Product Name(s): Rocket IPC Removal Kit - R54400-00-RK

ZDOCK306 Rev. 06

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NE38 9BZ, UK

EC REP

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Suite 6, 157 Gordon Street,
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NSW 2444. Australia

Product Name: Rocket™ IPC Dressing Pack Removal Kit

Product Code: R54400-00-RK

Device Image:

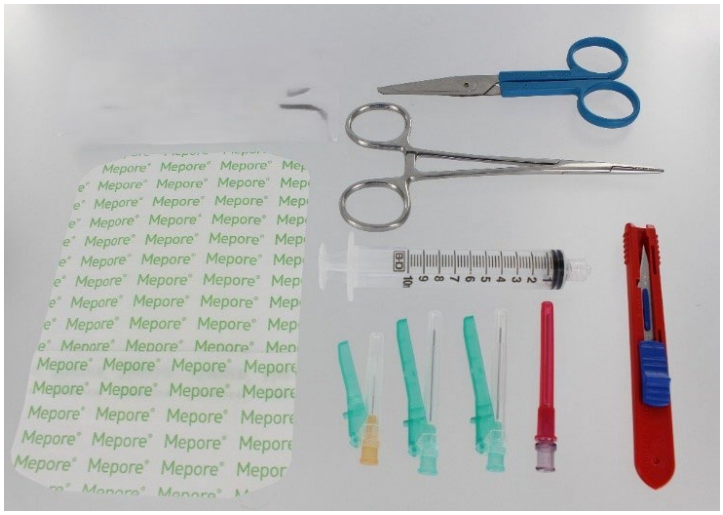


Image 1: R54400-00-RK Product Image

Device Contents: Check you have the full contents of the kit prior to use.

DEVICE REF	DEVICE NAME	QTY	LEGAL MANUFACTURER DETAILS
ZBAGS092	200mm x 350mm Uncoated Tyvek	1	**ROCKET MEDICAL PLC** Sedling Road, Washington, NE38 9BZ, UK www.rocketmedical.com CE 1639
ZBAGS133	75mm x 150mm Uncoated Tyvek	1	**Westfield Medical ltd.** Second Avenue Westfield Industrial Estate, Midsomer Norton, Radstock, Somerset, England, BA3 4DP https://www.westmed.co.uk/contact-us/
ZNDLE150	Microlance 21g 1.5" Ndle Green	2	**Mediq Healthcare UK Ltd,** Meridian Business Park, 29 Centurion Way, Leicester LE19 1WH, https://mediq.co.uk/
ZNDLE176	18g Blunt Fill Needle & Filter	1	**BD Medical,** 2153 12th Avenue, Columbus, NE 68601, USA, https://www.bd.com/en-uk
ZNDLE193	SOL -CARE Safety Needle 25G x 1.5"	1	**SOL-MILLENNIUM MEDICAL INC.** 1735 North Brown Road, Suite 120, Lawrenceville, GA 30043, USA https://www.solm.com/en
ZSYRG015	10ml Luer Lock Syringe	1	**BD Medical,** 2153 12th Avenue, Columbus, NE 68601, USA, https://www.bd.com/en-uk
ZSCIS006	Miniblue Scissor Complete	1	**Lonjyfan Enterprise Corp,** 12F-1 , NO. 716 , CHUNG CHENG RD. , CHUNG HO CITY , TAIPEI HSIEN , 235 TAIWAN, R.O.C. (FAR EAST CENTURY PARK. L BUILDING) http://www.lonjyfan.com.tw/about%20lonjyfan.html

Intended Use: Catheter removal.

Indications: For removal of an IPC Catheter.

Contraindications: Not for removal of any other catheter.

Catheter removal procedures: There may be a time when there have been three successive attempts to drain fluid but less than 50ml has been removed

WARNING: *Warnings alert reader about a situation that, if not avoided, can result in death or serious injury. State what could happen to user/patient/other in frank wording e.g. 'burns', not 'severe injury'.*
Precautions Alerts reader about a situation that, if not avoided, can result in minor injury and are listed second.

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.

	This section must not be relocated to a lower position. *Information must be listed in order of descending risk.* *Include phthalates statement where phthalates are present in the device (see below).* *Include warnings or precautions for a medical device administering medicinal or biological products, including information that indicates any limitations or incompatibility in the type of substances to be delivered.* *Include warnings or precautions related to lack of maintenance or calibration that could result in inaccurate measurements, diagnostic results or therapeutic treatment or use.* *Include methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices.* *Cross-reference to service manual as applicable.* *For implantable devices, include any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions.*
Precaution:	This device is manufactured with natural rubber latex. (For further details please see 'POL12' at www.rocketmedical.com.).

Benefit Risk: The use of IPC Catheter & Accessories gives the physician the possibility intended for the intermittent, long-term drainage of symptomatic, recurrent, pleural effusion and peritoneal ascites and other procedures with benefits well established in the literature.

Bench testing, pre-clinical testing, and manufacturing activities have been performed to reduce risks of the device. For the identified hazards, it is considered that the actions performed to control and reduce the hazards, result in residual risks that are acceptable when weighed against the product benefits. Further, the actions taken to reduce the risks identified do not pose any additional risks in themselves.

Other manufacturers have placed similar devices in the market for many years without reporting any critical incidences. Because of this clinical evaluation, the conclusions are that the Rocket Medical IPC Catheter & Accessories can be indicated for intermittent, long-term drainage of symptomatic, recurrent, pleural effusion and peritoneal ascites. This can include malignant pleural effusion and ascites plus other recurrent effusions or ascites that do not respond to medical management of underlying disease. This also includes the palliation of dyspnoea due to pleural effusion and providing pleurodesis or the palliation of symptoms related to recurrent ascites.

Undesirable Side Effects: We have not identified any undesirable side effects.

Description of the device: The IPC Insertion & Accessories are apparatus intended to be used for the following specific medical purpose: indicated for intermittent, long-term drainage of symptomatic, recurrent, ascites, including malignant ascites and other ascites that do not respond to medical management of underlying disease.

Furthermore, the IPC Insertion & Accessories intended actions are not achieved by pharmacological, immunological or metabolic means. Since these devices are used as part of the treatment of disease and do not achieve their principal intended action is not achieved by pharmacological, immunological, or metabolic means, these appliances fall under the scope of the definition of a "medical device".

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 form the qualified professional. The intended patient demographics are adult male and female patients requiring pleural or peritoneal ascites drainage.

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

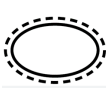
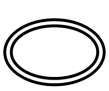
Environment: This device is for use in a clinical setting

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.

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.

Sterile: the device are 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.

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
	Authorized representative in the European Community/European Union		Keep dry
	Caution: Federal law restricts this device to sale by or on the order of a physician.		Temperature limit
	Date of manufacture		Do not re-use
	Use-by date		Consult the instructions for use
	Batch code		Caution
	Catalogue number		Contains or presence of natural rubber latex
	Serial number		Does not contain natural rubber latex
	Sterilized using ethylene oxide	 ***Remove any phthalates that do not apply***	Contains or presence of phthalate
	Sterilized using irradiation		Non-pyrogenic
	Sterilized using steam or dry heat		Medical device
	Do not resterilise		Do not use if package is damaged and consult instructions for use
	Non-sterile		Single sterile barrier system
	Single sterile barrier system with protective packaging outside		Double sterile barrier system

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.

	Distributor		Importer

Operating Instructions:
CHECK: do not use if the packaging is open or damaged *(for sterile devices only)* or the device is damaged. Ensure you have the full contents of the kit before use.

USE:

1. The patient should be placed in the supine position.
2. Aseptically clean around the catheter site on the patient's chest.
3. Anaesthetise the site, and remove the sutures if they are still present.
4. Dissect around the catheter cuff using forceps to break it free from the in-growth of tissue. The cuff must be completely free before proceeding.
5. Holding the catheter in one hand, pull the catheter slowly with a firm, constant pressure.
6. If the catheter begins to significantly stretch, recheck to ensure the cuff is loose
7. Cover the catheter site as appropriate.

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

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.

