



## Technical Data Sheet

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### PRODUCT:

Fuhrman Pleural Drainage Sets

### PRODUCT CODE:

C-PPD-1020-WCE-IMH  
C-PPD-1200-CHILDRENS-082694-IMH  
C-PPD-500-WCE-IMH  
C-PPD-600-WCE-IMH  
C-PPD-850-IMH  
C-PPD-850-WCE-IMH

**DIMENSIONS:**

| Product Catalogue Number Prefix | Catheter French Size (Fr) | Endhole Diameter (x .001") | Catheter Length (cm) | Proximal Fitting<br>M=Metal<br>P=Plastic | Sideports<br>S=Sideports | Distal Curve Configuration | Additional Identifiers |
|---------------------------------|---------------------------|----------------------------|----------------------|--|--------------------------|----------------------------|------------------------|
| PU                              | 8.5                       | 28                         | 15                   | P  | 6S                       | PPD                        | IMH                    |
| PU                              | 6.0                       | 28                         | 15                   | P  | 6S                       | PPD                        | IMH                    |
| PU                              | 10.2                      | 28                         | 15                   | P  | 6S                       | PPD                        | WCE-IMH                |

**PICTURE:****COMPONENTS:**

Catheter  
 Wire Guide  
 Dilator  
 Entry Access Needle  
 Luer Lock to Multipurpose Tubing Adapter  
 Stopcock

**DESCRIPTION:  
(C-PPD-/WCE-IMH)**

The Fuhrman Pleural Drainage Sets manufactured as devices by the product catalogue number suffix WCE-IMH are identified by the product catalogue numbers C-PPD-1020-WCE-IMH, C-PPD-850-WCE-IMH, C-PPD-600-WCE-IMH and C-PPD-500-WCE-IMH. These Fuhrman Pleural Drainage Sets are comprised of a polyurethane catheter measuring 15-centimeters in length, six distal sideports, and a 0.028-inch diameter endhole. The proximal fitting of the catheter is designed as an injected molded hub. Based upon set specifications, these catheters may be manufactured as 5.0, 6.0, 8.5, or 10.2 French devices. Six depth marks are placed on the catheter shaft located just proximal to the

curve, placed beginning eight centimeters from the catheter tip. The depth markings are placed one centimeter apart.

These sets also contain an 18-gage stainless steel access needle measuring 5-centimeters in length with a lancet bevel, an Amplatz Extra Stiff coated 0.028-inch diameter wire guide measuring 40-centimeters in length with a 2-millimeter curve radius, a clear low-pressure three-way stopcock, and a male Luer lock adapter. The corresponding dilator for each specific set is manufactured from polyethylene tubing and is designed with a 0.028-inch diameter endhole. These dilators measure 12-centimeters in length but may be manufactured as a 4.5, 5.5, 8.0, or 9.5 French device depending upon the set specifications.

Based upon device specification for the specific set, all components are identical, with the exception of the catheter and dilator. Sets manufactured with a 10.2 French catheter (1020-WCE-IMH) are designed to have a 9.5 French dilator; sets manufactured with a 8.5 French (850-WCE-IMH) catheter are designed to have a 8.0 French dilator; sets manufactured with a 6.0 French catheter (600-WCE-IMH) are designed to have a 5.5 French dilator; and sets manufactured with a 5.0 French catheter (500-WCE-IMH) are designed to have a 4.5 French dilator.

#### **(C-PPD-1200-CHILDRENS-082694-IMH)**

Fuhrman Pleural Drainage Sets manufactured by the product catalogue number C-PPD-1200-CHILDRENS-082694-IMH are comprised of a 12.0 French polyurethane catheter designed with a 0.038-inch diameter endhole and six distal sideports. This catheter measures 15-centimeters in length and has a pigtail distal curve configuration. The proximal fitting of the catheter is designed with an injected molded hub. This set also contains an 11.0 French polyurethane dilator measuring 12-centimeters in length with a 0.038-inch diameter endhole, an 18-gage stainless steel access needle with a lancet bevel, and a nominal length measurement of 7-centimeters, a male Luer lock adapter, and a low-pressure clear body three-way stopcock. A 0.028-inch diameter TFE coated Amplatz Extra Stiff wire guide measuring 40-centimeters with a 2-millimeter curve radius completes this set.

#### **(C-PPD-850-IMH)**

The Fuhrman Pleural Drainage Set identified by the product catalogue number C-PPD-850-IMH, is comprised of an 8.5 French polyurethane catheter with 6 distal sideports, a 0.028-inch distal endhole, and a pigtail distal curve configuration. This catheter measures 15-centimeters in length. The proximal fitting of the catheter is designed as a standard injected molded hub. The other components for this set include an 8.0 French polyurethane dilator with a length measurement of 12-centimeters and a 0.028-inch diameter endhole, an 18-gage stainless steel entry access needle with a lancet-bevel and a nominal length of 7-centimeters, a male Luer lock adapter, a low-pressure three-way stopcock, and an Amplatz Extra Stiff TFE coated 0.028-inch diameter wire guide. The wire guide component is designed with a 2-millimeter curve radius and a nominal length of 40-centimeters.

#### **INTENDED USE:**

The Fuhrman Pleural Drainage Set (C-PPD) is intended for drainage of air or fluid from the pleural space. The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard Seldinger technique for placement of needles, wire guides, dilators and catheters should be employed.

#### **CONTRAINDICATIONS:**

No known contraindications.

## WARNINGS

- Over-insertion of the access needle, wire guide, dilator, or chest tube may result in serious or life-threatening injury. Clinical judgement and consideration of patient size and anatomy should guide appropriate chest tube selection (e.g., French size and length) and insertion.
- The wire guide should always advance without impedance to avoid perforation of any surrounding structures.
- The wire guide should always extend beyond the catheter tip to avoid perforation of any surrounding structures.

## PRECAUTIONS:

- Possible allergic reactions should be considered
- A TFE-coated wire guide is recommended for a smoother catheter introduction.

## RECOMMENDED STORAGE INSTRUCTIONS:

Do not use the product if there is doubt as to whether the product is sterile.

Store in a dark, dry, cool place. Avoid extended exposure to light.

Upon removal from package, inspect the product to ensure no damage has occurred

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| <b>Direct patient contacting materials</b> | Polyether-Urethane<br>Silicone<br>Polyurethane<br>Polytetrafluoroethylene<br>Stainless Steel<br>Polyethylene<br>Polycarbonate<br>Acetal<br>Polyamide Nylon |
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|                             |                   |
|-----------------------------|-------------------|
| <b>CE Marked</b>            | Yes               |
| <b>Class</b>                | IIa               |
| <b>Notified body number</b> | 0123              |
| <b>Manufacturer</b>         | Cook Incorporated |

|                                 |  |
|---------------------------------|--|
| <b>Single use</b>               | Yes  |
| <b>Sterilized</b>               | Yes  |
| <b>Address of sterilization</b> | Cook Incorporated<br>Ellettsville, Indiana 47429 USA |
| <b>Method of sterilization</b>  | ETO  |
| <b>Shelf life</b>               | Up to 36 months                                      |
| <b>Biological origin</b>        | No   |
| <b>Latex</b>                    | No   |
| <b>Biocompatibility</b>         | Yes  |
| <b>Quantity supplied</b>        | 1  |