Spinal Manometer Sets

ZDOCK215 Rev. 17

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Product Names: Spinal Manometer - NRFit®, Spinal Manometer – Luer Lock, and Lumbar Puncture Tray with NRFit® Spinal Manometer.

Product Codes: R55990-ISO-6, and R55990

Procedure Pack Product Code: R55995-NRFIT

Device Image:

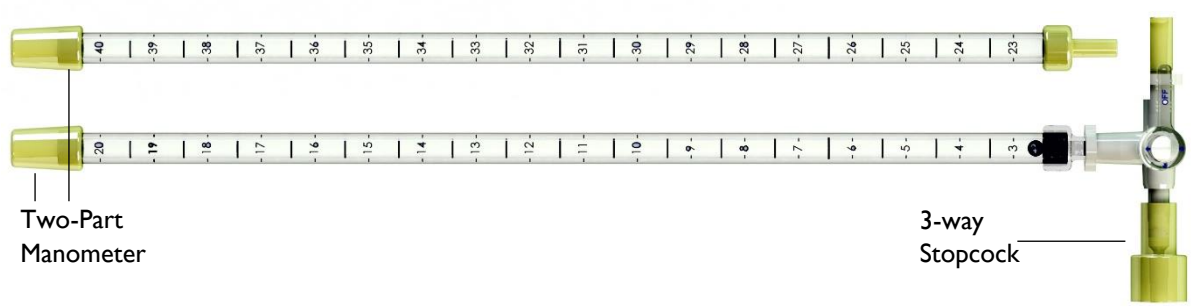

Figure 1: R55990-ISO-6 Spinal Manometer with NRFit® Connectors

Figure 2: R55995-NRFit® Lumbar Puncture Set

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.

Device Contents:

DEVICE REF	DEVICE NAME	QTY	LEGAL MANUFACTURER DETAILS
ZASEM317	Spinal Manometer Assembly	1	**ROCKET MEDICAL PLC** Sedling Road, Washington, England, NE38 9BZ www.rocketmedical.com (CE2797)
ZPACK001	30ml Container Capped Labelled (Qty: 3)	3	
	600 x 600 SMS - (10724) H100 Sterilisation Wrap	1	
	Adhesive Aperture Drape 2-Piece Fenestrated 75cm x 4	1	
	10cm x 10cm x 12 Ply Swab	5	
	Blue Stick Applicator	1	
	60mL Pot	1	
ZNDLE150	Microlance 21g 1.5" Green Needle	1	**BECTON DICKINSON S.A.**, Ctra. Mequinenza, s/n, 22520 – Fraga, HUESCA – ESPAÑA (CE0318)
ZNDLE193	SOL-CARE SAFETY Needle 25G x 1.5"	1	**SOL-MILENNIUM** MEDICAL INC. 1735 North Borwn Road Suite 120. Lawrenceville, Georgia 30043 USA (CE2797)
ZSYRG021	20mL Syringe Male Luer Lock	1	**BECTON DICKINSON S.A.**Camino de Valdeoliva s/n 28750 San Agustín del Guadalix, MADRID – ESPAÑA (CE0318)
ZSYRG030	10mL NRFit® Slip Syringe	1	**GBUK GROUP** Woodland House Blackwood Hall Business Park North Duffield, Selby North Yorkshire YO8 5DD United Kingdom (CE1639)

Intended Use: The Rocket Medical Spinal Manometers are intended for the measurement of CSF pressure and sampling of CSF.

Indications: The Rocket Medical Spinal Manometers are indicated for the diagnosis of suspected CNS infection, subarachnoid haemorrhage or related neurological condition.

Contraindications:
Rocket Medical Spinal Manometers are contraindicated:

- For use with, or administration of intrathecal agents, which could be fatal.
- For use on patients with spinal abnormalities or injury, or where distortion of the normal anatomy is suspected, as this could cause internal injury.
- In the presence of local skin infections over or around the proposed puncture site. This could cause tissue infection.
- In use during uncontrolled bleeding conditions or anticoagulant therapy. This could cause further bleeding.

WARNING:
- Not for administration.
- Do not attempt to reinfuse CSF.

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

Performance Claims and Clinical Benefit:
For the measurement of CSF pressure up to 40cm H_2O, and to enable the collection of CSF.

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Undesirable Side Effects: The procedure may cause CSF leak, with associated neurological symptoms including headache, disturbed balance, changes in hearing or vision, tinnitus, facial numbness, neck or shoulder pain, nausea or vomiting, and changes in cognition or behaviour. Infection, swelling and bleeding may occur at the needle insertion site.

Description of the device:
These devices comprise a plastic, graduated (1cm graduations from 0-40cmH_2O) tube complete with a 3-way stopcock, fitted with either Luer-Lock fittings (compliant to ISO80369-7) or NRFit® (compliant to ISO80369-6) to enable connection to a spinal needle and diversion of CSF into transport containers for subsequent analysis. Connection to an associated spinal needle is via a 'slip' connection.

User: The intended user is a healthcare professional proficient in the measurement of CSF pressure and sampling of CSF, working in accordance with local and national guidelines. The device may also be used by a trainee under the supervision of a healthcare professional who is proficient in taking measurements of CSF pressure and sampling of CSF.

Patient Population: The intended patient demographics are patients suspected of having a CNS infection, subarachnoid haemorrhage, or related neurological condition.

Environment: Clinical setting with close access to sharps and clinical waste bin.

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.

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
	Batch code		Caution
	Catalogue number		Does not contain natural rubber latex
	Sterilized using ethylene oxide		Non-pyrogenic
	Do not resterilise		Medical device

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	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:

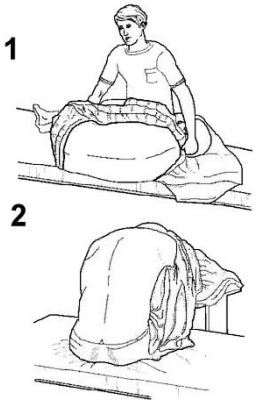
CHECK: do not use if the packaging is open or damaged or the device is damaged.

For all products, ensure that you have all the necessary devices and anaesthetic agent required to complete the procedure. For R55995-NRFIT procedure pack, ensure you have the full contents of the kit prior to use (see 'Device Contents').

USE:

Proper medical and surgical procedures are the responsibility of the physician. The appropriateness of any procedure must be based upon the needs of the patient.

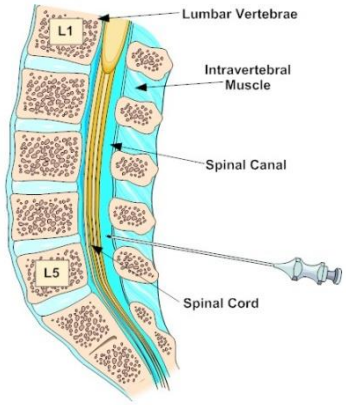
Procedure for CSF Pressure Measurement:



1. Position the patient either in a curled, lateral decubitus position (1) or seated, leaning over a suitable support (2).
2. Locate landmarks: between spinous processes at L4-5, L3-4, or L2-3 levels.
3. Prepare and drape the area after identifying the landmarks. If required, use a suitable local anaesthetic agent to anaesthetise the skin and infiltrate the deeper tissues under the insertion site.
4. Prior to assembly, operate the stopcock three or four times by rotating it fully 180° to release the seal which may have built up during storage.
5. Assemble the manometer set: locate the lower manometer tube (graduations 3-20cm H_20), insert the upper manometer tube (graduations 23-40cmH_2O) into the luer fitting on the lower tube. Insert the assembled manometer tubes into the vertical port of the 3-way stopcock (as illustrated).

Figure 3: R55990 LUER version illustrated

6. To minimise the risk of dural trauma and CSF leakage, the smallest gauge needle that is practical should be used. 25G needles tend to have low flow rates and fill the manometer slowly, therefore 21G or 22G needles are normally recommended for lumbar puncture and CSF collection.
7. If used, advance an introducer needle (Not provided)) through the skin and fascia, followed by the spinal needle through the deeper tissues to the spinal canal. Typically, a slight 'pop' or reduction in resistance is felt when the dura is punctured.
8. Remove the needle stylet. CSF flow confirms placement into the dural space. Attach the manometer assembly vertically to the needle. Rotate the 3-way stopcock to divert the CSF flow from the needle to the manometer whilst closing the proximal port.
9. Allow CSF to flow into the manometer tube, when the fluid level has stabilised, read the value from the manometer column in cmH_2O.



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WARNING: **Pressure readings are less reliable if the patient is in the sitting position**

10. Once the CSF pressure reading has been recorded, close the 3-way stopcock to the needle and drain the fluid from the manometer tube into collection tubes for subsequent analysis.

    WARNING: NOT for administration. Do NOT attempt to re-infuse CSF

11. When sampling is complete, remove the spinal needle, manometer assembly and introducer needle (if used) and apply a dressing to the puncture site.

12. Instruct the patient to remain lying down for 1-2 hours before getting up.

    WARNING: Lumbar puncture may cause dizziness, profound headache and can disturb balance.

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.

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.

