purple surgical

en: **LABELLING SYMBOLOGY** - Standard ISO 15223-1 unless otherwise stated es: **SIMBOLOGÍA DEL ETIQUETADO** - Norma ISO 15223-1 salvo que se indique lo contrario pt: **SÍMBOLOS UTILIZADOS NO RÓTULO** - Norma ISO 15223-1 excepto indicação em contrário de: **KENNZEICHNUNGS SYMBOLOGIE** - Standardmäßig laut ISO 15223-1, falls nicht anders vermerkt fr: **SYMBOLES D'ÉTIQUETAGE** - Norme ISO 15223-1 sauf indication contraire It: **SIMBOLI SULL'ETICHETTA** - Standard ISO 15223-1, se non diversamente specificato			
en: Manufacturer es: Fabricante pt: Fabricante de: Hersteller fr: Fabricant It: Produttore	en: Authorized representative es: Representante autorizado pt: Representante autorizado de: Bevollmächtigten fr: Mandataire It: Rappresentante autorizzato	en: Medical device es: Producto sanitario pt: Dispositivo médico de: Medizinprodukt fr: Dispositif médical It: Dispositivo medico	en: CE Mark es: Marca CE pt: Marca CE de: CE-Kennzeichnung fr: CE Marquage It: Marchio CE
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: Chargen-Code fr: Code de lot It: Codice lotto	en: Consult instructions for use es: Consultar las instrucciones de uso pt: Consultar instruções de utilização de: Gebrauchsanleitung beachten 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 seco de: Trocken aufbewahren. fr: À conserver dans un endroit sec It: Conservare all'asciutto	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: À conserver à l'abri de 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
en: Use-by date es: Fecha de uso recomendado pt: Data de validade de: Verfalldatum fr: Date limite d'utilisation It: Usare entro la data	en: Caution es: Precaución pt: Atenção de: Vorsicht fr: Avertissement It: Attenzione	en: Importer es: Importador pt: Importador de: Importeur fr: Importateur It: Importatore	en: Authorised representative in Switzerland es: Mandatario en Suiza pt: Representante autorizado na Suiça de: Bevollmächtigten in der Schweiz fr: Mandataire en Suisse It: Mandatario in Svizzera

purple surgical

Collection Sets - Non-sterile supply

CE

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

Purple Surgical International Limited / Purple Surgical UK limited
2 Chestnut House, Farm Close, Shenley, Hertfordshire,
WD7 9AD, England
Tel: +44 (0) 1923 839333
E-Mail: mail@purplesurgical.com
Web: www.purplesurgical.com

EC REP

Advena Limited
Tower Business Centre, 2nd floor, Tower Street,
Swatar, BKR 4013, Malta

purple surgical

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.