

Product Name: Rocket® Rectal Solution Injector Set

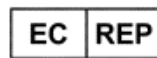
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Page
2-4



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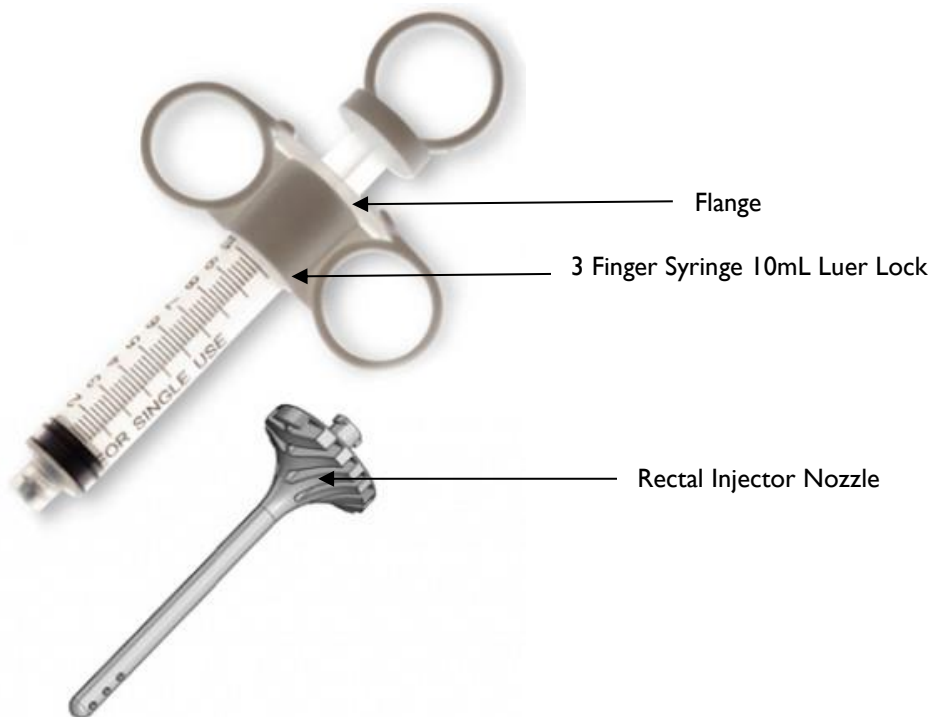
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Product Name: Rocket® Rectal Solution Injector Set

Product Code: R56215-M

Device Image:



Intended Use: For the rectal injection of prescribed rectal solutions to aid bowel movement in patients with neurogenic bowel dysfunction (e.g. spinal cord injury) or other conditions where normal bowel function is compromised. Suitable for self-administration of a rectal solution by the patient or administered by their personal carer.

Indications: Indicated for patients with neurogenic bowel dysfunction (e.g. spinal cord injury) or other conditions where normal bowel function is compromised.

Contraindications: Use only on the advice of your doctor, nurse specialist, community nurse or continence advisor who will assess your suitability for this device.

WARNING: This Product is non-sterile. Attempting sterilisation will damage this device.

Discard after use. Reusing this device can lead to contamination of the device and infection of the patient.

Benefit Risk: Rocket Medical PLC concludes that the overall medical benefits of the Rocket® Rectal Solution Injector Set outweigh the possible risks when used according to the intended use.

Performance Claims and Clinical Benefit: The Rectal Solution Set is an instrument / apparatus / appliance intended to be used for the following specific medical purpose: treatment of constipation.

Undesirable Side Effects: Undesirable side effects include infection, bleeding and bruising.

User: This device can be used by trained personnel in conjunction with current local clinical practice guidelines, the patient on their own, and/or their carer.

Patient Population: The intended patient demographics are adult patients suffering from a neurogenic bowel dysfunction, or have a compromised bowel function that require rectal injection of prescribed solutions to aid bowel movement.

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

Environment: This device can be used in a clinical setting, or at home provided it can comply with the necessary sanitation protocols and there patient has the appropriate disposal materials (ie. plastic wrapping).

















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.

Non-Sterile: The device is supplied non-sterile. They are not intended to be sterilised prior to use. Do not sterilise as doing so may compromise the structural integrity of the device, leading to device failure.

MRI Safety: MRI compatibility has not been verified.

General Information: The device is supplied non-sterile, and it is recommended to use gloves to protect against possible contamination with bodily fluids. Personal carers are expected to undertake this procedure with due regard to local standard precautions regarding hand washing and make appropriate use of personal protective equipment (gloves and aprons) as provided by their employer.

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.		Do not re-use
	Date of manufacture		Consult the instructions for use
	Use-by date		Caution
	Batch code		Does not contain natural rubber latex
	Catalogue number		Non-pyrogenic
	Non-sterile		Medical device
	Distributor		Do not use if package is damaged and consult instructions for use

Operating Instructions:

CHECK: Do not use if the device is damaged. Ensure you have the full contents of the kit prior to use.

USE:

1. First, wash your hands.
2. Open the pack and remove the syringe and moulded nozzle assembly.
3. Attach the nozzle to the syringe by gently screwing the moulding into the top of the syringe.
4. Locate and turn clockwise until tightened. **Do not over tighten.**

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5. Draw up the required dose of your rectal injection solution. The rectal injector can also be used to improve the administration of micro-enemas. With scissors, cut the top corner off the enema pack, insert the nozzle and draw up the contents. Alternatively, decant the micro-enema contents into a clean disposable container (e.g. a medicine pot) and draw up.
6. Note: The nozzle has a dead space of 0.7ml from the syringe connection to the first hole (counting up from the flange).
7. A lubricant such as KY® Jelly should be used to lubricate the nozzle if required.
8. Using the most convenient position (e.g. sitting on the toilet or lying on your side with your knees drawn up), gently insert the nozzle into the rectum. **Do not attempt to insert beyond the moulded flange.**
9. Slowly depress the plunger of the syringe to expel the contents into the bowel, wait for 30 seconds, then slowly withdraw the nozzle completely.
10. Discard the combined syringe and nozzle assembly and wash your hands.
11. Do not be tempted to re-use the device - even after washing. The nozzle is constructed of a soft medical grade material and is designed for single use.

Disposal:

At home, this device can be safely disposed of in normal domestic rubbish provided that it is well wrapped in a plastic bag before disposal.

In the hospital, this device should be handled and disposed of in accordance with local hospital policy and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment. Failure to do so may increase the risks of infection or other microbial hazards.

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