INTENDED PERFORMANCE

The loss of closed system pressure and deflation of the signal membrane will indicate only that the needle tip has entered a void or that the system is otherwise open.

The clinician must rely on her/his own experience and skills to confirm that the needle tip is in the epidural space.

An indication that the needle tip has entered the epidural space is given by the deflation of the signal diaphragm.

UNEXPECTED PERFORMANCE

Important Note:

The clinician must be aware that a false signal may be given by the Epidrum if its contents leak into the patient's tissues.

In the event that the signal diaphragm does not deflate but the clinician feels entry into the epidural space, it may be that the needle is blocked. In the event that the needle becomes occluded with the patient's own tissue or blood clot, the function of the Epidrum will be impaired when the needle is advanced. Alternatively, it may be that resistance to the needle continues to be felt but the signal diaphragm has deflated. In this event consideration of the following is required.

(a) The Epidrum has discharged into the patient's tissues.

(b) The assembly has leaked.

(c) The needle has entered the epidural or intrathecal space.

In the event of any failure of the equipment the procedure should be terminated and restarted with replacement devices and associated consumables.

RISKS/WARNINGS/SIDE EFFECTS/CONTRA INDICATIONS

***Important Warning:* Follow the user instructions carefully, failing which the outcome could be unpredictable and even potentially fatal.**

Risks

There is a risk, as with all epidural procedures, that potentially dangerous forces could be imposed on a patient if air is quickly and forcibly delivered through the device. This is misuse and could result in an unpredictable outcome or fatality.

Minimise the amount of air that enters patient. Do not exceed 3 ml!

There is a risk that a false signal may be given by the Epidrum if its contents leak into the tissues or if connections leak.

There is a risk that the Epidrum may not give the required signal if the needle is obstructed by tissue or blood.

There is a risk of dural tap.

If the Epidrum valve leaks and top up procedure proves unable to charge the device, discard it and consider the possibility of a false signal.

If the Epidrum fails to charge, consider whether the tip of the needle is already in the epidural space, in the sub-dural space or in the intrathecal space.

In the event of contamination of the equipment, including gloves, by Chlorhexadine, other surgical soap or any other contaminants, discard all components and restart the procedure with new equipment.

RISKS/WARNINGS/SIDE EFFECTS/CONTRA INDICATIONS Cont'd

Contra Indications

Absolute contra indications	***Relative contra indications***
Patient refusal	Uncooperative patient
Coagulopathy (refer to local protocol)	Pre-existing neurological disease
Local skin infection	Fixed cardiac output states
Raised intracranial pressure	Spinal anatomical abnormalities
Uncorrected hypovolaemia	Prophylactic low dose heparin therapy
	Thrombocytopenia

Side Effects

Side effects are limited to discomfort from subcutaneous bleeding and bruising from the needle entry point. There are no side effects directly attributable to the Epidrum.

HANDLING

Handle only with sterile gloved hands and, if gloves are punctured, start the procedure again, discard all components and follow local protocols in the event of an injury.

Set aside the unit label for patient's notes, peel the pouch and tip the device from the primary wrap onto a dedicated surgical sterile field.

Avoid touching the inlet or exit ports.

Do not use if sterile pack is breached, damaged or contaminated.

Do not use after the expiry of the use by date of shelf life, which is located on the unit/ lot number label.

STORAGE

Store in a clean, dry environment, at room temperature.

Avoid extremes of temperature and humidity. Optimal storage conditions are between 10 - 35°C and 20 - 80% relative humidity.

Store out of direct sunlight.

PATIENT BRIEFING (at clinician's discretion)

The user may wish to draw the patient's attention to the possibility of associated risks.

DISPOSAL

Follow local protocols in respect of the disposal of the equipment. Normally, it should be placed in a yellow disposal bin for subsequent incineration.

Failure to dispose of the device correctly could lead to serious infections.

If an incorrect method of disposal is employed, the outcome may be harmful to a third party or to the environment

In the event that the equipment is exposed to a highly infectious agent, it must be disposed of by way of incineration, following the highest level of local biohazard protocol.

Manufactured by **Exmoor Plastics Ltd** CE 0120
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PUB/193/W/1 17/05/2017

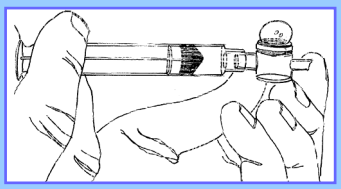
Epidrum®

Patent No. UK GB 2366729B; US 7,175,608

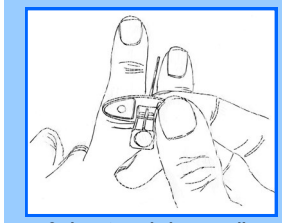
USER INSTRUCTIONS

For needle: 16G — 18G

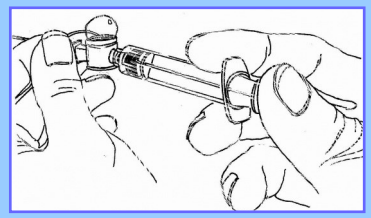
REF EPL/1
EPL/1a
EPL/1b



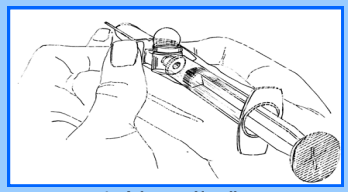
1. Manually occlude & test Epidrum



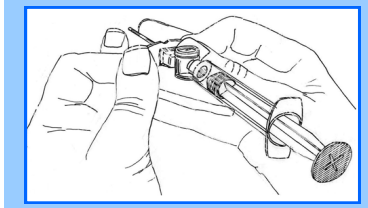
2. Locate and place needle



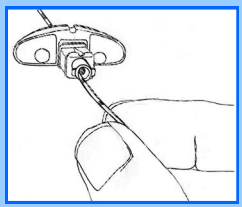
3. Charge Epidrum



4. Advance Needle



5. Endpoint — Epidrum discharges



6. Introduce catheter

HOW IT WORKS

Epidrum replaces the LOR syringe as a means of identifying the epidural space whilst performing epidural anaesthesia.

Epidrum is an optimal, constant, low pressure, air operated, LOR device, that is designed to operate at a high enough pressure to discharge into the epidural space but a low enough pressure to minimise leak into the patient's tissues.

This optimal pressure is generated by the thin diaphragm on top of the device that acts as the meniscus of a manometer, allowing the operator to interpret needle tip position.

By uncoupling the means of advancement from the means of epidural space detection, the Epidrum offers the following benefits:

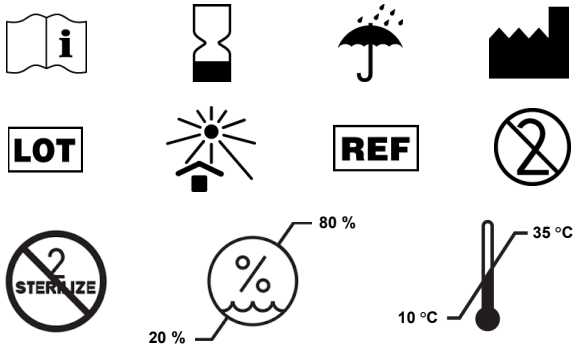
1. two hands on needle improve control of depth, direction and speed of insertion
2. visual signal more readily interpreted and can be supervised
3. continuous pressure in device gives the quickest possible signal change
4. in the future Epidrum may allow use of smaller gauge needles.

IMPORTANT:

- **Follow the user instructions carefully, failing which the outcome could be unpredictable and even potentially fatal**
- **Only to be used by a Competent Medical Practitioner who is trained in the use of Epidrum**
- **Epidrum has been optimised in trials on adult patients, for use with air only. Any use on small children is at the discretion of the clinician. It is always incumbent upon the clinician to consider the patient's age, weight and suitability**
- **Do not use if sterile pack is breached damaged or contaminated**
- **Do not use after expiry of the "use by" date which is located on the unit/lot number label**
- **Do not reuse**

CE 0120

STERILE EO



Do Not Use if Package is Damaged
Ne pas utiliser si l'emballage est abîmé
No utilizar si el paquete está dañado
Nicht verwenden, wenn Verpackung beschädigt ist
Non usare se la confezione é danneggiata

INDICATIONS FOR USE

The Epidrum is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space.

Important Note: This device is not intended to be interpretive and can merely act as a guide to aid the correct location of an epidural needle tip in an epidural space. The user must rely on her or his judgment to determine the correct placement of the epidural needle.

PREPARATION AND ASSEMBLY

General
The Competent Medical Practitioner, who must have been trained in the use of Epidrum, with responsibility for the procedure, shall direct the timing of the procedure and the sub activities.

The procedure should be carried out under the strictest sterile protocol.

Familiarisation
It is essential that users familiarise themselves with the features and performance characteristics of the device.

Please study the device and the user instructions carefully and do not proceed with a procedure until fully satisfied that the instructions are understood.

Environment and Safety
Epidural procedures should be carried out in an appropriate anaesthetic environment, having all emergency equipment and materials available, to ensure that the patient is safe.

Associated Consumables
An appropriate antiseptic should be used before the pack is opened, in order to minimise the risk of contamination.

Epidural Kits
Use this device with state of the art epidural kits, which have friction-fit Luer connections.

Syringe
Select a scaled and calibrated 5ml syringe.

The clinician must assure that Epidrum fits securely with the Luer fittings of the syringe and epidural needle with which the Epidrum is to be used.

Compatible Luers
The Epidrum Luers meet the British Standard BS EN20594-1: 1994 and are only suitable for use with Luers that meet that same British Standard. If used with Luers, which do not comply with that Standard, the outcome could be unpredictable, and may result in a failure to achieve the intended performance or indeed to perform the procedure at all. Note: It is a requirement of all device manufacturers to conform with BS EN 20594-1: 1994.

Function Testing
The function of the Epidrum may be tested prior to use by occluding the exit port (male Luer) and filling the device with air, so as to witness the expansion of the diaphragm.

The correct function would be assured if the signal membrane expands to a hemispherical shape and remains charged after the removal of the syringe from the inlet port.

TECHNIQUE

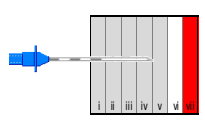
Important Note: *This device must not be used unless the user is fully familiarised with the user instructions, intended purpose, use, and intended performance of this device. Refer to the diagrams, which clearly demonstrate the expected behaviour of the device and demonstrate the signal mechanism, which can aid the identification of the epidural space.*

TECHNIQUE Cont'd

Sequence:
1. Test Epidrum
2. Insert needle through the layers and anchor in the ligamentum flavum (Diagram 1)
3. Remove stylet
4. Attach Epidrum
5. Charge Epidrum
6. Complete procedure observing Epidrum

1. Test the device (per 'Function Testing' q.v.) and then, following normal protocols, introduce the epidural needle into the best position possible, ensuring that the stylet is in place to minimise the 'coring effect' and subsequent blocking of the epidural needle. Anchor the epidural needle in the usual way and remove the obturator.

Diagram 1

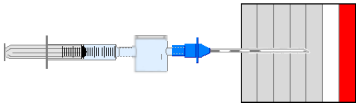


Key to numbered layers
i. Skin
ii. Subcutaneous Tissue
iii. Longitudinal Ligament
iv. Interspinous Ligament
v. Ligamentum Flavum
vi. Epidural Space
vii. Dura

2. Select a 5.0ml friction fit syringe, fill it (to 5.0ml) with air and inspect for the presence of foreign bodies.

3. The syringe is then attached with a firm, forward twisting motion, to the Epidrum.

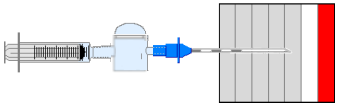
4 Remove the obturator from the epidural needle. Attach the syringe and Epidrum assembly, with a firm, forward twisting motion, to the epidural needle, which is already located in the best position possible in the patient's back.



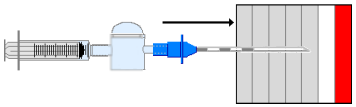
The diaphragm, which must be visible to the clinician, is surrounded by a coloured ring, for the purpose of its identification.

5. Slowly advance the plunger of the syringe to compress the air in the chamber, which will then charge the Epidrum, as the valve in its inlet port opens. Fill the Epidrum so that the diaphragm expands to form a clearly seen shape — a hemisphere.

A minimum of one ml of air is required. The volume will depend on the degree of leak of air into the tissue. The aim is to maintain the diaphragm's hemisphere (or more than a hemisphere) throughout the procedure and until the epidural space is located.

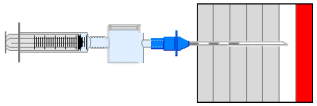


6. Grasp the wings of the epidural needle with the thumbs and forefingers of both hands, while allowing the remaining fingers to rest against the back of the patient and advance the needle's tip towards the epidural space, whilst continuously observing the signal membrane of the Epidrum.



7. When the epidural space is located, the diaphragm will deflate to a level depending on the patient's epidural pressure. In the majority of patients, the deflation will be crisp.

N.B. *In a small minority who have high epidural pressures, the deflation might be small and not easily noticeable. In these rare occasions, maintaining the inflation of the diaphragm to above a hemisphere throughout the procedure (before entry to the epidural space) as described in the user instruction, coupled with close observation of the membrane, should minimise this risk by identifying a change in the position of the membrane and signalling the entry to the epidural space. In a so called boggy back, the diaphragm, acting like the meniscus of a manometer, may slowly settle until the forces involved have re-equilibrated. Be aware that the signal depends on the pressure gradient from Epidrum to the epidural space. If it is small the signal will be attenuated. Epidural venous pulsation seen on the membrane may be further evidence of epidural needle tip position.*



Sometimes the Epidrum may even need to be recharged. It is important to note the qualitative difference between the slow discharging of leak into low density tissue and the crisp discharge that characterises the entry of the needle tip into the epidural space.