

Disposable Adjustable One Chamber Chest Drainage Unit
Instructions for use

Ref. No.: 0203-X1P3000; 0203-X1P3000S; 0203-X1P0700; 0203-X1P0700S

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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, aspiration microbiopsy 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.
 - To enable fluid evacuation by peritoneal catheter and fluid reaccumulation prevention in peritoneal cavity.

Description:
Adjustable Chest Drainage Unit is provided as sterile unit intended for single patient and procedure use. These instructions will address the set up and operation of the chest drainage units marked with the reference numbers indicated above. It can be supplied with standard taper patient connector (0203-X1P3000, 0203-X1P0700) or with sampling port (0203-X1P3000S, 0203-X1P0700S). Collection chamber capacity can be 3000 ml (0203-X1P3000, 0203-X1P3000S) or 700 ml (0203-X1P0700, 0203-X1P0700S).

Product illustration:

A. Protective cap	F. Collection chamber ring nut	K. Centimetre scale
B. Multigauge connector	G. Vacuum tube	L. Water seal level line
C. Sampling port (option)	H. Vacuum connector	P. Tip proximity indicator
D. Patient tube	I. Total volume scale	Q. Collection chamber
E. Rigid patient tube	J. Above water seal volume scale	

- 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.
 - Insert rigid tube (E) back into the collection chamber (Q) and screw down the ring nut (F). Be sure that rigid patient tube (E) tip is submerged about 2 cm under the water level.
 - 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 controlled suction source on (for active drainage) and increase air flow to obtain prescribed suction level.
 - Control fluid level in the 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 suction source adjustment only.

- Tube 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 (E) from thorax catheter.
 - Disconnect vacuum tube (G) from suction source.
 - Unscrew collection chamber ring nut (F) and remove tubing from the bottle.
 - Open the package with new tubing set using aseptic technique.
 - Follow the steps 2, 3, and 4 of Instructions for use.
 - Remove clamp from thorax catheter.
 - Follow the steps 5 and 6 of Instructions for use.

- Extending one chamber unit to two chamber chest drainage unit:**
One chamber chest drainage unit can be easily extended to two chamber set thanks to extension tubing set 0203-X1TUE and additional plastic bottle 0203-STP0700 or 0203-NSP0700. To do it apply following procedure:
- Leave one chamber chest drainage unit connected to the patient.
 - Disconnect vacuum connector (H) of vacuum tube (G) from suction source.
 - Fill additional sterile (0203-STP0700) plastic bottle with sterile water up to the prescribed level but never below "water seal level" line (L). This bottle will be suction control chamber.
 - Screw extension tubing set 0203-X1TUE on the new sterile (0203-STP0700) plastic bottle. Remove protective cap from taper connector of extension tube.
 - Connect vacuum connector (H) of vacuum tube (G) of one chamber glass bottle chest drainage unit with taper connector of extension tube.
 - Switch suction source on and increase air flow to obtain moderate bubbling from rigid suction control tube in the suction control chamber.
 - Suction level can be changed by adding / removing water in control chamber or by changing (up or down) suction control rigid tube position. Suction level expressed in cm H₂O is reflected by the distance between water level in suction control chamber and the tip of suction control rigid tube. Centimetre scale facilitates correct readings.

Compatibility:

Compatible with Grena disposable bottles are the following tubing sets for one chamber chest drainage units:	Compatible with Grena tubing sets are the following disposable bottles:
0203-X1T1U – disposable adjustable tubing set for one chamber chest drainage unit	0203-NSP3000 - 3 000 ml non sterile disposable bottle
0203-X1TUS – disposable adjustable tubing set with sampling port for one chamber chest drainage unit	0203-STP3000 - 3 000 ml sterile disposable bottle
0203-X1TUNA – disposable non-adjustable tubing set for one chamber chest drainage unit	0203-NSP0700 - 700 ml non sterile disposable bottle
0203-X1TUNAS – disposable non-adjustable tubing set with sampling port for one chamber chest drainage unit	0203-STP0700 - 700 ml sterile disposable bottle

- Additional warnings and precautions:**
- If any change of suction level is prescribed it is necessary to change suction source settings. Actual suction level can be read from suction source display only. Centimetre scale (K) on the suction control chamber (Q) cannot be used to read suction level.
 - It should be carefully considered if suction source used is fully reliable because one chamber set has no suction control and excessive suction can lead to aspiration microbiopsy followed by its medical consequences.
 - Use immediately after opening.
 - Check all the connections for tightness after drainage has started. Use adhesive plaster to seal them if necessary.
 - Tip proximity indicator (P) of the collection chamber (Q) 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 accurate volume readings it is recommended to use additional device with measuring function for accurate volume reading.
 - It is strictly forbidden to use patient tube (D) as a holder for the device. It could lead to water seal lost and danger to the patient.
 - The collected content of collection chamber (Q) 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 (C) (0203-X1P3000S and 0203-X1P0700S versions) standard hypodermic needles 18G (1,24 mm) or thinner should be used.
 - Monitor collection chamber (Q). To avoid overflow, replace the unit or empty collection chamber (Q) before exceeding the fill capacity of 3000 ml (or 700 ml for paediatric version) indicated by the volume graduation (K) printed on the collection chamber (Q).
 - Single floorstand is supplied with 6 units of 3000 ml version to stabilize chest drainage unit when it is set on the floor. Floorstand for 700 ml version does not come with the product.
 - Chest drainage unit requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
 - This product is intended for single patient and procedure use. Re-sterilization, reuse, modification may lead to serious consequences with death of patient included.
 - 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 re-sterilize	 Do not use if package is damaged	Authorized representative in EU