Mallinckrodt Pharmaceuticals

March 7, 2016

Subject: INOMAX Cylinder Label – MR Conditional Symbol Added

Dear Valued Customer:

The letter is to inform you of a recent update to the INOMAX cylinder label. The INOMAX cylinder label now displays a MR Conditional symbol (Fig 1).

There are no physical or drug content differences between the cylinders bearing the MR symbol label and those currently at your institution that may not bear the symbol. This symbol simply indicates testing has been completed and the 88A cylinder is now approved for use in the MRI suite at the 100 Gauss line or less.

The smaller D size transport cylinder will not have this symbol on the label because it does not qualify for use in the MRI environment.

All 88A cylinders in the current inventory, with or without the MR symbol, are compatible with all INOmax DSIR®, INOmax DSIR® Plus and INOmax DSIR® Plus MRI delivery systems.

The transition to the new label has been completed at our manufacturing facility. Therefore, as used 88A cylinders in your inventory rotate back to Mallinckrodt, you will begin to see the MR symbol on your replacement cylinders.

Please note, however, that the INOMAX DSIR PLUS MRI device is the only nitric oxide delivery device cleared as MR Conditional for use in the MRI environment.

Fig 1

We appreciate your business and look forward to serving you in the future.
For questions regarding this information please contact Customer Care at 877-566-9466.

"Refer to the INOmax DSIR® Operation Manual, which is the source for specific, updated information regarding device warnings, cautions and instructions relating to the operation of the device."