

Thoracentesis / Paracentesis Set Instructions for use

Ref. no.: 0204-01SN; 0204-01VN; 0204-02SN; 0204-02VN; 0204-02PC

 <p>GRENA Think Medical</p> <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: 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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Important:

These Instructions For Use cannot be used as a manual describing the use of thoracentesis and paracentesis sets. As needed, please contact our company or your authorized distributor. You should acquaint yourself with appropriate technical instructions, review the professional medical literature, and obtain formal graduate training under the supervision of a doctor experienced in thoracentesis and paracentesis techniques. We recommend thoroughly reviewing all information in this IFU; inattention to the instructions provided below may have serious clinical consequences such as patient injury, pneumothorax, haemothorax, pneumoperitoneum, haemoperitoneum contamination, cross-infection, or death.

Indications:

Thoracentesis / Paracentesis Set is used to enable easy evacuation of fluids of any origin like blood, pus, exudate, etc from pleural or peritoneal cavities by connected needle or soft catheter.

Function:

By subsequent back and forth movements of high volume syringe piston, fluid is transferred from the needle or catheter penetrating body cavity directly to closed bag protecting the user from any contact with potentially hazardous fluid. In case of bigger fluid volumes bag can be emptied easily with one hand.

Description:

Device consists of Veress needle or set of sharp needles or soft catheter, 3-way stopcock or one way automatic valve, 60ml 3-parts syringe and collection bag with bottom outlet. Syringe is used to draw the fluid from the needle or catheter penetrating body cavity and pump it directly to the collection bag. 3-way stopcock or automatic valve allows correct fluid passage from the patient to the bag. Available are following versions:

- 0204-01SN – Thoracentesis / Paracentesis Set with 3-way stopcock and 3 sharp needles
- 0204-01VN – Thoracentesis / Paracentesis Set with 3-way stopcock and Veress needle
- 0204-02SN – Thoracentesis / Paracentesis Set with one-way automatic valve and 3 sharp needles
- 0204-02VN – Thoracentesis / Paracentesis Set with one-way automatic valve and Veress needle
- 0204-02PC – Thoracentesis / Paracentesis Set with one-way automatic valve and soft catheter

Contraindications:

1. Do not use in case of local inflammation.
2. Do not use in the area of abscesses.
3. Haemophilia and severe coagulation system disorders.
4. Adhesions are relative contraindication.

Illustration of Thoracentesis / Paracentesis set:

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|-------------------|-----------------------|---|--------------------|
| Id. Sharp needles | If. for soft catheter | IIIa. One-way automatic valve and syringe | IV. Collecting bag |
| Ie. Veress needle | IIc. Connecting tube | IIIb. 3-way stopcock and syringe | |

Instructions for use:

Pos	0204-01SN	0204-01VN	0204-02SN	0204-02VN	0204-02PC
1	Straighten collection bag upper area to avoid tube entry twisting. Otherwise back flow may occur.				
2	Check if bottom tap of collection bag remains in closed position, connect syringe to the side port of 3-way stopcock or automatic valve and check if all the connections are tight.				
3	Turn 3-way stopcock to the position allowing fluid passage from the patient to the syringe. Opened directions are indicated by tap arms.		X		
4	Disinfect puncture site according to medical practice.				
5	Tightly connect appropriate needle from the set with free luer-lock connector.	Tightly connect Veress needle with free luer-lock connector. Check blunt mandrel for mobility. Open Veress needle tap (if closed).	Tightly connect appropriate needle from the set with free luer-lock connector.	Tightly connect Veress needle with free luer-lock connector. Check blunt mandrel for mobility. Open Veress needle tap (if closed).	X
6	Insert the needle into patient body cavity deep enough to reach fluid to be drawn.	Insert the needle into patient body cavity deep enough to reach fluid to be drawn. Monitor lens color. If it is red sharp needle tip is exposed, if it is green blunt mandrel is exposed and needle tip can be expected to reach fluid reservoir.	Insert the needle into patient body cavity deep enough to reach fluid to be drawn.	Insert the needle into patient body cavity deep enough to reach fluid to be drawn. Monitor lens color. If it is red sharp needle tip is exposed, if it is green blunt mandrel is exposed and needle tip can be expected to reach fluid reservoir.	<ol style="list-style-type: none"> 1. Insert the needle into patient body cavity deep enough to reach fluid to be drawn. 2. The emergence of the needle into the pleural space is determined by checking the catheter protective sheath: <ul style="list-style-type: none"> - in case of positive pressure the sheath inflates with air or liquid - in case of negative pressure the sheath collapses, thus creating a small local pneumothorax, equal to the volume of air enclosed in the sheath. The catheter is slightly longer than the needle and the protective sheath – when the needle emerges into the pleural space, the catheter is automatically expelled by a few millimeters, thus avoiding any possible contact between the needle bevel and internal organs. 3. Direct the introducing needle and advance the catheter towards the estimated drainage site. 4. Withdraw the introducing needle and the sheath while maintaining the catheter in place (no marking on the catheter should be apparent). 5. Remove the plastic proximal plug of the catheter and insert the stainless steel blunt needle of the 3-way stopcock into the catheter. 6. Suture the catheter to the skin. 7. Connect axial luer-lock port of 3-way stopcock with free luer-lock connector. 8. Check the catheter position by chest X-ray. Take care that side port of the stopcock will be closed by proper tap position and protected by cap during the whole procedure. Use side port of automatic valve for aspiration.

7	Aspirate fluid with the syringe.	
8	To expel the liquid and collect it into the bag turn 3-way stopcock to allow fluid passage from the syringe to the collection bag and push down the syringe's piston. Subsequent syringe's piston movements back and forth together with changing 3-way stopcock position draw the fluid from the patient to collection bag.	To expel the liquid and collect it into the bag push down the syringe's piston – the non-return valve does not allow the back flow. Subsequent syringe's piston movements back and forth draw the fluid from the patient to collection bag.
9	To empty the bag turn 3-way stopcock in the way that patient direction will be closed and open the bottom tap of collection bag. Close it back if you need to continue aspiration and follow procedure like in point 3, 7 and 8.	To empty the bag open the bottom tap of collection bag. Close it back if you need to continue aspiration and follow procedure like in point 7 and 8.
10	When decided procedure should be finished remove needle or catheter from the patient body	
11	Puncture site should be protected and dressed according to medical practice	

Additional warnings and precautions:

1. Always place the bag 50 cm below patients' level.
2. Check all the connections for tightness before using this product.
3. Top of the collection bag cannot be twisted during procedure. Always straighten it prior to use to avoid fluid backflow.
4. Graduation scale of collection bag 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.
5. The collected content of collection chamber should not be used for reinfusion.
6. Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear.
7. Monitor collection bag. To avoid overfilling, empty collection chamber before exceeding the fill capacity of 2000 ml indicated by the volume graduation printed on the collection bag.
8. Verify the correct position of the soft catheter.
9. Never withdraw soft catheter back through the needle.
10. After 2 or 3 days of use, 1 to 3 cm of the soft catheter should be pulled out in order to reposition the lateral eyes at the catheter tip.
11. Soft catheter markings should always remain inside body cavity.
12. Flush soft catheter regularly.
13. On soft catheter removal, check its integrity and that no fragments were left.
14. Never let the soft catheter to be in the body over 30 days.
15. Thoracentesis / paracentesis set 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.
16. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
17. Product is intended to be used exclusively by qualified medical staff under physician's control.
18. Use immediately after opening.
19. Do not store in excessive temperatures.



Keep dry

Caution, consult accompanying documents



Consult instructions for use



Do not resterilize



Manufacturer



Do not use if package is damaged



Authorized representative in EU