

Product Name: Rocket IPC Drainage Line with Wide Bore Connector

ZDOCK303 Rev. 05

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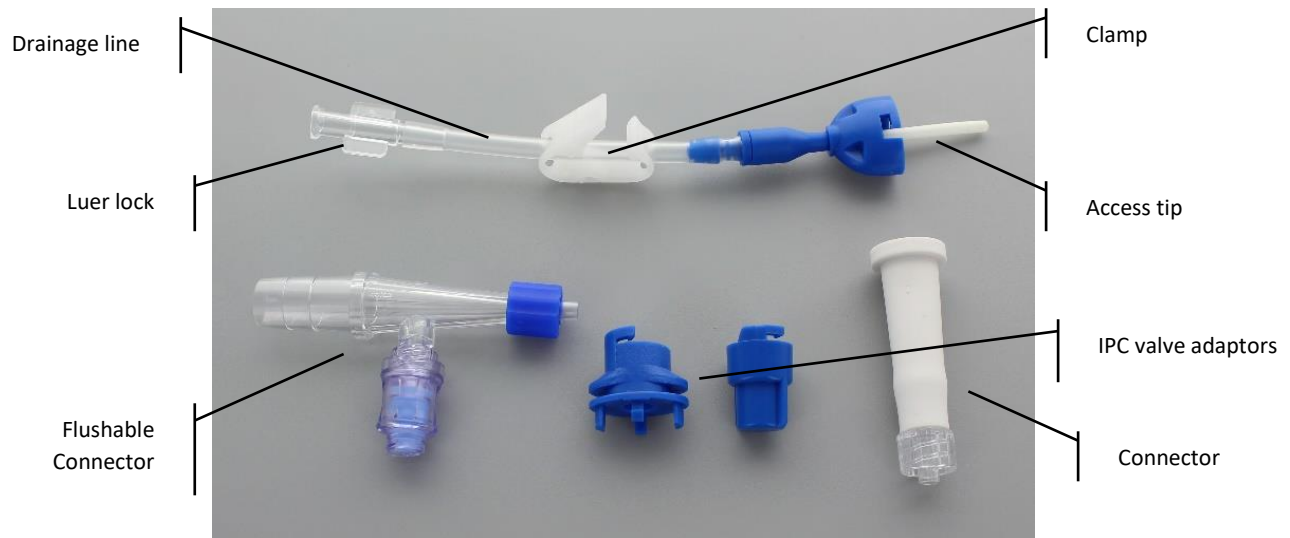
Rocket IPC Drainage Line with Wide Bore Connector

INSTRUCTIONS FOR USE

Product Name: Rocket IPC Drainage Line with Wide Bore Connector

Product Code: R54410-WB-DL

Device Image:



Intended Use: The Rocket IPC (Indwelling Percutaneous Catheter) Drainage Line is intended to connect an IPC to another drainage device such as an underwater seal chest drain or ambulatory bag and for flushing of the IPC using normal saline.

Indications: For connecting IPC Catheter to other drainage devices such as an underwater seal chest drain or ambulatory bag.

Contraindications: Not for connection to any other type of indwelling pleural or peritoneal catheter unless used with the correct adaptor provided by Rocket Medical.

Benefit Risk: Rocket Medical Plc concludes that the overall medical benefits of the Rocket Medical IPC Drainage Line outweigh the possible risks when used according to the intended use.

Performance Claims and Clinical Benefit: The IPC Drainage devices are apparatus intended to be used for external drainage of pleural effusions and abdominal ascites. The Rocket IPC Drainage Line is intended to connect an IPC to another drainage device such as an underwater seal chest drain or ambulatory bag and for flushing of the IPC using normal saline.

Undesirable Side Effects: No undesirable side effects identified from using the Rocket IPC Drainage Line.

Description of the device: Contains 80mm drainage line with clamp and funnel and wide bore connector with valve for connection to the Rocket IPC catheter.

User: The intended user is a healthcare professional proficient in the undertaking of ascites drainage, working in accordance with local and national guidelines. But also, the patient themselves can operate the catheter once implanted and has undertaken the training from qualified professional.

Proper instruction must be given to the patient(s) and/or carer on how to use the drainage line for draining the pleural space. The person(s) responsible must demonstrate their capability in performing the procedure before being trusted to do so. If the patient or carer is not willing or able to perform the drainage at home, a medical professional should perform the procedure.

Patient Population: The intended patient demographics are adult male and female patients requiring pleural or peritoneal ascites drainage.

For Single Use Only: the device may not have structural integrity to support reuse, resulting in harm to the patient and/or user. Re-use may result in harm to patients and users from cross-contamination and infection.

Sterile: the device is supplied sterile by Ethylene Oxide (EO). Do not re-sterilise; it may not be possible to achieve the required sterility assurance level upon re-sterilisation of a used device. Re-sterilisation may also compromise the structural integrity of the device, leading to device failure.

In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.



















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MRI Safety: MRI compatibility has not been verified.

General Information:

- This device may be used with Rocket Underwater Seal Chest Drainage Bottles or the Rocket Ambulatory Bag.
- This device is to be used with the following consumables (not provided)
 - Medical examination gloves
 - Skin cleansing alcohol wipes

Symbols and safety signs used on the device and labelling:

Symbol or Safety Sign	Meaning	Symbol or Safety Sign	Meaning
	Manufacturer		Keep away from sunlight
	Caution: Federal law restricts this device to sale by or on the order of a physician.		Keep dry
	Date of manufacture		Do not re-use
	Use-by date		Consult the instructions for use
	Batch code		Does not contain natural rubber latex
	Catalogue number		Medical device
	Sterilized using ethylene oxide		Do not use if package is damaged and consult instructions for use
	Do not re-sterilise		Single sterile barrier system
	Distributor		Single sterile barrier system with protective packaging outside

Operating Instructions:

CHECK: do not use if the packaging is open or damaged or the device is damaged. Ensure you have the full contents of the kit prior to use. Ensure you have access to alcohol wipes and sterile gloves.

PREPARE: Use a clean, clear workspace, ideally a table or bench top. Wear gloves. Remove the dressings from around the catheter site.

USE:

1. If required attach the connector you require to the luer lock.
2. If required close the clamp.
3. Remove cap from IPC catheter by rotating anti-clockwise and pulling gently.

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4. Clean valve with an alcohol wipe.
5. Attach drainage line to the collection or flushing device i.e. Underwater Seal Drain, Ambulatory Bag or syringe.
6. Remove the access tip cover, from the drainage line, keep sterile. Connect drainage line to IPC catheter by gently inserting the access tip into the valve. You will feel a little resistance while you do this, which is normal.
7. If you have closed the clamp, unclamp drainage line.
8. Monitor patient and if draining fluid - monitor the amount, colour and consistency of the fluid drained.
9. If flushing the catheter, ensure you are using a suitable material such as an anti-fibrinolytic.
10. When drainage complete, take the drainage line in one hand and the catheter valve in the other. Rotate the drainage line anti clockwise and slowly pull the access tip out of the valve in a smooth motion.
11. Use a **new alcohol wipe** to gently clean around the outside of the valve.
12. Take a **new** catheter valve cap and rotate it clockwise until it clicks into position.

Disposal: This device should be handled and disposed of in accordance with policy of the healthcare setting and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment.

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