

Disposable Plastic and Reusable Glass Bottles for Chest Drainage Unit

Instructions for use

Ref. No.: 0203-STP3000; 0203-STP0700; 0203-NSP3000; 0203-NSP0700; 0203-STG; 0203-NSG

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Important:

This instruction cannot be used as a manual for chest drainage technique. To learn adequate knowledge about chest drainage technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of medical doctor experienced in techniques of chest drainage.

Before use, we recommend reading precisely all information included in this manual. Not being obedient to this information may lead to serious medical consequences such as accumulation of fluid and/or air in the pleural cavity or tension pneumothorax.

Indications:

1. collection chamber replacement
2. control chamber replacement

Description:

Bottles are provided as sterile or non-sterile. Plastic bottles are intended for single patient and procedure use. Glass bottles can be resterilized after use. Non-sterile glass bottles should be sterilized before the first use, if necessary.

Available bottle types are as follows:

0203-NSP3000	- 3 000 ml non sterile disposable plastic bottle
0203-STP3000	- 3 000 ml sterile disposable plastic bottle
0203-NSP0700	- 700 ml non sterile disposable plastic bottle
0203-STP0700	- 700 ml sterile disposable plastic bottle
0203-STG	- 2 000 ml sterile reusable glass bottle
0203-NSG	- 2 000 ml non-sterile reusable glass bottle

Instructions for use:

1. Clamp patient's thorax catheter using ratcheted haemostatic forceps.
2. Switch suction source off.
3. To replace any chamber use the same type and size of bottle as it was used in this procedure.
4. To replace collection chamber fill the relevant new bottle with sterile water up to "water seal level" line first. In case of suction control chamber replacement fill the relevant new bottle with sterile water to the prescribed level but never below "water seal level" line.
5. Unscrew ring nut of the chamber to be replaced to disconnect tubing.
6. Remove rigid tube from the chamber to be replaced.
7. Insert rigid tube into the new sterile water pre-filled bottle and screw down the ring nut.
8. Depending which chamber has been replaced ensure if rigid patient tube tip is submerged about 2 cm under the water level or rigid suction control tube's tip is about 2 mm over the bottom.
9. Open and remove haemostatic forceps from thorax catheter.
10. Switch suction source on (for active drainage) and increase air flow to obtain moderate bubbling from rigid suction control tube.
11. Check all the connections for tightness.
12. Follow instructions for use relevant to the chest drainage unit which is in use.
13. Close used bottle with the screw cap provided with the new bottle.

Resterilization of glass bottles:

Glass bottles can be reesterilized after use. New non sterile glass bottles must be sterilized prior to the first use. Disinfection and cleaning should be performed according to hospital validated procedures. Recommended is steam sterilization method. Minimum validated steam sterilization parameters required to achieve a 10⁻⁶ sterility assurance level (SAL) are as follows:

- cycle type - gravity - temperature - 121°C (250°F) - pressure - 1,3 bar (18,2 psi) - exposure time – 20 minutes - drying time – 30 minutes.

Above parameters are for reference only. One should remember that any sterilization process should be validated.

Compatibility:

Compatible with Grena disposable plastic and reusable glass bottles are the following tubing sets:

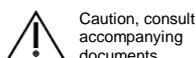
0203-X2TU	- disposable adjustable tubing set for two chamber unit
0203-X2TUS	- disposable adjustable tubing set with sampling port for two chamber unit
0203-X2TUNA	- disposable non-adjustable tubing set for two chamber unit
0203-X2TUNAS	- disposable non-adjustable tubing set with sampling port for two chamber unit
0203-X1TU	- disposable adjustable tubing set for one chamber unit
0203-X1TUS	- disposable adjustable tubing set with sampling port for one chamber unit
0203-X1TUE	- disposable extension tubing set for one chamber unit
0203-X1TUNA	- disposable non-adjustable tubing set for one chamber unit
0203-X1TUNAS	- disposable non-adjustable tubing set with sampling port for two chamber unit

Additional warnings and precautions:

1. Before collection or suction control chamber replacement read instructions for use of the chest drainage which chamber is to be replaced.
2. Sterile bottles should be used immediately after opening.
3. Graduation scale is for rough orientation only. If diagnosis or therapy needs to be taken based on the readings it is recommended to use additional device with measuring function for accurate volume reading.
4. Bottle replacement should be executed minimum 50 cm below the patient's chest level.
5. Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear.
6. Grena floorstand can stabilize 3000 ml disposable plastic bottles and reusable glass bottles when they are set on the floor. Floorstand is not suitable for 700 ml disposable plastic bottles.
7. Used disposable plastic bottles or broken reusable glass bottles require appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
8. Disposable plastic bottles are intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
9. Product is intended to be used exclusively by qualified medical staff under physician's control.



Authorized representative in EU



- 1 – refers to disposable sterile plastic bottles
2 – refers to disposable non-sterile plastic bottles
3 – refers to reusable sterile glass bottles
4 – refers to reusable non-sterile glass bottles

Notified Body number by CE mark refers to sterile products only