



URGENT
FIELD SAFETY NOTICE

Product(s) involved: Manual Pressure Infusors under the InfuseIT® brand.
Item numbers ZIT-500, ZIT-502, ZIT-1000, ZIT-1002

Scope: Applies to all lots with Rev. 11 (or earlier) version of the Instructions For Use.

Ref. #: 13-FEB-2015

Zefon International has been notified of an event where the subject device was not able to maintain arterial line pressure. In addition, Zefon has been asked to clarify usability of the device.

Description of Problem

When using the device to maintain arterial pressure on patients with elevated systolic blood pressure, line equilibrium may occur after several hours of use.

The device labeling does not make clear if the device is a single use device or not because the labeling indicates it is disposable, however cleaning instructions are provided in the IFU.

Action taken

In response to this event Zefon is modifying the provided instructions for use to include the following statement:

If using the device for arterial monitoring over the course of several hours on patients with high blood pressure, line pressure equilibrium may occur. For these applications, use of Zefon's Reusable InfuseIT® (p/n ZIT-520 and ZIT-1020) is recommended.

To further clarify the usability of the device, it is disposable and may be cleaned if desired. To communicate this more clearly, Zefon is modifying the provided instructions for use to include the following statement:

InfuseIT manual pressure infusors are disposable devices but may be cleaned by using the following method: (cleaning instructions will follow)

Required User Action

Please pass this field safety notice to all those who need to be aware of it within your organization and maintain awareness until receipt of such lots that are no longer within scope.

IF YOU ARE NOT THE END USER of these devices, you have an obligation to pass on this field safety notice to organizations to which the devices have been transferred.

Zefon staff is available to assist with any questions you may have regarding this FSN. If you need additional assistance, please contact Zefon's Quality Manager, Jonathan Heil, at +1-352-291-8444.

The undersigned confirms that all relevant Regulatory Agencies have been notified of this FSN.

[Redacted Signature]

Date: 18-FEB-2015

Jonathan Heil – Quality Manager