To: Paediatric critical care ODNs
Neonatal ODNs
Adult Critical care ODNs
Children's Surgery ODNs

Trust Directors of Nursing
Trust Medical Directors
Trusts heads of procurement
Trust Heads of EPRR
Trust Allied Health Professional Directors

ICB Directors of Nursing
ICB Medical Directors
ICB Procurement Leads
Community Nurses

cc. Regional Deputy Directors of EPRR
Regional Directors of Nursing
Regional Medical Directors
Regional AHP leads

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

14 June 2024

Dear colleagues,

ICU Medical (formerly Smiths Medical) - Urgent Field Safety Notice: Bivona® Neonatal/Paediatric and Adult Tracheostomy products

Background

We are writing to inform you of a safety issue regarding some product lines of Bivona Tracheostomy tubes used in neonatal, paediatric and adult patients

ICU Medical (formerly *Smiths Medical*) have discovered a manufacturing defect in multiple batches of their products manufactured between June 2019 and May 2024 and have issued a field safety notice (FSN) advising of next steps.

See **Annex B** for the FSN and full list of products affected. This information is also available online here.

The MHRA have been working with the company to receive assurance that the root causes of the issue have been addressed and corrective actions are in place on an ongoing basis.

Unaffected *ICU medical* stock and alternative products e.g. from Atos Health, are available. This can provide like-for-like replacement of affected stock where desirable.

Action required by Trusts

ACTION 1: Trusts are requested to follow the directions of the FSN, review and if necessary, quarantine and then dispose of all affected products in accordance with local policy. The list of affected product codes can be used to check batch numbers of all locally held stock. Both central stores and areas where smaller quantities may be deployed (such as resuscitation trolleys) should be checked.

ACTION 2: Trusts are asked to ensure the FSN and this accompanying advice is shared with relevant clinicians. This will likely include, (but is not limited to) any team caring for an adult, child or neonate with a tracheostomy in situ or which might be responsible for inserting a tracheostomy: this would include critical care teams (neonates, children and adult), surgical teams, paediatricians, community nursing and speech and language therapy teams.

ACTION 3: Clinicians should read and follow the instructions in the FSN, and then contact all affected patients and care partners in the community to update them of the situation. The FSN notes that "if, the device is currently in-situ for a patient currently being ventilated, the clinician should consider the risks and benefits of leaving the device in situ (for a maximum of 29 days as per the intended purpose) versus explantation and exchange for an alternative product". Please consider ease of access to hospital as part of the risk assessment as well as creating escalation plans based on risk.

Given that alternative products or unaffected ICU Medical stock are available for new patients or replacement of expired tubes, existing local stock of affected batches should not be used, unless in extremis. The FSN notes that "If, due to extenuating circumstances, an alternative device cannot be used, all instructions, including warnings and cautions contained in the Instructions for Use Documentation must be followed with heightened awareness when checking the device prior to use, securing and checking devices in use".

A flowchart to support clinical decision making has been developed and is available in Annex A to this letter.

Availability of unaffected ICU Medical stock

Impacted stock in national supply depots has now been quarantined.

Unaffected stock from ICU Medical is available from NHS Supply Chain across most paediatric and neonatal product lines, with the exception of one 4.5mm Paediatric tracheostomy tube (NPC FDG257, MPC 60P045). An alternative product matrix is available via NHS Supply Chain and should be reviewed, in conjunction with your own clinical review.

NHS Supply Chain is working to ensure sufficient supply to allow for replenishment of local stockholdings where it is necessary to replace quarantined stock.

Alternative products from other suppliers

Potentially suitable alternative products from other suppliers are available with good national stockholding. However, any switch of products should be subject to a risk assessment. See **Annex A** for a flowchart to help guide this process.

How can I access replacement products?

For NHS Supply Chain customers*:*

Customers who purchase through NHS Supply Chain are advised to continue ordering through normal routes. Your NHS Supply Chain Customer Services Advisor can support with placing additional orders. An NHS Supply Chain Important Customer Notice (ICN) detailing the affected products has been produced and will be kept updated: NHS Supply Chain ICN - Smiths Medical Bivona® Neonatal/ Paediatric and Adult Tracheostomy Tubes (ICN 2569)

Trusts who purchase direct from ICU Medical:

Customers who purchase direct from ICU Medical are advised to follow the contact details listed in the FSN.

Independent providers

There is potential that the affected products will also be use in the Independent sector, whether for NHS-funded or private healthcare.

ICBs are asked to contact relevant independent providers in their locality to ensure they are aware of the situation and taking action accordingly in light of the FSN. This may include major acute providers and hospices.

Contact details

Escalations - Should Trusts have concerns about immediate supply of key products and be at risk of running out of stock in the next 4-5 days, please escalate to the National Supply Disruption Response (NSDR) helpline - 0800 915 9964.

Supply chain customer queries - Where Trusts purchase through NHS Supply Chain, your existing NHS Supply Chain ICS Manager should be your first point of contact for general queries.

Ongoing national oversight of the issue

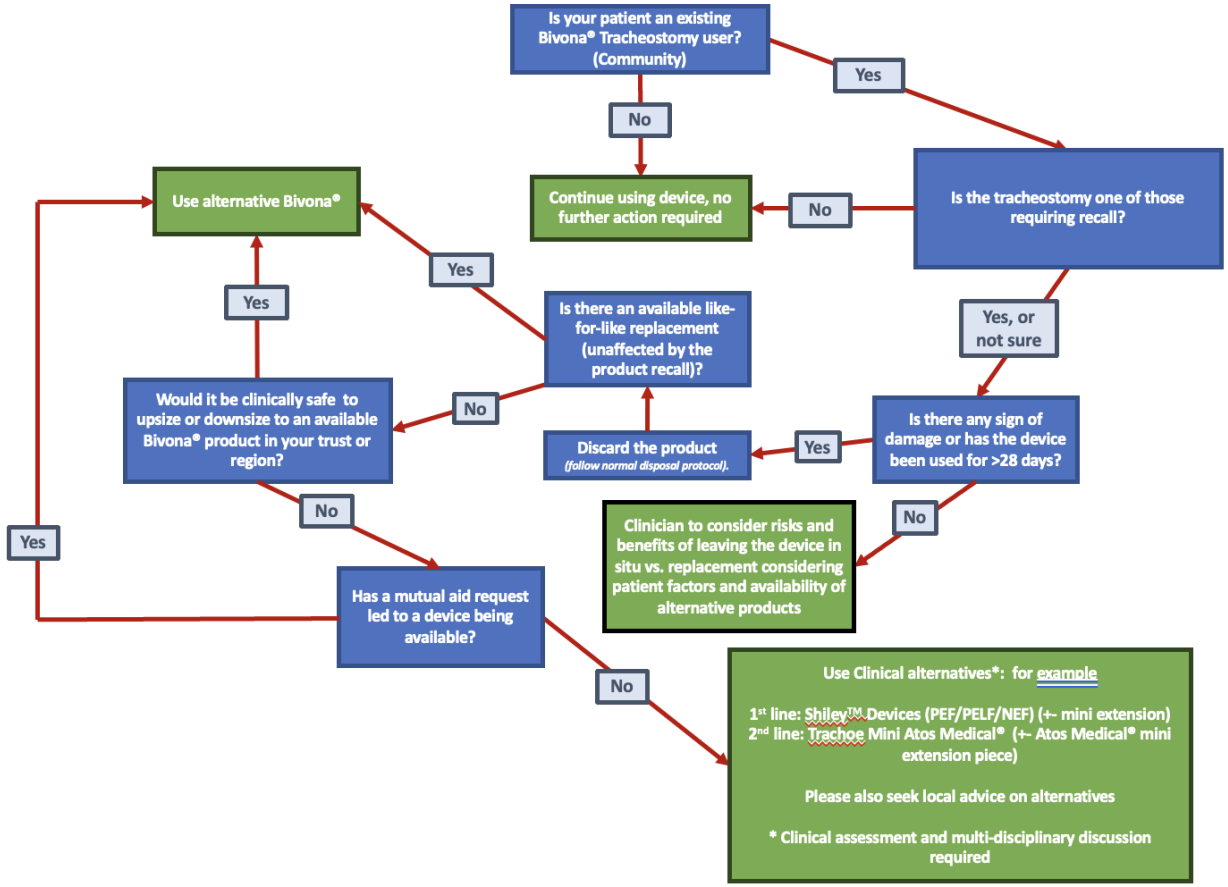
NHS England is working closely with DHSC, NHS Supply Chain and MHRA and are in regular contact with ICU Medical regarding this issue. Longer-term monitoring of the safety of the products will continue by MHRA over the coming months.

Your cooperation and proactive engagement are vital to mitigating the risk of this product issue, ensuring we continue to provide safe and effective care across all settings.

Yours sincerely,

Mike Prentice
National Director for Emergency Planning and Incident Response, NHS England

Annex A: Decision tree to support clinical decision-making



Any change of device will require clinical assessment, as these products have varying lengths, curvature, flanges and external diameters. If this difference has a potential clinical impact or patient specific risks, consider contacting the specialist clinical team at your tertiary trust for advice and or a face-to-face assessment of the infant, child, or young person.

Any changes will need to involve clear communication with patients and their families and or carers and their usual clinical teams. Extra support may be needed for patients, families and their carers during this transition including providing appropriate training on the new device.

Annex B – FSN and list of affected lots / batches:

URGENT Field Safety Notice - FA2404-01 -

2569 Bivona Product Listing.xlsx