Technical Bulletin

Ref: TB-17001-ENG  Issue date: February 2017
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)

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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:

\[ \text{No Reuse Symbol} \]

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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