



Mallinckrodt[™]
Pharmaceuticals

Technical Bulletin

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Product: INOmax DS_{IR}[®], INOmax DS_{IR}[®] Plus

Priority: Low

INOmax DS_{IR}[®] Plus MRI, INOflo DS

Affected parts: Single-Use Parts (disposable parts)

Classification: Information for Distribution

Subject: **Reusing Single-Use Devices (disposable parts and/or accessories)**

WARNING: Do not attempt to reprocess or re-use single-use devices. This can lead to risk of cross-contamination, compromised functionality and bio-incompatibility.

A device that is categorized as single-use will have the following symbol on the packaging label:



A single-use device is intended for one use or for use on a single patient during a single procedure. Do not reuse. Single-use devices are not meant to be reprocessed and used again, even on the same patient.

Reprocessing single-use devices can lead to the following unsafe conditions:

- Cross-contamination due to the inability to clean and decontaminate due to design.
- Compromised functionality due to device failure from reprocessing or reuse because of fatigue, material alteration and embrittlement, leading to patient injury.
- Bio-incompatibility due to residues/toxins from chemical decontamination agents left on materials that can absorb chemicals.

Choosing to reprocess or reuse a single-use device may impact the safe performance of the INOmax DS_{IR}, INOmax DS_{IR} Plus, INOmax DS_{IR} Plus MRI or INOflo DS.

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