VentStar Bag Set

Instructions for use

WARNING
To properly use this medical device, read and comply with these instructions for use.

VentStar Breathing Bag Set

Trademarks

Trademarks owned by Dräger

Trademark
VentStar®

The following web page provides a list of the countries in which the trademarks are registered: www.draeger.com/trademarks

Safety information definitions

WARNING
A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION
A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.

NOTE
A NOTE provides additional information intended to avoid inconvenience during operation.

User group requirements

The term "user group" describes the personnel responsible who have been assigned by the operating organization to perform a particular task on a product.

Duties of the operating organization

The operating organization must ensure the following:

– Every user group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).
– Every user group has been trained to perform the task.
– Every user group has read and understood the relevant chapters in this document.

User groups

Clinical users

This user group operates the product in accordance with the intended use.

Users have medical specialist knowledge in the application of the product.

For your safety and that of your patients

WARNING
Risk of incorrect operation and of misuse
Any use of the medical device requires full understanding and strict observation of all sections of these instructions for use. The medical device must only be used for the purpose specified under Intended use. Strictly observe all WARNING and CAUTION statements throughout these instructions for use and all statements on medical device labels.
Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.

WARNING
To avoid contamination and soiling, keep the medical device packaged until ready to be used. Do not use the medical device if the packaging is damaged.

WARNING
Installation to the main device must be in accordance with the instructions for use of the main device on which this medical device is used.
Make sure that the connection to the main device is secure.

WARNING
Do not modify the medical device. Modification may damage or impair the proper functioning of the device which may lead to patient injury.

WARNING
Risk of malfunction
Obstructions, damage, and foreign matter can lead to malfunction.
Check all system components for obstructions, damage, and foreign matter before installation.

CAUTION
The medical devices are not available individually. Only one copy of the instructions for use is included in the clinical package and must therefore be kept in a location accessible for users.

Mandatory reporting of adverse events

Serious adverse events with this product must be reported to Dräger and the responsible authorities.

Intended use

Breathing bag system intended for use with anesthesia machines, as a reservoir during automatic ventilation and as a breathing bag during manual ventilation. Intended for single-use only.

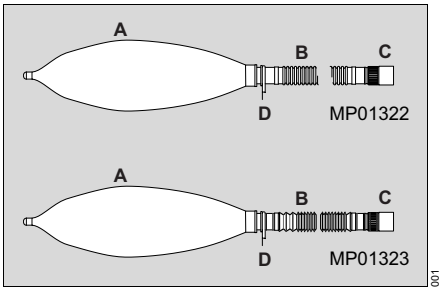
The medical device is tested for system compatibility and released for use with specific main devices, e. g. Primus.

For further information on system compatibilities, see the lists of accessories of the main devices or other documents issued by Dräger.

WARNING
Select the appropriate breathing circuit according to the patient. Higher resistance or compliance values might lead to an improper ventilation and possible injury of the patient

NOTE
The circuit diameter of 22 mm (0.87 in) is specially designed for adults. Adults include individuals weighing above 40 kg (88 lb).

Overview



A Breathing bag
B Breathing bag hose
C Device-side connector
D Hook hose

Symbols

Additional information about the symbols is available on the following web page: www.draeger.com/md-symbols

LATEX	Not made with natural rubber latex		Keep away from sunlight
	Caution		Consult instructions for use
	Do not reuse		Storage temperature limitation
	Do not use if package is damaged		Do not open with knife
	Ambient pressure		Relative humidity
	Use by		Do not use with oil and grease
	Date of manufacture	NON STERILE	Non-sterile
	Manufacturer	REF	Part number
	Quantity	LOT	Lot number
MD	The product is a medical device (CE conformity assessment procedure)		

Installation and operation

WARNING
Confirm that all connections are secure and free of leakages.
Before the selftest pull extendable hoses out to the desired length. Otherwise, incorrect compliance values are determined.
Perform a selftest of the main device including a leakage test after the breathing circuit (hose, filter, etc.) has been completely installed and before use on the patient.

WARNING
Risk of patient injury
During installation position the breathing circuit so that the risk of tripping or of stepping on the breathing circuit is minimized.

WARNING
Risk of patient injury
Make sure to install the breathing circuit without loops and kinks as they may increase resistance.

WARNING
Risk of patient injury
If too much condensate accumulates, a partial or complete blockage of the breathing circuit can occur.
Regularly check the breathing circuit for condensate and empty if necessary.

WARNING
Risk of patient injury
Adding further components and using incompatible components may increase inspiratory and expiratory resistance and adversely affect the performance of the main device.

WARNING
Risk of fire
In combination with oxygen or nitrous oxide, ignition sources such as electrosurgery and laser surgery devices can cause fires.
To protect patient and users, prevent leakages from hoses carrying oxygen or nitrous oxide.
Before beginning electrosurgery or laser surgery, flush the vicinity of gas-carrying parts (endotracheal tube, mask, Y-piece, hoses, filter, and breathing bag) sufficiently with air (<25 % O_2); flush beneath the surgical drapes as well.

WARNING
Risk of fire
In order not to damage the breathing circuit, keep a distance of at least 200 mm (7.9 in) between hoses carrying oxygen or nitrous oxide and a possible ignition source (e.g., electrosurgery or laser surgery devices).

The breathing bag system can be used with the following gases and anesthetic agents: Nitrous oxide, sevoflurane, desflurane, isoflurane, halothane, enflurane.

Cleaning and disposal

The user is responsible for regularly replacing the medical device according to the hygiene regulations.

WARNING
Reuse, reprocessing, or sterilization can lead to failure of the medical device and cause injury to the patient.
This medical device has been designed, tested, and manufactured exclusively for single use. The medical device must not be reused, reprocessed, or sterilized.

WARNING
Following use, the medical device must be disposed of according to local public health and waste disposal regulations in order to avoid possible contamination.

NOTE
This medical device has been designed, tested, and manufactured for single use and a maximum period of use of 7 days.

Technical data

	MP01322	MP01323
Breathing bag hose length	1.8 m (30 in)	0.5 to 1.8 m (7.8 to 30 in)
Breathing bag volume	2 L	2 L
Bag hose volume	<0.7 L	<0.7 L
Material		
Breathing bag	CR	CR
Breathing bag hose	EVA/PP	PP
Connector and Y-piece	PP	
Hose hook	TPR	
Performance data		
Bag resistance at 60 L/min	<0.6 mbar[1] (<0.6 cmH_2O)	<2.3 mbar (<2.3 cmH_2O)
Bag resistance at 30 L/min		<0.5 mbar (<0.5 cmH_2O)
Bag compliance at 60 mbar and 30 mbar	<1.5 mL/mbar	<1.0 mL/mbar
Leakage at 60 mbar	<25 mL/min	
Ambient conditions		
During storage		
Temperature	–20 to 60 °C (–4 to 140 °F)	
Humidity	5 to 95 % (non-condensing)	
Ambient pressure	500 to 1200 hPa (7.3 psi to 17.4 psi)	
During operation		
Temperature	5 to 40 °C (41 to 104 °F)	
Humidity	5 to 95 % (non-condensing)	
Ambient pressure	500 to 1200 hPa (7.3 psi to 17.4 psi)	
Classification Medical Device Europe	Class IIa	
UMDNS code		
Universal Medical Device Nomenclature System – Nomenclature for medical devices	14-238	
Protection class	Type BF	

The medical device meets the requirements of the ISO 80601-2-13 standard

1) 1 bar = 1 kPa x 100

Order list

Designation	Order No.
VentStar Bag Set Basic, AU	MP01322
VentStar Basic	MP00300
VentStar Bag Set Flex, AU	MP01323
VentStar Flex	MP00305
VentStar Anesthesia Basic, AU	MP01320
VentStar Anesthesia Flex, AU	MP01321

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