

## Urgent Field Safety Notice

### Delta™ Neonatal Valves

Part Numbers 27219-1, 27219-2, 27219-5

December 2020

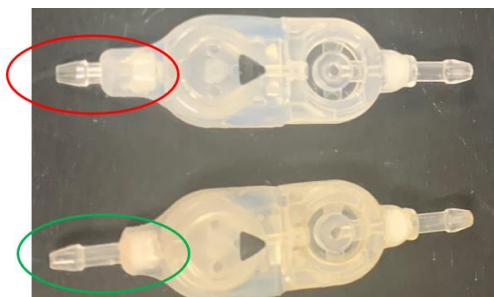
Medtronic Reference: FA950

Dear Healthcare Professional,

Medtronic is voluntarily recalling specific lots of the Delta™ Neonatal Valves due to a manufacturing issue involving the proximal connector site of the valve.

#### Issue Description:

Medtronic has identified that specific lots of the Delta™ Neonatal Valves were manufactured with a shortened ventricular catheter connection site. This defect can lead to difficulty in adequately securing the valve to the proximal catheter with suture and can potentially result in disconnection of the ventricular catheter from the valve and shunt malfunction. Since October 26, 2020, Medtronic has received two complaints on this issue, one of which involved disconnection leading to revision surgeries.



Top: Nonconforming valve (red circle)  
Bottom: Conforming valve (green circle)

#### Patient Management:

For patients who have been implanted with an impacted valve, close observation is recommended. Elective removal or revision is **not** recommended for this issue.

#### IMPACTED LOTS

Part Number	Description	Impacted Lots		
27219-1	Delta™ Neonatal Valve, Performance Level 1.0	0219927059	0220149614	0220393237
		0220601648	0220601649	0220813029
27219-2	Delta™ Neonatal Valve, Performance Level 2.0	0219281777		
27219-5	Delta™ Neonatal Valve, Performance Level 1.5	0219948893	0220166870	0220236215
		0220704352	0220720015	0220752505

**Required Actions:**

1. Identify, segregate, and quarantine affected valves within your inventory.
2. Contact your Medtronic representative directly to return affected valves and receive replacement(s).

The Competent Authority of your country has been notified of this action.

We regret any inconvenience that this issue may have caused. Medtronic is committed to patient safety and appreciates your prompt attention to this matter.

If you have questions related to this issue, please contact your local Medtronic representative directly or via Tel No: 01 511 1400.

Sincerely,



Keith Taverner  
Regulatory Affairs Manager UK & Ireland