

IRADIMED CORPORATION Issues Urgent Medical Device Correction

Letter Notifying Customers of Potential Issues with MRidium 1057 MRI Syringe Adapter Set

WINTER SPRINGS, Fla., Feb. 24, 2023 — IRADIMED CORPORATION (the “Company”) (NASDAQ: IRMD) issued an Urgent Medical Device Correction Letter to notify affected customers of a potential issue with some 1057 Syringe Adapter Sets related to the syringe venting function during use which can lead to reduced flow with the MRidium infusion pump resulting in subsequent inlet occlusion and alarm indication. The 1057 Syringe Adapter Set is a unique IV fluid administration set with a vented syringe adapter (disposable tubing), which allows for the delivery of IV fluids from syringes while on the Company’s infusion pump. The customer notification, which outlines the potential risks associated with the 1057 Syringe Adapter Set, lists the affected products, and the updated labeling provides specific actions users should take to identify any venting and infusion delivery issues before an unexpected inlet occlusion occurs.

Iradimed received five customer complaints of an unexpected inlet occlusion alarm resulting in the infusion being stopped, none of which were associated with injuries or death. Upon investigation, the Company identified a defective injection molded part that can limit the effectiveness of the syringe vent and result in this condition in an estimated 0.4% of recently manufactured 1057 infusion sets.

This action was taken voluntarily to maximize the safety of the device’s use and with the knowledge of the FDA. No other of the Company’s IV sets or disposables are involved, and the Company does not expect any material financial impact from this action.

About IRADIMED CORPORATION

IRADIMED CORPORATION is a leader in developing innovative Magnetic Resonance Imaging (“MRI”) compatible medical devices. We design, manufacture, market, and distribute MRI-compatible medical devices, accessories, disposables, and related services.

We are the only provider of a non-magnetic intravenous (“IV”) infusion pump system designed to be safe during MRI procedures. We were the first to develop an infusion delivery system that eliminates many dangers and problems during MRI procedures. Standard infusion pumps contain magnetic and electronic components which can create radio frequency interference and are dangerous to operate in the presence of the powerful magnet that drives an MRI system. Our patented MRidium® MRI-compatible IV infusion pump system has a non-magnetic ultrasonic motor, uniquely designed non-ferrous parts, and other unique features to deliver anesthesia safely and predictably and other IV fluids during various MRI procedures. Our pump solution provides a seamless approach that enables accurate, safe, and dependable fluid delivery before, during, and after an MRI scan, which is essential to critically ill patients who cannot be removed from their vital medications and children and

infants who must generally be sedated to remain immobile during an MRI scan.

Our 3880 MRI-compatible patient vital signs monitoring system has been designed with non-magnetic components and other unique features to monitor a patient's vital signs safely and accurately during various MRI procedures. The IRADIMED 3880 system operates dependably in magnetic fields up to 30,000 gauss, which means it can operate virtually anywhere in the MRI scanner room. The IRADIMED 3880 has a compact, lightweight design allowing it to travel with the patient from the critical care unit to the MRI and back, resulting in increased patient safety through uninterrupted vital signs monitoring and decreasing the amount of time critically ill patients are away from critical care units. The features of the IRADIMED 3880 include wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms; non-magnetic respiratory CO2; invasive and non-invasive blood pressure; patient temperature, and optional advanced multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements. The IRADIMED 3880 MRI-compatible patient vital signs monitoring system has an easy-to-use design and effectively communicates patient vital signs information to clinicians.

For more information, please visit www.iradimed.com.

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