purple surgical

LIGHT HANDLE COVERS

CE

REF	PS4611NS1000
	en - Light Handle Cover es - Cubierta para mango de lámpara pt - Capa de proteção para punhos de candeeiros cirúrgicos de - Lichtgriffabdeckung fr - Cache pour poignée d'appareil d'éclairage it - Copertura dell'impugnatura della luce cs - Kryt rukojeti světla da - Afdækning til lyshåndtag sv -Lamphandtagsskydd no - Deksel for lyshåndtak

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EC REP

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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 sterile device designed specifically to cover the handle of a piece of medical equipment (e.g. operating light) to provide a physical sterile barrier between the handle and the hand of a healthcare professional, e.g. during a surgical procedure and mitigate against the risk of transfer of infection from the non-sterile equipment to patient.

INDICATIONS FOR USE
Use is governed by the clinical application of the operating light system

PRODUCT CHARACTERISTICS
The Light Handle Cover is of single use, flexible plastic, one-piece, friction fit design.

HOW SUPPLIED
This is a BULK 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.

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
- **Gamma Irradiation Sterilisation** - Maximum Dose of 40kGy

OTHER DEVICES REQUIRED FOR USE AND INTEROPERABILITY REQUIREMENTS
The Purple Surgical Light Handle Cover has been specifically designed to fit the Litex Manufacturing Inc. 'Universal Light Handle Adaptors', available from Purple Surgical as required.

CONTRAINDICATIONS
No restrictions apply.

PRECAUTIONS / WARNINGS / RESIDUAL RISKS
Prior to use, the user shall confirm that the Light Handle Cover is of a compatible fit to the handle grip installed on the lighting system. It shall be capable of being fitted fully over the handle grip without splitting or damage and shall be sufficiently tight so as not to detach from the grip whilst being manipulated.

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. 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. Apply the singe-use Light Handle Cover to the universal light handle utilising a one handed technique & using a 360 degree upward rotating / twisting motion until the circular flange of the Light Handle Cover reaches the circular flange of the universal light handle. The clinician should avoid directly touching the universal light handle during the application of the Light Handle Cover

3. Discard after single patient use by gripping the flange of the Light Handle Cover & peeling it off the universal light handle.

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.

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
da: MÆRKNINGSSYMBOLER - Standard ISO 15223-1 medmindre andet er angivet
sv: MÄRKNINGSSYMBOLOGI - Standard ISO 15223-1 om inget annat anges
cs: SYMBOLY OZNAČENÍ - norma ISO 15223-1, pokud není uvedeno jinak
no: MERKINGSSYMBOLER - Standard ISO 15223-1 med mindre annet er oppgitt

en: Manufacturer **es:** Fabricante **pt:** Fabricante **de:** Hersteller **fr:** Fabricant **It:** Produttore **da:** Producent **sv:** Tillverkare **cs:** Výrobce **no:** Produsent	**en:** Authorized representative **es:** Representante autorizado **pt:** Representante autorizado **de:** Bevollmächtigten **fr:** Mandataire **It:** Rappresentante autorizzato **da:** Repraesentant **sv:** Behörig representant **cs:** Zplnomocněný zástupce **no:** Autorisert representant	**en:** Medical device **es:** Producto sanitario **pt:** Dispositivo médico **de:** Medizinprodukt **fr:** Dispositif médical **It:** Dispositivo medico **da:** Medicinsk udstyr **sv:** Medicinteknisk produkt **cs:** Zdravotnický prostředek **no:** Medisinsk utstyr	**en:** CE Mark **es:** Marca CE **pt:** Marca CE **de:** CE-Kennzeichnung **fr:** CE Marquage **It:** Marchio CE **da:** CE-mærke **sv:** Oznaka CE **cs:** Značka CE **no:** CE-merke
en: Catalogue number **es:** Número de catálogo **pt:** Número de catálogo **de:** Katalognummer **fr:** Numéro de catalogue **It:** Numero di catalogo **da:** Katalognummer **sv:** Katalognummer **cs:** Katalogové číslo **no:** Katalognummer	**en:** Batch code **es:** Código de lote **pt:** Código de lote **de:** Chargen-Code **fr:** Code de lot **It:** Codice lotto **da:** Batchkode **sv:** Batch-kod **cs:** Číslo šarže **no:** Batchkode	**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 **da:** Se brugsanvisningen **sv:** Läs instruktionerna före användning **cs:** Viz pokyny pro použití **no:** Les bruksveiledningen	**en:** Do not reuse **es:** No reutilizar **pt:** Não reutilizar **de:** Nicht wiederverwenden **fr:** Ne pas réutiliser **It:** Non riutilizzare **da:** Må kun anvendes én gang **sv:** Återanvänd inte **cs:** Nepoužívejte opakovaně **no:** Ikke til gjenbruk
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 **da:** Opbevares tørt **sv:** Förvaras torrt **cs:** Uchovávejte v suchu **no:** Holdes tørt	**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 **da:** Holdes væk fra sollys **sv:** Förvaras skyddad för solljus **cs:** Chraňte před slunečním světlem **no:** Beskytt mot sollys	**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 **da:** Må ikke bruges, hvis emballagen er beskadiget **sv:** Använd inte om förpackningen är skadad **cs:** Nepoužívejte, pokud je obal poškozen **no:** Anvendes ikke dersom pakningen er skadet	**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 **da:** Anvendes inden **sv:** Utgångsdatum **cs:** Spotřebujte do **no:** Forbruksdato
en: Non Sterile **es:** No estéril **pt:** Não estéril **de:** Nicht steril **fr:** Non stérile **It:** Non Sterile **da:** Ikke steril **sv:** Inte steril **cs:** Není sterilní **no:** Ikke steril	**en:** Caution **es:** Precaución **pt:** Atenção **de:** Vorsicht **fr:** Avertissement **It:** Attenzione **da:** Forsigtig **sv:** Försiktighet **cs:** Upozornění **no:** Forholdsregler	**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 **da:** Autoriseret repræsentant i Schweiz **sv:** Behörigt ombud i Schweiz **cs:** Zplnomocněný zástupce ve Švýcarsku **no:** Autorisert representant i Sveits	**en:** Importer **es:** Importador **pt:** Importador **de:** Importeur **fr:** Importateur **It:** Importatore **da:** Importør **sv:** Importörerna **cs:** Dovozce **no:** Importør
en: UKCA Mark **es:** Marca UKCA **pt:** Marca UKCA **de:** UKCA-Kennzeichnung **fr:** UKCA Marquage **It:** Marchio UKCA **da:** UKCA-mærke **sv:** Oznaka UKCA **cs:** Značka UKCA **no:** UKCA-merke			