REDAX® S.p.A.
MEDICAL DEVICES

Sede legale: 46025 Poggio Rusco (MN),Via Galileo Galilei n. 18
Cap. sociale Euro 1.000.000 i.v. iscritta al
Reg. Imprese di Mantova C.F. e N. iscr. 01796710810
ed al n. 245014 R.E.A. di Mantova
Tel.: + 39 0386 830582 - Fax: +39 0386 51898
Codice fiscale 01796710810 - Partita I.V.A. n. 02556750368
E-Mail: info@redax.it

Poggio Rusco, 27th January 2016

Urgent Field Safety Notice

Product Name**: PVC Trocar catheter CH 24**
ID FSCA: **270116**
Action: **Voluntary recall of medical devices**

To the kind attention of: Hospital general Direction, Vigilance System Managers, Local distributors.

Dear Valued Customer,

The purpose of this communication is to inform you about a potential safety problem relative to product:

PVC Trocar Catheter CH 24
Code: 21124
Lot: F1504010

Problem description:
From the post-marketing surveillance data evaluation appears that the lot above indicated may have a potential detachment of the distal blue connector of drain.

Potential risk:
The blue connector is usually connected to the fluid collection system. If any detachment occurs, the drain could be detached from the system causing possible infection of the pleural cavity or possible pneumothorax.

Action requested on Your part:

1. If the units have been already used, no further actions should be implemented.
2. If the product corresponding to the code and lot above indicated is in Your warehouse, identify the products and segregate them in order to be sure that none use them.
3. Recall immediately the units, if the product has been distributed to third parties (customers, wards, etc..).
4. Throw away the units collected.
5. Get in touch with our Customer Service Office to receive a replacement or a credit note.

Other actions
Read, fill in and sign **Customer confirmation form** in Annex A, even if You don't have any stock. Send the form by fax or email to the attention of Quality Assurance office as soon as possible and not later than 10 (ten) days from receiving this communication.

REDAX® S.p.A.
MEDICAL DEVICES

Sede legale: 46025 Poggio Rusco (MN),Via Galileo Galilei n. 18
Cap. sociale Euro 1.000.000 i.v. iscritta al
Reg. Imprese di Mantova C.F. e N. iscr. 01796710810
ed al n. 245014 R.E.A. di Mantova
Tel.: + 39 0386 830582 - Fax: +39 0386 51898
Codice fiscale 01796710810 - Partita I.V.A. n. 02556750368
E-Mail: info@redax.it

Safety notice Communication:
This notice has been sent because our records suggest that Your Factory has purchased this product. This notice shall be passed to any health professional of your organization that need to be aware of this issue or to any other organization where the potentially affected devices have been transferred.

The Competent Authority has been notified in regard to this Field Safety Notice.

We thank you for Your kind collaboration.
Redax is committed to promoting a fair and continuous information to users and health professionals on important issues such as the health of users and their recommendations concerning medical devices and services.
For any further information or questions we invite you to contact our offices (Customer Service/ Quality Assurance):

Redax SpA

Tel. +39 0386 830582

Fax. +39 0386 51898

E-mail: daniela.malavasi@redax.it

E-mail: andrea.gibertoni@redax.it

We apologize for any inconvenience this situation could cause.

Yours sincerely,

REDAX® S.p.A.
MEDICAL DEVICES

Sede legale: 46025 Poggio Rusco (MN),Via Galileo Galilei n. 18
Cap. sociale Euro 1.000.000 i.v. iscritta al
Reg. Imprese di Mantova C.F. e N. iscr. 01796710810
ed al n. 245014 R.E.A. di Mantova
Tel.: + 39 0386 830582 - Fax: +39 0386 51898
Codice fiscale 01796710810 - Partita I.V.A. n. 02556750368
E-Mail: info@redax.it

Annex A

Customer confirmation form

Please complete all of the details below and return the form duly filled in to Redax SpA by Fax or e-mail within 10 days from receiving this communication

Customer name: _____

Contact person name:_____

Section A – Verify quantity to recall and throw away	
Quantity in stock	Quantity distributed to ward or third parties

(only for Distributors) Section B – Distribution to the customers		
Name of customer/hospital to whom the product has been distributed	Quantity sold	Quantity withdrawn

☐ I confirm to have collected all the unused units and to have thrown away them.

Date: _____

Signature: _____