NETWORK
MEDICAL PRODUCTS

ASPIRATING SUCTION TUBES AND FINE ENDS

PRODUCT INFORMATION AND INSTRUCTIONS

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CE 1639

LOT

GB - Lot Number
DE - Chargennummer
DK - Lotnummer
ES - Número de lote
FI - Eränumero
FR - Numéro de Lot
IT - Numero di lotto
NL - Partijnummer
NO - Lotnummer
PT - Número de lote
SV - Partinummer

GB - Use Until Date
DE - Verwendbar bis Datum
DK - Sidste anvendelsesdato
ES - Usar antes de la fecha
FI - Viimeinen käyttöpäivä
FR - Date limite d'utilisation
IT - Utilizzare entro
NL - Uiterste gebruiksdatum
NO - Utløpsdato
PT - Utilizar até
SV - Används före

GB - Do Not Re-use
DE - Nicht wiederverwenden
DK - Må ikke genbruges
ES - No reutilizar
FI - Ei saa käyttää uudelleen
FR - Ne pas réutiliser
IT - Non riutilizzare
NL - Voor eenmalig gebruik
NO - Skal ikke gjenbrukes
PT - Não reutilizar
SV - Får ej återanvändas.

GB - Manufacturer
DE - Hersteller
DK - Producent
ES - Fabricante
FI - Valmistaja
FR - Fabricant
IT - Fabbricante
NL - Fabrikant
NO - Produsent
PT - Fabricante
SV - Tillverkare

GB - Date of Manufacture
DE - Herstellungsdatum
DK - Produktionsdato
ES - Fecha de fabricación
FI - Valmistuspäivämäärä
FR - Date de fabrication
IT - Data di fabbricazione
NO - Produksjonsdato
NL - Productiedatum
PT - Data de fabrico
SV - Tillverkningsdatum

GB - Caution
DE - Vorsicht
DK - Forsigtig
ES - Advertencia
FI - Varoitus
FR - Avertissement
IT - Attenzione
NL - Waarschuwing
NO - Forsiktig
PT - Advertência
SV - Försiktighet

GB - Do not use if product is opened or damaged.
DE - Nicht verwenden, wenn das Produkt bereits offen oder beschädigt ist.
DK - Må ikke anvendes, hvis produktet er blevet åbnet eller beskadiget.
ES - No utilizar si el producto está abierto o dañado
FI - Ei saa käyttää, jos tuote on avattu tai vaurioitunut.
FR - Ne pas utiliser si l'emballage est ouvert ou endommagé.
IT - Non usare se la confezione è aperta o danneggiata
NL - Dit product niet gebruiken als het is geopend of beschadigd.
NO - Skal ikke brukes hvis produktet er åpnet eller skadet.
PT - Não utilizar se o produto estiver aberto ou danificado
SV - Använd inte om produkten har öppnats eller skadats.

STERILE EO

GB - Sterilised by Ethylene Oxide
DE - Ethylenoxid-Sterilisation
DK - Steriliseret med ethylenoxid
ES - Estéril por oxido de etileno
FI - Steriloitu etyleenioksidilla
FR - Stérilisation par oxyde d'éthylène
IT - Sterilizzato mediante ossido di etilene
NL - Gesteriliseerd met ethyleenoxide
NO - Sterilisert med etylenoksid
PT - Esterilizado por óxido de etileno
SV - Steriliserad med etylenoxid

NEW_015

GB - Consult Electronic Instructions for Use
DE - Elektronische Gebrauchsanweisung beachten
DK - Se den elektroniske brugsanvisning
ES - Consultar instrucciones de empleo electrónicas
FI - Katso sähköohjeet käytölle
FR - Consulter le mode d'emploi électronique
IT - Consultare le Istruzioni per l'uso elettroniche
NL - Raadpleeg elektronische gebruiksaanwijzing
NO - Les den elektroniske bruksanvisningen
PT - Consultar as instruções de utilização eletrónicas
SV - Se bruksanvisningen i elektroniskt format.

℞ Only

GB - Caution: US Federal law restricts this device to sale by or on the order of a physician

DE - Vorsicht: Nach dem US-amerikanischen Bundesgesetz darf dieses Medizinprodukt nur von medizinischen Fachkreisen oder auf Anordnung dieser gekauft werden.

DK - Forsigtig: Ifølge amerikansk lov må denne anordning kun sælges af en læge eller efter lægeordination

ES - Advertencia: la legislación federal de EE. UU. establece la restricción de que este dispositivo debe venderse solo a médicos o por orden de estos.

FI - Varoitus: Yhdysvaltain liittovaltion lain mukaan tätä laitetta saa myydä vain lääkäri tai lääkärin määräyksestä.

FR - Avertissement : la loi fédérale américaine limite la vente et l'utilisation aux médecins ou à la demande d'un médecin

IT - Attenzione: la legge federale degli Stati Uniti d'America limita la vendita di questo dispositivo ai medici o su prescrizione del medico

NL - Waarschuwing: Volgens de Amerikaanse Federale wetgeving is verkoop en gebruik van dit apparaat uitsluitend toegestaan door of op voorschrift van een arts.

NO - Forsiktig: I henhold til føderale lover i USA skal dette utstyret bare selges av lege eller etter ordinasjon fra lege

PT - Cuidado: A Legislação Federal dos EUA restringe a venda deste dispositivo a médicos ou mediante prescrição médica.

SV - Försiktighet: I USA får enligt federal lag denna produkt endast försäljas av läkare eller enligt läkares ordination

EC REP

GB - EU Authorised Representative
DE - EU-Bevollmächtigter
DK - Autoriseret repræsentant i EU
ES - Representante autorizado de la UE
FI - Valtuutettu edustaja EU:ssa
FR - Représentant UE autorisé
IT - Mandatario nell'Unione europea
NL - Gevolmachtigde in de EU
NO - Autorisert representant i EU
PT - Representante autorizado na UE
SV - Auktoriserad representant i EU

REF

GB - Catalogue Number
DE - Bestellnummer
DK - Katalognummer
ES - Número de catálogo
FI - Tuotenumero
FR - Numéro du catalogue
IT - Riferimento di catalogo
NL - Catalogusnummer
NO - Artikkelnummer
PT - Número de catálogo
SV - Katalognummer

GB - Do not resterilise
DE - Nicht erneut sterilisieren
DK - Må ikke resteriliseres
ES - No reesterilizar
FI - Ei saa steriloida uudelleen
FR - Ne pas restériliser
IT - Non risterilizzare
NL - Niet opnieuw steriliseren
NO - Skal ikke resteriliseres
PT - Não voltar a esterilizar
SV - Får ej återsteriliseras

MD

GB - Medical Device
DE - Medizinprodukt
DK - Medicinsk udstyr
ES - Dispositivo medico
FI - Lääkinnällinen laite
FR - Dispositif médical
IT - Dispositivo medico
NL - Medisch instrument
NO - Medisinsk utstyr
PT - Dispositivo medico
SV - Medicinteknisk produkt

GB - Sterile barrier system
DE - Steriles Barrieresystem
DK - Sterilbarrieresystem
ES - Sistema de barrera estéril
FI - Steriili sulkujärjestelmä
FR - Système de barrière sterile
IT - Sistema di barriera sterile
NL - Steriel barrièresysteem
NO - Sterilt barrieresystem
PT - Sistema de barreira estéril
SV - Sterilbarriärsystem

UDI

GB - Unique Device Identifier
DE - Eindeutige Medizinprodukt-Kennung
DK - Unik udstyrsidentifikator
ES - Identificador único del dispositivo
FI - Yksilöivä laitetunniste
FR - Identifiant unique du dispositif
IT - Identificatore univoco del dispositivo
NL - Unieke apparaat-identificatiecode
NO - Utstyrets unike identitet
PT - Identificador de dispositivo único
SV - Unik produktidentifiering

GB - Instructions for Use

Description

The Network Aspirating Suction Tubes and Fine Ends are 'single use only' tubes designed essentially for ENT applications and can be attached to all commonly available suction systems found in ENT theatres and Out Patient Departments.

The yankauer is a tool used to suction oropharyngeal secretions in order to prevent asphyxiation. A yankauer can also be used to clear operative sites during general surgical procedures and the suctioned volume counted as blood loss during surgery.

The tubes are supplied in a variety of diameters and angles pertinent to the surgical application and can be further reduced in diameter down to 26G (0.4mm) by the use of Fine End inserts.

Intended Use

Network Aspirating Suction Tubes and Fine Ends are designed particularly for ENT applications when excess fluids and debris need to be removed from the surgical site.

The tubes can be attached directly to any standard suction system commonly found in an ENT theatre or Out-Patient Departments. The aspiration tubes attach directly to the suction handle of a standard suction system and the fine end can reduce further the diameter of any standard suction tube.

CAUTIONS:

- This device is supplied STERILE and ready to use.
- The device is for SINGLE USE ONLY. Do NOT re-sterilise or re-use.
- Do not use if the packaging has been opened or damaged.
- This device is intended for use by trained medical persons possessing the requisite skill and experience to use the device in accordance with the prevailing standards of medical practice and in conjunction with the instructions for this device.
- The product comes into contact with bodily fluids, which can be contaminated. Care should be taken in the handling and disposal of the device after use to prevent contamination.
- CAUTION: US Federal law restricts this device to sale by or on the order of a physician
- This product contains nickel which may cause allergic reaction in patients with sensitivity to nickel. Risk assess the use of the devices in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to nickel.
- Suction tubing can obstruct when viscous or particulate materials are suctioned, which has in some cases led to problems with airway management.
- Care should be taken that a tube with a sufficiently large diameter is used to remove any particulate. If the tube becomes blocked it should be detached and discarded, or a stylet used to remove the debris. The stylet should be passed through the whole length of the tube to remove the debris.
- There is a risk that aspiration during tympanostomy tube insertion can cause tympanosclerosis

Incident Reporting

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

Sterilisation

- The device is a SINGLE USE ONLY device supplied sterile and ready for use. Sterilisation is by Ethylene Oxide (EO)

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE USE ONLY DEVICES:

1. Single use devices have not been validated for re-use.
- If you re-use a device you may be held Legally Liable for the safe performance.
2. Cross-contamination and infection risks to patients. Including transmission of:
- CJD & Variant CJD.
- Prion Diseases.
- Bacterial Endotoxins.
- Hepatitis B & Hepatitis C.
- Risks posed by HIV and AIDS
3. Device failure through material fatigue or degradation caused by initial use and design:
- Plastics: Can be weakened, warped or become brittle.
- Metals: Can be damaged or subject to rusting.
4. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.

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