

Reusable Adjustable Two Chamber Glass Bottle Chest Drainage Unit
Adjustable and Non-adjustable Disposable Tubing Sets for Two Chamber Chest Drainage Unit
Instructions for use

Ref. No.: 0203-X2G, 0203-X2GS, 0203-X2TU, 0203-X2TUS, 0203-X2TUNA, 0203-X2TUNAS

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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:**
- To enable air and/or fluid evacuation by thoracic catheter from the chest cavity or mediastinum.
 - To help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum.
 - To help re-establish and maintain normal intrathoracic pressure gradients.
 - To facilitate complete lung re-expansion to restore normal breathing dynamics.

Description:
 Adjustable Chest Drainage Unit and Tubing Sets are provided as sterile products. Tubings are intended for single patient and procedure use. Bottles of Chest Drainage Unit can be resterilized and reused afterwards. These instructions will address the set up and operation of the Chest Drainage Units and Tubing Sets marked with the reference numbers indicated above. They can be supplied with standard taper patient connector (0203-X2G, 0203-X2TU, 0203-X2TUNA) or with sampling port (C) (0203-X2GS, 0203-X2TUS, 0203-X2TUNAS). Collection chamber capacity is 2000 ml.

- Product illustration:**
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|--------------------------------|----------------------------------|-------------------------------|
| A. Protective cap | G. Vacuum tube | M. Control chamber ring nut |
| B. Multigauge connector | H. Vacuum connector | N. Suction control rigid tube |
| C. Sampling port (option) | I. Total Volume scale | P. Tip proximity indicator |
| D. Patient tube | J. Above water seal volume scale | Q. Collection chamber |
| E. Rigid patient tube | K. Centimetre scale | R. Control chamber |
| F. Collection chamber ring nut | L. Water seal level line | S. Holder |

- Instructions for use:**
- Fill the collection chamber (Q) with sterile water up to "water seal level" line (L). To do it unscrew ring nut (F) of collection chamber (Q) and lift it about 10 cm up what gives access to the bottle through its neck.
 - Fill the suction control chamber (R) with sterile water to the prescribed level but never below "water seal level" line (L). To do it unscrew ring nut (M) of suction control chamber (R) and lift it about 10 cm up what gives access to the bottle through its neck.
 - Insert both rigid tubes (E and N) back in the relevant chambers (Q and R) (patient rigid tube (E) to collection chamber (Q) and suction control rigid tube (N) to suction control chamber (R)) and screw down the ring nuts (F and M). Be sure that rigid patient tube (E) tip is submerged about 2 cm under the water level and rigid suction control tube's (N) tip is about 2 mm over the bottom.
 - Connect the vacuum tube (G) (short one ended with green connector (H)) to the controlled aspiration source or use as breather pipe if the device is used by gravity.
 - Remove the protective cap (A) from the multigauge connector (B) (semitransparent taper connector) and connect it to the thorax catheter of the patient.
 - Switch suction source on (for active drainage) and increase air flow to obtain moderate bubbling from rigid suction control tube (N).
 - Control fluid level in collection chamber (Q) and take care to keep rigid patient tube (E) submerged about 2 cm during the whole drainage.
 - Suction level can be changed by adding / removing water in control chamber (R) or by changing (up or down) suction control rigid tube (N) position. Suction level expressed in cm H₂O is reflected by the distance between water level in suction control chamber (R) and the tip of suction control rigid tube (N). Centimetre scale (K) facilitates correct readings.

- Tubing replacement:**
 If necessary, tubing can be replaced by a new set according to the following steps:
- Clamp thorax catheter using ratcheted haemostatic forceps.
 - Disconnect multigauge connector (B) of patient tube (D) from thorax catheter.
 - Disconnect vacuum tube (G) from suction source.
 - Unscrew both collection and control chamber ring nuts (F and M) and remove tubing from the bottles (Q and R).
 - Open the package with new compatible tubing set using aseptic technique.
 - Follow the steps 3, 4 and 5 of Instructions for use.
 - Remove clamp from thorax catheter.
 - Follow the steps 6 and 7 of Instructions for use.

- Compatibility:**
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| Compatible with Grena glass bottles are the following tubing sets for two chamber chest drainage units: | Compatible with Grena tubing sets are the following glass bottles: |
| 0203-X2TU – disposable adjustable tubing set for two chamber chest drainage unit | 0203-NSG – 2 000 ml non sterile glass bottle |
| 0203-X2TUS – disposable adjustable tubing set with sampling port for two chamber chest drainage unit | 0203-STG – 2 000 ml sterile glass bottle |
| 0203-X2TUNA – disposable non-adjustable tubing set for two chamber chest drainage unit | |
| 0203-X2TUNAS – disposable non-adjustable tubing set with sampling port for two chamber chest drainage unit | |

Resterilization:
 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.

- Additional warnings and precautions:**
- If any change of suction level is prescribed it is necessary to change water level in the suction control chamber. Actual suction level in cm of water can be read from cm scale on the suction control chamber provided rigid control tube tip is about 2 mm from the bottom.
 - Use immediately after opening.
 - Check all the connections for tightness after drainage has started. Use adhesive plaster to seal them if necessary.
 - Water level in the suction control chamber should be examined successively and eventually filled up due to evaporation.
 - Tip proximity indicator of the collection chamber should be kept under fluid level at all times to avoid water seal loss followed by pneumothorax.
 - 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.
 - It is strictly forbidden to use patient tube as a holder for the device. It could lead to water seal lost and danger to the patient.
 - The collected content of collection chamber should not be used for reinfusion.
 - Chest tubes should not be clamped except when changing chest drainage unit or emptying collection chamber. In the event of air leak, clamped chest tubes could lead to tension pneumothorax.
 - Keep the chest drainage unit minimum 50 cm below the patient's chest level at all times.
 - Avoid loops in the patient tubing
 - Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear.
 - To take samples through the self-sealing sampling port (0203-X2GS, 0203-X2TUS, 0203-X2TUNAS) standard hypodermic needles 18G (1,24 mm) or thinner should be used.
 - Monitor collection chamber. To avoid overflow, replace the unit or empty collection chamber before exceeding the fill capacity of 2000 ml indicated by the volume graduation printed on the collection chamber.
 - Chest drainage tubings 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.
 - Chest drainage tubings are intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
 - Caution should be exercised when handling glass bottles which due to possible damage bear high risk of injury.
 - Glass bottles should be always checked for possible damage prior to each use. Special attention must be paid to the screw and neck upper surface. Discard bottles with any signs of damage. Attempt to use damaged bottles can be dangerous to the patient and personnel.
 - Product is intended to be used exclusively by qualified medical staff under physician's control.

 *	 Keep dry	 Consult instructions for use	 Manufacturer	
	 Caution, consult accompanying documents	 Do not reesterilize *	 Do not use if package is damaged	Authorized representative in EU

* refers to complete chest drainage unit and tubings only. Does not refer to glass bottles.