBOL DEFINITION:

: Don't use if packaging is damaged *

: Single use only *

STEAM: STEAM process indicator **

*Symbol according to NF EN ISO 15223-1, **Symbol according to NF EN ISO 11140-1

DESCRIPTION
Pouches and Reels are made of two materials. The non-permeable blue transparent layer is a polyester (PET) / polypropylene (PP) laminate; the white porous layer is a non-woven polyolefin (PP).

Compliant with EN 868-5 and EN ISO 11607-1 standards

DIRECTIONS FOR USE:

A. Packaging and sealing

Insert the medical device into the pouch. For reels, cut to desired length, seal one open end using a heat sealer, and insert the medical device.

Seal the non-welded end of the heat sealable pouch or reel using a heat sealer.

Recommendation: In order to allow a more efficient and homogeneous penetration of the sterilizing agent and to avoid any risk of bursting, the packaging must not be filled to more than 2/3 of the useful volume.

When heat sealing the pouch or reel for the first time, the operator should establish the seal temperature/dwell time range for their specific machine in order to obtain a resistance of the welding according to the EN 868-5 standard and a good peelability at the opening of the packaging Typical conditions for heat sealer vary by machine, but are typically between 135°C - 155°C, the sealing time usually required is 1 to 2 second for impulse sealers.

Sealing is done by means continuous (rotary) or impulse heat sealers.

Indicative sealing parameters:

	ROTARY HEAT SEALERS	IMPULSE HEAT SEALERS
TEMPERATURE (Celsius)	**135 - 155°C**	**135 - 155°C**
PRESSURE	**90 – 120 N/mm²**	**90 – 120 N/mm²**
DWELL TIME	**10 m/min**	
SEALING CONTACT TIME		**1 – 2 s**

Note: To comply with EN ISO 11607-2, the use of validated heat sealers that is highly recommended. Depending on the type and brand of the equipment, the validated parameters may differ from the indicative ranges mentioned in the table above. Consult heat sealer manufacturer's instructions for use for proper set up.

B. Packaging aseptic opening
The opening of Reels is possible in both directions from one or the other ends (see logo « 1 »)
For the opening of pouches, remove the 2 attachment points first and peel off from chevron side in the direction indicated by the arrow (see logo « 1 »)
The opening is done by holding the porous layer with one hand and pulling with the other hand on the plastic film layer.

AND WASTE MANAGEMENT:
- Store at room temperature, 10°C - 30°C under dry conditions (30-60% humidity) in their original packaging. Don't expose the product to light.
- You may dispose this product in accordance with your National, Federal, State and Local regulations or per healthcare facility's policies and procedures.

CAUTION:

- Don't use after use by date printed on the packaging label.
- Single use only. Don't reuse. Do not reuse as the pouches and reels have been developed and validated for single processing. Should a cycle cancellation occur, repack the devices using new pouches and reels when proceeding with a new sterilization cycle.
- Don't use if pouch or reel is damaged.
- Don't fold the packaging (risk of breaking the integrity of the packaging)

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- If the chemical indicator has not completely changed at the end of the sterilization cycle, introduction of sterilizing agent, essential phase in the sterilization cycle, may not have taken place.
- Chemical indicators (class 1 according to ISO 11140-1) provide an indication that Sterile Barrier System and its content have been subjected to a sterilization cycle with contact of the sterilant. However, it does not demonstrate the sterile condition of the packaging and contents

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