

JD-1000 Chest Drainage kit

Chest Drainage Kit with 12/16/24 FR Chest tubes with Safety stylet
(No Lidocaine/Skin Prep Supplies Included)



Customer Service

If you have any questions or concerns about the use of the JD-1000 Chest Drainage Kit, please contact at:



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REG.NO.:XXXXXXXX

eIFU can be found at www.jfdpkmedical.com/eIFU

INSTRUCTIONS FOR USE (IFU)

Intended Use

The JD-1000 Chest Drainage Kit is used to drain fluid and air from the pleural space. The pleural space is the space between the two layers of the pleura, the membrane that lines the lungs and the inside of the chest wall. Fluid or air in the pleural space can cause pain, shortness of breath, and other symptoms. The Kit can be used to remove this fluid or air and relieve these symptoms.

Contraindications

- Active bleeding
- Bleeding disorders
- Coagulation disorders
- Unstable cardiovascular status
- Severe respiratory distress
- Penetrating chest trauma
- Open pneumothorax
- Tension pneumothorax

Warnings/Precautions

- Immunocompromised patients
- Patients with diabetes
- Patients with liver disease
- Patients with kidney disease
- Patients with heart disease
- Patients with a history of allergies
- Patients taking anticoagulants
- Patients taking antiplatelet drugs

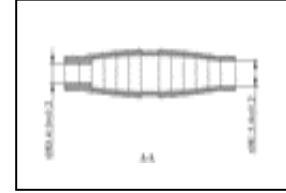
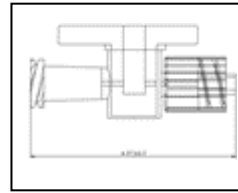
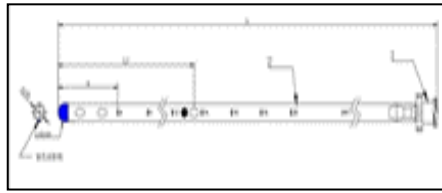
Indications for use

The kit is indicated for short-term drainage of symptomatic pleural space collections of air or fluid, including simple and purulent pleural effusions, and other recurrent effusions that do not respond to medical management of the underlying diseases. Also indicated for the palliation of dyspnea due to malignant pleural effusion.

Components

The JD-1000 Chest Drainage Kit contains following components:

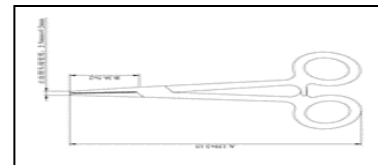
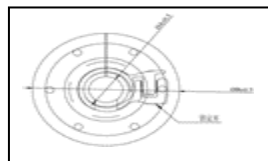
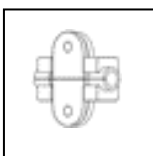
- 1 JD-Hook[®] Safety Stylet
- 3 Chest tubes (For each 12 FR, 16 FR, 24 FR size)
- 2 Drain stopcocks
- 1 Mini Skin lock device (for 12 FR Chesttube)
- 2 Skin lock devices (for 16/24 FR Chest tubes)
- 2 Christmas Tree Adaptors
- 1 Clamp Scissors
- 2 Drain connector tubings
- 1 Scalpel
- 1 Slit gauze pad
- 1 Silk suture
- 1 Instructions for use Manual



A: JD Safety Stylet B: Chest Tube
Adaptor

C: Drain Stopcock

D: Christmas Tree



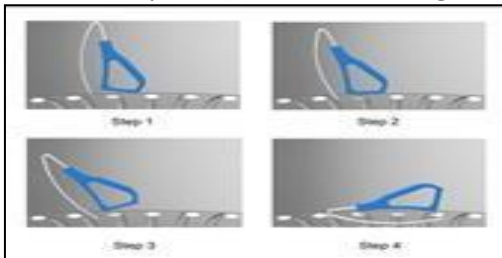
E: Mini Skin lock device
(For 12 FR)

F: Skin lock device (For 16/24 FR)

G: Clamp Scissors

Directions for Use

1. **SITE PREPARATION:** After locating appropriate site for insertion of chest tube, prepare the area with standard sterile precautions including sterile drape. (Note: Skin Sterile preparation supplies are NOT included in this kit).
2. Anesthetize the insertion site including skin, subcutaneous tissue and intercostal space with 1% lidocaine. Use adequate amount of local anesthetics to include the chest tube insertion site and the skin suture application site.
(Note: Lidocaine Analgesia items are NOT included in this kit).
3. Open the JD-1000 Chest Drainage Kit.
4. Use the scalpel blade to make a local skin incision at insertion site. Advance the incision deep up to the level of intercostal muscle attachment at the upper rib border. Use gauze pieces for local hemostasis.
5. The kit contains 3 choices of chest tubes, including 12FR, 16 FR and 24 FR sizes. Load the appropriate size chest tube onto the JD-Hook[®] Safety Stylet.
6. The JD-Hook[®] Safety Stylet is inserted into the chest tube at insertion point marked with a BLACK DOT at 12.5 cm from the tip of chest tube.
7. Once loaded properly, the stylet tip lies within the blunt radiopaque tip of chest tube.
8. Insert the chest tube loaded stylet at the incision site, into the prepared intercostal space, entering the pleural space at the upper margin of the lower rib within the selected intercostal space. (Refer to below figure for insertion technique)



Insertion steps for JD-Hook[®] Safety Stylet placement and advancement.

Load the selected chest tube (not shown), as per instructions, onto the stylet before advancing the stylet into the pleural space.

9. Advance the stylet until you feel a pop, which indicates that you have entered the pleural space.
10. Advance the stylet into the chest cavity till the proximal curved end of stylet is at the skin level.
11. Advance the chest tube by advancing it over the stylet into the pleural cavity. Advance the chest tube till all the drainage holes and access point is located within the pleural cavity.
12. Retract and remove the JD-Hook[®] Safety Stylet.
13. Attach the appropriate connecting adaptor with the stopcock, to the distal end of Chest tube.
14. Attach the collection chamber to the drainage adaptor tubing. Use the included Christmas tree adaptors if needed.
15. Keep the stopcock in closed position, till the appropriate drainage setup has been connected (closed bag, or with water seal collection system) and the vacuum/wall suction has been connected.
16. For 16 FR and 24 FR Chest tubes: Attach the external blue disc lock (F) to the chest tube at skin exit site. Deploy the disc lock to secure the chest tube. Suture the blue disc to skin with silk suture provided
17. For 12 FR Chest tube: Attach the skin lock Device (E) by placing the inner segment of the lock device to the 12 FR chest tube at skin exit site, and press the outer cover onto the inner segment. Secure the locking device with silk suture provided.
18. Secure the collection tubing to the patient's chest with tape, to prevent any kinks or blockage of drainage.
19. Apply Sterile dressing at Chest tube exit site in standard sterile fashion. (Note: Sterile dressing supplies are not included in chest drainage Kit)

20. Monitor the patient's condition and the collection chamber for drainage.

Disposal

Dispose off the kit contents including used sharps and stylet in an appropriate biohazard disposal container, in accordance with local hospital policy and with regard to all applicable local, state and Federal regulations, including but without limitation to, those pertaining to human health & safety and care of the environment.

Post Use Instructions

1. Monitor the patient for signs of bleeding, infection, and respiratory distress.
2. Keep the collection chamber below the level of the patient's chest.
3. Empty the collection chamber when it is full.
4. Change the collection tubing every 24 hours.
5. Remove the drainage catheter when the patient no longer needs it. To remove the chest tube, remove the sutures with suture removal kit (not included), and any cover dressings. To minimize the risk of iatrogenic pneumothorax, remove the chest tube by retracting it out of the pleural space completely, with one swift motion, DURING THE EXHALATION phase of patient breathing cycle.

Storage and Handling

The Kit should be stored in a cool, dry place and protected from heat, light, and moisture.

Post-Insertion Monitoring

If the patient develops any of the symptoms like Fever, Chills, Worsening Pain at insertion site, Shortness of breath, Cough, Chest pain, call the doctor immediately.














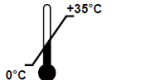







Adverse Events

The most common adverse events associated with the use of the Chest Drainage Kit are:

- Bleeding
- Infection
- Pneumothorax
- Pain
- Dyspnea
- Hypoxia
- Hypercapnia
- Arrhythmia
- Shock

Do not use the kit if:

- The kit is damaged.
- The expiration date has passed.
- The kit has been opened or used previously.

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Revision: June 06 2023