




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

Ref. no.: 0203-X1G; 0203-X1GS; 0203-X1TU; 0203-X1TUS; 0203-X1TUNA; 0203-X1TUNAS; 0203-X1TUE

 <p>Grena (Qingdao) Medical Devices Ltd. No 318 Huanghe West Road, Huangdao District, Qingdao City, Shandong Province, 266555, China</p>	<p>Contact information: Phone: +86 0532-86769190 Fax: +86 0532-86767322</p>	 <p>MDML INTL Limited 10 McCurtain Hill Clonakilty, Co. Cork Republic of Ireland</p>	
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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 of the device:

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 marked with the reference numbers indicated above. It can be supplied with standard taper patient connector (0203-X1G, 0203-X1TU, 0203-X1TUNA) or with sampling port (0203-X1GS, 0203-X1TUS, 0203-X1TUNAS). Collection chamber capacity is 2000 ml. Extension tubing set 0203-X1TUE is intended for easy extension of one chamber chest drainage unit to two chamber chest drainage unit.

Product illustration:

A. Protective cap	D. Patient tube	G. Vacuum tube	J. Above water seal volume scale	P. Tip proximity indicator
B. Multigauge connector	E. Rigid patient tube	H. Vacuum connector	K. Centimetre scale	Q. Collection chamber
C. Sampling port (option)	F. Collection chamber ring nut	I. Total volume scale	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 and lift it about 10 cm up what gives access to the bottle through its neck.
- Insert rigid tube (E) back in 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 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.

Tubing replacement:

If necessary, tubing can be replaced by a new set according to the following steps:

- | | |
|---|--|
| 1. Clamp thorax catheter using ratcheted haemostatic forceps. | 5. Open the package with new tubing set using aseptic technique. |
| 2. Disconnect multigauge connector (B) of patient tube (D) from thorax catheter. | 6. Follow the steps 2, 3, and 4 of Instructions for use. |
| 3. Disconnect vacuum tube (G) from the suction source. | 7. Remove clamp from thorax catheter. |
| 4. Unscrew collection chamber ring nut (F) and remove tubing from the bottle (Q). | 8. 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 glass bottle 0203-STG or 0203-NSG. To do it apply following procedure:

- Leave one chamber glass bottle chest drainage unit connected to the patient.
- Disconnect vacuum connector (H) of vacuum tube (G) from the suction source.
- Fill additional sterile (0203-STG) or sterilized (0203-NSG) glass bottle with sterile water up to the prescribed level but never below "water seal level" line. This bottle will be suction control chamber.
- Screw extension tubing set 0203-X1TUE on the bottle prepared as described above. 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.

NOTE: extension tubing set 0203-X1TUE can be also used to extend disposable one chamber chest drainage units (0203-X1P3000, 0203-X1P3000S, 0203-X1P0700 and 0203-X1P0700S) to two chamber unit. Procedure is described in the instructions for use of disposable one chamber chest drainage units mentioned above.

Compatibility:

Compatible with Grena glass bottles are the following tubing sets for one chamber chest drainage units:

0203-X1TU	- disposable adjustable tubing set for one chamber chest drainage unit
0203-X1TUS	- disposable adjustable tubing set with sampling port for one chamber chest drainage unit
0203-X1TUNA	- disposable non-adjustable tubing set for one chamber chest drainage unit
0203-X1TUNAS	- disposable non-adjustable tubing set with sampling port for one chamber chest drainage unit

Compatible with Grena tubing sets are the following glass bottles:

0203-NSG	- 2 000 ml non sterile glass bottle
0203-STG	- 2 000 ml sterile glass bottle

Resterilization of glass bottles:

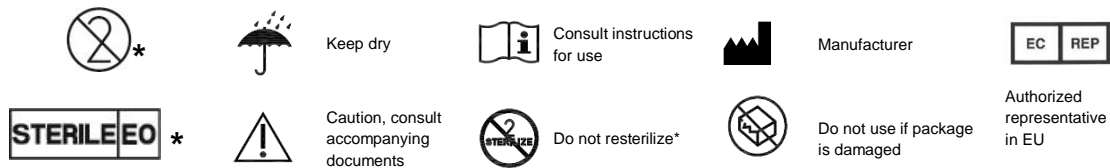
Glass bottles can be resterilized after use. New non sterile glass bottles must be sterilized prior to the first use. Disinfection and cleaning should be performed according to hospital validated procedures. Recommended is steam sterilization method. Minimum validated steam sterilization parameters required 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.

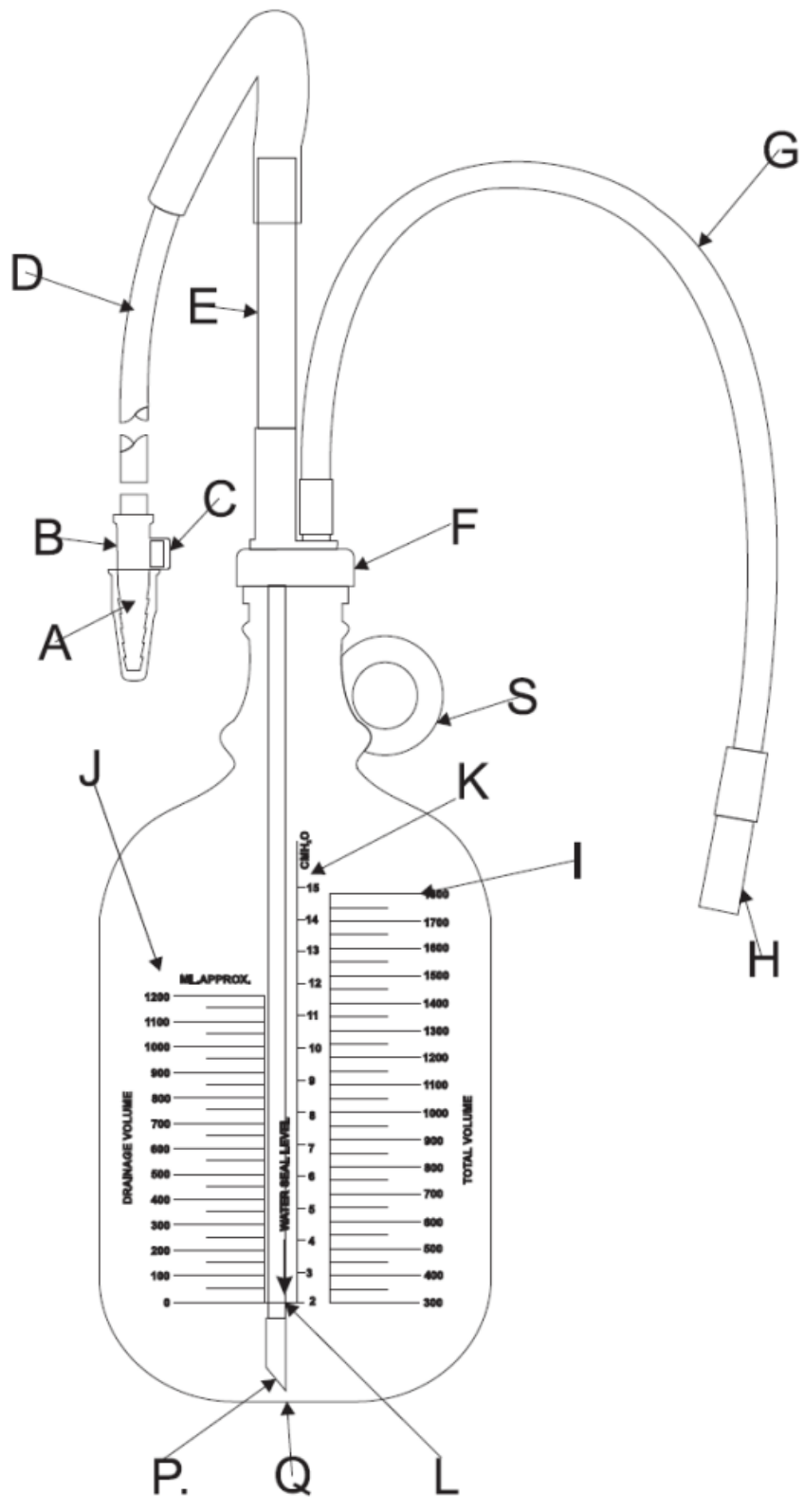
Above parameters are for reference only. One should remember that any sterilization process should be validated.

Additional warnings and precautions:

1. 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 on the collection chamber cannot be used to read suction level.
2. 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.
3. Use immediately after opening.
4. Check all the connections for tightness after drainage has started. Use adhesive plaster to seal them if necessary.
5. 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.
6. 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.
7. 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.
8. The collected content of collection chamber (Q) should not be used for reinfusion.
9. Chest tubes should not be clamped except when changing chest drainage unit or emptying collection chamber (Q). In the event of air leak, clamped chest tubes could lead to tension pneumothorax.
10. Keep the chest drainage unit minimum 50 cm below the patient's chest level at all times.
11. Avoid loops in the patient tubing (D)
12. Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of a protective wear.
13. To take samples through the self-sealing sampling port (C) (0203-X1GS, 0203-X1TUS 0203-X1TUNAS) standard hypodermic needles 18G (1,24 mm) or thinner should be used.
14. Monitor collection chamber (Q). 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.
15. 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.
16. Chest drainage tubings are intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
17. Caution should be exercised when handling glass bottles which due to possible damage bear high risk of injury.
18. 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.
19. Product is intended to be used exclusively by qualified medical staff under physician's control.





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



Disposable Adjustable One Chamber Chest Drainage Unit
Instructions for use

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

 <p>Grena (Qingdao) Medical Devices Ltd. No 318 Huanghe West Road, Huangdao District, Qingdao City, Shandong Province, 266555, China</p>	<p>Contact information: Phone: +86 0532-86769190 Fax: +86 0532-86767322</p>	<table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="padding: 2px;">EC</td> <td style="padding: 2px;">REP</td> </tr> </table> <p>MDML INTL Limited 10 McCurtain Hill Clonakilty, Co. Cork Republic of Ireland</p>	EC	REP	
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Indications:

1. To enable air and/or fluid evacuation by thoracic catheter from the chest cavity or mediastinum.
2. To help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum.
3. To help re-establish and maintain normal intrathoracic pressure gradients.
4. To facilitate complete lung re-expansion to restore normal breathing dynamics.
5. 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:

1. 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.
2. 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.
3. 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.
4. Remove the protective cap (A) from the multigauge connector (B) (semitransparent taper connector) and connect it to the thorax catheter of the patient.
5. Switch controlled suction source on (for active drainage) and increase air flow to obtain prescribed suction level.
6. 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.
7. Suction level can be changed by suction source adjustment only

Tubing replacement:

If necessary, tubing can be replaced by a new set according to the following steps:

1. Clamp thorax catheter using ratcheted haemostatic forceps.
2. Disconnect multigauge connector (B) of patient tube (E) from thorax catheter.
3. Disconnect vacuum tube (G) from suction source.
4. Unscrew collection chamber ring nut (F) and remove tubing from the bottle.
5. Open the package with new tubing set using aseptic technique.
6. Follow the steps 2, 3, and 4 of Instructions for use.
7. Remove clamp from thorax catheter.
8. 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:

1. Leave one chamber chest drainage unit connected to the patient.
2. Disconnect vacuum connector (H) of vacuum tube (G) from suction source.
3. 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.
4. Screw extension tubing set 0203-X1TUE on the new sterile (0203-STP0700) plastic bottle. Remove protective cap from taper connector of extension tube.
5. Connect vacuum connector (H) of vacuum tube (G) of one chamber glass bottle chest drainage unit with taper connector of extension tube.
6. Switch suction source on and increase air flow to obtain moderate bubbling from rigid suction control tube in the suction control chamber.
7. 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:










0203-X1TU	- disposable adjustable tubing set for one chamber chest drainage unit
0203-X1TUS	- disposable adjustable tubing set with sampling port for one chamber chest drainage unit
0203-X1TUNA	- disposable non-adjustable tubing set for one chamber chest drainage unit

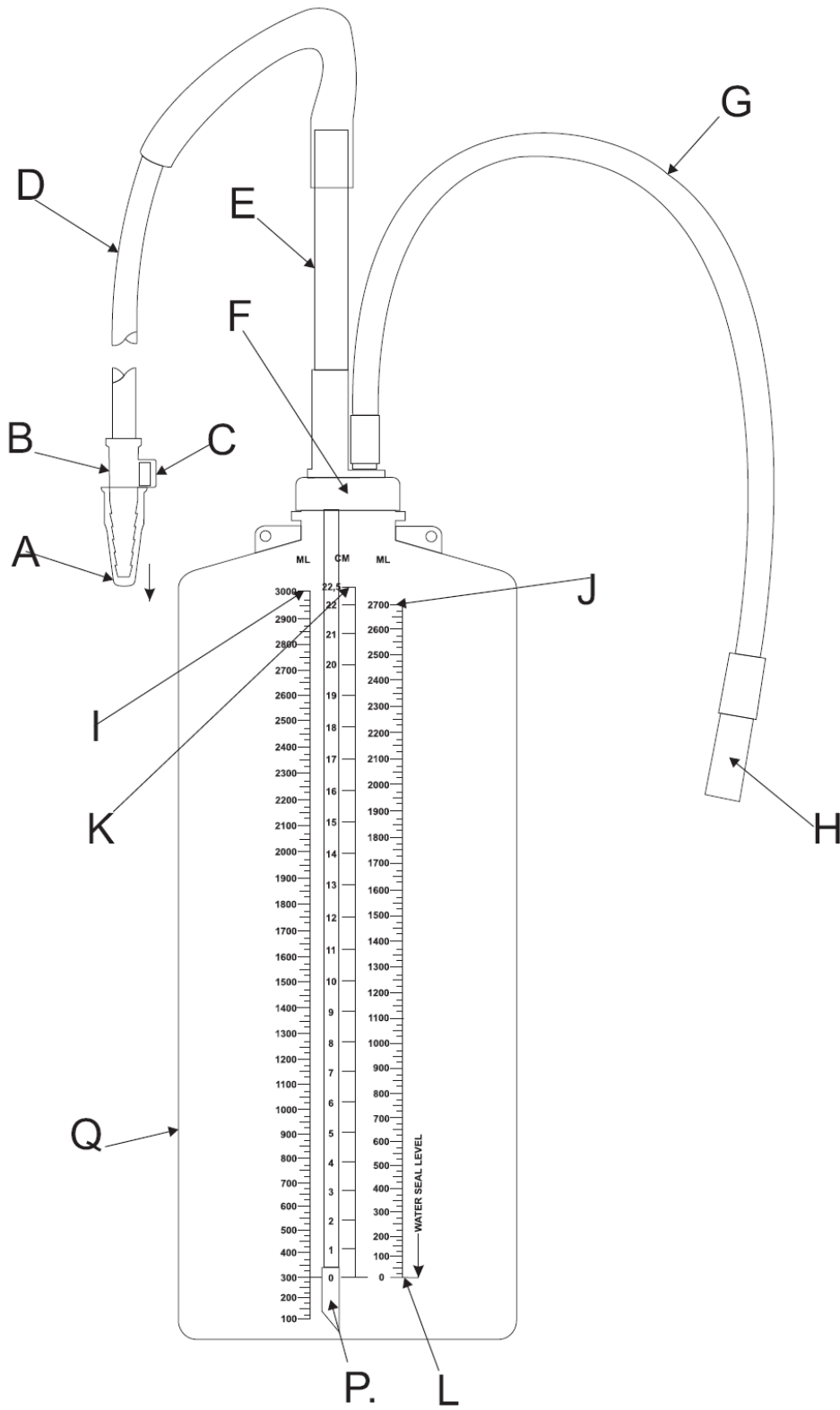
Compatible with Grena tubing sets are the following disposable bottles:

0203-NSP3000	- 3 000 ml non sterile disposable bottle
0203-STP3000	- 3 000 ml sterile disposable bottle
0203-NSP0700	- 700 ml non sterile disposable bottle

Additional warnings and precautions:



1. 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.
2. 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.
3. Use immediately after opening.
4. Check all the connections for tightness after drainage has started. Use adhesive plaster to seal them if necessary.
5. 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.
6. 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.
7. 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.
8. The collected content of collection chamber (Q) should not be used for reinfusion.
9. 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.
10. Keep the chest drainage unit minimum 50 cm below the patient's chest level at all times.
11. Avoid loops in the patient tubing.
12. Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear.
13. 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.
14. 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).
15. 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.
16. 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.
17. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
18. 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 resterilize		Do not use if package is damaged	Authorized representative in EU



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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Indications:

1. To enable air and/or fluid evacuation by thoracic catheter from the chest cavity or mediastinum.
2. To help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum.
3. To help re-establish and maintain normal intrathoracic pressure gradients.
4. 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:

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:

1. 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.
2. 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.
3. 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.
4. 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.
5. Remove the protective cap (A) from the multigauge connector (B) (semitransparent taper connector) and connect it to the thorax catheter of the patient.
6. Switch suction source on (for active drainage) and increase air flow to obtain moderate bubbling from rigid suction control tube (N).
7. Control fluid level in collection chamber (Q) and take care to keep rigid patient tube (E) submerged about 2 cm during the whole drainage.
8. 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:

1. Clamp thorax catheter using ratcheted haemostatic forceps.
2. Disconnect multigauge connector (B) of patient tube (D) from thorax catheter.
3. Disconnect vacuum tube (G) from suction source.
4. Unscrew both collection and control chamber ring nuts (F and M) and remove tubing from the bottles (Q and R).
5. Open the package with new compatible tubing set using aseptic technique.
6. Follow the steps 3, 4 and 5 of Instructions for use.
7. Remove clamp from thorax catheter.
8. Follow the steps 6 and 7 of Instructions for use.

Compatibility:

Compatible with Grena glass bottles are the following tubing sets for two chamber chest drainage units:

0203-X2TU	- disposable adjustable tubing set for two chamber chest drainage unit
0203-X2TUS	- disposable adjustable tubing set with sampling port for two chamber chest drainage unit
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

Compatible with Grena tubing sets are the following glass bottles:

0203-NSG	- 2 000 ml non sterile glass bottle
0203-STG	- 2 000 ml sterile glass bottle

Resterilization of glass bottles:

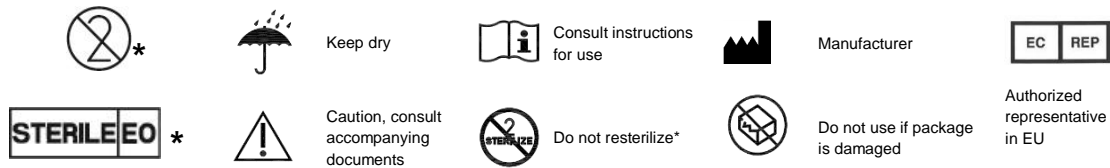
Glass bottles can be resterilized after use. New non sterile glass bottles must be sterilized prior to the first use. Disinfection and cleaning should be performed according to hospital validated procedures. Recommended is steam sterilization method. Minimum validated steam sterilization parameters required 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.

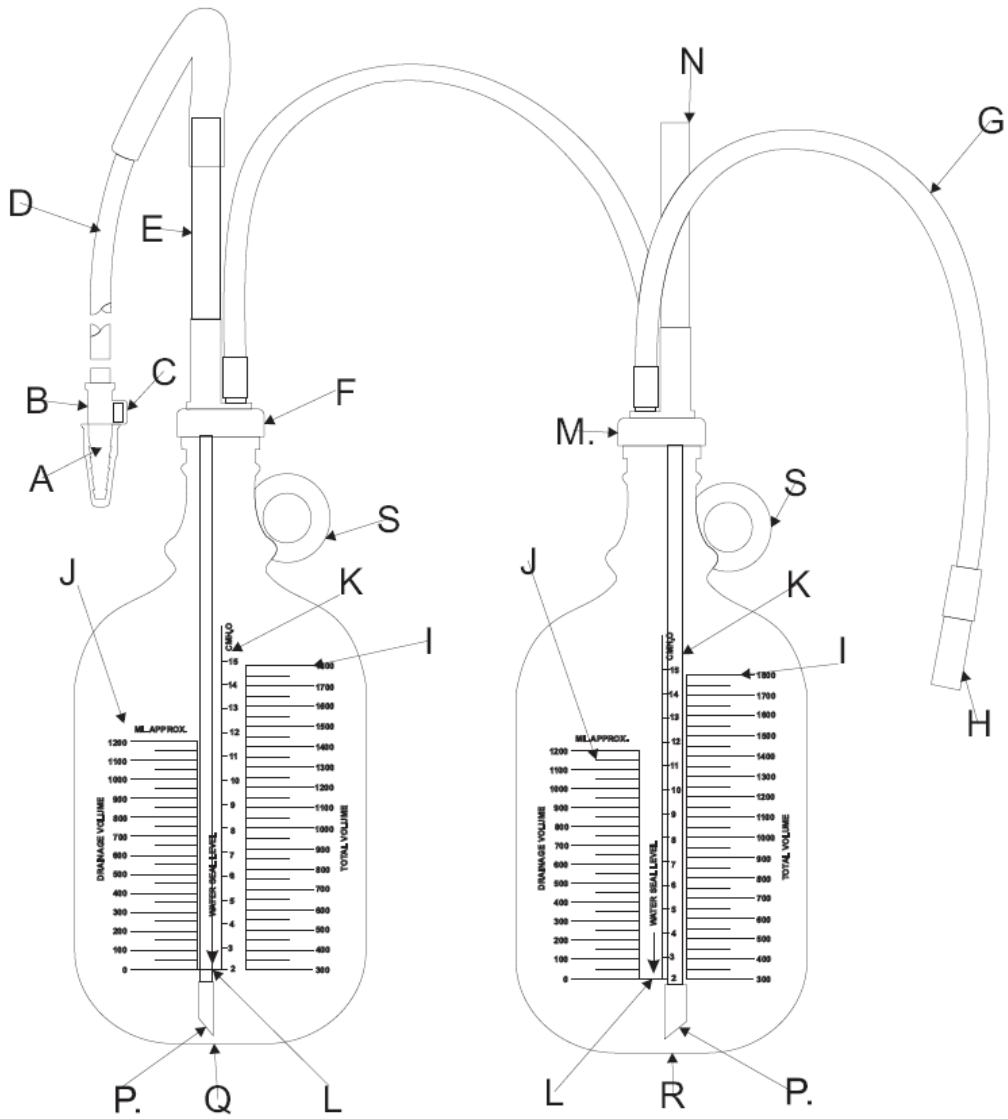
Above parameters are for reference only. One should remember that any sterilization process should be validated.

Additional warnings and precautions:

1. 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.
2. Use immediately after opening.
3. Check all the connections for tightness after drainage has started. Use adhesive plaster to seal them if necessary.
4. Water level in the suction control chamber should be examined successively and eventually filled up due to evaporation.
5. Tip proximity indicator of the collection chamber should be kept under fluid level at all times to avoid water seal loss followed by pneumothorax.
6. 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.
7. 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.
8. The collected content of collection chamber should not be used for reinfusion.
9. 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.
10. Keep the chest drainage unit minimum 50 cm below the patient's chest level at all times.
11. Avoid loops in the patient tubing
12. Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear.
13. 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.
14. 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.
15. 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.
16. Chest drainage tubings are intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
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Disposable Adjustable Two Chamber Chest Drainage Unit
Instructions for use

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- To facilitate complete lung re-expansion to restore normal breathing dynamics.

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-X2P3000, 0203-X2P0700) or with sampling port (0203-X2P3000S, 0203-X2P0700S). Collection chamber capacity can be 3000 ml (0203-X2P3000, 0203-X2P3000S) or 700 ml (0203-X2P0700, 0203-X2P0700S). Chambers of 3000 ml version are fixed together by a solid plate. Chambers of 700 ml paediatric version are not fixed together.

Product illustration:

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	O. Hangers
D. Patient tube	J. Above water seal volume scale	P. Tip proximity indicator
E. Rigid patient tube	K. Centimetre scale	Q. Collection chamber
F. Collection chamber ring nut	L. Water seal level line	R. Control chamber

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. To do it unscrew ring nut (M) of suction control chamber 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 (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 tip is submerged about 2 cm under the water level and rigid suction control tube's 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 (Q) and control chamber (R) ring nuts (F and M) and remove tubing from the bottles.
- Open the package with new 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:

Compatible with Grena disposable bottles are the following tubing sets for two chamber chest drainage units:

0203-X2TU	- disposable adjustable tubing set for two chamber chest drainage unit
0203-X2TUS	- disposable adjustable tubing set with sampling port for two chamber chest drainage unit
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

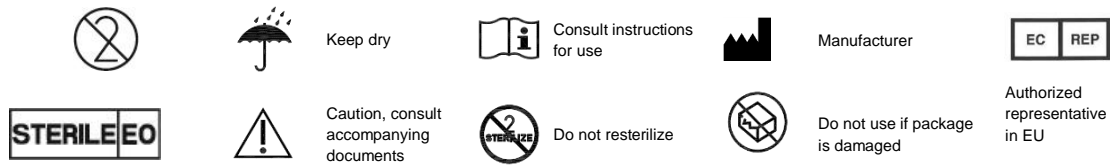
Compatible with Grena tubing sets are the following disposable bottles:

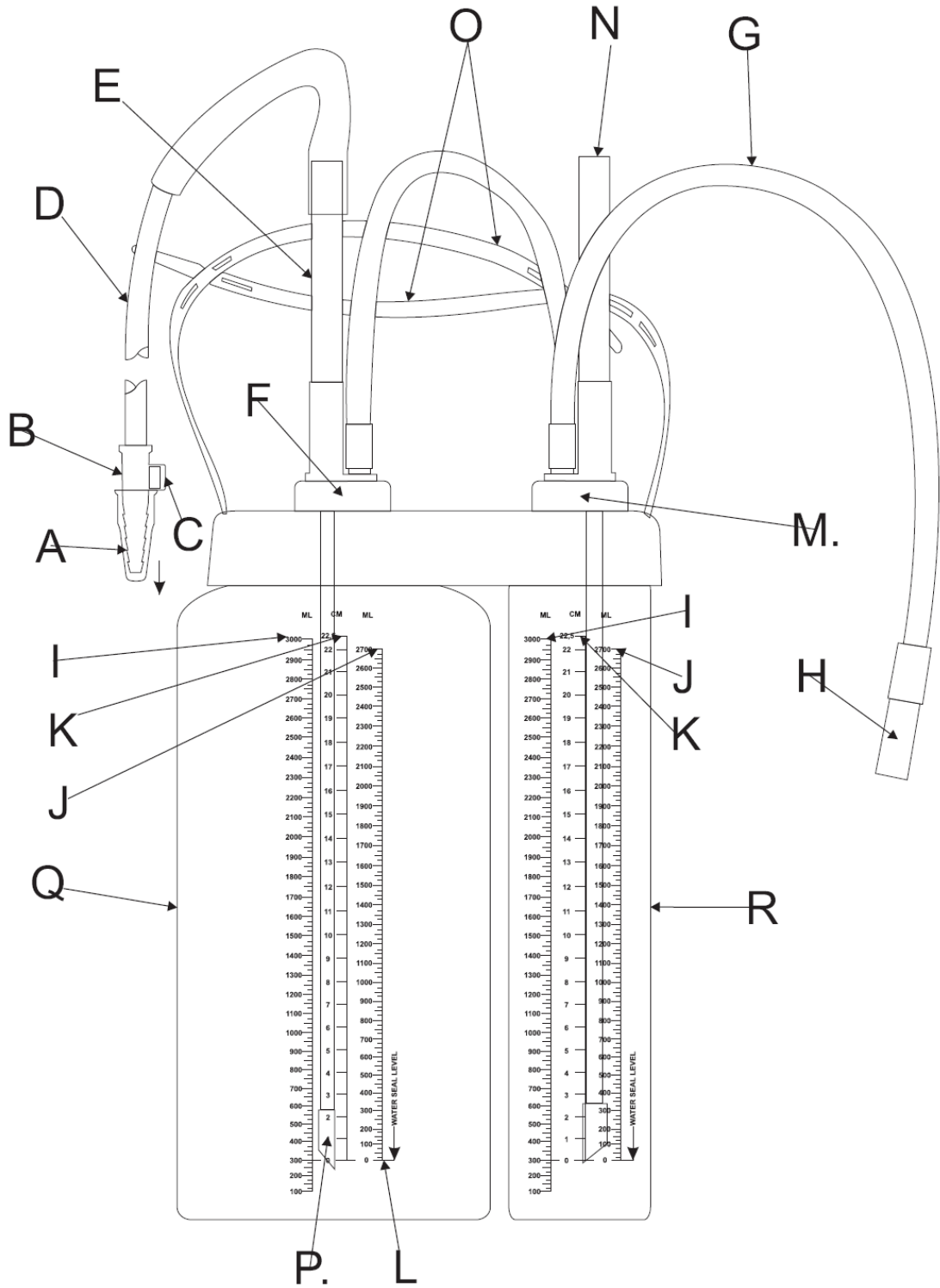
0203-NSP3000	- 3 000 ml non sterile disposable bottle
0203-STP3000	- 3 000 ml sterile disposable bottle
0203-NSP0700	- 700 ml non sterile disposable bottle
0203-STP0700	- 700 ml sterile disposable bottle

Additional warnings and precautions:

- If any change of suction level is prescribed it is necessary to change water level in the suction control chamber (R). Actual suction level in cm of water can be read from cm scale on the suction control chamber (R) provided rigid control tube (N) tip is about 2 mm from the bottom.
- Use immediately after opening.



3. Check all the connections for tightness after drainage has started. Use adhesive plaster to seal them if necessary.
4. Water level in the suction control chamber (R) should be examined successively and eventually filled up due to evaporation.
5. 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.
6. 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.
7. 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.
8. The collected content of collection chamber (Q) should not be used for reinfusion.
9. 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.
10. Keep the chest drainage unit minimum 50 cm below the patient's chest level at all times.
11. Avoid loops in the patient tubing.
12. Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear.
13. To take samples through the self-sealing sampling port (C) (0203-X2P3000S and 0203-X2P0700S versions) standard hypodermic needles 18G (1,24 mm) or thinner should be used.
14. 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 printed on the collection chamber.
15. Two hangers (O) are provided to hang the chest drainage unit from a bed, O.R. stand or to use it as a carrying handle.
16. Single floorstand is supplied with 5 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.
17. 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.
18. This product is intended for single patient and procedure use. Reesterilization, reuse, modification may lead to serious consequences with death of patient included.
19. Product is intended to be used exclusively by qualified medical staff under physician's control.





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

 <p>Grena (Qingdao) Medical Devices Ltd. No 318 Huanghe West Road, Huangdao District, Qingdao City, Shandong Province, 266555, China</p>	<p>Contact information: Phone: +86 0532-86769190 Fax: +86 0532-86767322</p>	<table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="padding: 2px;">EC</td> <td style="padding: 2px;">REP</td> </tr> </table> <p>MDML INTL Limited 10 McCurtain Hill Clonakilty, Co. Cork Republic of Ireland</p>	EC	REP	
EC	REP				

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 prefilled 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 resterilized 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.

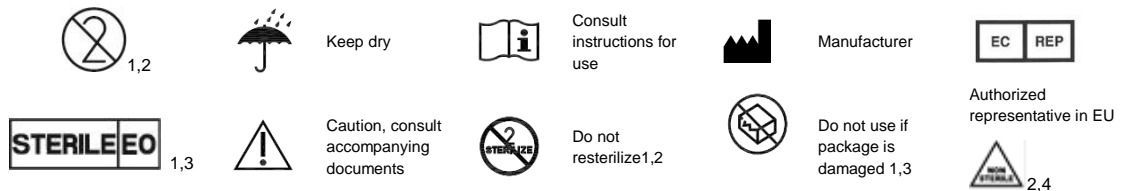
Compatibility:

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.



- 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