

**Product Name: Rocket Seldinger Chest Drain Kits**

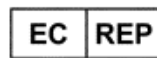
**ZDOCK180 Rev. 23**

**Language**  
en

**Page**  
2-4



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



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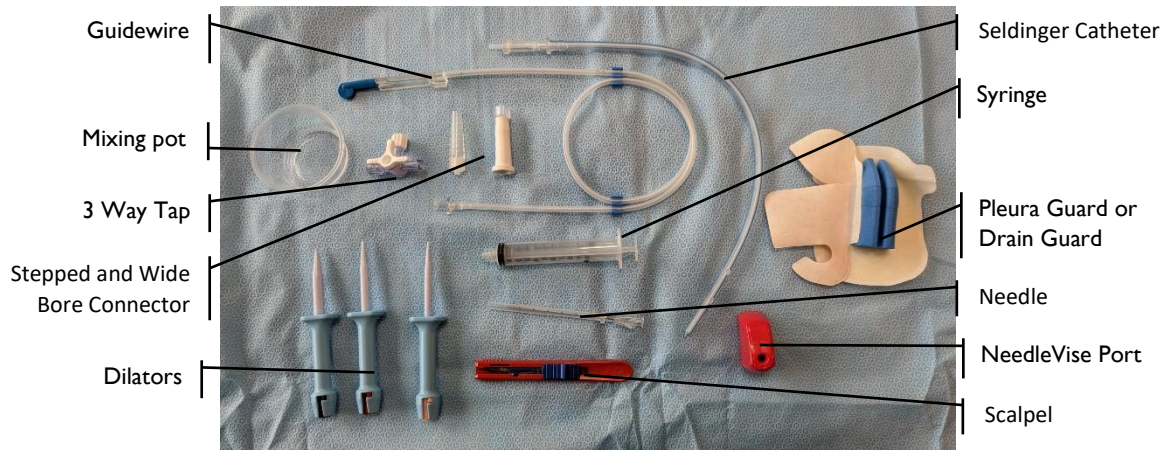
Australian Sponsor: **ROCKET MEDICAL PTY LTD**  
Suite 209, 1 Katherine Street,  
Chatswood, NSW 2067 Australia

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**Product Name:** Rocket Seldinger Chest Drain Kit.

**Procedure Pack Product Codes:** R54544-12-SG, R54544-18-SG, R54544-12-PK, R54544-18-PK, R54549-16-PK and R54549-20-PK

**Device Image:**



**SG Seldinger Chest Drainage Kit**



**PK Chest Drainage Kit**

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

DEVICE REF		DEVICE NAME	QTY	LEGAL MANUFACTURER DETAILS	
R54544-12-SG	ZPACK018	12 Fg Seldinger Catheter	1	<b>ROCKET MEDICAL PLC</b> Sedling Road, Washington, England, NE38 9BZ <a href="http://www.rocketmedical.com">www.rocketmedical.com</a>	
		14 Fg Safety Guard Dilator	1		

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		18G Echo Seldinger Needle			
		Seldinger Wide bore Connector			
		Stepped Male Luer Lock			
		4 Way Stopcock Large Bore			
		NeedleVise Port			
	ZBLAD019	11 Blade Safety Scalpel		<b>SWANN MORTON LIMITED</b> , Owlerton Green, Sheffield, S6 2BJ, UK (CE 2797, UKCA 0086)	
	ZDRES012	Drain Guard Fixation Device		<b>Lina Medical</b> , Naerum Hovedgade 10, 2850 Naerum, Denmark	
	ZPAPR048	910 x 910 SMS H100 Sterilisation Wrap		<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America	
	ZSYRG015	10ml Luer Lock Syringe		<b>BECTON DICKINSON S.A.</b> , Ctra. Mequinenza, s/n, 22520 – Fraga, HUESCA – ESPAÑA (CE 0318)	
R54544-18-SG	ZPACK021	18 Fg Seldinger Catheter		<b>ROCKET MEDICAL PLC</b> Sedling Road, Washington, England, NE38 9BZ <a href="http://www.rocketmedical.com">www.rocketmedical.com</a>	
		14 Fg Safety Guard Dilator			
		16 Fg Safety Guard Dilator			
		20 Fg Safety Guard Dilator			
		18g Echo Seldinger Needle			
		Seldinger Wide bore Connector			
		Stepped Male Luer Lock			
		4 Way Stopcock Large Bore			
		NeedleVise Port			
		Guidewire 70 cm			
	Cap Sealed – Use on Stopcock				
		ZBLAD019	11 Blade Safety Scalpel		<b>SWANN MORTON LIMITED</b> , Owlerton Green, Sheffield, S6 2BJ, UK (CE 2797, UKCA 0086)
		ZDRES013	Pleura Guard Fixation Device		<b>Lina Medical</b> , Naerum Hovedgade 10, 2850 Naerum, Denmark
	ZPAPR048	910 x 910 SMS H100 Sterilisation Wrap		<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America	
	ZSYRG015	10ml Luer Lock Syringe		<b>BECTON DICKINSON S.A.</b> , Ctra. Mequinenza, s/n, 22520 – Fraga, HUESCA – ESPAÑA (CE 0318)	
R54544-12-PK	ZPACK017	12 Fg Seldinger Catheter		<b>ROCKET MEDICAL PLC</b> Sedling Road, Washington, England, NE38 9BZ <a href="http://www.rocketmedical.com">www.rocketmedical.com</a>	
		14 Fg Safety Guard Dilator			
		18G Echo Seldinger Needle			
		Seldinger Wide bore Connector			
		Stepped Male Luer Lock			
		4 Way Stopcock Large Bore			
		NeedleVise Port			
		Guidewire 70 cm			
		Polypropylene Mixing Pot			

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		Blue Stick Applicators	2	
		Cap Sealed – use on Stopcock	1	
	ZBLAD019	11 Blade Safety Scalpel	1	<b>SWANN MORTON LIMITED</b> , Owlerton Green, Sheffield, S6 2BJ, UK (CE 2797, UKCA 0086)
	ZGOWN007	Disposable Surgical Gown	1	<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
	ZNDLE193	25G x 1.5" Safety Needle	1	<b>SOL-MILLENNIUM MEDICAL INC.</b> , 1735 North Brown Road, Suite 120, Lawrenceville, GA 30043,USA (CE 2797)
	ZNDLE150	21G x 1.5" Safety Needle	2	<b>SOL-MILLENNIUM MEDICAL INC.</b> , 1735 North Brown Road, Suite 120, Lawrenceville, GA 30043,USA (CE 2797)
	ZPAPR048	910 x 910 SMS H100 Sterilisation Wrap	1	<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
	ZPAPR051	Adhesive Drape Sheet	1	<b>Medline International, France SAS</b> , 5 Rue Charles Lindbergh, 44110, Chateaubriant, France (CE)
	ZPAPR052	Adhesive Aperture Drape 2 Piece	2	
	ZSWAB018	Gauze Swabs	5	<b>Premier Healthcare &amp; Hygiene</b> Unit 5 Lloyds Court, St. Omers Road, Gateshead, Tyne and Wear, NE11 9EP, UK
ZSYRG015	10ml Luer Lock Syringe	1	<b>BECTON DICKINSON S.A.</b> , Ctra. Mequinenza, s/n, 22520 – Fraga, HUESCA – ESPAÑA (CE 0318)	
ZSYRG021	20ml Syringe Male Luer Lock	1		
R54544-18-PK	ZPACK020	18 Fg Seldinger Catheter	1	<b>ROCKET MEDICAL PLC</b> Sedling Road, Washington, England, NE38 9BZ <a href="http://www.rocketmedical.com">www.rocketmedical.com</a>
		16 Fg Safety Guard Dilator	1	
		18 Fg Safety Guard Dilator	1	
		20 Fg Safety Guard Dilator	1	
		18G Echo Seldinger Needle	1	
		Seldinger Wide bore Connector	1	
		Stepped Male Luer Lock	1	
		4 Way Stopcock Large Bore	1	
		NeedleVise Port	1	
		Guidewire 70 cm	1	
		Mixing Pot	1	
		Blue Stick Applicators	2	
		Cap Sealed – Use On Stopcock	1	
		ZBLAD019	11 Blade Safety Scalpel	
ZGOWN007	Disposable Surgical Gown	1	<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America	
ZNDLE193	25G x 1.5" Safety Needle	1	<b>SOL-MILLENNIUM MEDICAL INC.</b> , 1735 North Brown Road, Suite 120, Lawrenceville, GA 30043,USA (CE 2797)	
ZNDLE150	21G x 1.5" Safety Needle	2		
ZPAPR051	Adhesive Drape Sheet	1	<b>Medline International, France SAS</b> , 5 Rue Charles Lindbergh, 44110, Chateaubriant, France (CE)	
ZPAPR052	Adhesive Aperture Drape 2 Piece	2		
ZSWAB018	Gauze Swabs	5	<b>Premier Healthcare &amp; Hygiene</b> Unit 5 Lloyds Court, St. Omers Road, Gateshead, Tyne and Wear, NE11 9EP, UK	
ZSYRG015	10ml Luer Lock Syringe	1	<b>BECTON DICKINSON S.A.</b> , Ctra. Mequinenza, s/n, 22520 – Fraga, HUESCA – ESPAÑA (CE 0318)	
ZSYRG021	20ml Syringe Male Luer Lock	1		

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R54549-16-PK	ZPACK022	16/18 Fg Seldinger Catheter		<b>ROCKET MEDICAL PLC</b> Sedling Road, Washington, England, NE38 9BZ <a href="http://www.rocketmedical.com">www.rocketmedical.com</a>
		14 Fg Dilator		
		18 Fg Safety Guard Dilator	1	
		20 Fg Safety Guard Dilator	1	
		18G Echo Seldinger Needle	1	
		Seldinger Wide bore Connector	1	
		Stepped Male Luer Lock	1	
		4 Way Stopcock Large Bore	1	
		NeedleVise Port	1	
		Guidewire 70 cm	1	
		Polypropylene Mixing Pot	1	
		Blue Stick Applicators	2	
		Cap Sealed – Use On Stopcock	1	
		ZDRES012	Drain Guard Fixation Device	
ZGOWN007	Disposable Surgical Gown	1	<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America	
ZNDLE193	25G x 1.5" Safety Needle	1	<b>SOL-MILLENNIUM MEDICAL INC.</b> , 1735 North Brown Road, Suite 120, Lawrenceville, GA 30043,USA (CE 2797)	
ZNDLE150	21 G x 1.5" Safety Needle	2		
ZPAPR048	910 x 910 SMS H100 Sterilisation Wrap	1	<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America	
ZPAPR051	Adhesive Drape Sheet	1	<b>Medline International, France SAS</b> , 5 Rue Charles Lindbergh, 44110, Chateaubriant, France (CE)	
ZPAPR052	Adhesive Aperture Drape 2 Piece	2		
ZSWAB018	Gauze Swabs	5	<b>Premier Healthcare &amp; Hygiene</b> Unit 5 Lloyds Court, St. Omers Road, Gateshead, Tyne and Wear, NE11 9EP, UK	
ZSYRG015	10ml Luer Lock Syringe	1	<b>BECTON DICKINSON S.A.</b> , Ctra. Mequinenza, s/n, 22520 – Fraga, HUESCA – ESPAÑA (CE 0318)	
ZSYRG021	20ml Syringe Male Luer Lock	1		
R54549-20-PK	ZPACK023	20 Fg Seldinger Catheter	1	<b>ROCKET MEDICAL PLC</b> Sedling Road, Washington, England, NE38 9BZ <a href="http://www.rocketmedical.com">www.rocketmedical.com</a>
		14 Fg Safety Guard Dilator	1	
		18 Fg Safety Guard Dilator	1	
		20 Fg Safety Guard Dilator	1	
		18G Echo Seldinger Needle	1	
		Seldinger Wide bore Connector	1	
		Stepped Male Luer Lock	1	
		4 Way Stopcock Large Bore	1	
		NeedleVise Port	1	
		Guidewire 70 cm	1	
		Mixing Pot	1	
		Blue Stick Applicators	2	

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ZBLAD019	11 Blade Safety Scalpel	2	<b>SWANN MORTON LIMITED</b> , Owlerton Green, Sheffield, S6 2BJ, UK (CE 2797, UKCA 0086)
ZDRES013	Pleura Guard Fixation Device	1	<b>Lina Medical</b> , Naerum Hovedgade 10, 2850 Naerum, Denmark
ZGOWN007	Disposable Surgical Gown	1	<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
ZNDLE193	25G x 1.5" Safety Needle	1	<b>SOL-MILLENNIUM MEDICAL INC.</b> , 1735 North Brown Road, Suite 120, Lawrenceville, GA 30043, USA (CE 2797)
ZNDLE150	21G x 1.5" Safety Needle	2	
ZPAPR048	910 x 910 SMS H100 Sterilisation Wrap	1	<b>O&amp;M Halyard Inc</b> , 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
ZPAPR051	Adhesive Drape Sheet	1	<b>Medline International, France SAS</b> , 5 Rue Charles Lindbergh, 44110, Chateaubriant, France (CE)
ZPAPR052	Adhesive Aperture Drape 2 Piece	2	
ZSWAB018	Gauze Swabs	5	<b>Premier Healthcare &amp; Hygiene</b> Unit 5 Lloyds Court, St. Omers Road, Gateshead, Tyne and Wear, NE11 9EP, UK
ZSYRG015	10ml Luer Lock Syringe	1	<b>BECTON DICKINSON S.A.</b> , Ctra. Mequinenza, s/n, 22520 – Fraga, HUESCA – ESPAÑA (CE 0318)
ZSYRG021	20ml Syringe Male Luer Lock	1	

**Intended Use:** The Rocket Medical Seldinger Devices are intended for the percutaneous introduction into the pleural cavity for drainage of air and pleural fluid.

**Indications:** The Rocket Medical Seldinger Devices are indicated for patients requiring drainage of air and pleural fluid from the pleural cavity.

**Contraindications:**

The Rocket Medical Seldinger Devices are contraindicated:

- for patients requiring non-pleural drainage (as the clinical benefit has not been established)
- The 12Fg & 16Fg catheters are not suitable to be used for drainage of viscous fluids (because they are too narrow and blockages can result).

<b>WARNING:</b>	<ul style="list-style-type: none"> <li>• Over insertion of the dilator into the chest cavity is associated with serious injury and <b>MUST</b> be avoided.</li> <li>• Only insert the dilator sufficient to dilate the superficial track.</li> <li>• This device should only be used by, or under the supervision of, appropriately trained personnel and in conjunction with current local clinical practice guidelines</li> </ul>
<b>Caution</b>	<ul style="list-style-type: none"> <li>• Insertion should be just <b>ABOVE</b> the rib to avoid damage to the intercostal neurovascular bundle.</li> </ul>
<b>Caution</b>	<ul style="list-style-type: none"> <li>• The wire guide should pass through the needle and advance into the pleural space without resistance.</li> </ul>
<b>Caution</b>	<ul style="list-style-type: none"> <li>• Ensure sufficient length of wire guide remains external to the chest to facilitate controlled introduction of the dilators and drain.</li> </ul>
<b>Caution</b>	<ul style="list-style-type: none"> <li>• It is important to advance the chest tube assembly into the pleural space whilst maintaining its direction in the same plane as the wire guide. This will make introduction easier and avoid kinking of the wire guide.</li> </ul>
<b>Caution</b>	<ul style="list-style-type: none"> <li>• Ensure all side holes of the chest tube are positioned within the pleural space.</li> </ul>
<b>Precaution:</b>	<p><b>Potential for DEHP Exposure from use of this device.</b> 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. Lack of research in humans means it is difficult to predict the adverse effects of DEHP because certain animal models may not apply to humans. Most studies utilise mice and rats, however breakdown of DEHP in the human body differs to the mechanism observed in these animals. These effects are also seen only at levels far in excess of normal human exposure. (For further details please see 'POL58' at <a href="http://www.rocketmedical.com">www.rocketmedical.com</a>.)</p>



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**Benefit Risk:** Rocket Medical plc has taken all necessary steps to ensure that residual risks associated with the use of Seldinger Chest Drain Kits 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 Seldinger Chest Drain Kits, outweigh the possible risks when used according to the intended use.

**Performance Claims and Clinical Benefit:** The Seldinger Chest Drains act as a conduit between the pleural space and the chest drainage unit, allowing the drainage of air and/or fluid following percutaneous insertion.

**Undesirable Side Effects:** Infection, Pain, Subcutaneous 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 procedure pack to allow percutaneous insertion, supplied with connectors to allow attachment to chest drain bottle devices.

**User:** The intended user is an appropriately trained healthcare professional or a trained caregiver in a home care setting proficient in the undertaking of external drainage of pleural effusions or abdominal ascites, working in accordance with local and national guidelines.

**Patient Population:** The intended patient demographics are adult patients requiring drainage of air and pleural fluid from the pleural cavity.

**Environment:** Clinical setting with sterile field with close access to sharps bin e.g. within 2 metres.

**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 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 radiopaque material 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:**

Devices are supplied with a series of luer lock connectors for attachment to chest drain bottles.

**Symbols and safety signs used on the device and labelling:**

Symbol or Safety Sign	Meaning	Symbol or Safety Sign	Meaning
	Manufacturer		Keep away from sunlight
	Caution: Federal law restricts this device to sale by or on the order of a physician.		Keep dry
	Date of manufacture		Do not re-use
	Use-by date		Consult the instructions for use

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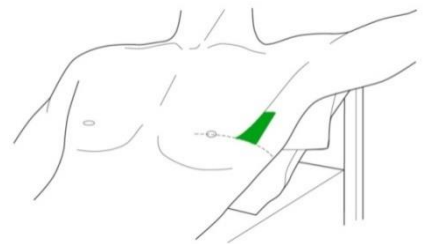
	Batch code		Caution
	Catalogue number		Does not contain natural rubber latex
	Sterilized using ethylene oxide		Contains or presence of phthalate
	Do not resterilise		Medical device
	Distributor		Do not use if package is damaged and consult instructions for use
	Single sterile barrier system with protective packaging outside		Single sterile barrier system

**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')

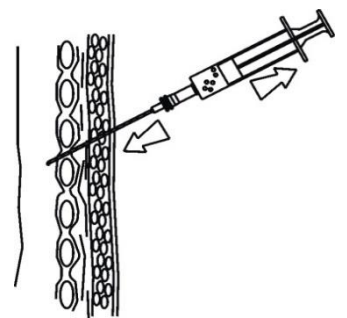
**USE:**

- Following local hospital policy, and wearing the sterile gown, prepare the chest tube insertion site with an approved solution such as povidone-iodine and drape with fenestrated drape to maintain aseptic technique.
- Identify and mark the insertion point following current practice guidelines. After injection of local anaesthetic, make a small skin incision 4-5mm.



When removing the protective sheath on the access needle, hold the silicone ring to prevent it from being removed. The measurement provided by using the silicone ring can be used to determine if the correct length of dilator is being used, and if the safety guard needs to be removed.

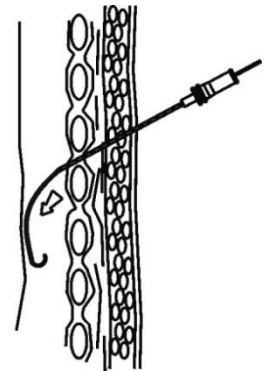
- Attach the introducer needle to a syringe filled with a local anaesthetic e.g. lignocaine, and administer additional local anaesthetic to the skin and underlying tissues.
- Advance the introducer needle over the superior border of the rib and into the pleural space. Fluid or air should be aspirated to verify correct position.
- The needle should be introduced and directed with appropriate orientation inferiorly or superiorly.
- Remove the syringe and advance the soft "J" end of the wire guide through the needle and into the pleural space. Before removing the needle, move the silicone measurement ring down to the patient's skin.



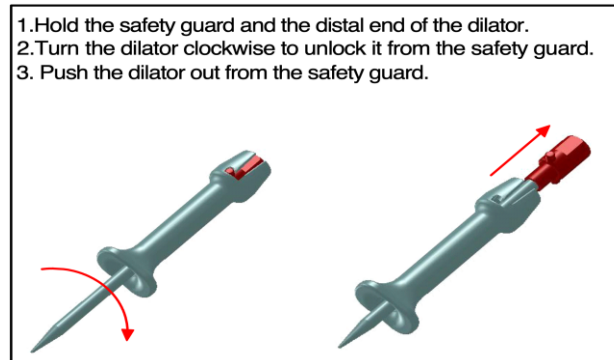
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7. Remove the introducer needle.
8. Using the measurement obtained using the depth marker on the introducer needle; measure against the safety guard dilator to ensure the correct length of dilator is being used. If the depth required is longer than the preset 50mm then remove the Safety Guard as described below.

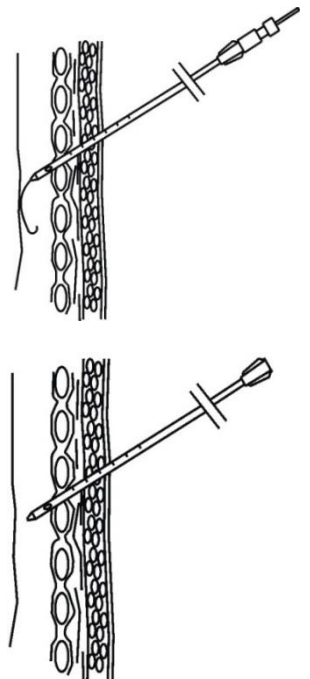


**Removing the safety guard:**



**CAUTION:** Ensure sufficient length of wire guide remains external to the chest to facilitate controlled introduction of the dilators and drain.

9. While maintaining the wire guide position, dilate the track and opening into the pleural space by advancing and withdrawing, one by one, the supplied dilator(s) over the wire guide. Introduction into the pleural space is facilitated by rotating and advancing the dilators in the same plane as the wire guide to prevent kinking.
10. Remove the final dilator from the wire guide
11. Locate the drain set. Insert the free end of the guide wire into the distal catheter tip ensuring it travels through the stiffening tube.
12. With the wire guide still positioned within the pleural space, advance the chest tube inserter/chest tube assembly over the wire guide and into the pleural space
13. Remove the wire guide and chest tube inserter leaving the chest tube in place.
14. The chest tube can now be secured to the skin by using the fixation device R54960-PG-FX or suture or both and is ready for connection to a suitable sealed drainage system such as the Rocket Blue Bottle or Rocket Ambulatory Bag
15. Confirm the correct positioning of the drain with imaging as soon as possible.



**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.

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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

**How to apply the Catheter Fixation Device**

Indications: For use with the Rocket Seldinger catheter.

Contraindications: Not for use with catheters other than included in the Rocket Seldinger pack.

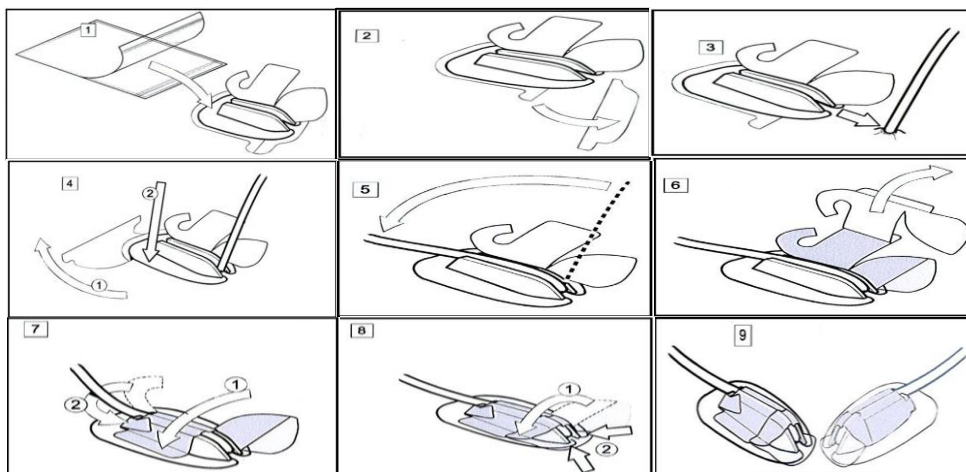
Device Description: The Fixation device can be used as secondary dressing, use of a suture to secure the catheter is recommended. This dressing is not designed to replace a suture to hold the catheter in place. The dressing will normally stay in-situ for 4 – 5 days, or up to seven days if required.

Procedure: For application of the drain fixation device follow the diagrams below.

The catheter fixation device enables the following:

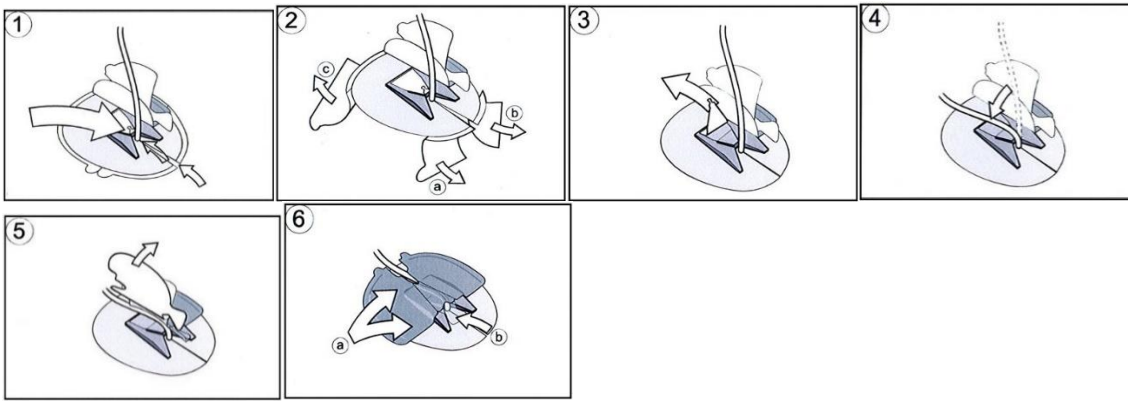
1. Reduction of risk from an accidental displacement of catheter,
2. Reduction of risk of the catheter being expelled by the body
3. Safe anchoring and protection of catheter for up to one week.
4. The patient to shower with catheter inserted.
5. Hydrocolloid carrier absorbs exudate from puncture site
6. Prevents contamination of puncture site from environment.
7. Prevents kinking of catheter

**Catheter fixation instructions for catheters 16Fg to 30Fg**



**Catheter fixation instructions for catheters 5Fg to 16Fg**

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**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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