

## PRODUCT DISRUPTION BRIEF

# Cranial access kits and CSF external drainage kits (reviewed October 15)

**Natus is on backorder for Cranial access kits and CSF external drainage kits; recovery times are improving.**

## Current conditions

Natus Medical is currently experiencing increased demand for their cranial access kits and Cerebrospinal Fluid (CSF) external drainage kits due to multiple product recalls for other suppliers within the market:

- **Class 1 device recall Medtronic Duet external drainage and monitoring system, interlink injection sites, lumbar catheter** - Potential for catheter disconnection from the patient line stopcock connectors.
- **Class 2 device recall: Integra cranial access kit** - A defect in the sterile packaging (header bag) of the Cranial Access Kit failing the required packaging integrity testing criteria. Therefore, product sterility may be compromised.
- **Class 2 device recall: Natus EDS 3 CSF external drainage system** - sterility assurance cannot be guaranteed for external drainage systems due to incomplete bioburden testing.
- **Medtronic neurosurgery recalls Duet external drainage and monitoring system catheter tubing** due to a potential for the catheter disconnection from the patient line stopcock connectors.

Natus is currently on backorder for both cranial access kits and CSF external drainage kits and will remain on manual allocation until further notice.

- CSF external drainage kits – Natus is receiving weekly shipments consistently are allocating product first priority to current customers.
- Cranial access kits – Natus starting to receive more consistent shipments, but currently allocating product to the best of their abilities.

## Mitigation strategy

Due to the increased demand, Natus has implemented the **Natus Choice Standing Order Program** for these products. This is a standing order program that gives first priority to current customers taking part in this program. Priority for allocations will be given to providers who create a standing order for a monthly cadence of shipping. Natus has stated that the agreement can be changed at any time, and that their goal is to have full disclosure with all customers to understand how much product is needed, where it's going to, and when it's needed in order to be able to meet such increased demand. Providers should evaluate the program to determine if it is suitable for their organization's needs.

Providers should monitor and discuss inventory levels with clinicians, administrators and procurement specialists and engage in collaborative planning strategies as Natus builds up their safety stock. In addition, reviewing clinical practices and implementing conservation measures should help providers mitigate this disruption.

## Additional resources

Supply assurance webpage; Vizient Newsroom



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