

# IFU for Renosem Co., Ltd.

## TYVEK Pouch

---

### Descriptions of Use

The see-through heat-sealable TYVEK pouches are intended for use as packing material for medical devices by sterilization by plasma.

### Prior to Use

1. Before sealing, remove as much air as possible from the pouch.
2. Confirm that the temperature setting on the heat sealer is appropriate for TYVEK pouches.  
Recommended sealing temperature for final closing is 120-160°C depending on pressure and time.
3. Seal the pouch securely.
4. Leave enough space beyond the seal for the opener to easily grasp (usually 10 mm).

### Instructions for Use

1. Hold the pouch taut in the sealer, to prevent wrinkles or air bubbles from forming in the seal.
2. If using a rolling type heat sealer, let the peel pouch move along the guide on its own.
3. Once the pouch completes the slide down rolling side verify the pouch is sealed and that material beyond the seal from the opening is 10mm to allow for aseptic presentation.

### Documentation

- Renosem See-Through range of peel packages confirm to the international product standards and norms; ISO 11607-1:2006, ISO 11607-2: 2006, EN 868-5: 2009.
- The products are registered by ISO 13485: 2004;
- Renosem sterilization packages are designed, validated, and manufactured to suit their intended purposes.

### Warnings and Cautions

- Renosem standard range of see-through packages is not suitable for sterilization by irradiation or by hot, dry air at the temperatures over 140°C.

### Specifications

Model: RENO-P75, P150, P200, P250 and P300

Material : TYVEK, Vinyl, etc.

### Storage

- When kept in the original packaging, no special conditions are required. When stored in the original, closed transportation packaging items are protected from moisture, heat and direct sunlight or other sources of UV light.
- Once the pouches and rolls are removed from the packaging they are to be stored at a temperature of 18-24°C and humidity 40-60°C.
- Pouches should be stored in closed cabinets otherwise protected from a UV-light source. The process indicator is sensitive to UV-light and may change color over time, if not stored properly.

### Shelf Life of Unprocessed Pouches/Rolls

- It is recommended that the pouches/rolls are used within 5 years of manufacture.
- The recommended “best before” date and the manufacturing date are stated on the carton level.
- Shelf life of processed pouches/rolls is event-related. Facilities should develop a policy identifying events that may compromise the sterility of packaged items. This could include a maximum period of time for storage.

### Additional information

- The products are for single use only.
- Validated for double-pouching (see Double Pouching Verification Study)

### Renosem Co., Ltd.

Unit 103-806, 397, Seokcheon-ro  
Bucheon, Gyeonggi  
14449  
South Korea

T: +82 32 222 0143

F: +82 32 222 0110