Thursday 18th February 2021

URGENT MEMO re MEDTRONIC VALIANT NAVION THORACIC ENDOGRAFT

Many users of the Medtronic Valiant Navion thoracic endograft will be aware that, approximately 48 hours ago, Medtronic advised that it should no longer be implanted. As we understand it currently, this relates to durability concerns and is *not* related to any deployment issues.

Medtronic is actively working with Trusts and other industry partners to ensure adequate alternative stock across the UK. They aim to restock consignment with Valiant Captivia devices within the next few days and are prioritising centres with a higher volume emergency service, MTCs and those with no other stock of, or experience with, other thoracic endografts. This may mean that if your Trust has consignment of Captivia devices, some sizes may need to be re-distributed and we would support cooperation with this.

Planned cases are not affected and Medtronic will be able to deliver an appropriately sized Captivia graft for an individual case within the standard timeframe. The current situation really applies to the following conditions (when consignment stock would be used):

a. Emergency treatment of a complicated type B dissection
b. Thoracic rupture
c. Traumatic blunt aortic injury

As a Society, if your unit is impacted by this, we would advise the following interim measures would be sensible:

1. Inform your Medical Director of the potential risk now.
2. Use other devices where possible and consider mentoring of colleagues on the emergency rota where there is less experience with an alternative device.
3. Consider transfer of a patient (if safe and appropriate to do so) to a local centre if there is alternative device stock on that site.
4. Only in extreme situations implant a Navion device, as a life-saving procedure, when all other alternative options have been exhausted.

Medtronic is actively working to resolve this as fast as possible. Further advice will be issued in due course regarding the management of patients who have already had Medtronic Navion implants.

The MHRA is already aware of the directive from Medtronic, but individuals are still encouraged to use the Yellow card reporting structure if they are aware of any adverse outcomes.

Michael Jenkins
President VSGBI