



en: LABELING SYMBOLS - Standard ISO 15223-1 unless otherwise stated
 es: SIMBOLOGIA DEL ETIQUETADO - Norma ISO 15223-1 salvo que se indique lo contrario
 pt: SÍMBOLOS UTILIZADOS NO RÓTULO - Norma ISO 15223-1 exceto indicação em contrário
 de: SÜMBOLISCHES ETIKETTIEREN - Standardmäßig laut ISO 15223-1, falls nicht anders vermerkt
 fr: SYMBOLES D'ÉTIQUETAGE - Norme ISO 15223-1 sauf indication contraire
 it: SIMBOLI DELLA ETICHETTA - Standard ISO 15223-1, se non diversamente specificato

	EC REP	MD	CE
en: Manufacturer es: Fabricante pt: Fabricante de: Hersteller fr: Fabricant it: Produttore	en: Authorized representative es: Representante autorizado pt: Representante autorizado de: Mandatierter fr: Mandataire it: Rappresentante autorizzato	en: Medical device es: Producto sanitario pt: Dispositivo médico de: Medizinisches Gerät fr: Dispositif médical it: Dispositivo medico	en: CE Mark es: Marca CE pt: Marca CE de: CE-Kennzeichnung fr: Marquage CE it: Marchio CE
REF	LOT		
en: Catalogue number es: Número de catálogo pt: Número de catálogo de: Katalognummer fr: Numéro de catalogue it: Numero di catalogo	en: Batch code es: Código de lote pt: Código de lote de: Losnummer fr: Code de lot it: Codice lotto	en: Consult instructions for use es: Consultar las instrucciones de uso pt: Consultar instruções de utilização de: Nicht verwenden, wenn das Paket beschädigt ist fr: Consulter le mode d'emploi it: Consultare le istruzioni per l'uso	en: Do not reuse es: No reutilizar pt: Não reutilizar de: Nicht wiederverwenden fr: Ne pas réutiliser it: Non riutilizzare
en: Keep dry es: Mantener en un lugar seco pt: Manter ao abrigo da luz solar de: Trocken aufbewahren. fr: Conserver à l'abri de la lumière it: Conservare al riparo dal sole	en: Keep away from sunlight es: Mantener alejado de la luz del sol pt: Manter ao abrigo da luz solar de: Fern von Sonnenlicht aufbewahren. fr: Éviter l'exposition à la lumière it: Tenere lontano dalla luce del sole	en: Do not use if package is damaged es: No usar si el envase está dañado pt: Não usar caso a embalagem esteja 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	en: Non-sterile es: sin esterilizar pt: Não estéril de: Nicht-steril fr: Non stérile it: Non sterile
			CH REP
en: Use-by date es: Fecha de uso recomendado pt: Data de validade de: Verfallsdatum fr: Date limite d'utilisation it: Usare entro la data	en: Caution es: Precaución pt: Atenção de: Vorsicht fr: Attention it: Attenzione	en: Importer es: importador pt: importador de: Importeur fr: importateur it: Importatore	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



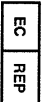
Collection Sets - Non-sterile supply



REF	PS6100NS, PS6101NS
en - Collection set es - Kit de extracción pt - Conjunto de Recolha de - Set mit Steckverbinder fr - Tubulure d'aspiration it - Set di raccolta	



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en - 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

A device to be used in conjunction with a vacuum system to facilitate the evacuation of bodily fluids and foetal tissue.

INDICATIONS FOR USE

The collection sets are designed for use in surgical vacuum aspiration termination of pregnancy procedures.

PRODUCT CHARACTERISTICS

Available in standard 10mm internal diameter with Male and Female connections. The Purple Surgical Collection Sets are high vacuum, sterile tubing with a swivel handle for connection to sterile Curettes.

HOW SUPPLIED

Supplied in Non-sterile format to a Kit packer, for sterilisation as part of a kit prior to market release to intended user.

SHELF LIFE

Use by date as denoted on labelling in format YYYY-MM

INDICATIONS FOR STERILISATION PROCESSING

The device performances have been qualified as suitable with consideration to the following methods and limitations, of sterilisation:

- Ethylene Oxide Sterilisation - Maximum Temperature of 59°C and Minimum Pressure of 50mBarA

OTHER DEVICES REQUIRED FOR USE AND INTEROPERABILITY REQUIREMENTS

The Collection Sets can be connected to the Purple Surgical Safe Term Canister and the Purple Surgical Specimen Cup. The distal end of the Collection Set tubing incorporates a swivel handle for tapered push fit connection to Curette devices.

CONTRAINDICATIONS

The devices are for suction aspiration purposes only. They are not intended, nor qualified, for delivery of any substance to the patient.

PRECAUTIONS / WARNINGS / RESIDUAL RISKS

Ensure you have selected the relevant connector so that the correct fit can be achieved with the vacuum device.

POSSIBLE ADVERSE REACTIONS

None apply.

SINGLE USE PRECAUTION

These device(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. Prior to use inspect the product to ensure no damage, if damaged the product should be discarded.
2. Ensure you have selected the relevant connector so that the correct fit can be achieved with the vacuum device.
3. If the Collection set is being used with the Purple Surgical Safe Term Canister and the Purple Surgical Specimen Cup, ensure you use the Female connector and attach this to the vacuum port once you have removed the cap.
4. Select the required Curette and connect it to the swivel handle ensuring a secure fit.
5. A vacuum control slide is present on the swivel handle for in use aspiration control.

DISPOSAL

This product 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.