

# Denssima<sup>®</sup> Centesis Drainage Set

## Device Description

Centesis Drainage set processed through plastic, metal and hydrophilic coating consists of a Drainage tube with side holes, Introducer needle & Guide Wire to perform puncturing a body cavity or organ with a hollow needle and introduce tube in order to draw out fluids, Cavities from which fluid can drain is pleural, abdominal and peritoneal.

### Denssima<sup>®</sup> Centesis Drainage Set package includes

- Drainage tube with spiral holes
- Introducer needle
- 0.038-inch / 50 cm guidewire
- Drainage bag connector

### Denssima<sup>®</sup> Single Step<sup>®</sup> Centesis Drainage Set package includes

- Drainage tube with spiral holes
- Puncture needle with stopper
- Urine bag connector

### Size (Fr)

5, 6 & 7

### Length (cm)

10 & 16

### Model

Straight and Pigtail

## Intended Purpose & Duration

Intended to be used for percutaneous placement of a tube for drainage of ascitic & pleural effusions by Seldinger or direct stick technique for short term use.

## Indications For Use & Contraindications

Indicated to place drainage tube percutaneously for drainage of fluids during procedures such as paracentesis and thoracentesis.

No known contraindications.

## Potential Complications

Potential complications include but not limited to Bleeding complications, Catheter dislocation/dislodgement, Catheter occlusion/obstruction, Damage/perforation to adjacent organs, Mechanical catheter damage, pain, Infection and pneumothorax.

## Warnings And Precautions

- Follow manufacturers instructions prior to use.
- Do not use the device if product is damaged or expired and do not reuse the device. Do not use after expiration date.
- For single patient use only. Do not reuse, reprocess or re sterilize.
- Reuse, reprocessing or re-sterilization 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 re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, 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.
- This device is intended for use by physicians/healthcare professionals trained and experienced in diagnostic and interventional techniques, standard techniques for placement of percutaneous drainage catheters/tubes should be employed.
- If a catheter has become malpositioned or if drainage ceases, the catheter should be promptly exchanged or removed.
- Use only accessories supplied along with package.
- Manipulation of the product needs ultrasound or fluoroscopic guidance.
- Dispose of the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.
- Periodic evaluation of the catheter is advised; catheter should not remain indwelled for more than 07 days after deployment.
- Do not forcefully advance any components during removal or placement of the catheter. Carefully remove the components if any resistance is occurred.
- For direct puncture catheter tubes, do not reinsert the needle after catheter gets deployed in collection system or catheter is still in patient.

## Catheter Placement Procedure

**Note:** Activate the hydrophilic coating, by wetting the catheter with sterile water or saline. For best results, keep catheter surface wet during placement.

### Centesis drainage Set (Straight & Pigtail)

1. Locate the collection site by fluoroscopic means.
2. Remove the protective boot of introducer needle and puncture at marked site. Confirm the correct placement of needle by aspiration.
3. Advance the guidewire through the introducer needle cannula into the collection system and confirm its position by ultrasound/CT scan or other means of fluoroscopy. Retrieve the needle maintain the guidewire in position.
4. Load the distal end of drainage tube over the guidewire and advance up to drainage collection system. Then remove the guidewire.
5. Secure the catheter by tape over the skin.
6. Using the drainage bag connector, connect the catheter to the drainage collection bag.

### Single Step<sup>®</sup> Centesis Drainage Set

#### Straight

1. Locate the collection site by fluoroscopic means. Identify and prepare the puncture site. Mark the site and make a small nick over the skin.
2. Catheter/Tube is supplied in ready to use condition. Now activate the hydrophilic coating over the catheter surface by standard procedure as described.
3. Now introduce the drainage tube assembled with needle into the collection system by direct puncture i.e., the body cavity or organ from where the drainage needs to be performed.
4. After placement remove the stopper on the needle to aspirate the fluid to confirm the placement into desired cavity.
5. Remove the needle leaving drainage tube. Secure the catheter tube by tape over the skin and fix the drainage bag connector to the tube for collection of fluids into collection bag.

#### Pigtail

1. Locate the collection site by fluoroscopic means. Identify and prepare the puncture site. Mark the site and make a small nick over the skin.
2. Catheter need to prepared to get into condition by which it allows to puncture directly.
3. Remove the protective boot of needle. Needle and stylet assembly system have blue protective covering at the tip. Do not remove this covering. Advance the needle and metal stylet system into the catheter tube and straighten the pigtail retention means of catheter. Now, blue protective cover will protrude out from catheter tip. Now remove the protective cover over the tip and metal stylet. Now butt the stopper at back of the needle hub.
4. Now activate the hydrophilic coating over the catheter surface by standard procedure as described.
5. Now introduce the drainage tube assembled with needle into the collection system by direct puncture i.e., the body cavity or organ from where the drainage needs to be performed.
6. After placement remove the stopper on the needle to aspirate the fluid to confirm the placement into desired cavity.
7. Remove the needle leaving drainage tube. Secure the catheter tube by tape over the skin and fix the drainage bag connector to the tube for collection of fluids into collection bag.

## Catheter Removal

- Detach the catheter from skin.
- Remove the tube from body carefully.
- Or if necessary, place a guidewire, into the collecting system to maintain access while removing the catheter.
- Remove the catheter gently and carefully.

## Supply and Storage

The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20°C to 40°C and away from direct sunlight.

## Target Population Group

In patients who have, or might have, fluid accumulation or obstruction due to various reasons, an external drainage tube called a 'catheter' is commonly placed in order to prevent or to temporarily relieve from the obstruction.

## Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

# Symbol Glossory And Definations

## Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

Symbol	Symbol Title
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barrier system with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription



- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.



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