

## Mallinckrodt Pharmaceuticals, INOmax™ and Coronavirus Preparation

### Frequently Asked Questions (FAQs) for Customers 4<sup>th</sup> May, 2020

- 1. Q: Is Mallinckrodt experiencing operational interruptions due to the COVID-19 Pandemic?**  
No. There is currently minimal impact to our logistics or supply chain as a result of COVID-19 Pandemic.
- 2. Q: How is Mallinckrodt responding to the COVID-19 pandemic?**  
We rely on close communication with authorities and our customers. We are monitoring the impact of COVID-19 Pandemic, and responding with appropriate inventory and supplies to meet patient and customer demand during the current situation.
- 3. Q: How is Mallinckrodt supporting current demand for medical equipment in light of COVID-19 Pandemic?**  
Mallinckrodt maintains a reasonable number of INOmax™ DSIR Plus devices for the delivery of Inhaled Nitric Oxide on hand and is actively increasing the number of devices to maximize availability and readiness to meet demand as needed. *Please note that additional devices beyond current stock may take 4 – 6 weeks to arrive in Australia. If you wish to discuss your inventory needs at any time, please speak to your Mallinckrodt Critical Care Business Manager on 1300 198 565.*
- 4. Q: Can we relocate devices outside our hospital?**  
During this time, as per existing contractual agreements, customers should not relocate devices outside of their current facilities, as proper relocation procedures need to be followed to ensure the device integrity and patient safety. If you are contacted to provide a device to another facility, please call us so we can work with you to make appropriate arrangements.
- 5. Q: Does Mallinckrodt have sufficient stock on hand in response to INOmax™ Total Care requests if needed?**  
Yes. The needs of patients and customers remain our highest priority. We are working closely with all our customers to ensure that sufficient devices, drug and consumables are available to support patient treatment.
- 6. Q: How are you ensuring your equipment is clean, sanitized and patient-ready before delivering to our hospital?**  
Mallinckrodt is ISO 13485:2016 compliant across all Regional Service Centres. Our standard policies and procedures for prioritising patient safety and minimising infection risks include:

  - Cleaning procedures as per our operation manual
  - Distinct equipment work areas for separation of returned and available equipment, within a clean air environment
  - Dedicated technicians trained on correct decontamination procedures for each device
  - Appropriate personal protective equipment (PPE) is being used
  - Regional Service Centers are audited annually to ensure compliance
- 7. Q: As a customer, do I need to take additional steps to clean my INOmax™ DSIR Plus Delivery System?**  
We ask that you use cleaning procedures listed in the operations manual and your institutions current cleaning policy.

We appreciate that the coming weeks and months may also see an increased demand for delivery devices and, while we are committed to providing a minimally interrupted service to the healthcare system, we are operating with finite resources at our disposal. We are working with our global counterparts to increase our resources at this time and will keep our customers informed of additional capacity and other developments as the information becomes available.

*If you have any additional questions about our preparedness and response related to COVID-19 Pandemic, please contact **Mallinckrodt Customer Care at 1300 198 565.***

Mallinckrodt Pharmaceuticals advises prescribers that any use of a medicine outside its TGA approved indication must be under the TGA Special Access Scheme (SAS) which provides access to non-approved therapeutic goods / indications. Details of the SAS process are provided at <https://www.tga.gov.au/form/special-access-scheme>.

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