Instruction For Use

Cuff Inflator

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[Product name]： Cuff Inflator

[Model and specification]：

JS-LC1040(10-40 cmH_2O)

JS-LC1550(15-50 cmH_2O)

[Volume]:

20ml/cc

[Intended use]:

The cuff inflator Cuffsure can be used to inflate and regulate the cuff pressure of Endotracheal tubes, Tracheostomy tubes and Laryngeal Masks Airways (supraglottic airways). It should be used only under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated. This product is non-sterile.

[Product description/composition]:

The product is composed of injection device, pressure gauge and connecting pipeline.

[Contraindication]:

/

[Cleaning Instructions]:

Wipe the surface thoroughly with an alcohol-based disinfectant or 1.4% hydrogen peroxide. While cleaning, prevent entry of any fluid into the Cuffsure.

[Caution and warning]:

1. Handle gently, avoid contact with hard and sharp objects;
2. It is recommended to use one cuff inflator Cuffsure per patient;
3. For use by medical professionals;
4. It is recommended to use a single device for no more than 180 times or for no more than 30 days after opening.
5. The product should be treated as medical waste after use to avoid environmental pollution.

[Method]:

1. Check and Activate the Cuffsure

To activate the Cuffsure for initial use or after a period of disuse, retract the plunger slightly, then place one index finger on the injection port to block it, and proceed to push the plunger. Ensure that the indicator pole pops out smoothly to confirm proper function.

2. Cuff Inflation:

2.1 Position the plunger accurately, set it at a scale that exceeds the evaluated volume required for the cuff. In the case where the evaluated volume is greater than 20ml (such as for larger sized LMA cuffs), it is recommended to directly inject one or two full syringes initially.

2.2 Securely attach the Cuffsure to the inflation valve by firmly connecting them together. When holding the valve, use your thumb and index finger to grasp the hard part of the pilot (refer to FIG. 1), and avoid touching the soft part of the pilot (refer to FIG. 2).

2.3 Push the plunger in a stable manner, using the posture illustrated in FIG. 3, and avoid unstable postures like that shown in FIG. 4, particularly when the indicator pole begins to move upwards.

Keep a close eye on the indicator pole and slow down the pushing speed once you notice it beginning to move up.

2.4 Once the indicator pole reaches the suggested position (e.g. green belt 30-35cmH_2O for adult cuffed endotracheal tube or tracheotomy tube, as shown in FIG. 5, JS-LC1550) or the user's target pressure, cease pushing the plunger and hold it in place, maintaining the indicator pole at the target scale position for approximately one second, without allowing it to retract.

2.5 Use one hand thumb and index finger hold the valve (hard part of the pilot), disconnect Cuffsure quickly.

3、Cuff pressure resetting

3.1 Position the plunger around the scale 5-10ml (suggested position) or or at a position where you feel most comfortable.

3.2 Repeat cuff inflation steps (2.1-2.5); the suggested position is between 25-30 cmH_2O (FIG.6) for adult cuffed endotracheal tube maintenance.

4、Cuff deflation

Perform the cuff deflation process as you would using a regular syringe. However, please note that it is important to avoid using excessive negative pressure to deflate the cuff, as doing so may decrease the device's reusability.

ATTENTION:

During step 2.4, if you push the plunger quickly without holding the indicator scale pole at the target position for around one second, and immediately disconnect the inflation valve, the cuff result-pressure may be lower than the instantaneous pressure shown on the indicator scale. This is because the long-thin inflation line (especially for ET tube) and the cuff-wall (particularly the thick and wrinkled cuff-wall) require approximately one second to transfer and balance the inside pressure.

NOTE: The recommended cuff pressure for LMA is 40-45cmH_2O, while for pediatric ETT cuff, it is 20-25cmH_2O. However, users may set the cuff pressure based on their personal clinical experience and clinic guidelines.

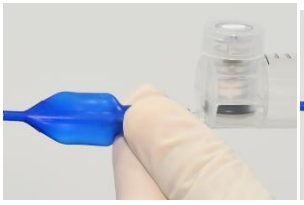

FIG.1

FIG.2

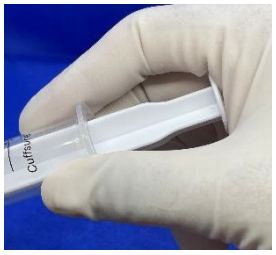

FIG.3

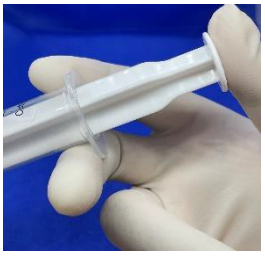

FIG.4

FIG.5

FIG.6

FIG.7

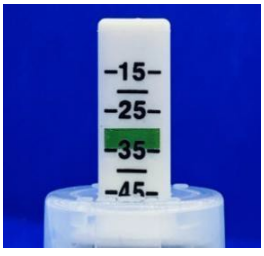

FIG.8

[Storage and transportation]:

The packaged products should be stored in clean, dark, non-corrosive, and well-ventilated rooms with a relative humidity of no more than 80%. During transportation, the products must be handled with care and in accordance with the order contract to prevent exposure to heavy pressure, direct sunlight, rain, and snow.

[Shelf life]:

5 years. See sales package for the production date and expiration date of the product.

[Recommended]:

Temperature operating rage: 5-45℃

For ICU patient used: One Cuffsure per patient.

Number of operations: no more than 180 times.

If using in a pre-hospital setting: 30 Days

For more study materials and videos, please visit www.cuffsure.com.

[Manufacturer]:

Company name： Xinxiang Jans Medtech Ltd

Address: No.299, Xindong Rd South, Hongqi District, Xinxiang City, Henan Province, China

Tel: +86- 373-8123207

Email: info@jans.ltd

[European union authorization representative]:

Company name： Lotus NL B.V.

Address： Koningin Julianaplein 10,1e Verd,2595AA, The Hague, Netherlands.

Tel： +31644168999

Email： peter@lotusnl.com

[Label Identification]:

LOT	Batch code		Use-by date
	Please read the instructions for use carefully before using.	MD	Medical Device
	Warning and attention, please refer to the instructions for use.		Manufacturer
EC REP	Authorized representative in the European Community		Keep dry.
NON STERILE	Non-sterile		Do not use if package is damaged.
	Date of manufacture	CE	The product meets the basic requirements of European in REGULATION (EU) 2017/745.