

## Field Safety Notice

Ref: 50051029

### FIELD SAFETY NOTICE

**Commercial name of the product:**

**Type of action:** Advice  
**Attention:** Theatre Manager, Distributor

**Details on affected devices:** See List provided

**Description of the problem:**

Mölnlycke Health Care has identified that some ProcedurePak® trays have been delivered with a different catheter size (19G instead of 20G). The resulting impact has been assessed some resistance when inserting the associated needle into incorrect catheter size and a potential issue when needle is being removed from catheter post procedure. This can possibly delay the procedure.

Mölnlycke Health Care's Advisory Notice is for the customer to make a visual check to see if the right catheter is in the tray (20G). If the tray contains the wrong catheter the tray should be scrapped and be replaced with a tray containing the correct catheter (20G).

**Actions to be taken by the user:**

1. Please identify and isolate all affected unused product at your facility.
2. **Please affix a copy of this advisory notice to each tray and make sure that its contents are brought to the attention of all relevant personnel**
3. Please complete the attached Confirmation form and email/fax back per its instructions. This step is required to confirm receipt of communications with all customers.
4. Return the attached response form (product concerned by this FSN).
5. If you have forwarded any affected product to any other healthcare institutions, please forward a copy of this letter and fax back containing affected serial numbers to those institutions

Please contact your local Mölnlycke Health Care Customer Service or Account Manager if you have any questions or concerns regarding this notification. You may also contact:

Vigilance: Thomas Pettersson ([vigilance@Mölnlycke.com](mailto:vigilance@Mölnlycke.com)) or +46 (0)31 722 33 89

Mölnlycke Health Care also confirms that this notice has been notified to the appropriate Regulatory Agency. Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,



Thomas Pettersson

Global Vigilance Manager



Caroline Allen

Global Director of Regulatory Affairs



# TABLE B - GMDN CODES AND TERMS

Country	Product	LOT	Product Name	Material group descripton	GMDN code	GMDN term	GMDN definition	NRL	Serilization Cycle
FR	37003655-02	B14030	ANAESTHESIA KIT 401511M	Loco-regional anaesthesia - epidural	P46308	Epidural/intratheca / anaesthesia kit	A collection of sterile devices designed to deliver an analgesic or anaesthetic agent into the epidural and subarachnoid (intrathecal) spaces around the spinal cord for pain management. It typically includes a procedural needle(s), syringe, catheter(s), and filter(s), but does not include medication. This is a single-use device.	WITHOUT NRL	NA

<b>STATUS</b>
NA