

INFORMATION FOR LIMITED DISTRIBUTION



Mallinckrodt[™]
Pharmaceuticals

Technical Bulletin

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Product: INOmax DS_{IR}[®] Plus MRI

Priority: Low

Affected Parts: INOMAX[®] Cylinder, Cart Auto-Brake and Transport Regulator/Cap Assembly

Classification: Information for Limited Distribution

Subject: **MRI User Updates**

WARNING:

Only use a size “88” (1,963 liters) cylinder that is marked “MR Conditional. Keep cylinder at 100 gauss or less.” Use of any other cylinder may create a projectile hazard.

INOMAX cylinder valve cap and INOmeter lock

Each INOMAX cylinder is shipped with a red plastic INOmeter lock (1) which prevents the INOmeter from moving during shipping and a metal cylinder valve cap (2), which protects the valve outlet (see Figure #1). The INOmeter lock and cylinder valve cap are attached to a locking metal snap ring (3) using a vinyl coated wire (4) and chain (5).

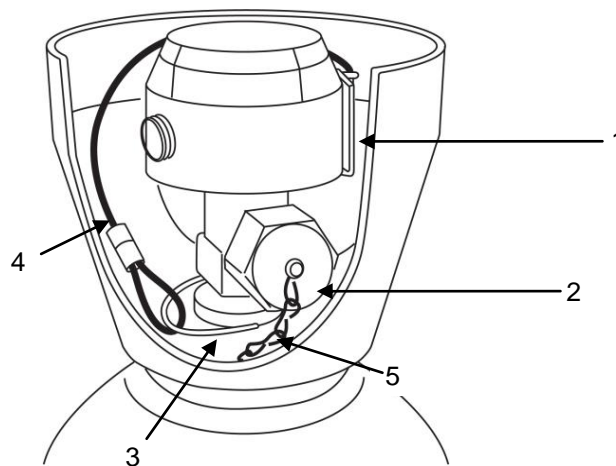


Figure #1

The cylinder valve cap, vinyl coated wire, metal locking snap ring and chain contain ferromagnetic materials and may represent a projectile hazard if not properly attached. When the INOmax DSIR Plus MRI is used according to the manufacturer's instructions in areas where the field strength is less than 100 gauss, they do not present a projectile hazard . The metal locking snap ring must be inspected to confirm attachment prior to entering the MR scanner room.

Complete the following steps prior to entering the scanner room on all INOMAX MR Conditional cylinders:

Step one:

Remove the tape and shrink film from the INOmeter and valve (see Figure #2).

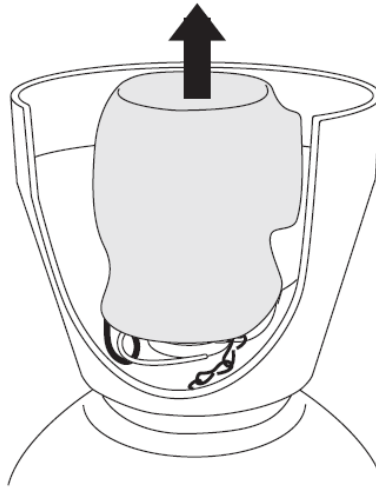


Figure #2

Step two:

Verify that the metal locking snap ring is latched and secured around the cylinder valve (see Figure #3). Reconnect and secure the snap ring if it is not properly latched.

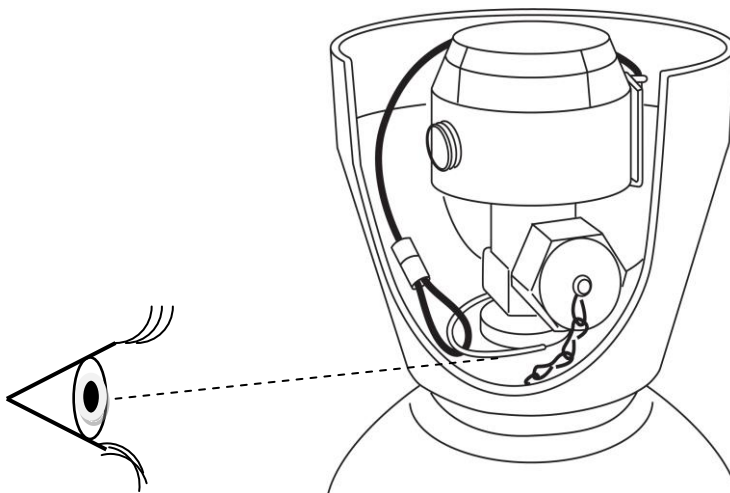


Figure #3

Alternatively, if hospital policy dictates, the INOMAX cylinder valve cap and INOmeter lockout assembly may be removed by unlatching the metal locking snap ring and removing the assembly (see Figure #4). Do not dispose of the lock/valve cap assembly, reattach when the cylinder is returned to Mallinckrodt.

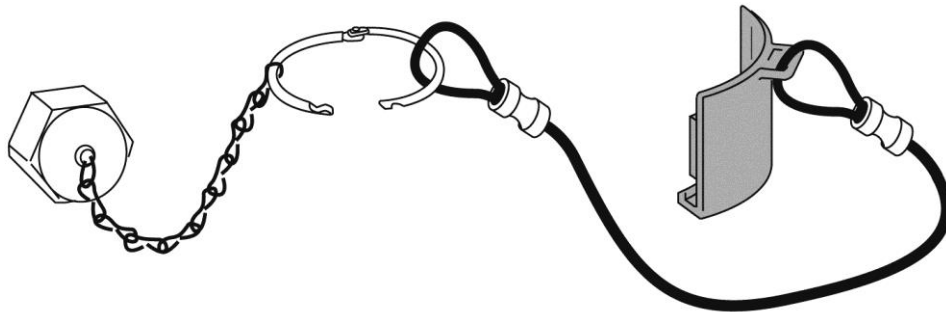


Figure #4

Testing the INOmax DS_{IR} Plus MRI Cart Auto-Brake

Pull up on the brake handle (see Figure #5), the INOmax DS_{IR} Plus MRI cart should now move freely. While pulling the cart towards you, release the handle, the cart should stop or be difficult to move. If the cart continues to move freely when the brake handle is released, do not use the device and contact your local representative.

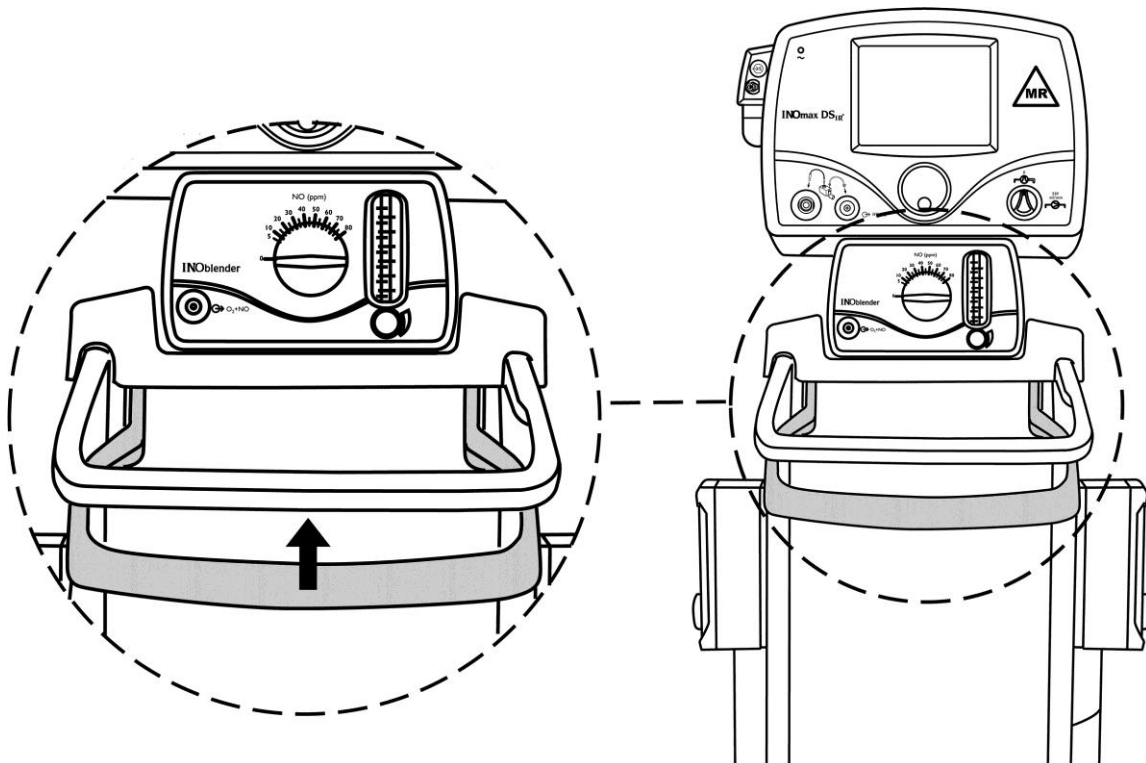


Figure #5

WARNING: If the cart moves freely when the brake handle is released, do not use the device.

Transport Regulator/Cap Assembly

Do not use the transport regulator/cap assembly in the MR scanner room.

Although the transport regulator/cap assembly may be used to prevent external light/Infrared (IR) communication interference in the ICU, the transport regulator/cap assembly has not been validated for use in the MR scanner room.

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