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Reliance[®] Tandem 2

Instructions for use

Product description

Reliance® Tandem 2 is a combination of two interleaved SMMMS sheets of nonwoven Reliance 435 Green (inner layer) and Reliance 435 Blue (outer layer), providing a superior sterile barrier system.

Both nonwovens deliver the barrier protection and sterilant permeability required for optimal sterilization of medical devices Reliance® Tandem 2 is effectively lint and memory-free and is soft and strong.

It is compatible with steam, ethylene oxide, low temperature steam formaldehyde and hydrogen peroxide gas sterilization processes. Manufactured to comply with SANS 11607-1, SANS 50868-2, EN 868-2 & DIN 58953-6..

Tandem 2 has been validated for use as a 2 layer sterile barrier system. The layers MUST NOT BE used separately.

Sheet Sizes

PACK SIZES		
DESCRIPTION	SHEET SIZE (mm)	NO. OF SHEETS/PACK
Reliance Tandem 2	580 x 600	50 x 2
Reliance Tandem 2	880 x 900	50 x 2
Reliance Tandem 2	880 x 1200	50 x 2
Reliance Tandem 2	880 x 1500	50 x 2
Reliance Tandem 2	1160 x 1200	50 x 2
Reliance Tandem 2	1160 x 1400	50 x 2
Reliance Tandem 2	1160 x 1700	50 x 2

Indications for use

Reliance® Tandem 2 sterilization wrap is intended to be used to enclose medical devices that are to be sterilised by a healthcare provider by Steam at 121°C to 134°C, Ethylene Oxide (EtO), Formaldehyde and Vapor Hydrogen Peroxide GAS PLASMA.

- **DO NOT USE:**
- If damage or a foreign particle is detected prior to use
- If torn or wet
- If there is any sign of potential contamination

- **DO NOT USE** wrap for the following sterilization methods:
 - Dry heat
 - Radiation – such as Gamma, E-Beam or other radiation methods

Precautions

- **DO NOT:**
 - Open case or packaging with a sharp knife because the knife could cut the wrap

Storage prior to use

- Clean
- Dust free
- Use FIFU first in, first out (stock Rotation)

Prior to use

- Examine wrap and **DO NOT USE** if damage or a foreign particle is detected prior to use
- Items to be wrapped must be thoroughly clean and dry

Direction for use

Wrap your devices and packs using a wrapping method in line with your country and institution guidelines. When using individual sheets of sterile barrier material a sequential technique can be used. Wrapping methods include the envelope, parallel, square and Pasteur folds (ISO 16775:2014). Depicted below is an example of the sequential square/parallel fold that can be used with this product. In the case of Tandem 1 or Tandem 2 the green or blue layer can be used as the inner or outer wrap.

STANDARD OPERATING PROCEDURE

HOW TO WRAP AN INSTRUMENT SET OR PACK



STEP ONE

Select the correct size wrap for the instrument tray/ pack to be wrapped
Lay two layers of wrap length ways
Place the tray in the centre of the wrap
Fold the first side to cover the entire tray



STEP TWO

Fold back the first wrap to create a cuff ensuring the tray is still covered



STEP THREE

Fold the opposite side over the set, create the cuff to end in the centre



STEP FOUR

Fold both ends of the wrap to create a V
Repeat for the second layer of wrap
Wrap the set firmly but no too tight
Secure the wrap with an adequate length of masking tape Apply autoclave tape
Do not write directly onto wrap
Label pack according to hospital policy

Depicted below is the modified sequential square/parallel that can also be used with this product



STEP ONE

Select the correct size wrap for the instrument tray/ pack to be wrapped
 Lay two layers off wrap length ways
 Place the tray of centre of the wrap to create extra length
 Fold the first side to cover the entire tray



STEP TWO

Pick up the opposite (long) side and fold back to the level of the tray



STEP THREE

Pick up the opposite (long) side and fold back to the level of the tray



STEP FOUR

Fold both ends of the wrap to create a V
 Repeat for the second layer of wrap
 Wrap the set firmly but no too tight
 Secure the wrap with an adequate length of masking tape
 Apply autoclave tape
 Do not write directly onto wrap
 Label pack according to hospital policy

Wrap Model Recommendations

Reliance® sterilization wrap models	Intended loads
Tandem 2	Light to moderate weight package
Tandem 1	Moderate to heavy weight package
Reliance 440	Moderate to heavy weight package
Tandem 340 Non-Woven Green	Moderate to heavy weight package
Reliance 310 Sensitive	Light to moderate weight package

Post-sterilization cooling/unloading

- Sterilised packs should be left until cool to avoid compromising packaging sterility
- Important to visually check wrapped items and **DO NOT USE** if they are torn, wet or compressed

Sterility maintenance

The shelf life of facility-sterilized items is event-related and should be based on:

- The quality of the packaging material
- The storage conditions
- The methods and conditions of transport
- How often they were handled

Important Note: Stacking trays can result in damage to the wrap caused by pressure from the weight.

Opening

- DO NOT USE wrap:
- If damage or a foreign particle is detected prior to use
- If torn or wet
- If there is any sign of potential contamination prior to or after opening

Important Note: Open packages aseptically in accordance with the healthcare facilities policy

IMPORTANT: This is a single use product. Discard as per healthcare facility policies and procedures. DO NOT re-use.