

Indwelling Peritoneal Catheter (IPC) Insertion Kit

ZDOCK249 Rev. 13

Language
en

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ROCKET MEDICAL PLC
Sedling Road, Washington,
NE38 9BZ, UK

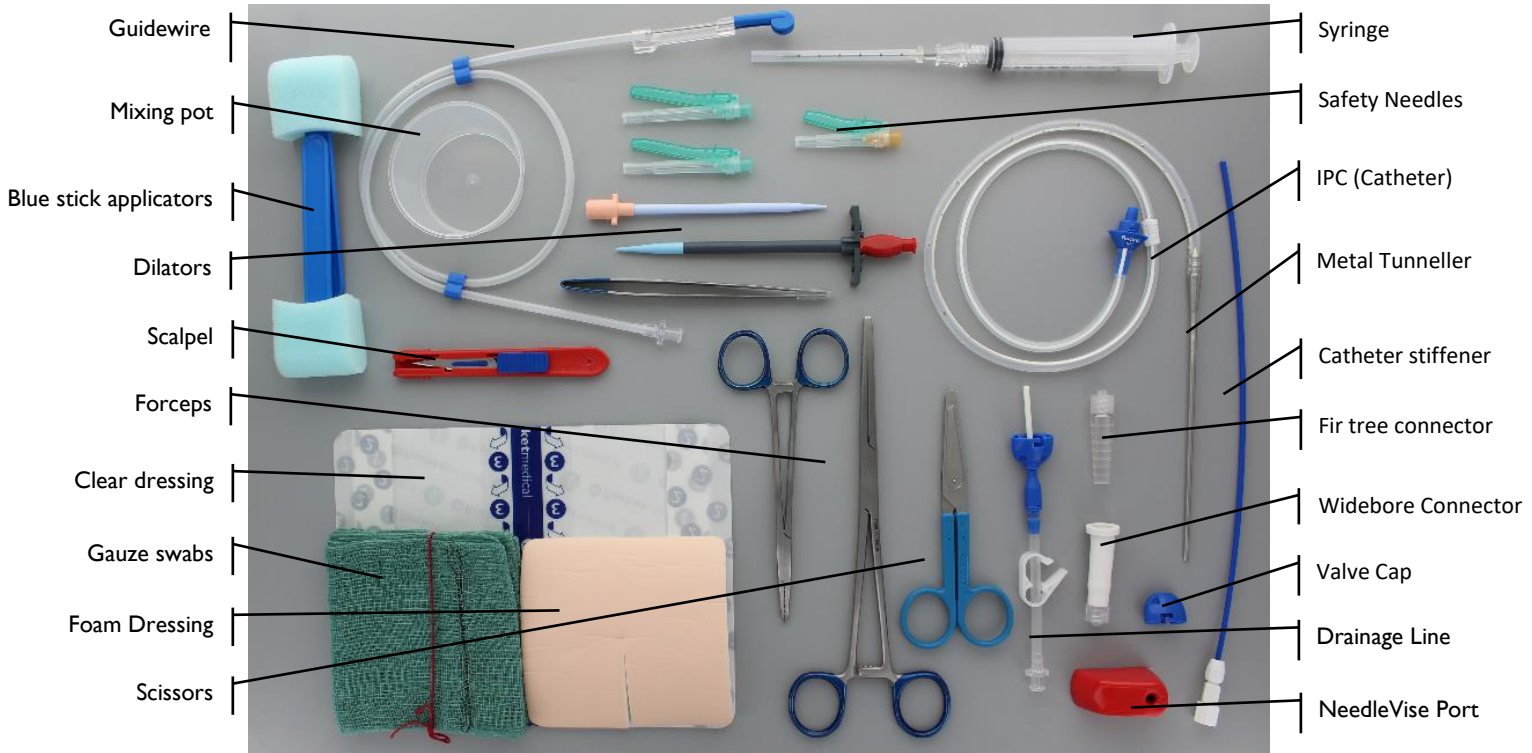
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Product Name: IPC Insertion Kits


Procedure Pack Product Code(s):

R54400-16-MT Rocket IPC Pleural or Peritoneal Catheter Insertion Set with Metal Tunneller
R54400-MINI Rocket IPC Mini Insertion Kit

Device Image:



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

DEVICE REF	DEVICE NAME	QTY	LEGAL MANUFACTURER DETAILS
ZPACK002 (Only in R54400-16-MT)	IPC Catheter	1	 ROCKET MEDICAL PLC Sedling Road, Washington, England, NE38 9BZ www.rocketmedical.com (CE 2797)
	IPC Catheter Stiffener	1	
	IPC Drainage Line	1	
	IPC Catheter Cap	1	
	Male Luer Connector	1	
	Clear Dressing	1	
	Polyurethane Foam dressing	1	
	Disposable Gloves	1	
	Suture Forcep	1	
	Needle Holder	1	
	8" Rochester Pean Forceps	1	
	Wide Bore Connector	1	
	Stepped Male Luer	1	
	14fg Dilator	1	
	16Fg Tear Away Dilator	1	
	18G Needle	1	
	NeedleVise Port	1	
	Mixing Pot	1	
	Scissors	1	
	Blue Stick Applicators	2	
Gauze Swabs	5		
Guidewire	1		

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.

ZPACK004 (for R54400-MINI)	IPC Catheter	1	ROCKET MEDICAL PLC Sedling Road, Washington, England, NE38 9BZ www.rocketmedical.com (CE 2797)
	IPC Drainage Line	1	
	IPC Catheter Cap	1	
	Clear Dressing	1	
	Polyurethane Foam dressing	1	
	8" Rochester Pean Forceps	1	
	Stepped Male Luer	1	
	16Fg Tear Away Dilator	1	
	18G Needle	1	
	Guidewire	1	
ZBLAD019 (Only in R54400-16-MT)	No 11 Blade Safety Scalpel	1	SWANN MORTON LIMITED , Owlerton Green, Sheffield, S6 2BJ, UK (CE 2797, UKCA 0086)
ZPAPR051 (Only in R54400-16-MT)	Adhesive Drape Sheet	2	MEDLINE INTERNATIONAL, FRANCE SAS , 5 Rue Charles Lindbergh, 44110, Chateaubriant, France (CE)
ZPAPR052 (Only in R54400-16-MT)	Adhesive Aperture Drape 2 Piece	2	
ZNDLE193 (Only in R54400-16-MT)	25G x 1.5" Safety Needle	1	SOL-MILLENNIUM MEDICAL INC. , 1735 North Brown Road, Suite 120, Lawrenceville, GA 30043, USA (CE 2797)
ZNDLE150 (Only in R54400-16-MT)	21G x 1.5" Safety Needle	2	BECTON DICKINSON S.A. , Ctra. Mequinenza, s/n, 22520 – Fraga, HUESCA – ESPAÑA (CE 0318)
ZSYRG015 (Only in R54400-MINI)	10ml Luer Lock Syringe	1	
ZSYRG021 (Only in R54400-16-MT)	20ml Syringe Male Luer Lock	1	

Intended Use: The Rocket Indwelling Peritoneal Catheter (IPC) is a fenestrated silicone catheter with a barium sulphate stripe through its length. There is a polyester cuff for attachment to the patient with a one-way valve whilst under negative pressure for attachment to the patient that remains closed to prevent air or fluid passing through, this valve can only be operated by the specifically designed drainage line and drainage products supplied by Rocket Medical Plc.

Indications: The Rocket IPC Insertion Kit is 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. The device is also indicated for the palliation of symptoms related to recurrent malignant ascites.

Contraindications: Use of the Rocket IPC Drainage system is contraindicated in the following situations:

- If the peritoneal cavity is multi-loculated, and the drainage of a single loculation would not be expected to provide relief from any symptoms.
- If the peritoneal cavity is infected.
- When there is a coagulopathy.
- When the ascites is known to be chylous.

WARNING:	Exercise caution when inserting the needle. Consider Ultrasound guidance to minimise risk of puncture or laceration to the liver or bowel.
WARNING:	Avoid cutting or occluding the catheter by exercising caution when placing suture.
WARNING:	Do not attempt to use anything other than the drainage lines and bottles recommended by Rocket Medical Plc to operate the valve as this could damage the valve. A damaged valve may not function correctly and could let air into the patient's chest or fluid leak out from the catheter.

Benefit Risk: Rocket Medical plc has taken all necessary steps to ensure that residual risks associated with the use of IPC Catheter & Accessories are reduced as far as possible through application of existing state of the art techniques in the design and manufacture of these medical devices to ensure safe usage. Rocket Medical plc concludes that the overall medical benefits of IPC Catheter & Accessories, outweigh the possible risks when used according to the intended use.

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.

Undesirable Side Effects:

- Peritonitis
- Leakage from catheter site
- Mild cellulitis
- Catheter related infection
- Drain dislodgement
- Localized bruising
- Mild pain
- Catheter obstruction or blockage
- The loss of electrolytes, immune factors or proteins
- Tract metastases seeding

Description of the Device: Kit provides all necessary equipment as shown in “device contents” to safely insert the IPC catheter into the patient to allow intermittent, long-term drainage of symptomatic, recurrent, ascites, including malignant ascites and other ascites that do not respond to medical management of underlying disease.

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 the qualified professional.

Proper instruction must be given to the patient(s) and/or carer on how to use the kit to drain the peritoneal 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.

Environment: clinical setting with close access to sharps bin e.g. within 2 metres.

For Single Patient Use Only: intended to be used multiple times by one patient only. Use by other patients may result in cross-contamination and infection with transmissible diseases.

Sterile: the devices 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.





















MRI Safety: This device is not intended to be routinely found in an MRI environment and compatibility has not been verified. However, the only metal used in the construction of the device is present to facilitate imaging and the type and quantity is well evidenced to be safe to use with MRI.

General Information:

- Do not attempt to use anything other than the drainage lines and bottles recommended by Rocket Medical Plc to operate the valve as this could damage the valve. A damaged valve may not function correctly and could let air into the patient's chest or fluid leak out from the catheter.
- The device has a bespoke one-way valve whilst under negative pressure that prevents air or fluid passing through; this valve can only be operated by the specifically designed drainage line and drainage products supplied by Rocket Medical.
- Refer to “Operating Instructions” for device connectivity to accessories and drainage devices.
- The IPC can stay in situ while the patient undergoes chemotherapy

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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		Keep dry
	Date of manufacture		Do not re-use
	Use-by date		US: Federal law prohibits dispensing without prescription
	Importer		Consult the instructions for use
	Batch code		Caution
	Catalogue number		Does not contain natural rubber latex
	Sterilized using ethylene oxide		Medical device
	Do not re-sterilize		Indicates a medical device that should not be used if the package has been damaged or opened
	Single sterile barrier system		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 (see 'Device Contents')

PREPARE: The insertion of the device requires understanding of tunnelling and Seldinger techniques.

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USE:

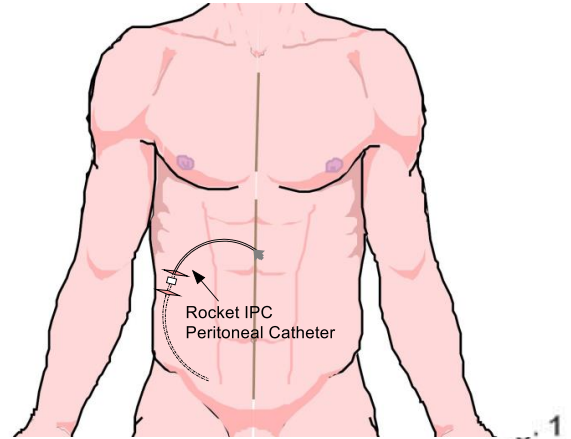
Recommended Placement Procedure:

Proper medical and surgical procedures are the responsibility of the physician. The appropriateness of any procedure must be based upon the needs of the patient. **Fig 1** illustrates the placement of the Rocket IPC, as described in the following procedure.

1. Assess the patient carefully to determine the length of catheter required.

The fenestrated length of the catheter supplied is 25cm. This may be reduced by cutting through the fenestrated part of the catheter only with sterile scissors prior to insertion. Ensure that a suitable length remains in the peritoneum after the cuff has been positioned correctly in the subcutaneous tunnel. Prior to insertion, ensure that no loose fragments of catheter material remain at the cut edge.

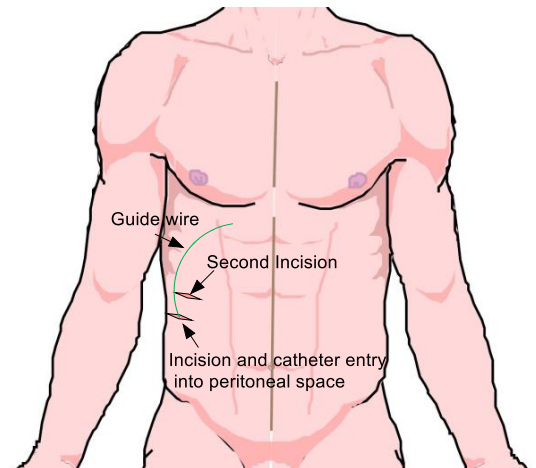
2. It is recommended that the patient is placed suitably as to access the desired insertion site. The insertion site is similar to non-tunnelled paracentesis typically in the right flank, 6-10cm below the costal margin, and above the patient's belt line.
3. Identify the insertion site for the planned catheter placement, aseptically clean the insertion site area.
4. Place the fenestrated drape over the insertion and tunnelling site.
5. Anaesthetise the insertion site and the course of the tunnelling.
6. Take the 10ml syringe with the 18G needle attached, insert obliquely through the abdominal wall at the identified insertion site ensuring free aspiration of ascitic fluid.



Exercise caution when inserting the needle.

Consider Ultrasound guidance to minimize the risk of puncture or laceration to the liver or bowel.

7. Make a 1cm incision through the guide wire insertion site.
8. Remove the syringe but leave the 18G needle in place. Insert the guidewire through the needle and into the peritoneal cavity.
9. Leaving the guide wire in place, remove the needle. If no longer needed place needle in the port of the NeedleWISE needle safety device.
10. At approximately 5cm away from the guide wire site make a 1cm incision through which the catheter will exit the skin.
11. If needed use the blunt dissection forceps and create a tunnel from the second incision up to the guidewire incision site. Take the tunneller and the catheter and pass from the second incision to and out of the guide wire incision site. Draw the catheter through the channel until the catheter cuff passes approx. 2-3cm into the track. (This will be pulled back later so that it is no more than 1cm from the incision site).

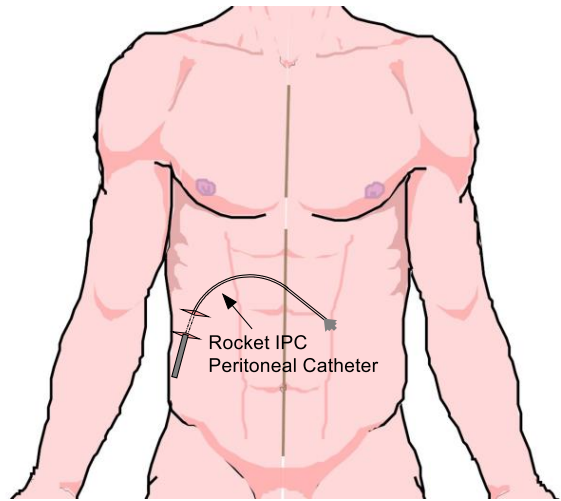


Caution: If using additional instruments, use rubber-shod instruments to eliminate the risk of cutting or tearing the catheter.

12. Cut the tunneller off the catheter.

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13. Take the I6FG tearaway sheath/dilator and pass it over the guide wire into the peritoneal space to a depth no longer than the I8G needle. Caution should be taken when inserting the dilator so that it is not pushed in its full length as this could puncture other organs.
14. Once in position, remove the guidewire.
15. Remove the dilator and guidewire together ensuring that the sheath stays in position. As you remove the dilator place your thumb over the end of the sheath to restrict fluid coming out.
16. Take the fenestrated end of the catheter, remove your thumb from the end of the sheath and place the catheter into the sheath while advancing it in to the peritoneal cavity. Taking care to keep the catheter in position within the peritoneal space, begin to gently peel away and remove the



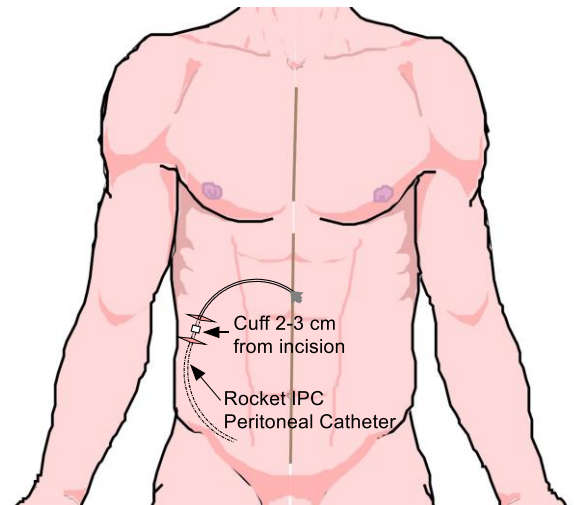
Try to place the catheter towards the pelvis for best drainage.

sheath. The fenestrations are placed along the barium sulphate stripe so that this can be verified under fluoroscopy if needed.

To support the catheter during difficult insertions through the split sheath dilator, fully insert the stylet into the catheter through the proximal fenestration to the cuff. Remove the stylet once all fenestrations have been inserted into the split sheath.

17. Now gently pull the catheter back so that the cuff lies no more than 1cm beyond the incision line, this should adjust the catheter within the tunnel so it lies flat and without kinks as it passes from one incision to another.
18. Close the incision at the guide wire and dilator insertion site. It is important that there is no restriction of the catheter.

Caution: Avoid cutting or occluding the catheter by exercising caution when placing sutures.



How to use the Swann Morton Safety Scalpel.

1. Grasp the scalpel and carefully extend the blade by moving the slide toward the tip of the scalpel, using the thumb of the hand holding the scalpel.
2. Extend the slider until you reach the positive stop, the slider will fit in the notch when it is completely extended.
3. To retract the blade, grasp the scalpel carefully and move the slide toward the back of the scalpel, using the hand holding the scalpel.
4. You should feel clicks as the blade is retracted and a positive stop once the blade is completely retracted.
5. To retract the blade permanently, move the slider past the notch at the back of the scalpel.
6. Dispose of the Swann Morton Retractable Disposable Scalpel in a puncture resistant container approved for sharps disposal, or in a manner consistent with your hospital procedure.

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.

Replacement Catheter Valve: Should a catheter valve malfunction or the catheter is in for a long period of time a replacement valve can be purchased. The R54400-00-VV replacement catheter valve pack has all the components required for valve replacement.

Caution: Replacement valves should only be replaced by a medical professional.

Catheter removal procedures: If there have been three or four successive attempts to drain fluid but less than 15ml has been removed. This may indicate one of the following:

1. The area has been drained to dryness.
2. The catheter is loculated away from the fluid
3. The catheter has become occluded

It may therefore be necessary to remove the catheter by using the following method:

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. Grasping the catheter in one hand, pull the catheter slowly with a firm, constant pressure.
6. Cover the catheter site as appropriate.

Additional Supplies:

Description	Stock code
Rocket IPC Dressing Pack & Bag	R54401
Rocket IPC Valve Cap	R54410-00-CP
Rocket IPC Drainage Line	R54410-00-DL
Rocket IPC Replacement Catheter Valve	R54410-00-VV
Rocket IPC Split Sheath Introducer (17cm long)	R54410-16-17
Rocket IPC Split Sheath Introducer (11cm long)	R54410-16-11

Expected Device Lifetime: 6 months.

Follow-up: Recurring drainage will take place as required by the healthcare provider

Disposal: This device, its accessories and the consumables used with it, 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 and safety and care of the environment. Failure to do so may increase the risks of infection or other microbial hazards. Take care when handling sharps, to avoid needlestick injuries. Ensure sharps are disposed of in sharps containers

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