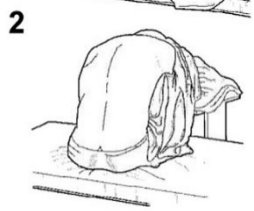
Rocket Spinal Manometer Sets
INSTRUCTIONS FOR USE

Scope: These instructions cover R55997 and R57997-NRFIT 'Push-Button' Spinal Manometers and derivatives

Intended Use: For the measurement of cerebrospinal fluid (CSF) pressure and sampling of CSF to aid the diagnosis of suspected CNS infection, subarachnoid haemorrhage or related neurological condition. This device should only be used by, or under the supervision of, appropriately trained personnel and in conjunction with current national and local clinical practice guidelines.

Contraindications: This device is NOT to be used for the administration of intrathecal agents. Blind intrathecal puncture is contraindicated in spinal abnormality or injury. Where distortion of normal anatomy is suspected, the use of direct imaging guidance is strongly recommended. Intrathecal puncture is contraindicated in the presence of local skin infections over proposed puncture site, in uncontrolled bleeding conditions or anticoagulant therapy.



Procedure for CSF Pressure Measurement:

1. Position 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. Prep and drape the area after identifying landmarks. If required, use suitable local anaesthetic agent to anaesthetise the skin and infiltrate the deeper tissues under the insertion site.
4. Assemble the manometer set with the extension tube.
5. To minimise the risk of dural trauma and CSF leakage, the smallest gauge needle that is practical should be used. However, needles of >22G tend to give lower flows and extend the period required for stabilisation of the manometer reading.
6. Advance the introducer needle through the skin and fascia, followed by the spinal needle through the deeper tissues to the cord. Typically, a slight pop or reduction in resistance is felt when the dura is punctured.
7. Remove the needle stylet. CSF flow confirms placement into the dural space. Attach the manometer assembly to the needle hub.
8. On connection, CSF will flow into the manometer column. Typically, CSF pressure is in the range 18-24cmH_20 but can be significantly higher. Pressure readings are less reliable if the patient is in the sitting position.
9. Allow the CSF level to stabilise. Record the value against the graduated scale.
10. To collect the sample for subsequent analysis: apply an empty sterile container to the lower port and push the button forward with the thumb whilst supporting the manometer. Allow the CSF to fully drain from the column into the container. Flow from the spine is occluded while the button remains pressed.
11. Release the button and allow CSF to flow into the manometer tube once again. Remove the container and replace. Repeat for the required number of CSF samples.

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

12. When sufficient sampling has been completed, remove spinal needle, manometer assembly and introducer needle if used and apply a dressing to the puncture site.
13. Instruct the patient to remain lying down for 1-2 hours before getting up. Lumbar puncture may cause dizziness, profound headache and can disturb balance.

Disposal: 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.

NATURAL LATEX — **This device is not manufactured with natural rubber latex** — Rx ONLY — STERILE EO — PHT DEHP

ROCKET MEDICAL PLC Sedling Road, Washington, England, NE38 9BZ www.rocketmedical.com

EC REP

Rocket Medical GmbH
Am Rosengarten 48,
15566 Schöneiche.
Germany

NOT FOR LONG TERM USAGE.
Unless opened or damaged, contents of package are sterile.

Potential of DEHP Exposure

Medical procedures using PVC medical devices containing DEHP have the potential to lead to DEHP exposure due to DEHP leaching from the device. The extent of exposure largely depends upon the medical treatments administered, the duration of the treatment, and in the case of plastic blood bags, by the length of storage and the storage temperature. 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 full statement visit www.rocketmedical.com

CE

