

**purple surgical**



**Ultrasound Probe Covers**



REF	PS9050NS
	en – Ultrasound Probe Cover – Non-Sterile Supply es - Cubierta para sonda ecográfica - Suministrada no estéril pt - Capa para sonda ecográfica - Dispositivo não estéril de - Ultraschallsondenabdeckung – nicht steriles Produkt fr - Protection de sonde à ultrasons - produit non stérile it - Copertura della sonda a ultrasuoni – Fornitura non sterile



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## en – Ultrasound Probe Cover



**The following should be thoroughly read before use.**

### **IMPORTANT NOTES**

This document is designed to provide instructions on how this product/s is used. It is not a reference to clinical techniques and does not replace local or national guidance or protocols.

### **INTENDED USER**

This product should only be used by suitably trained healthcare professionals within a healthcare establishment.

### **INTENDED PURPOSE**

The Ultrasound Probe Cover is used to provide a disposable hygienic interface between the ultrasound probe and the patient, protecting the ultrasound equipment from contamination.

### **INDICATIONS FOR USE**

The device is placed over the ultrasound transducer to create a barrier between the ultrasound transducer and the patient's skin.

### **PRODUCT CHARACTERISTICS**

The Ultrasound Probe Cover is used to maintain a sterile field and provide a hygienic interface between the ultrasound probe and patient.

### **HOW SUPPLIED**

This is a pouched non-sterile supply option intended for a kit packer for their inclusion and sterilisation of the device within a procedure pack, before being provided to the end user.

### **INDICATIONS FOR STERILISATION PROCESSING**

The device performance has been qualified as suitable for Ethylene Oxide Sterilisation with consideration to the following parameters: Maximum Temperature of 59°C, Maximum Humidity of 75%RH and Minimum Pressure of 50mBara

### **SHELF LIFE**

4 years from date of sterilisation

### **OTHER DEVICES REQUIRED FOR USE AND INTEROPERABILITY REQUIREMENTS**

The Ultrasound Probe Cover has been designed to cover the ultrasound probe head during use and the device is supplied with bands to hold the cover in place.

### **CONTRAINDICATIONS**

This device is not intended for use when ultrasound techniques are contraindicated.

### **POSSIBLE ADVERSE REACTIONS**

None apply.

### **PRECAUTIONS / WARNINGS / RESIDUAL RISKS**

Do not use if package is opened or damaged.

### **SINGLE USE PRECAUTION**

This product/s are designed and sold for single patient use only.

Re-processing and/or re-sterilisation is not permitted. The effects of unauthorised reprocessing or re-sterilisation can result in the following complications:

1. Infection due to cross contamination as a result of ineffective re-processing/re-sterilisation.
2. Mechanical fatigue and performance failure, due to the effects of the re-processing / re-sterilisation method.

### **DIRECTIONS FOR USE**

1. Visually inspect the sterile barrier system pouch prior to its opening so as to ensure it is not already open or compromised. If a sterile barrier failure is found, the contained product shall be considered non-sterile and it shall not be used.
2. Open packaging for presentation of sterile product to the sterile field using aseptic technique.
3. Apply the single-use cover over the ultrasound probe head and secure with the fixation bands supplied before patient use.
4. Discard after single patient use.

### **DISPOSAL**







Discard after single use.

This product/s is to be disposed of as controlled medical waste according to national guidelines.

### **SERIOUS INCIDENT REPORTING**

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



<p>en: LABELLING SYMBOLS - Standard ISO15223-1, unless otherwise stated  es: SIMBOLOGÍA DEL ETIQUETADO - Norma ISO15223-1, salvo que se indique lo contrario  pt: SIMBOLOGIA UTILIZADOS NO ROTULO - Norma ISO15223-1, exceto indicado em contrário  de: KENNZEICHNUNGS SYMBOLOGIE - Standardmäßig laut ISO15223-1, falls nicht anders vermerkt  fr: SYMBOLES D'ÉTIQUETAGE - Norme ISO15223-1, sauf indication contraire  It: SIMBOLI SULL'ETICHETTA - Standard ISO15223-1, se non diversamente specificato</p>			<p>en: Use-by date  es: Fecha de uso recomendada  pt: Data de validade  de: Verfallsdatum  fr: Date de validité  It: Usare entro la data</p>
 <p>en: Manufacturer  es: Fabricante  pt: Fabricante  de: Hersteller  fr: Fabricant  It: Produttore</p>	<p>en: Authorized representative  es: Representante autorizado  pt: Representante autorizado  de: Vertreter  fr: Mandataire  It: Mandatario</p>	<p>en: Medical device  es: Producto sanitario  pt: Dispositivo médico  de: Medizinprodukt  fr: Dispositif médical  It: Dispositivo medico</p>	
 <p>en: Consult instructions for use  es: Consulta las instrucciones de uso  pt: Consulte as instruções de uso  de: Gebrauchsanleitung beachten  fr: Consulter le mode d'emploi  It: Consultare le istruzioni per l'uso</p>	<p>en: Caution  es: Precaución  pt: Atenção  de: Vorsicht  fr: Attention  It: Attenzione</p>	<p>en: Catalogue number  es: Número de catálogo  pt: Número de catálogo  de: Katalognummer  fr: Numéro de catalogue  It: Numero di catalogo</p>	<p>en: Batch code  es: Código de lote  pt: Código de lote  de: Chargen-code  fr: Code par-couche  It: Codice lotto</p>
 <p>en: Do not use if package is damaged  es: No usar si el envase está dañado  pt: Não usar se o embalagem estiver danificada  de: Nicht verwenden, wenn das Paket beschädigt ist  fr: Ne pas utiliser si l'emballage est endommagé  It: Non usare se la confezione è danneggiata</p>	<p>en: Keep dry  es: Mantener en lugar seco  pt: Manter no local seco  de: Trocken aufbewahren  fr: À conserver dans un endroit sec  It: Conservare all'asciutto</p>	<p>en: Keep away from sunlight  es: Mantener alejado de la luz del sol  pt: Manter ao abrigo da luz solar  de: Lichtempfindlich  fr: Tenir éloigné de la lumière  It: Tenere lontano dalla luce del sole</p>	<p>en: Do not reuse  es: No reutilizar  pt: Não reutilizar  de: Nicht wiederverwenden  fr: Ne pas réutiliser  It: Non riutilizzare</p>
 <p>en: CE Mark  es: Marcado CE  pt: Marcação CE  de: CE-Kennzeichnung  fr: Marquage CE  It: Marchio CE</p>	<p>en: Non Sterile  es: No estéril  pt: Não esteril  de: Nicht steril  fr: Non stérile  It: Non Sterile</p>	 <p>en: Importer  es: Importador  pt: Importador  de: Importeur  fr: Importateur  It: Importatore</p>	<p>en: Authorized representative in Switzerland  es: Mandatario en Suiza  pt: Representante autorizado na Suíça  de: Bevollmächtigter in der Schweiz  fr: Mandataire en Suisse  It: Mandatario in Svizzera</p>
 <p>en: UKCA MARK  es: Marca UKCA  pt: Marca UKCA  de: UKCA-Kennzeichnung  fr: Marquage UKCA  It: Marchio UKCA</p>			