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1 Abbreviations

Table 1 - Abbreviations

Abbreviation	Definition
CER	Clinical Evaluation Report
EUDAMED	European Database on Medical Devices
FDA	US Food and Drug Administration
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
IFU	Instructions for Use
IPC	Indwelling Pleural/Peritoneal Catheter
LTAD	Long-term Abdominal Drainage
LVP	Large-volume Paracentesis
MA	Malignant Ascites
MDCG	Medical Device Coordination Group
MDD	MDD Directive 93/42/EEC
MDR	Medical Device Regulations
MPE	Malignant Pleural Effusion
NB	Notified Body
PMCF	Post-Market Clinical Follow Up
SSCP	Summary of Safety and Clinical Performance

2 Introduction

This SSCP is not intended to replace the Instruction for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

This SSCP is divided in two (2) parts: The following information is intended for healthcare professionals. Following this information there is a summary intended for patients.

3 Background

This SSCP for the target devices has been prepared in accordance with:

- EU Regulation 2017/745 as amended and consolidated (inclusive of the amendment effected by EU REGULATION 2020/561).
- Medical Device Coordination Group (MDCG) 2019-9 Summary of safety and clinical performance. A guide for manufacturers and Notified Bodies.

The SSCP is a living document that shall be uploaded in EUDAMED and will be updated in parallel with the updates of the Post-market Clinical Follow-up (PMCF) Evaluation Report and the Periodic Safety Update Report (PSUR) to reflect that all clinical and/or safety information in the SSCP remains up-to-date and aligned with relevant documents of the Technical Documentation of the device (i.e. the Clinical Evaluation Report (CER) and the IFU).

4 Device identification and general information

4.1 Device trade name(s)

Table 2 – Device trade names

Reference Code	Device Name
R54400-16-MT	Rocket IPC Pleural or Peritoneal Catheter Insertion Set with Metal Tunneller
R54400-16-MI	Rocket Post VAT's Insertion Set
R54400-MINI	Rocket IPC Mini Insertion Kit

Table 3 – Accessory trade names

Reference Code	Device Name
R54410-00-CP	Rocket IPC Replacement Valve Cap
R54410-00-DL	Rocket IPC Drainage Line
R54410-DL-LX	Rocket IPC Extended Drainage Line
R54410-WB-DL	Rocket IPC Drainage Line with Wide Bore Connector
R54410-00-VV	Rocket IPC Replacement Valve
R54410-16-11	Rocket IPC Split Sheath Dilator 16G x 11cm
R54410-16-17	Rocket IPC Split Sheath Dilator 16G x 17cm

4.2 Device classification

The IPC catheter are class IIb implantable devices based on the European Classification System.

4.3 Market history of the target device

The IPC Catheter and Accessories were first CE marked and placed on the market in Europe in 2007. At this time Rocket Medical used a peroxide cured catheter. Since then, the device has been modified to a platinum cured catheter which is a fenestrated silicone catheter with a barium sulfate stripe. This came in to production in 2021. This is identical to the Rocket Indwelling Pleural Catheter which has been in clinical use in the European Union since November 2007 and the United States since 2013. There is no physical difference between the two catheters; only the clinical indications (implant locations) and labelling are different. Identical materials, processes, facilities and equipment, and trained personnel are used to manufacture. MDSAP certification was achieved in November 2019.

The first CE mark for the peroxide cured catheter was issued by SGS in 2007.
The device is being sold in the following countries under the following brand names:

United Kingdom	IPC Long Term Indwelling Catheters
EU	IPC Long Term Indwelling Catheters
Australia	Pleural/Peritoneal cavity drain insertion set
Canada	Rocket IPC Sets
New Zealand	Pleural/Peritoneal Catheter Insertion Set
USA	Rocket IPC System

The first CE mark for IPC Platinum cured catheter was issued by SGS in 2021.
The device is being sold in the following territories under the following brand names:

United Kingdom	IPC Long Term Indwelling Catheters
EU	IPC Long Term Indwelling Catheters
Australia	Pleural/Peritoneal cavity drain insertion set
Canada	Rocket IPC Sets
New Zealand	Pleural/Peritoneal Catheter Insertion Set
USA	Rocket IPC System

4.4 Legal Manufacturer

The legal manufacturer of the devices encompassed by this Technical File is:

Rocket Medical PLC.
Sedling Road,
Washington,
Tyne and Wear,
NE38 9BZ,
UK
(SRN) GB-MF-000025375

Rocket Medical Plc is also the System/Procedure Pack Producer.

4.5 Authorized representative

The following entity has been appointed as the legal manufacturer's European Union (EU) Authorised Representative.

Rocket Medical GmbH
Am Rosengarten 48
15566 Schöneiche
Germany
(SRN) DE-AR-000011752

Other economic operators:

Importer

The following entity has been appointed as the legal manufacturer's Importer of the devices into the EU:

Rocket Medical GmbH
Am Rosengarten 48
15566 Schöneiche
Germany

Physical manufacturer

The devices encompassed by this Technical File are manufactured and assembled by Rocket Medical Plc at Rocket Medical PLC, Sedling Road, Washington, Tyne and Wear, NE38 9BZ UK.

4.6 Basic UDI-DI

The Basic Unique Device Identification-Device Identifier (UDI-DI) is a code to unambiguously identify a device in the distribution chain. It is the primary identifier of a device model and is composed of a unique numeric or alphanumeric code. The UDI-DI for the *IPC Catheter is* "TF_R013a" for Pleural Use & "TF_R013b" for Peritoneal Use.

4.7 Notified body

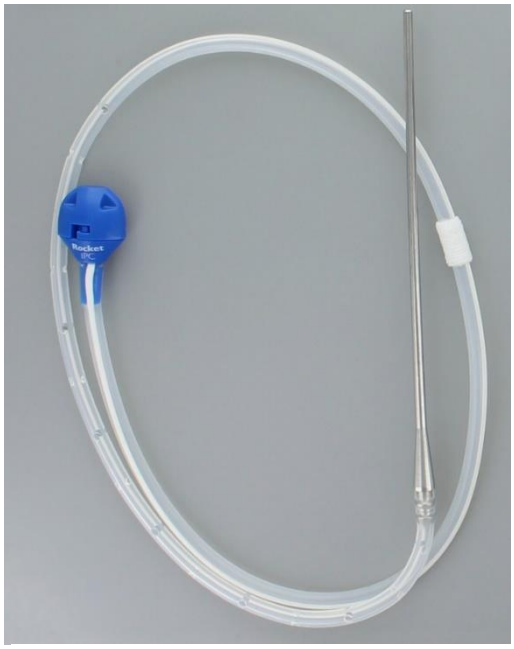
Notified Body Name: BSI Group the Netherlands B.V.
Notified Body Address:
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands
T: +31 (0)20 346 07 80
Notified Body Identification Number: 2797

5 Labelling statements

5.1 Intended purpose

Pleural

The Rocket Indwelling Pleural 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 and a silicone valve that remains closed to prevent air or fluid from passing through, this valve can only be operated by the specifically designed drainage products supplied by Rocket Medical plc.



IPC Catheter with IPC valve cap attached

Peritoneal

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.

5.2 Indication(s)

Plural

The Rocket IPC Insertion Kit is indicated for intermittent, long-term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of underlying disease.

The devices are indicated for:

- The palliation of dyspnoea due to pleural effusion
- Providing pleurodesis (resolution of the pleural effusion)

Peritoneal

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.

5.3 Contraindications

Pleural

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

- When there is a shift ≥ 2cm in the mediastinum towards the ipsilateral side of the effusion.
- When the pleural space is multi-loculated, and the drainage of a single loculation would not be expected to provide relief of dyspnoea.
- When there is a coagulopathy.
- When the pleural space is infected.
- When the effusion is known to be chylous

Peritoneal

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.

5.4 Intended target population

The intended user is a healthcare professional proficient in the undertaking of pleural or 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.

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

5.5 Intended lifetime of the device(s)

The lifetime of the device is six months.

5.6 Intended clinical benefit of the device(s)

The clinical benefits of the devices are listed below. The references to support these claims can be found in table 4:

- To palliate dyspnoea due to pleural effusion
- To provide pleurodesis
- To palliate symptoms related to recurrent ascites

Table 4 – Key references to support clinical benefits

Clinical benefit	References	Title
Pleural Drainage		
To palliate dyspnoea due to pleural effusion	Davies et al, 2012.	Effect of an Indwelling Pleural Catheter vs Chest Tube and Talc Pleurodesis for Relieving Dyspnea in Patients with Malignant Pleural Effusion The TIME2 Randomized Controlled Trial
	Muruganadan et al, 2018.	Aggressive versus symptom-guided drainage of malignant pleural effusion via indwelling pleural catheters (AMPLE-2): an open-label randomised trial
To provide pleurodesis	Davies et al, 2012.	Effect of an Indwelling Pleural Catheter vs Chest Tube and Talc Pleurodesis for Relieving Dyspnea in Patients with Malignant Pleural Effusion The TIME2 Randomized Controlled Trial

	Muruganadan et al, 2018.	Aggressive versus symptom-guided drainage of malignant pleural effusion via indwelling pleural catheters (AMPLE-2): an open-label randomised trial
Peritoneal drainage		
To palliate symptoms related to recurrent ascites	Macken et al, 2020	Randomised clinical trial: palliative long-term abdominal drains vs large-volume paracentesis in refractory ascites due to cirrhosis

Dyspnoea palliation

In the TIME2 unblinded, randomised controlled trial, Davies *et al*, compared the impact on dyspnoea in patients with malignant pleural effusion, following either insertion and use of a Rocket IPC or talc slurry pleurodesis. Patients were recruited from 7 UK hospitals. 54 patients were randomised to the talc group and 52 to the IPC group. The interventions involved use of the Rocket IPCs and drainage bottle. These components are intended for use together. Patients, relatives, or community nurses were trained in IPC management, to allow for regular drainage at the patient's home.

Patients completed a daily visual analogue scale (VAS) of dyspnoea. Dyspnoea improved in both groups, with no significant difference after 42 days. The IPC group had a mean VAS dyspnoea score of 24.7 (95% CI, 19.3-30.1mm) and the talc group, a mean score of 24,4mm (95% CI, 19.4-29.4mm). There was a statistically significant improvement in dyspnoea in the IPC group at 6 months, with a mean difference in VAS score between the IPC group and the talc group of −14.0 mm (95% CI, −25.2 to −2.8 mm; P=0.01). (Davies *et al*, 2012).

The study showed pleural drainage with a Rocket IPC is as effective as treatment with talc pleurodesis at palliating symptoms and relieving patient-reported dyspnoea, the primary goal of the treatment.

In the AMPLE-2 randomised, open-label randomised trial, Muruganadan *et al* compared daily versus symptom-guided drainage using a Rocket IPC and vacuum drainage bottles in patients with malignant pleural effusions. Patients kept a logbook of their breathlessness score recorded every day for 60 days and then weekly until the end of the study. The breathlessness score was measured by use of a validated 100 mm visual analogue scale (VAS), a 100 mm line anchored with "best breathing" at 0 mm and "worst breathing imaginable" at 100 mm. The breathlessness of the patients involved improved compared to their base readings, although there was no significant difference between the two groups. The trial showed that both methods of drainage (aggressive and symptom-guided) are sufficient to alleviate breathlessness (Muruganadan *et al*, 2018).

Provide pleurodesis

In the TIME2 unblinded, randomised controlled trial, Davies *et al*, compared the impact on dyspnoea in patients with malignant pleural effusion, following either insertion and use of a Rocket IPC or talc slurry pleurodesis. The mean IPC drainage frequency in the first 42 days was twice weekly. Twenty-nine of 51 patients (57%) had their IPCs removed; however, 6% required further pleural intervention. There was therefore a 51% spontaneous pleurodesis rate in the IPC group (Davies et al, 2012).

In the AMPLE-2 randomised, open-label randomised trial, Muruganadan *et al* compared daily versus symptom-guided drainage using a Rocket IPC and vacuum drainage bottles in patients with malignant pleural effusions. More patients in the daily drainage group developed spontaneous pleurodesis than in the symptom-guided group in the first 60 days (37.2% vs 11.4%, p=0.0049) and at 6 months (44.2% vs 15.9%, p=0.004; hazard ratio 3.287 [95% CI 1.396–7.740]; p=0.0065) (Muruganadan *et al*, 2018). As both patient groups were using the Rocket device the data supports the claim that the device can provide pleurodesis.

Palliation of ascites-related symptoms

In the REDUCe study, Macken *et al* performed a nonblinded randomised controlled trial, to compare large-volume paracentesis (LVP) versus long-term abdominal drains (LTAD) using Rocket Medical IPCs, in refractory ascites due to end-stage liver disease. 36 patients were randomised: 17 to LTAD and 19 to LVP.

There were no IPC-related serious adverse events and none had to be removed after insertion due to complications. It was noted from interviews that ascites drainage in both groups provided temporary relief from symptoms (Macken, *et al*, 2020).

6 Device description

The IPC Insertion Set, comprises sterile, single patient use components that have been developed to provide a means of allowing the insertion of a 16Fg cuffed catheter via a combined Seldinger and tunnelled catheter technique. The catheter should enter the pleural space or peritoneum to facilitate the drainage of effusion or ascites.

The insertion of the IPC device should only be performed by, or under the supervision of, appropriately trained personnel and in conjunction with current local clinical practice guidelines.

The IPC Catheter is implanted into the patients pleural or peritoneal cavity depending on where the drainage is necessary. A metal tunneller, sheath dilator and guidewire allow the catheter to be placed into position with ease so that it can be secured.

Once in situ, the drainage of fluid from the affected pleural space or peritoneum can be achieved via the catheter using the pre-evacuated Rocket Drainage Bottle or Drainage Bag. The fluid collection vessels are for single use and are only in situ for the immediate drainage of fluid.

The catheter is either directly inserted and locked to the catheter with the valve fitting, or using the drainage line with the luer locking mechanism connected. The silicone valve remains closed to prevent air or fluid from passing through, this valve can only be operated by the specifically designed drainage products supplied by Rocket Medical plc. The pre-evacuated drainage device will create a vacuum to start the drainage through the catheter and into the container. Once the container is full, the drainage controls are used to prevent more fluid being extracted so that the catheter can be disconnected and sealed via the IPC valve cap and secured to the patient using the included dressings.

Drainage should be performed regularly to relieve symptoms and should only minimally interfere with the patient's daily activities. Drainage can be performed safely at home, by the patient or caregiver once appropriate training has been given and competency achieved.

The Rocket IPC Insertion Kit and the Rocket IPC Dressing Pack and Bottle are intended for the intermittent, long-term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of underlying disease.

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.

The Rocket IPC Catheter is an implantable fenestrated silicone catheter with a barium sulfate stripe through its length. There is a polyester cuff for attachment to the patient. There is a one-way valve whilst under negative pressure for attachment to the patient; this valve can only be connected to the specifically designed drainage line and drainage products supplied by Rocket Medical.

The Rocket IPC is indicated for pleural and peritoneal drainage.

The IPC Insertion Sets (procedure packs) are available in 3 versions.

Table 5 – IPC insertion sets

Reference Code	Device Name
R54400-16-MT	Rocket IPC Insertion Set with Metal Tunneller
R54400-16-MI	Rocket IPC Post VATs Insertion Kit
R54400-MINI	Rocket Mini Insertion Kit

All 3 insertion sets utilize the same catheter assembly; however, they are supplied with differing components to assist with insertion.

Once *in situ*, the drainage of fluid from the affected pleural space or peritoneum can be achieved via the catheter using the pre-evacuated Rocket Drainage Bottle or Drainage Bag. The fluid collection vessels are for single use and are only in situ for the immediate drainage of fluid.

Table 6 – Fluid collection vessels

Reference Code	Device Name
R54400	Rocket IPC Dressing Pack & 500ml Bottle Set
R54401	Rocket IPC Dressing Pack & 2000ml Drainage Bag
R54410	Rocket IPC Pre-evacuated 500ml bottle
R54411	Rocket IPC 1000ml Bottle & Dressing Pack
R54411-00-00	Rocket IPC Pre-evacuated 1000ml Bottle

7 Risks and warnings

According to EU Regulation 2017/745, Art. 2 (23-24), 'risk' means the combination of the probability of occurrence of harm and the severity of that harm, while 'benefit-risk determination' means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer.

According to ISO 14971:2021, harm refers to physical injury or damage to the health of people, or damage to property or the environment. Therefore, 'risks' include both clinical and non-clinical harms.

The probability is estimated based on relevant historical data and clinical expertise/experience. Determination of the acceptability of the benefit-risk ratio is based on the comparison of risks of alternative treatment options for the same indication(s) and intended patient population, as well the evaluation of device-specific clinical data.

7.1 Residual risks and undesirable effects

According to ISO 14971:2019, the term 'residual risk', is defined as "risk remaining after risk control measures have been taken". If residual risks are not deemed acceptable, further risk control measures or modification of the device(s) or intended use may be considered. Alternatively, manufacturers may gather and review data and literature to determine if the benefits of the intended use outweigh the residual risk(s). There are no residual risks for the Rocket IPC Catheter and Accessories.

The insertion of an IPC is generally safe and well-tolerated. They can be placed as and outpatient procedure, with patients being discharged on the same day (Meier, Mortensen and Larsen, 2016 and Bhatnagar and Maskell, 2014). However, there are several potential undesirable side-effects resulting directly from the IPC, including early and long-term complications.

Pleural drainage

Early complications of IPC placement:

- *Pneumothorax* (1.1%) (Patil *et al*, 2016)
- *Subcutaneous emphysema* (1.1%) (Patil *et al*, 2016)
- *Pain* was reported for some patients a few days after the insertion. It is usually mild and resolves within 3 days after insertion. (35%) (Efthymiou, *et al,* 2009)
- *Drain dislodgement* (0.7-18%) (Chalhoub *et al*, 2018, Patil *et al*, 2016)
  Dislodgement may occur more readily if the polyester cuff is sited too close to the skin incision, or if the patient has persistent episodes of coughing or retching. (Bhatnagar & Maskell, 2014).
- A degree *of localized bruising* is expected in the region of the dissection track for a few days after insertion. (Bhatnagar & Maskell, 2014).
- *Cellulitis* can also occur in the skin around the catheter insertion site (3.4%) Van Meter *et al*, 2011).

Longer term complications:

- Pleural infections (2.8-4.9%) (Van Meter *et al*, 2011, Fysh *et al*, 2013). Rarely these may be fatal (0.29%) (Fysh *et al*, 2013).
- Local infections (1.3-3%) (Patil *et al*, 2016, Van Meter *et al*, 2011, Warren *et al*, 2008)
- Catheter obstruction or blockage can occur as a result of fibrinous exudates inside and around the catheter lumen (1.1-5%). (Chalhoub *et al*, 2018, Patil *et al*, 2016, Van Meter *et al*, 2011, Warren *et al*, 2008)
- Mechanical failure of IPCs (up to 2%). Van Meter *et al*, 2011
- Tract metastases seeding (<1%). Van Meter *et al*, 2011
- The loss of electrolytes and proteins has occasionally been raised as a concern of the long-term use of IPCs (Chalhoub *et al,* 2018).

Peritoneal drainage

- Possible complications include:
- Peritonitis (4.4%) (Fleming *et al,* 2009)
- Leakage from catheter site (6.8%)
- Mild cellulitis (0.9%) (Fleming *et al,* 2009)
- Catheter-related infection (5.9%) (Fleming *et al,* 2009)
- Drain dislodgement (5.4%) (Fleming *et al,* 2009)
- Localized bruising
- Mild pain
- Catheter obstruction or blockage (5.4%) (Fleming *et al,* 2009)
- The loss of electrolytes, immune factors or proteins – This has been raised occasionally as a concern during long term use of IPCs.
- Tract metastases seeding (<1%) (Fleming *et al,* 2009)

7.2 Warnings and precautions

Warnings - pleural use:

- Exercise caution when inserting the needle. Consider Ultrasound guidance to avoid puncturing the lung or sub diaphragmatic structures.
- Avoid cutting or occluding the catheter by exercising when placing suture.
- 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.

Cautions – pleural use:

- Exercise caution when inserting the needle. Consider Ultrasound guidance to avoid puncturing the lung or sub diaphragmatic structures
- If using additional instruments use rubber shod instruments to eliminate risk of cutting or tearing the catheter
- Do not pinch the sheath as this may cause it to kink and impede insertion of the silicone catheter
- Avoid cutting or occluding the catheter by exercising when placing suture.

Warnings - peritoneal use:

- Exercise caution when inserting the needle. Consider Ultrasound guidance to minimise risk of puncture or laceration to the liver or bowel.
- Avoid cutting or occluding the catheter by exercising when placing suture.
- 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.

Cautions – peritoneal use:

- Exercise caution when inserting the needle. Consider Ultrasound guidance to minimise risk of puncture or laceration to the liver or bowel.
- Caution if using additional instruments use rubber shod instruments to eliminate risk of cutting or tearing the catheter.
- Avoid cutting or occluding the catheter by exercising care when placing sutures
- Replacement valves should only be changed by a medical professional.

7.3 Other relevant safety issues

Data provided by the Legal Manufacturer and publicly accessible vigilance databases were searched to identify field safety corrective actions (FSCA), including field safety notices (FSN) for IPC Catheters and Accessories. There were no FSCAs during the period from 14 JUL 2017 – 13 JUL 2022 for the IPC Catheters and Accessories.

8 Summary of clinical evaluation and PMCF

8.1 Summary of clinical data related to equivalent device(s)

Rocket Medical does not claim equivalence for IPC Catheter and Accessories to any medical devices.

8.2 Summary of clinical data from clinical investigations, prior to CE marking

Rocket Medical has not conducted any clinical investigations prior to CE marking.

8.3 Summary of clinical data from other sources

Rocket Medical plc has performed a clinical evaluation and bench testing to support IPC Catheter & Accessories approvals and registrations. There is sufficient data available from its clinical use to demonstrate safety and performance.

The evaluation included a systematic literature review of published clinical data, risk management output, biocompatibility assessment, post-market surveillance data and benchtop testing.

Literature

A comprehensive literature search was conducted in accordance with a systematic literature review methodology. 12 articles were deemed to be high-quality where IPC devices were used, allowing the drainage of effusion or ascites. Among these articles, 5 were meta-analyses (Clive *et al*, 2016, Yeung *et al*, 2020, Kheir *et al*, 2016, Wang *et al*, 2020, Patil *et* al, 2017), 4 Randomised Controlled Clinical Trials (Davies *et al*, 2012, Muruganandan *et al*, 2018, Lentz *et al*, 2020, Macken *et al,* 2020), and 3 Randomised Clinical trials (Bhatnagar *et al*, *2018*, Thomas *et* al, 2017, Wahidi *et al,* 2017). Three out of 12 of these articles specifically use Rocket IPC insertion kit, including Rocket IPC drainage bottles, bags and dressing kits (Davies *et al*, 2012, Muruganandan *et al,* 2018, Macken *et* al, 2020). 2 of these articles used Rocket Indwelling Pleural Catheters (Davies *et al,* 2012, Muruganandan *et al,* 2018) and one of them used Indwelling Peritoneal Catheters (Macken *et al,* 2020). One article out of 12 mentions the use of Rocket Medical equipment (Thomas *et al,* 2017).

3 articles used Becton Dickinson PleurX (Bhatnagar *et al,* 2018, *Clive et al, 2016*, Wahidi *et al,* 2017). One article discussed gravity drainage using Safe-T-Centesis, BD attached to a drainage bag and vacuum drainage using a syringe, both for pleural drainage, helping support the use of the drainage bottles and bags for the treatment of pleural effusions (Lentz *et al,* 2020). The rest of the articles did not identify the IPC model or brand that was used for the clinical investigation (Yeung, *et al,* 2020, Kheir *et al,* 2016, Wang *et al,* 2020, Patil *et al,* 2017, Benmassaoud *et al,* 2020).

The patient population involved in this systematic literature search included patients suffering symptomatic, malignant and benign pleural effusions and refractory ascites. The performance of Rocket IPC insertion kit was evaluated considering their ability to drainage of effusion or ascites, as part of a safety measure currently used in patients with intermittent, long-term drainage of symptomatic, recurrent, pleural effusion and peritoneal ascites, including malignant pleural effusion and ascites and other recurrent effusions or ascites.

Dyspnoea improvement or palliation, improvement or palliation of symptoms, breathlessness relief, symptoms relief and pleurodesis were used as the performance outcome measures, present in the evaluated high-quality articles, that reflects Rocket IPC insertion kit's intended use.

In this systematic literature search, the safety of Rocket IPC insertion kit has been addressed by the reported adverse events in the clinical investigations. In all cases, the risk/limitations associated with the device usage were described when applicable.

The systematic literature search shows that pleural and peritoneal drainage by using IPCs has been performed over many years, and that these maintain its performance and safety. For this reason, the studies utilising Rocket IPC insertion kit can be used as pivotal data to directly evaluate clinical

performance and safety of the device since these data was generated directly from the device under evaluation according to its intended purpose.

Safety:

The appraised studies contributed to assessing the safety aspects of Rocket IPC insertion kit. The safety aspects of Rocket IPC insertion kit included serious and non-serious adverse events, overall ranging from 40-67% (Davies *et* al, 2012, Muruganandan *et al,* 2018). Deaths related to IPC intervention were reported in one metanalysis, representing 0.3% of the patients, which was attributed to severe sepsis secondary to empyema (Patil *et* al, 2017), whereas deaths caused by underlying medical conditions ranged from 3.9-86% in other 4 clinical investigations (Bhatnagar *et al,* 2018, Davies *et al,* 2012, Yeung *et al,* 2020, Clive *et al,* 2016). Infections ranged from 2.6 to 13.6% (Bhatnagar *et al,* 2018, Davies *et al,* 2012, Kheir *et al,* 2016, Muruganandan *et al,* 2018), pneumothorax 1.2 2.3- (Muruganandan *et al,* 2018, Patil *et al,* 2017, Thomas *et al,* 2017b) catheter obstruction or blockage 0.5-17.3% (Kheir *et al,* 2016, Bhatnagar *et al,* 2018, Davies *et al,* 2012b, Muruganandan *et al,* 2018, Patil *et al,* 2017, Thomas *et al,* 2017), pain 1.5-27.3 % (Davies *et al,* 2012, Thomas *et al,* 2017, Wang *et al,* 2020, Yeung *et al,* 2020), cellulitis 1.9-41 (Davies *et al,* 2012, Kheir *et al,* 2016, Macken *et al,* 2020, Muruganandan *et al,* 2018, Thomas *et al,* 2017) and empyema 2.3-6.7% (Kheir *et al,* 2016, Patil *et al,* 2017), no catheter migrations or fractures were reported.

Performance:

Regarding performance, from the studies that used of Rocket IPC insertion kit, success rates reported were 23% (Bhatnagar *et al,* 2018) while spontaneous pleurodesis reported was 51.3% (Patil *et al,* 2017). In addition, when compared to talc pleurodesis, IPC use reported higher or similar improvement in breathlessness when compared to talc (Clive *et al,* 2016, Thomas *et al,* 2017, Wang *et al,* 2020), improved dyspnoea at 6 months, fewer days in hospital (Thomas *et al,* 2017, Yeung *et al,* 2020), while reported similar survival (Wang *et al,* 2020), improvement in dyspnoea at first 42 days, quality of life (Davies *et al,* 2012, Thomas *et al,* 2017), pleurodesis (Yeung *et al,* 2020) and success rates (Kheir *et al,* 2016, Yeung *et al,* 2020). In a different comparison, IPC gravity drainage vs active aspiration reported no significant differences in volumes drained, while longer duration of drainage was reported for IPC gravity drainage (Lentz *et al,* 2020). Other studies compared daily versus symptomatic or standard (every other day) drainage using IPCs, in these studies, no difference was observed in breathlessness scores (Muruganandan *et al,* 2018), while significant differences were observed in generating spontaneous pleurodesis (Muruganandan *et al,* 2018, Wahidi *et al,* 2017). Similar or higher quality of life daily drainage was also reported (Muruganandan *et al,* 2018, Wahidi *et al,* 2017). In the last comparison, long-term abdominal drain group vs large-volume paracentesis group was compared, were quality of life scores increased in most domains in the LVP group and reduced in the LTAD group and total attrition was similar (Macken *et al,* 2020).

The findings in this report confirmed the safety and performance of IPC Catheter & Accessories when used under the conditions and for the purposes intended.

Risks associated with the use of IPCs can be extensively minimised by using a good technique and alignment with the current clinical guidelines. Many risks are not device-related but are direct complications of these underlying medical conditions that lead to a high mortality. These include pneumothorax, kidney failure, empyema and peritonitis. There are also several risks that have been associated with the device that should be addressed by hospitals as a matter of staff training, including device proper insertion and removal, to avoid risks as injuries, infections, catheter dislodgment, fracture and obstruction, among others.

No information was identified in the body of evidence to indicate any new safety issues in the clinical setting that were previously unknown. This body of evidence is representative of the intended population presenting with the intended indications for IPC Catheter & Accessories.

8.4 An overall summary of the clinical performance and safety

A determination of the level of clinical evidence required to demonstrate an indirect clinical benefit was made on the basis of a thorough risk assessment and evaluation of the clinical risks. The safety of IPC Catheter & Accessories, when used in combination with the adjunctive accessories, has been established.
The findings of the systematic literature review confirmed the safety and performance of IPC Catheter & Accessories when used under the conditions and for the purposes intended.

The results of the post-market surveillance data demonstrate that the benefits of the continuing usage of IPC Catheter & Accessories versus the potential risks are in favour when used for the listed clinical indications and in accordance with the IFU and published Clinical Practice Guidelines.

No residual risks have been identified in the Risk Assessment or other risks, associated with the treatment of intermittent, long-term drainage of symptomatic, recurrent, pleural effusion and peritoneal ascites, including malignant pleural effusion and ascites and other recurrent effusions or ascites that do not respond to medical management of underlying disease, and for the palliation of dyspnoea due to pleural effusion and providing pleurodesis or the palliation of symptoms related to recurrent ascites. Risks cannot be mitigated further and are considered acceptable when weighed against the benefits to the patient. All harms have been defined with their potential causes of failure and associated mitigation activities.

IPC Catheter & Accessories IFUs and Datasheets clearly demonstrate the safe usage of the device, and mandatory physician training or supervision by trained personnel ensures all users are fully conversant with all aspects of device use.

The Rocket IPC is considered to have met the requirements of ISO 10993-1 and the European Union Medical Device Directive 93/42/EEC for an implanted device with permanent contact with tissue and can be considered safe 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, and also the palliation of symptoms related to recurrent malignant ascites.

Indirect clinical benefits were demonstrable by technical performance. Bench-top testing confirmed that IPC Catheter & Accessories performs well throughout the lifespan when subjected to the stresses, which can occur during normal conditions of use. This includes testing to demonstrate similar performance to competitor devices already on the market.

In conclusion, it has been shown that there is sufficient evidence to establish the safety and performance of the IPC Catheter & Accessories when used in accordance with their Instructions of Use (IFU). The data are adequate to assess the benefits and risks associated with the subject device, concluding that the benefit-risk profile is acceptable. Therefore, this clinical evaluation demonstrates that the available clinical data are sufficient to establish conformity with all applicable General Safety and Performance Requirements (Annex I) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) and confirm the safety and performance of IPC Catheter & Accessories. With this Clinical Evaluation, IPC Catheter & Accessories has been confirmed to be within the current state-of-the-art practice.

8.5 Ongoing or planned post-market clinical follow-up

A literature review and clinician survey are planned to assess whether the device design is adequate to meet the needs of patients with a high BMI.

9 Possible diagnostic or therapeutic alternatives

Alternatives to drainage via IPC are summarised below, according to clinical condition.

Malignant pleural effusion

Additional options for the management of patients with Malignant Pleural Effusion (MPE) include:

- Thoracentesis (drainage using a small-bore catheter).
- Pleurodesis using a chemical agent (e.g., tetracycline, doxycycline and bleomycin, talc).
- Surgical options (mechanical pleurodesis at surgery, pleurectomy).

Current guidelines recommend the treatment of MPE via talc pleurodesis or IPC drainage. Both procedures are highly effective and significantly improve symptoms.

Talc pleurodesis requires more days of hospitalisation than the treatment with IPCs (1 day for IPCs versus 6.5 days for talc pleurodesis). On the other hand, IPCs are associated with a modest increase in adverse events with long-term use (Bibby et al., 2018).

Talc pleurodesis is expected to be successful around 70–80% of the time, however, the recurrence of the disease (accumulation of pleural fluid) in this type of patient is common (Bibby et al., 2018). Pain is a common side effect of talc pleurodesis, by causing inflammation and irritation of the pleura (Clive et al, 2016), which can therefore lead to chronic pain in patients, reducing quality of life.
Surgical options for MPE include talc poudrage (see above), pleurectomy and abrasion pleurodesis. Pleurectomy/abrasion pleurodesis success rates are not significantly different than talc pleurodesis, however the hospital stay and the mortality rate were reported to be lower in the case of other surgical procedures (*e.g.,* abrasion) rather than talc pleurodesis (Bibby et al., 2018).

Thoracentesis also remains a surgical option for ascites and effusion treatment, which involves removal of fluid/air from the pleural or peritoneal cavities. Although, thoracentesis requires repeat trips to hospital, which can take up a large proportion of patient's time, which is vital to consider, especially during end-of-life care, for example, if the patient is struggling with MPEs.

A further risk of thoracentesis treatment is increased chance of loculation, in which fibrotic scar tissue may develop, preventing effective drainage of the fluid (Bhatnagar et al, 2018).

Non-malignant pleural effusion
Effusions from non-malignant causes are common, however, there is relatively little information regarding the use of IPCs in these situations, with limited data only beginning to emerge in the last years (Bhatnagar & Maskell, 2014).

A study compared non-malignant and malignant patients treated with IPCs. IPC was effective in achieving pleurodesis in all patients, had a low rate of catheter-related complications and high satisfaction scores. (Harris & Chalhoub, 2011).

Ascites
The management of ascites patients depends on the type and recurrence of the ascites, but overall, there are several treatments:

- Large-volume paracentesis is the standard treatment for patients with advanced scarring and medically untreatable ascites (Macken et al., 2020). The excess fluid is removed from the peritoneal cavity via a needle and aspiration technique (Knight et al., 2018). Paracentesis has been shown to provide relief of symptoms in up to 90% of patients, however, requires repeated hospital visits, repeated punctures and a small but serious risk of secondary peritonitis, bowel perforation, hypotension, and haemorrhage (De Gottardi et al., 2009; Markman, 2012).

- Pharmacological treatment: spironolactone, furosemide, aldosterone antagonist plus furosemide, albumin, diuretics and salt restriction, antibiotics in case of bacterial cause etc) (EASL, 2010).
- Permanent indwelling peritoneal catheters are an accepted strategy in the palliation of recurrent malignant ascites in the case of patients with end-stage liver disease presenting refractory ascites (90%) (Macken et al., 2020).

IPCs are relatively easily placed and can be an effective alternative to other malignant ascites (MA) management options. Once they are placed, the patient can manage their own ascites symptoms at home and do not require repeat hospitalisation (Narayanan et al., 2014). IPC use has a high success rate in terms of the palliation and low incidence of complications which, coupled with the reduced impact on hospital resource, makes it a good management option for MA (Knight et al., 2018).

10 Suggested profile and training for users

The intended user is a healthcare professional proficient in the undertaking of pleural or ascites drainage, working in accordance with local and national guidelines.
The user should be proficient in the use of ultrasound, seldinger and tunnelling techniques.

11 Reference to any harmonized standards and common specifications applied

The following standards are applicable to the devices:

Table 7 - List of applicable harmonized standards for the IPC catheter devices

STANDARD	TITLE
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971: 2012	Medical devices – Application of risk management to medical devices
ISO 14971: 2019	Medical devices — Application of risk management to medical devices
EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 14937:2009	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)

EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices Part 6: Tests for local effects after implantation
EN ISO 10993-7:2008	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2013	Biological evaluation of medical devices. Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
EN ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
ISO 11135:2014+A1:2019	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018+A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

EN 868-5:2018	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous materials and plastic film construction. Requirements and test methods
BS EN ISO 7886-1:2018	Sterile hypodermic syringes for single use Part 1: Syringes for manual use
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments. Classification of air cleanliness by particle concentration
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments — Part 3: Test methods
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments. Operations
EN 1617:1997	Sterile drainage catheters and accessory devices for single use
EN ISO 14155:2020	Clinical investigation of Medical Devices for human subjects — Good clinical practice

12 Revision history

Table 8 – Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1		New document	☐ Yes Validation Language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
			☐ Yes Validation Language: ☐ No

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SSCP INTENDED FOR PATIENTS AND/OR LAY PERSONS

Table of Contents

1 Introduction

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the target device(s). The information presented below is intended for patients and/or lay persons. A more extensive summary of its safety and clinical performance prepared for licensed healthcare professionals (doctors) is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your doctor in case you have questions about your medical condition or about the use of the device(s) in your situation. This SSCP is not intended to replace an implant card or the Instructions For Use (IFU) to provide information on the safe use of the device.

2 Device identification and general information

2.1 Device trade name(s)

Reference Code	Device Name
R54400-16-MT	Rocket IPC Pleural or Peritoneal Catheter Insertion Set with Metal Tunneller
R54400-16-MI	Rocket Post VAT's Insertion Set
R54400-MINI	Rocket IPC Mini Insertion Kit
R54410-00-CP	Rocket IPC Replacement Valve Cap
R54410-00-DL	Rocket IPC Drainage Line
R54410-DL-LX	Rocket IPC Extended Drainage Line
R54410-WB-DL	Rocket IPC Drainage Line with Wide Bore Connector
R54410-00-VV	Rocket IPC Replacement Valve
R54410-16-11	Rocket IPC Split Sheath Dilator 16G x 11cm
R54410-16-17	Rocket IPC Split Sheath Dilator 16G x 17cm

2.2 Manufacturer

The legal manufacturer of the IPC Catheter and Accessories is:

Rocket Medical PLC.
Sedling Road,
Washington,
Tyne and Wear,
NE38 9BZ,
UK

2.3 Basic UDI-DI

The Basic Unique Device Identification-Device Identifier (UDI-DI) is a code to identify a device in the distribution chain. It is the primary identifier of a device model and is composed of a unique numeric or alphanumeric code.
The UDI-DI for the IPC Catheter is "TF_R013a" for Pleural Use & "TF_R013b" for Peritoneal Use.

2.4 Year when the device was first CE-marked

Certain medical devices must be marked with a special 'CE' logo to be sold within the EU. This CE mark:

- shows that the manufacturer has checked that the medical device(s) meet EU safety, health, or environmental requirements.
- shows that the medical device(s) meets EU laws.
- allows the free movement of medical devices within the EU market.

The first IPC catheter used a peroxide cured catheter and was issued by SGS in 2007.
The device is being sold in the following countries under the following brand names:

United Kingdom	IPC Long Term Indwelling Catheters
EU	IPC Long Term Indwelling Catheters
Australia	Pleural/Peritoneal cavity drain insertion set
Canada	Rocket IPC Sets
New Zealand	Pleural/Peritoneal Catheter Insertion Set
USA	Rocket IPC System

The CE mark was updated for a new IPC catheter using a platinum cured catheter and was issued by SGS in 2021.
The device is being sold in the following territories under the following brand names:

United Kingdom	IPC Long Term Indwelling Catheters
EU	IPC Long Term Indwelling Catheters
Australia	Pleural/Peritoneal cavity drain insertion set
Canada	Rocket IPC Sets
New Zealand	Pleural/Peritoneal Catheter Insertion Set
USA	Rocket IPC System

2.5 What is the device used for?

The Rocket Indwelling Pleural Catheter (IPC) is a catheter that allows the long-term drainage of excess fluid that has built up around the lungs (pleural effusion), or fluid that has built up in the peritoneal cavity (peritoneal ascites), and which keeps recurring following medical treatment and is causing symptoms. The catheter does this by being implanted in the chest/abdominal wall, so that fluid can be drained through it.

When used to drain pleural effusion, the Rocket IPC Kit us used to help reduce shortness of breath (dyspnoea) and to help resolve the pleural effusion (pleurodesis).

When used to drain abdominal ascites, the Rocket IPC Kit is used to help to reduce symptoms associated with the presence of the fluid.

A typical initial IPC drainage frequency might be 3 times per week, with later adjustments based upon drainage volumes and symptoms. With normal drainage lasting around 15 min, you can maintain a high quality of life without significant disruption to home life.

2.6 When is the device used?

Pleural Effusion

The chest contains a double-layered membrane called the pleura. These membranes make pleural fluid, which allow the lungs to move smoothly when breathing. If fluid builds up between these layers, this is called pleural effusion. Pleural effusion may occur due to a lung infection, cancer (including lung, breast and ovarian cancer, lymphoma and mesothelioma), heart failure, rheumatoid arthritis, SLE (systemic lupus erythematosis) or liver cirrhosis. Some patients with pleural effusion may have no symptoms. In other cases, patients may have symptoms including chest pain, a cough, shortness of breath (dyspnea) or orthopnea (difficulty breathing unless upright in a sitting or standing position).

Pleural effusion can be diagnosed via chest x-ray, CT, ultrasound, thoracentesis (when a biopsy or fluid sample is collected using a needle from between the ribs) or analysis of a sample of pleural fluid.

Treatment depends on the underlying condition and the severity of symptoms, for example, if dyspnea is present or there is difficulty breathing. Small effusions may be observed to see if they resolve. Larger effusions require drainage, for example via thoracentesis using a needle, or via a chest drain. If these reoccur treatment options include the insertion of an IPC catheter for long term-drainage, pleurodesis (using talc to seal the pleura together) or thoracoscopy (using a thorascope with a camera and light source to locate and then drain the fluid).

Peritoneal Ascites

The abdomen contains a double-layered membrane called the peritoneum. This makes ascitic fluid, which allows the abdominal organs to move smoothly over each other. If fluid builds up between the two layers this is termed ascites. Ascites can arise due to cancer, advanced liver disease and heart failure. The main symptom of ascites is abdominal bloating and associated discomfort. The patient may become nauseous, have loss of appetite, indigestion, constipation, dyspnea and may become fatigued and weak.

Removal of ascites relieves symptoms and improved patient comfort. This may take place in a hospital a day case, or if a recurrent problem, may be undertaken via IPC, to provide a long-term drainage option. It is also possible to treat recurrent ascites via a peritovenous shunt, which drains the fluid away from the peritoneum into a large vein.

2.7 Who is the device meant for?

The device is meant to be used for adult patients requiring pleural drainage or peritoneal ascites drainage.

2.8 When should the device not be used?

There are some situations in which the device(s) should not be used. These are known as contraindications.

Pleural Drainage

- When the part of your chest that contains the heart, major blood vessels, trachea and oesophagus move from their normal position.
- When the fluid is contained in small compartments called loculations, and the loculation is not large enough to allow the IPC catheter to drain enough fluid to reduce your breathlessness.
- When your blood thinners may cause an issue
- When you have an infection in your pleural space.
- When the collection of fluid is not pleural fluid, but chyle, which is a milky fluid from the lymph.

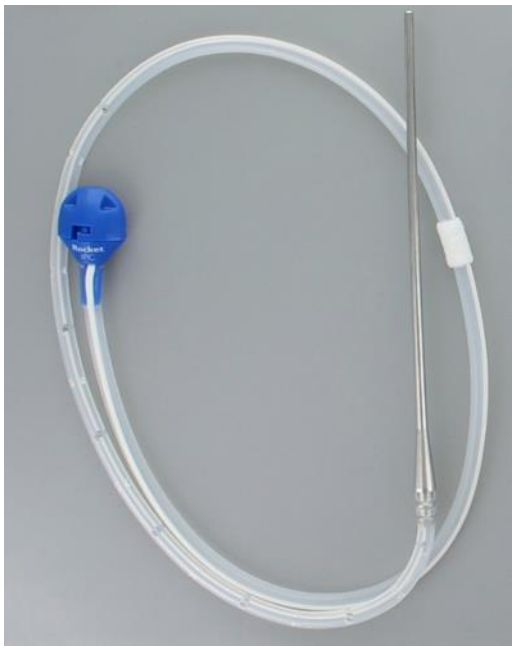
Peritoneal Drainage

- When the fluid is contained in small compartments called loculations, and the loculation is not large enough to drain enough to allow the IPC catheter to drain enough fluid to reduce your symptoms.
- When your abdomen has an infection
- When your blood thinners may cause an issue
- When the collection of fluid is not ascitic fluid, but chyle, which is a milky fluid from the lymph

If you are not sure whether there is anything that may prevent you from safely using the devices you should discuss this with your healthcare professional.

2.9 Device description

The Rocket IPC Catheter is an implantable silicone catheter. It has a polyester cuff for attachment to the patient. It has a one-way valve which can only be connected to the specifically designed drainage line and drainage products supplied by Rocket Medical.



IPC Catheter with IPC valve cap attached

The IPC Insertion Set, comprises sterile, single patient use components that have been developed to provide a means to insert the catheter into the pleural space or peritoneum to allow the drainage of effusion or ascites.

The implantation of the IPC device should only be performed your doctor, who has the qualifications, expertise and knowledge needed to perform the procedure. Once inserted, the catheter can remain in place for up to six months. The catheter can remain in place if you require chemotherapy.

Drainage of fluid can be achieved via the catheter by connecting the Rocket Drainage Bottle or Drainage Bag. The fluid collection vessels are for single use.

Drainage takes only a few minutes. Once the container is full the drainage controls are used to prevent more fluid being extracted so that the catheter can be disconnected and sealed using the IPC valve cap. Dressings are provided to hold the catheter in position when not in use.

Drainage should be performed regularly to relieve symptoms and should only minimally interfere with your daily activities. Drainage can be performed safely at home, by you or caregiver once appropriate training has been provided and competency achieved.

Ask your healthcare professional for more information on pleural effusion and drainage systems.

2.10 Risks and warnings

Contact your healthcare professional (HCP) (doctor/nurse/pharmacist) if you believe that you are experiencing side-effects related to the devices or its use or if you are worried about risks. This document is not meant to replace an appointment with your healthcare professional, if needed.

Your doctor should be qualified by appropriate training and be familiar with the implant system and trained on its use. If you or your caregivers will be managing drainage at home following catheter placement, you will be provided with training before use.

2.11 How potential risks have been controlled or managed

All medical devices are associated with risks. A risk is a possible harm, which is determined by how likely it is and how serious the harm would be. How likely the harm is to occur is estimated by clinical experts and by seeing how many times it has happened before. If risks are found, actions are taken by the device manufacturer to make them less likely or less harmful. The risk of using a medical device is acceptable if the benefit of using the medical device is determined to be higher than the risk.

2.12 Remaining (residual) risks and undesirable effects

Remaining (or 'residual') risks are possible harms that could still happen even after actions have been taken to make risks as rare as possible. These risks might be accepted if they are unlikely and the benefit of using the medical device(s) is greater than the possible risk.

Following an assessment of risks and risk mitigation, there are no residual risks associated with the IPC Catheter and Accessories.

Side-effects (undesirable effects)

The insertion of an IPC is generally safe and well-tolerated. They can be placed as and outpatient procedure.

There are several potential side-effects (undesirable side-effects) resulting from the IPC:

Pleural Drainage

Early complications of IPC placement:

- Pneumothorax (1.1%) – This is a collection of air in the space around the lungs.
- Subcutaneous emphysema (1.1%) – This is air in the tissue around the insertion site of the catheter.
- Mild pain – This can be caused by the insertion process and can be treated with oral pain killers, if it does not resolve within a few days consult your doctor or nurse.
- Drain dislodgement (0.7-18%) – if the cuff is showing or the catheter comes out. This can occur at any time.
- Localized bruising – this can be caused by the insertion process, if it does not resolve with a few days consult your doctor or nurse.
- Cellulitis is an infection of the skin around the catheter site (3.4%). This can occur at any time.
- Longer term complications:
- Pleural infections (2.8-4.9%)– this is an infection of the space the around your lungs the catheter is placed in. Rarely these may be fatal (0.29%)
- Local infections (1.3-3%) – This is an infection of the insertion site
- Catheter obstruction or blockage can occur as a result of fibrinous exudates inside and around the catheter lumen (1.1-5%) – This happens if the catheter collects particles called fibrin which can cause the catheter to block
- Mechanical failure of IPCs (up to 2%). - If the catheter was to fracture or the valve to break.
- Tract metastases seeding (<1%). - If you have a tumour in the pleural space, the tumour can sometimes grow in to where the catheter was inserted in to the pleural space
- The loss of electrolytes and proteins has occasionally been raised as a concern of the long-term use of IPCs.

Peritoneal Drainage

Possible complications include:

- Peritonitis (4.4%) - Infection of the abdomen where your catheter is placed.
- Leakage from catheter site (6.8%) - When the catheter is placed, fluid can sometimes leak from around the site.
- Mild cellulitis (0.9%) - This is an infection of the skin around insertion site.
- Catheter-related infection (5.9%) - This is an infection caused by the catheter being in place.

- Drain dislodgement (5.4%) if the cuff is showing or the catheter comes out.
- Localized bruising - This can be caused by the insertion process, if it does not resolve with a few days consult your doctor or nurse.
- Mild pain - This can be caused by the insertion process and can be treated with oral pain killers, if it does not resolve within a few days consult your doctor or nurse.
- Catheter obstruction or blockage (5.4%) – This happens if the catheter collects particles called fibrin which can cause the catheter to block.
- The loss of electrolytes, immune factors or proteins – This has been raised occasionally as a concern during long term use of IPCs.
- Tract metastases seeding (<1%). If you have a tumour in the peritoneum space, the tumour can sometimes grow in to where the catheter was inserted in to the peritoneal space.

Contact your healthcare professional (HCP) (doctor/nurse/pharmacist) immediately if you experience shortness of breath, difficulty draining fluid, a high temperature or other signs of infection. You should also seek help if the catheter becomes dislodged or damaged. Pain is usually mild and resolves within 3 days following insertion. It can usually be managed using over the counter medication, but if pain becomes severe, or goes on for longer than expected, please contact your healthcare professional.

2.13 Warnings and precautions

You and your caregivers should be aware of the following warnings and cautions, which are applicable to use of the device following insertion. Other warnings and cautions apply during catheter placement and your clinician has been provided with these in the device Instructions for Use:

Pleural Drainage

Warnings

- 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 your chest or cause fluid to leak out from the catheter.

Peritoneal Drainage

Warnings

- 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 your chest or cause fluid to leak out from the catheter.

Cautions

- Replacement valves should only be changed by a medical professional.

2.14 Summary of any field safety corrective action, (FSCA including FSN) (if applicable)

A Field Safety Corrective Action (FSCA) is an action taken by a manufacturer to report any reason leading to the device being changed or recalled from the market so that it cannot be bought and used. Once taken off the market, any problems can be safely fixed before the device is sold again.

There were no FSCAs during the period from 12 JUL 2017- 13 JUL 2022 for the IPC Catheter and Accessories.

2.15 Summary of clinical evaluation and PMCF

2.15.1 Clinical background of the device - history of the device when used in patients

The use of indwelling pleural catheters is well-established, with the first devices being introduced in 1997. Peritoneal use was introduced in 2005.

The Rocket IPC catheter was first introduced in 2007. For further information, please see section 2.4,

2.15.2 The clinical evidence for the CE-marking of the devices

The benefits of the Rocket IPC Catheter and Accessories are:

- To reduce breathlessness (dyspnoea) due to pleural effusion
- To provide resolution of the pleural effusion (pleurodesis)
- To reduce symptoms related to recurrent abdominal ascites

Reduction of breathlessness

In one clinical study (the TIME2 study), two groups of patients with a pleural effusion due to cancer were either treated with a Rocket IPC or with another technique which uses the introduction of talc into the pleural space to induce inflammation, which may help to resolve the effusion. There was a reduction in breathlessness in both groups. After 42 days both groups achieved the same reduction in breathlessness; however, there was a reduction in breathless for the IPC group compared to the talc group after 6 months.

In another study (the AMPLE-2 study), two groups of patients with a pleural effusion due to cancer were treated using a Rocket IPC and vacuum drainage bottles. Patients kept a logbook of their breathlessness score every day for 60 days and then weekly until the end of the study. The breathlessness of the patients improved compared to their base readings, although there was no difference in breathlessness between the two groups. The trial showed that both methods of drainage were sufficient to alleviate breathlessness.

Provide pleurodesis

In the TIME2 study, there was therefore a 51% spontaneous pleurodesis rate in those patients treated using a Rocket IPC catheter.

In the AMPLE-2 study, more patients in the daily drainage group achieved resolution of the effusion than in the symptom-guided group in the first 60 days and at 6 months. As both patient groups were using the Rocket device the data supports the claim that the device can provide pleurodesis.

Palliation of ascites-related symptoms

A clinical study called the REDUCEe study compared two groups of patients with ascites due to end-stage liver disease. One was treated using a technique called large-volume paracentesis (LVP), and the other was treated using long-term abdominal drainage (LTAD) using Rocket Medical IPCs.

There were no serious adverse events due to the use of the IPC. No IPCs had to be removed early due to complications. In interviews both groups confirmed that their treatment provided them with temporary relief from their symptoms.

2.15.3 Safety of the devices

The current knowledge / state of the art on the safety and performance of pleural and peritoneal catheter insertion for the drainage of effusion or ascites was derived from the collective clinical data available for relevant and established similar benchmark devices. In total, 12 scientific publications were identified through a systematic literature search. This included 3 papers which referred to the use of the Rocket Medical catheter specifically.
Data and information from these sources contributed to the assessment of clinical safety and performance.

The devices and their similar devices have shown:

- To palliate breathlessness (dyspnoea) due to pleural effusion
- To provide resolution of the effusion (pleurodesis)
- To palliate symptoms related to recurrent ascites

The available information on the target devices derived from various sources is consistent with the state of the art, i.e. with what is being done to manage pleural effusion with other medical devices or other treatment options

Adverse events associated with the use of the device and their respective occurrences have been identified from scientific literature and available post-market data and include pain, bruising, pleural, peritoneal or local infection, cellulitis, catheter dislodgement, mechanical failure (including leakage and fracture), pneumothorax, subcutaneous emphysema and tract metastases.

All have been assessed and are covered by an established risk management process. It was confirmed that all risks are acceptable when weighed against the benefits. Continued analysis of post-market surveillance data, including data collected through post-market clinical follow-up activities, will provide evidence for the ongoing assessment of safety and performance of the devices.

Based on the existing clinical evidence, it is confirmed that the devices are safe and perform as intended when used according to the manufacturer's Instructions for Use and labelling.

3 Possible alternatives to the device

The Rocket IPC Catheter and Accessories are used in IPC procedures for the long-term drainage of pleural effusion or peritoneal ascites which is causing symptoms and which recurs.

For patients with pleural effusion arising due to cancer, alternative treatment options to IPC include:

- Thoracentesis – a small, temporary catheter or needle is inserted into the chest, and fluid is drained
- Pleurodesis using a chemical agent, which is introduced into the pleural cavity to create an inflammatory response to allow the pleura to join together so that the fluid does not return
- Surgery

For patients with pleural effusion which has not arisen due to cancer, alternative treatment options are:

- The use of medicines such as diuretics, which help you to pass water, and
- Thoracentesis.

For patients with peritoneal ascites, there are several alternatives to IPC:

- Large volume paracentesis – a needle is inserted into the peritoneal cavity, and the ascites drained away, to provide temporary relief of symptoms in up to 90% of patients
- Treatment with medication

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation. The choice of the treatment depends on your overall health and the conditions of injury.

4 Suggested training for users

Your healthcare professional is the primary intended user of the devices. Your doctor should be qualified by appropriate training and be familiar with the implant system and trained on its use.

IPCs offer long-term symptom control via regular home drainage of fluid. Therefore, it is possible that once they are placed, you may be given the option to manage your own drainage and symptoms at home. In such cases, training will be provided to you or your caregiver, before beginning treatment.

Ask your healthcare professional to train yourself, relatives, community nurses or other home carers before they start drainage at home.