Rocketmedical

Product Names: Thoracic Catheters – Straight Pull Through, Angled Pull Through, Straight Flared, Angled Flared

CE 1639

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

EC REP **ROCKET MEDICAL GmbH**
Am Rosengarten 48,
15566 Schöneiche,
Germany

ROCKET MEDICAL GmbH
Am Rosengarten 48,
15566 Schöneiche,
Germany

ROCKET MEDICAL LLC
50 Corporate Park Drive #890,
East Pembroke, MA, 02359,
USA

Australian Sponsor: **ROCKET MEDICAL PTY LTD**
Suite 209, 1 Katherine Street,
Chatswood, NSW 2067 Australia

THORACIC CATHETERS
INSTRUCTIONS FOR USE

Rocketmedical (en)

Product Names: Thoracic Catheters – Straight Pull Through, Angled Pull Through, Straight Flared, Angled Flared

Product Codes: R34691, R34694, R34700, R34701, R34704, R34706, R34708, R34747, R34750, R34756, R34760, R34762, R34764, R34770, R34790, R34800, R34804, R34806, R34808, R34854, R34856, R60503, R60505, R60509, R60560

Device Image:

Intended Use: Rocket Medical Thoracic Catheters are intended for the intersitation of a chest tube for drainage of air and/or fluid (including blood) within the pleural space during cardiothoracic surgery or when using the blunt dissection technique. The intended patient demographics are adult and paediatric patients whose pleural and intercostal space has been clinically assessed as being able to accommodate a 14Fg catheter or larger.

Indications: The Rocket Medical Thoracic Catheters (Flared and Pull Through) are indicated for patients undergoing cardiothoracic surgery and requiring drainage of air and/or fluid (including blood) from the pleural space.

The Rocket Medical Flared Thoracic Catheters (20Fg and above) are also indicated for patients requiring large bore drainage of air and/or fluid (including blood) from the pleural space.

Contraindications: None identified.

WARNING: Do not apply more than 180kPa of thoracic suction to the chest tube (catheter will collapse and drainage will cease).

Precaution: **Potential for DEHP Exposure from use of this device.** DEHP may leach from this device, which may cause reproductive harm in male neonates, pregnant women carrying male fetuses, and peripubertal males. The extent of exposure largely depends upon the medical treatments administered and the duration of the treatment. Studies in rodents have shown that DEHP causes liver, testicular, and developmental effects at 18.6 P. Because certain animal models may not apply to humans, these studies utilize mice and rat, however So-called-ness of DEHP in the human body differs to the mechanism observed in these animals. These studies have shown effects at levels far in excess of normal human exposure. (For further details please see 510(k)S at www.rocketmedical.com.)

Benefit Risk: No benefit/risk has been performed as all residual risk scores are rated as acceptable.

Performance Claims and Clinical Benefit: The Thoracic catheters act as a conduit between the pleural space and the chest drainage unit, allowing the drainage of air and/or fluid following cardiothoracic surgery or following blunt dissection.

Undesirable Side Effects: Infection, Surgical Emphysema

Description of the device: Chest tube manufactured from PVC, with fenestrations and a barium stripe to the indicated French gauge size. Supplied with a flared end or pull through end, with a connector if required.

User: The intended user is a healthcare professional/proficient is the undertaking of cardiothoracic surgery or the blunt dissection technique, working in accordance with local and national guidelines.

Patient Population: The intended patient demographics are adult and paediatric patients whose pleural and intercostal space has been clinically assessed as being able to accommodate a 14Fg catheter or larger.

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

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Environment: This device is intended to be used in a sterile field.

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

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

MRI Safety: MRI compatibility has not been verified.

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
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician.		Keep dry
	Date of manufacture		Do not re-use
	Use-by date		Consult the instructions for use
LOT	Batch code		Caution
REF	Catalogue number	LATEX	Does not contain natural rubber latex
STERILE EO	Sterilised using ethylene oxide	DEHP	Contains or presence of phthalates
	Do not resterilise	MD	Medical device
	Single sterile barrier system with protective packaging outside		Do not use if package is damaged and consult instructions for use
	Single sterile barrier system	EC REP	Authorised representative in the European Community/European Union.
	Distributor		Importer

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

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Operating Instructions:

USE:

1. Unwrap the catheter, if in an operating theatre use standard protocol for this.
2. Insert the catheter into the pleural space. If in a surgical scenario use a suitable technique. If inserting via blunt dissection use a suitable technique.
3. If using a pull through catheter, insert the catheter into the pleural space by creating a track in the chest wall to pass through. Then pass a suture through the yellow moulded end of the catheter, thread through the track in the chest wall and pull the thoracic catheter into position so the drainage fenestrations remain inside the pleural space, or place forceps through the aforementioned track, grip the yellow moulded end of the catheter and pull into position. Remove the yellow moulded end by cutting it off.
4. Connect the catheter to the chest drainage collection device.
5. Secure the catheter to the chest using a fixation device or suitable suture technique.
6. X-ray the patient to ensure the correct position of the catheter

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 & safety and care of the environment.