

ONE STEP™

CENTESIS CATHETER

INSTRUCTIONS FOR USE

DESCRIPTION OF THE PRODUCT

The One-Step Centesis Catheter is a short-term drainage catheter, available in straight, pigtail, valved and non-valved configurations with introducer needle.

INDICATIONS FOR USE

The One-Step Centesis Catheter is indicated for the percutaneous drainage of fluids such as during paracentesis and thoracentesis procedures.

CONTRAINDICATIONS

None known.

CLINICAL BENEFITS

Use of the One-Step Centesis Catheter relieves symptoms such as dyspnea and discomfort associated with unwanted fluid collections.

PRECAUTIONS

- Read manufacturer's instructions prior to use
- **Rx Only Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of the device.
- Contents of unopened, undamaged package are sterile via ethylene oxide.
- Do not leave in patient longer than 24 hours.
- Store in a cool, dry place.
- Do not use if packaging is damaged.
- Inspect the device prior to use to verify that no damage has occurred during shipping.
- Do not use after expiration date
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Placement of the One-Step Centesis Catheter is intended to be performed by appropriately trained healthcare professionals.
- If the flow slows or stops, it could be a sign that the catheter is kinked, occluded, or no longer in fluid. If there is still fluid that needs to be drained, adjust the catheter or replace with a new one.

POTENTIAL COMPLICATIONS

- Pneumothorax
- Bleeding complications
- Re-expansion pulmonary edema
- Vasovagal syncope
- Infection
- Perforation

INSTRUCTIONS FOR USE- PIGTAIL CATHETER

1. Remove the needle from the protective boot.
2. Insert the needle into catheter.
3. Insert the needle through the catheter until the needle hub is fully seated in the catheter hub.
4. Remove the distal obturator from the needle prior to inserting catheter into patient. (see Figure 1)

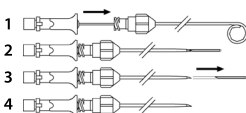


Figure 1

Warning: Do not re-attach distal obturator to needle.

5. Insert catheter into fluid collection site using standard insertion technique.
6. When catheter is in appropriate position, remove needle from catheter. **Warning:** Do not reinsert needle into catheter while the catheter is still in the patient.
7. Attach a device with a standard Luer fitting to catheter hub to remove fluid.
8. Following the procedure, gently withdraw the catheter and dress the site accordingly.

INSTRUCTIONS FOR USE- STRAIGHT CATHETER

1. Remove the catheter and needle from protective boot(s).
- Note:** Steps 2 and 3 below are only for 6F and 8F Valved One-Step Centesis Catheters.
2. Insert the needle through the catheter until the needle hub is fully seated in the catheter hub.
3. Remove the distal obturator from the needle prior to inserting catheter into patient. (see Figure 2)

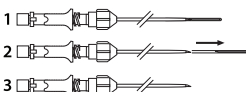


Figure 2

Warning: Do not re-attach distal obturator to needle.

4. Insert catheter into fluid collection site using standard insertion technique.

5. When catheter is in appropriate position, remove needle from catheter.

Warning: Do not reinsert needle into catheter while the catheter is still in the patient.

6. Attach a device with a standard Luer fitting to catheter hub to remove fluid.

7. Following the procedure, gently withdraw the catheter and dress the site accordingly.



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