



Mallinckrodt[™]
Pharmaceuticals

Technical Bulletin

Ref: **TB-20006-ENG**

Issue date: 2020

Product: INOmax DS_{IR}[®], INOmax DS_{IR}[®] Plus, INOmax DS_{IR}[®] Plus MRI, INOflo DS, INOvent, Investigational Blinded NO Delivery System, Investigational NO Delivery System for Human Use Only, Investigational NO Delivery System for Animal Use Only.

Priority: Low

Affected parts: Accessories

Classification: Information for Distribution

Subject: Part Number Changes for Accessories

The purpose of this Technical Bulletin is to inform the user of part number changes for accessories relating to the above listed products.

The following part numbers have been changed as a consequence of implementing US Unique Device Identification (UDI) labeling requirements. This is a labeling change only with no accessory impact.

UDI information will appear on each accessory label for manufacturers tracking purposes.

IMPORTANT: Please continue to use your existing inventory of accessories until exhausted. There is no set expiration date for your existing accessory inventory. When ordering new accessories, please refer to the tables listed below:

Note: Not all accessories listed below are required in all regions.

Cautions:

- Each accessory must be used prior to the date of expiry that has been stated on the label.
- If past its expiration date, the accessory, with the exception of the Injector Module, Injector Module Cable Assembly, and MR Injector Module Cable Assembly below, should be disposed of as per hospital guidelines.
- For the Injector Module, Injector Module Cable Assembly, and MR Injector Module Cable Assembly, follow the recommended cleaning procedures outlined in the Device IFU if used beyond the Use By date on the packaging. The Injector Module, Injector Module Cable Assembly, and MR Injector Module Cable Assembly do not expire.

If the Injector Module, Injector Module Cable Assembly, and MR Injector Module Cable Assembly are not in original packaging, ensure item(s) are cleaned per the instructions in the Device IFU prior to use.

The 'Use By' date will appear on each accessory label in the following format:



Example ONLY

Accessories

Description	Previous Part Number	New Part Number
Injector Module Cable Assembly	90838	91342
Injector Module	90849	91359

MRI Accessories

Description	Previous Part Number	New Part Number
MR Injector Module Cable Assembly	90850	91369

Accessories (5 pack)


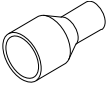


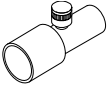







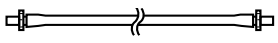

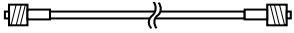


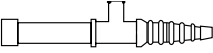

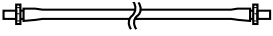

Image	Description	Previous Pack of Five (Part Number)	New Pack of Five (Part Number)
	Adapter, 15M Fits 4.5mm ID Tubing	50244	50411
	Adapter, 22F X 15M	50243	50410
	Adapter, 22M/15F X 22M/15F	50242	50409
	Adapter, Cuff, 22mm ID X 22mm ID	50253	50420
	Adapter, Gas Sample Tee	50241	50408
	Adapter, 90 Degree Sample Port	50252	50419

Image	Description	Previous Pack of Five (Part Number)	New Pack of Five (Part Number)
	Bunnell Life Pulse Disposable Adapters Convenience Pack	50249	50416
	Patient Sample Gas Line Disk Filter, 1.0 micron, glass fiber	50258	50425
	Patient Gas Sample Line with Filter	50194	50404
	Water Separator Cartridge, INOmax DS _{IR}	50247	50414
	Water Separator Cartridge, INOvent	50256	50423
	Neonatal Tubing, 10mm (2 pieces)	50255	50422
	NO/N ₂ Injector Tube	50240	50407
	One-Way Valve, 22F X 22M	50245	50412
	Patient Gas Sample Line	50259	50426
	Patient Gas Sample Line with (Nafion)	50257	50424
	Pediatric Extension, 15 mm, 6 inches	50254	50421
	Sample Tee, O ₂ Tubing	50246	50413
	Sensormedics 3100A/B Filtered Circuit Disposable Adapters Convenience Pack	50251	50418

DS_{IR} Plus MRI accessories (5 pack)

Image	Description	Previous Pack of Five (Part Number)	New Pack of Five (Part Number)
	MR, NO/N ₂ Injector Tube	50260	50427
	MR, Patient Gas Sample Line with Filter	50275	50429

For technical assistance regarding any of the above devices, please contact Product Support at 1-877-566-9466 (North America) or your specific country manager.

Mallinckrodt Manufacturing LLC
6603 Femrite Drive,
Madison, WI 53718-6801 USA

Mallinckrodt, the “M” brand mark and the Mallinckrodt Pharmaceuticals logo are trademark of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owner. ©2020 Mallinckrodt.

