DEAS

IT CIRCUITI RESPIRATORI E ACCESSORI
Istruzioni per l'uso

EN BREATHING CIRCUITS AND ACCESSORIES
Instructions for use

DE BEATMUNGSSCHLÄUCHE UND ZUBEHÖR
Gebrauchsanweisung

FR CIRCUITS RESPIRATOIRES ET ACCESSOIRES
Mode d'emploi

EL ΑΝΑΠΝΕΥΣΤΙΚΑ ΚΥΚΛΩΜΑΤΑ ΚΑΙ ΒΟΗΘΗΤΙΚΑ ΕΞΑΡΤΗΜΑΤΑ
Οδηγίες χρήσης

ES CIRCUITOS DE RESPIRACIÓN Y ACCESORIOS
Instrucciones de uso

HU LÉGZŐKÖRÖK ÉS KIEGÉSZÍTŐI
Használati utasításokat

NL BEADEMINGSCIRCUITS EN ACCESSOIRES
Gebruiksaanwijzing

PL OBWODY WENTYLUJĄCE I AKCESORIA
Instrukcja użycia

PT CIRCUITOS DE RESPIRAÇÃO E ACESSÓRIOS
Instruções de utilização

RO CIRCUITE RESPIRATORII ŞI ACCESORII
Instrucţiunile de utilizare

SV ANDNINGSSYSTEM OCH TILLBEHÖR
Bruksanvisning

CS DÝCHACÍ OKRUHY A PŘÍSLUŠENSTVÍ
Návod k použití

CE 0123

Deaflux
RESPIRATORY PRODUCTS

INTENDED USE

Breathing circuits and related accessories (Mount catheter, reservoir bag, gas monitoring line, face mask, CPAP mask, PEEP valve), single use, for anaesthetic apparatus and lung ventilators, to conduct gases and/or vapour from the apparatus (V) to the patient (P). DEAS breathing circuits are manufactured in compliance with EN ISO 5367 standard. This device is intended for short term use (less than 30 days) in accordance with Directive 93/42/EEC and subsequent amendments.

TECHNICAL INFORMATION

Recommended maximum operating pressure: < 8,826 kPa (90 cmH_2O)

Patient category	Intended delivered volume ml	Internal diameter mm	Increase in pressure hPa/l/min (cmH_2O/l/ min)	At flow l/min	Compliance limit ml/hPa	At pressure hPa
Adult	≥ 300	19	< 0.06	30	< 5.0	60 ± 3
Paediatric	50 < 300	15	< 0.12	15	< 4.0	60 ± 3
Neonatal	≤ 50	11	< 0.74	2.5	< 1.5	60 ± 3

DIRECTIONS FOR USE

Carefully read the product label and this leaflet before using the device. Open the packaging, checking that it is complete and free from foreign bodies. Do not use the device if the package is damaged. Any damage or opening in the package may affect sterility and/or device performance. In this case do not use the device concerned.

BREATHING CIRCUIT

Connect the breathing circuit's components as shown on the graphical representation. Make sure that the connections are properly secured. Pay special attention to the instructions provided below:

- if the breathing circuit contains a water trap to collect condensation (Fig. C point 7), this must be kept vertical and in a position which allows the fluid collecting inside the tubes to drain; check the level of filling frequently and empty it when necessary. Then make sure that the water trap is properly closed;
- the monitoring ports (Fig. . B, C, D, E, F point 4) allow the respiratory gases and/ or airway pressure to be checked and should remain closed when not in use;
- if there is a gas monitoring line (Fig. D, E, F point 5) in the breathing circuit, this must be connected to the control outlet positioned on the ventilator (V). Regularly make sure that large amounts of condensation are not forminginside as this can stop the ventilator (V) from functioning properly;
- if the device has an expiratory port (Fig. D, E, F point 6) this must not be sealed or obstructed. If it is obstructed this may cause serious damage to the patient or even his death;
- if there are unidirectional valves in the device, check that they are working properly and the direction of flow prior to use;
- if the circuit contains a pressure-limiting valve (Fig. E point 8), make sure that it is working properly before using it with a patient. If it needs to be deactivated, use the appropriate stop switch;
- the breathing circuits represented in Fig. D, E must only be installed on models of ventilator (V) as indicated on the label. Installing the breathing circuit on a different model of ventilator can prevent the system from working correctly. Should the user want to install the circuit on ventilator models not indicated on the label, the user should first contact DEAS or its local representative to verify the compatibility of the circuit to be installed with the relevant ventilator model.

ACCESSORIES

Catheter Mount: The Catheter Mount (Fig. A, B, C, D point 2) is a flexible adaptor for joining or connecting the breathing system to a tracheal or tracheostomy tube connector or to a face mask. The patient side connector can be straight or at an angle, with or without a cap. Connect the catheter Mount to the breathing circuit as shown in the illustration. Remove the cap (Fig. A, B, C, D point 3) only for the time strictly necessary for carrying out tracheal aspiration or a bronchoscopy. Opening the cap causes a loss of pressure in the breathing system and the impossibility of ventilating the patient Routinely check the patency of the device. Using this device causes the increase of the dead space.

Reservoir bag: The reservoir bag (Fig. A point 10) is a device for inhaled anaesthesia induction or for ventilatory support. It is connected to the anaesthesia machine or the manual breathing unit. Check that it is functioning properly before using on the patient. Do not use the device in case of malfunction.

Gas monitoring line: The gas monitoring line (Fig. D, E, F point 5) is a device for checking respiratory gases and/or airway pressure. It is connected to the control port of the ventilator or monitoring apparatus and to the monitoring port on the breathing circuit. Regularly make sure that large amounts of condensation are not forming inside it as this can stop the monitoring apparatus from functioning properly. Regularly make sure that large amounts of condensation are not forminginside as this can stop the ventilator (V) from functioning properly.

Face mask: The face mask (Fig. A point 1) is a device for inhaled anaesthesia induction or for ventilatory support. It is supplied with a pre- inflated or inflatable pad. The inflation of the pad can be adjusted by injecting or removing air through a syringe which must be connected to the appropriate valve; disconnect the syringe when the adjustment is complete and check that the system is sealed. Make sure that the apparatus (V) or the breathing circuit has an adequate system for CO_2 elimination. The mask must be removed if the patient suffers claustrophobia, skin irritation or retching. Using this device causes the increase of the dead space.

CPAP mask: The CPAP face mask (Fig. F point 11) is a device for positive airway pressure mechanical ventilation. It is connected to the patient's face through a mask. It is supplied with two connections: inspiratory, for connecting the circuit or the ventilation tube, and expiratory for connecting the PEEP valve. Both connections have unidirectional valves. It is also equipped with a port for monitoring pressure or $EtCO_2$. At the edge of the mask is an inflatable pad. The inflation of the pad can be adjusted by injecting or removing air through a syringe which must be connected to the appropriate valve; disconnect the syringe when the adjustment is complete and check that the system is sealed. Check that it is functioning properly before using on the patient. Do not use the device in case of malfunction. The mask must be removed if the patient suffers claustrophobia, skin irritation or retching. Using this device causes the increase of the dead space.

PEEP valve: The PEEP valve (Fig. F point 9) is a device for maintaining positive end-expiratory pressure. It is connected to the expiratory connection of the CPAP face mask (Fig. F point 6) or to that of the expiratory valve (Fig. D point 6). It can be fixed or adjustable. Check that it is functioning properly before using on the patient. Do not use the device in case of malfunction. Select or adjust the PEEP appropriately. Regularly check the level of positive expiratory pressure set using an adequate monitoring system. Once the breathing system is connected to the apparatus, check the seal in pressure using a test lung following the manufacturer's instructions. Make sure that there are no leaks or blockages. Then connect the patient and monitor him throughout the ventilation process. During use, regularly check that all the connections are properly secured and that there are no leaks or blockages. For all the alarms issued by the connected apparatus make sure that the connection is adequate and check the patient's condition and the adequacy of the connection each time there is a signal.

WARNINGS

This device should be used only by qualified and/or trained personnel. Before using the device, ensure that an appropriate pressure-limiting device is correctly installed in the breathing system and is functioning. Excessive pressures can cause barotrauma! Ensure that the breathing circuit is adequately supported and positioned by a supporting arm. If the circuit is insufficiently supported or wrongly positioned, this may cause tensile stress to the circuit, unexpected disconnections or inhalation of any condensation produced by the humidifier and collected in the bend in the circuit. Using an inadequate supporting arm can damage the breathing circuit. Regularly check that condensation is not forming inside the device as this could cause an increase in resistance to flow, trigger the ventilator's alarm or cause incorrect measurements of respiratory signs. Do not stretch the device, allow it to form kinks or other types of mechanical stress. When connecting and disconnecting the breathing circuit, avoid compressing or pulling on the tube to prevent dam- age that could cause leaks in the breathing system, compromising ventilation. Operating temperatures above 43 °C can damage the breathing circuit. Non-conductive and inflammable product not suitable for use with inflammable (non-AP/APG) anaesthetic gases, electrosurgery or lasers. Use of the device in these situations can lead to the risk of fire. Do not use after lapse of the use- by date.

DURATION OF USE

Single-use device to be used on a single patient. Reuse may cause cross- infections. DO NOT soak, wash, sterilize or reuse this product. Avoid contact with chemical substances,cleaning products or sanitisers. These substances may damage the device and cause the product to malfunction. Duration of use of the device on the same patient must be determined by the personnel responsible and in accordance with proven procedures for controlling infection. Prolonged use of the device may alter its mechanical safety characteristics Replace the device immediately in case of leakage, occlusion, and if connections become unsafe.

STORAGE AND DISPOSAL

The device should be stored respecting the instructions given by the symbols on the packaging. After use, the device must be treated and / or disposed of as hazardous medical waste according to local regulations in force.

RESPONSIBILITY

DEAS devices guarantee top quality and products which are in compliance with the standard in force for safe use.
DEAS will not be responsible for any consequences resulting from incorrect choice of model or size or use other than that indicated. If you notice that the device's features or performance have deteriorated or are malfunctioning and/or there are serious problems, inform DEAS straight away.
If this happens, we will need you to send the device concerned along with appropriate photos, placed in the original packaging so the batch can be traced.

DIRECT TECHNICAL ASSISTANCE

If you are unsure about interpreting this instruction leaflet or if you would like any additional technical information, contact the DEAS customer services directly at the address indicated overleaf.

	IT	EN	DE	FR
	LEGENDA DEI SIMBOLI SUL CONFEZIONAMENTO	KEY TO SYMBOLS ON PACKAGING	ERKLÄRUNG DER SYMBOLE AUF DER VERPACKUNG	SIGNIFICATION DES SYMBOLES SUR L'EMBALLAGE
	Codice	Re-order number	Katalog-Nummer	Numero de référence
	Monouso	Single use	Einwegprodukt	A usage unique
	Lotto	Lot number	Chargennumwmer	Numéro de lot
	Data di scadenza	Use by	Mindesthaltbarkeits-datum	Date de péremption
	Misura	Size	Größe	Taille
	Sterilizzato ad ETO	Sterilised by ETO	ETO sterilisiert	Stérilisé à l'ETO
	Non sterile	Non-sterile	Unsteril	Non stérile
	Senza ftalati	Phthalates free	Phthalaten frei	Sans phtalates
	Senza lattice	Latex free	Latex frei	Sans latex
	Aprire qui	Open here	Hier öffnen	Ouvrir ici
	Consultare le istruzioni per l'uso	See instructions for use	Beachten Sie die Gebrauchsinformation	Lire le mode d'emploi
	Quantità	Quantity	Menge	Quantité
	Teme l'umidità	Keep dry	Trocken aufbewahren	Craint l'humidité
	Teme il calore	Keep cool	Kühl aufbewahren	Craint la chaleur
	Non usare ganci	Do not use hooks	Keine Haken verwenden	Ne pas utiliser de crochets
	Non utilizzare lame	Do not use blades	Keine Messer/Scheren verwenden	Ne pas utiliser de lames
	Limiti di temperatura	Temperature limitations	Zulässiger Temperaturbereich	Limites de température
	Non utilizzare se la confezione è danneggiata	Do not use if package is damaged	Nicht verwenden, wenn die Verpackung beschädigt ist	Ne pas utiliser si l'emballage est endommagé
	Produttore	Manufacturer	Hersteller	Producteur

FIG. A

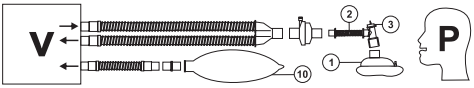


FIG. B

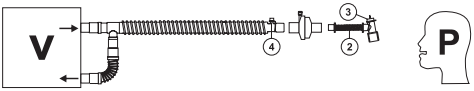


FIG. C

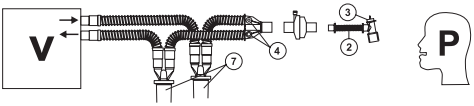


FIG. D

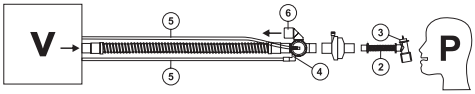


FIG. E

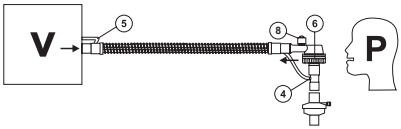
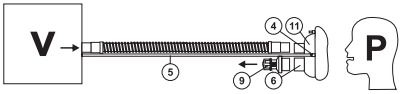


FIG. F



IT

CONFIGURAZIONI TIPICHE
Per altre configurazioni, contattare DEAS o i suoi rappresentanti locali.

EN

TYPICAL CONFIGURATIONS
For other configurations, please contact DEAS or its local representatives.

DE

TYPISCHE KONFIGURATIONEN
Für weitere Konfigurationen wenden Sie sich an DEAS oder den nächstgelegenen Vertreter.

FR

CONFIGURATIONS HABITUELLES
Pour les autres configurations, contactez DEAS ou ses représentants locaux.

EL

ΤΥΠΙΚΕΣ ΔΙΑΜΟΡΦΩΣΕΙΣ
Για άλλες διαμορφώσεις, επικοινωνήστε με την DEAS ή τους τοπικούς αντιπροσώπους της.

ES

CONFIGURACIONES TÍPICAS
Para información sobre otras configuraciones, contacte con DEAS o con sus representantes locales.

HU

TIPIKUS KONFIGURÁCIÓ
További konfigurációkért lépjen kapcsolatba a DEAS-al vagy helyi képviselőjével.

NL

STANDAARD CONFIGURATIES
Neem voor andere configuraties contact op met DEAS of met een plaatselijke vertegenwoordiger van dit bedrijf.

NO

TYPISKE KONFIGURASJONER
For andre konfigurasjoner må du kontakte DEAS eller den lokale representanten.

PL

TYPOWE KONFIGURACJE
W przypadku innych konfiguracji skontaktować się z DEAS lub lokalnymi przedstawicielami.

PT

CONFIGURAÇÕES TÍPICAS
Para outras configurações, por favor contacte DEAS ou os seus representantes locais.

RO

CONFIGURAȚII TIPICE
Pentru alte configurații, vă rugăm să luați legătura cu DEAS sau reprezentanții săi locali.

SV

TYPISKA KONFIGURATIONER
Kontakta DEAS eller dess lokala representanter för andra konfigurationer.

CS

TYPICKÁ KONFIGURACE
Pro jiné konfigurace laskavě kontaktujte výrobce - společnost DEAS, nebo místního autorizovaného zástupce.

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