

Spinal Manometer Sets

ZDOCK215 Rev. 18

Language
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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 (1 cm graduations from 0-40cmH₂O) 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 re-sterilise		Medical device

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.

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.