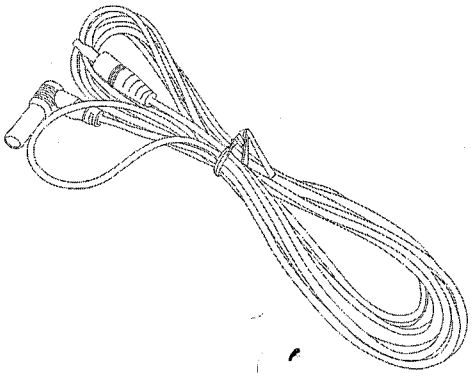
purple surgical

REF **PS3551C4NS, PS3551C8NS** CE

en	Monopolar instrument cables
es	Cables de instrumentos monopolares
pt	Cabos de instrumentos monopolares
de	Monopolare Instrumentenkabel
fr	Câbles d'instruments monopolaires
it	Cavi strumenti monopolari
cs	Monopolární přístrojové kabely



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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 surgical techniques.
INDICATIONS
The Purple Surgical 'Monopolar instrument cables' should be used with suitable monopolar devices and an appropriate electrosurgical generator.
PRODUCT CHARACTERISTICS
The instrument/s are designed for Monopolar use only
- Device conforms to Electrical Safety Standard IEC 60601-2-2.
- The maximum rated voltage this device has been tested in conformance to is 3,500Vpeak.

HOW SUPPLIED
Supplied in Non sterile format to Kit packer, for sterilisation as part of a kit prior to market release to intended user.
SHELF LIFE
4 years from date of sterilisation - 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 method, and limitations, of sterilisation:

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

Note* It is the responsibility of the kit packer to validate the sterilisation process employed, with respect to the conditions of their presentation of the packaging system.
COMPATIBILITY AND CONNECTIVITY
The Purple Surgical 'Monopolar instrument cables' are used to connect a monopolar device by means of the 4mm female socket on the cable to the 4mm Monopolar Instrument post on the device.
The cables are available with either a 4mm (PS3551C4) or 8mm (PS3551C8) monopolar pin for connection to the electrosurgical generator.
CONTRAINDICATIONS
- This device is not to be used for connection to bipolar instrumentation.
- DO NOT USE on patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

PRECAUTIONS / WARNINGS
(1) DO NOT use if package is received opened or damaged.
(2) Procedures should be performed only by clinicians with adequate training and knowledge. Medical literature should be consulted for techniques, hazards, contraindications and complications prior to the procedure.
(3) Connect adaptors and accessories to the electrosurgical unit only when the unit is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
(4) Refer to appropriate electrosurgical system user manual for indications and instructions to ensure that all safety precautions are followed.
(5) Laparoscopic instruments may vary in diameter from manufacturer to manufacturer. When laparoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of procedure.
(6) The user should review the instructions for use of all devices, being used in conjunction with these product/s.
(7) During monopolar surgery, the PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.).
(8) During monopolar surgery, Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze.
(9) During monopolar surgery, the PATIENT leads should be positioned in such a way that contact with the PATIENT or other leads is avoided.
Temporarily unused ACTIVE ELECTRODES should be stored in a location that is isolated from the PATIENT.
(10) During monopolar surgery, the output power selected should be as low as possible for the intended purpose, and it shall not exceed the maximum rated voltage of the cable and any connected device
(11) During monopolar surgery, the use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.
(12) Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives should be allowed to evaporate before the application of HF surgery. There is a RISK of pooling of flammable solutions under the PATIENT or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF SURGICAL EQUIPMENT is used.
(13) Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton and gauze, when saturated with oxygen may be ignited by sparks produced in NORMAL USE of the HF SURGICAL EQUIPMENT.
(14) For PATIENTS with electrically conductive implants, a possible HAZARD exists due to concentration or re-direction of HF currents. In case of doubt, qualified advice should be obtained.
(15) During Monopolar Surgery, it is recommended that the use of smoke-plume extraction is employed.
ADVERSE REACTIONS
No known issues.
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) Using aseptic technique, remove the product/s from its packaging.
(3) The 4mm female socket on the cable should be connected to a standard 4mm monopolar diathermy post on any monopolar instrument.
(4) The male connector on the cable should be connected to the relevant monopolar power outlet on an appropriate electrosurgical generator, whilst the generator is switched off.
SINGLE USE PRECAUTIONS
This product/s are designed and sold for single use only. Re-processing and, or, re-sterilisation is not permitted.
The effects of any unauthorised re-processing or re-sterilisation can result in the following complications:
1. Cross contamination due to ineffective re-processing/re-sterilisation.
2. Mechanical fatigue, and associated failure, due to the effects of the re-processing / re-sterilisation method.

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.

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
cs: SYMBOLY OZNAČENÍ - norma ISO 15223-1 pokud není uvedeno jinak

			
en: Manufacturer **es:** Fabricante **pt:** Fabricante **de:** Hersteller **fr:** Fabricant **it:** Produttore **cs:** Výrobce	**en:** Authorized representative **es:** Representante autorizado **pt:** Representante autorizado **de:** Bevollmächtigten **fr:** Mandataire **it:** Rappresentante autorizzato **cs:** Zplnomocněný zástupc	**en:** Medical device **es:** Producto sanitario **pt:** Dispositivo médico **de:** Medizinprodukt **fr:** Dispositif médical **it:** Dispositivo medico **cs:** Zdravotnický prostředek	**en:** CE Mark **es:** Marca CE **pt:** Marca CE **de:** CE-Kennzeichnung **fr:** CE Marquage **it:** Marchio CE **cs:** Značka CE
			
en: Catalogue number **es:** Número de catálogo **pt:** Número de catálogo **de:** Katalognummer **fr:** Numéro de catalogue **it:** Numero di catalogo **cs:** Katalogové číslo	**en:** Batch code **es:** Código de lote **pt:** Código de lote **de:** Chargen-Code **fr:** Code de lot **it:** Codice lotto **cs:** Číslo šarže	**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 **cs:** Viz pokyny pro použití	**en:** Do not reuse **es:** No reutilizar **pt:** Não reutilizar **de:** Nicht wiederverwenden **fr:** Ne pas réutiliser **it:** Non riutilizzare **cs:** Nepoužívejte opakovaně
			
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 **cs:** Uchovávejte v suchu	**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 **cs:** Chraňte před slunečním světlem	**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 **cs:** Nepoužívejte, pokud je obal poškozen	**en:** Caution **es:** Precaución **pt:** Atenção **de:** Vorsicht **fr:** Avertissement **it:** Attenzione **cs:** Upozornění
			
en: Type BF applied part **es:** Escribir la pieza aplicada de tipo BF **pt:** Peça aplicada de tipo BF **de:** Anwendungsteil vom Typ BF **fr:** Partie appliquée de type BF **it:** Parte applicata di tipo BF **es:** Aplikovaná součást typu BF	**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 **cs:** Spotřebujte do	**en:** Non Sterile **es:** No estéril **pt:** Não estéril **de:** Nicht steril **fr:** Non stérile **it:** Non Sterile **cs:** Není sterilní	**en:** Importer **es:** Importador **pt:** Importador **de:** Importeur **fr:** Importateur **it:** Importatore **cs:** Dovozce
			
en: Authorised representative in Switzerland **es:** Mandatario en Suiza **pt:** Representante autorizado na Suíça **de:** Bevollmächtigten in der Schweiz **fr:** Mandataire en Suisse **it:** Mandatario in Svizzera **cs:** Zplnomocněný zástupce ve Švýcarsku	**en:** UKCA Mark **es:** Marcado UKCA **pt:** Marcação UKCA **de:** UKCA-Kennzeichnung **fr:** Marquage UKCA **it:** Marchio UKCA **cs:** Značka UKCA se schváleným číslem organizace		