



URGENT MEDICAL DEVICE VOLUNTARY RECALL

Affected Devices: EXEL Huber Needle or EXELint Huber Needle
EXEL Huber Infusion Set or EXELint Huber Infusion Set
EXEL "Securetouch +" Safety Huber Sets or EXELint "Securetouch +"
Safety Huber Sets

**ALL LOT NUMBERS BEGINNING WITH 07, 08 or 09 ARE
AFFECTED BY THIS VOLUNTARY RECALL.**

Date: January 26, 2010

Attention: Distributors, Risk/Safety Managers, Clinicians, Nursing Staff, Patients
and other users of the above products

Products Affected

Exelint International Co. is voluntary recalling Exel Huber Needles produced between January, 2007 and August, 2009 because results from laboratory testing demonstrated that the affected Huber needles could core 60-72% of the time. These needles are labeled as "non-coring needles" and should not produce cores. Leakage from a port septum and transmission of cores into a port were observed during testing of the affected needles.

Huber needles are specially-shaped needles used to access subcutaneously implanted ports used for the withdrawal of blood samples, the infusion of medications, total parenteral nutritional solutions, blood products and imaging solutions into a patient.

Description of the Problem

When inserted into a port, the needles have been shown during testing to core (i.e. "punch-out") the silicone port septum which may then result in damage to the port septum. A damaged port may require surgery to replace.

Damage to the port septum could result in leakage. Depending on the nature of the therapy being infused, extravasation resulting from coring of the port septum may lead to localized tissue damage as well as incomplete administration of therapy.

In addition, if a Huber needle cores a port septum, a silicone sliver (foreign body) may possibly enter into the patient's body when the port is accessed and flushed for patency. Silicone slivers may not be visible to the naked eye, or may be flushed into the patient depending on the technique used by the healthcare practitioner.

All of these potential consequences may result in serious injury and/or death. **The company is therefore voluntarily recalling these products, although there have been no reports of patient injury to date.**

It is important to be vigilant in observing the signs and symptoms of a damaged port, because it is possible that a port has already been or can become damaged.

INTERNATIONAL HEADQUARTERS
MEDICAL PRODUCTS DIVISION

All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1168 Bank: City National Bank
e-mail: info@exelmed.com



ACTIONS TO BE TAKEN

FOR HOSPITALS, CLINICS, AND ANY OTHER USERS:

DO NOT USE THESE AFFECTED PRODUCTS. PLEASE RETURN ALL AFFECTED PRODUCTS IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED BELOW.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Please see the attached list of affected products. Purchasers should check the lot numbers of products in inventory to determine if they have product lots affected by this voluntary recall. The lot number identifier is indicated on the "Inner Box/25pcs" as well as on the "Outer Box/50pcs".

Please complete and return the enclosed Customer Response Form by fax or email so that we can provide return information and issue credit for the returned products. Please take this action no later than 30 days from the date of this letter.

The US Food and Drug Administration is aware of this action.

FOR DISTRIBUTORS:

Quarantine any product that is currently in your possession and do not distribute. Please complete and return the enclosed Customer Response Form immediately upon your receipt of this letter.

FOR SUB ACCOUNTS:

Please contact all of your customers, including any user facilities, including Hospitals, clinics, oncology centers or any Doctor's offices about this withdrawal. Instruct your customers to stop using the products immediately and ask for the product to be returned.

DIRECT ALL INQUIRIES TO:

EXEL International Customer Service 727-827-1922 ext. 0 Monday through Friday 9am-5pm EST or E-mail: info@exelint.com

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Customer Response Form

Date: _____

EXEL Huber Needles & Huber Infusion Sets

Please check all appropriate boxes.

I have read and understand the withdrawal instructions provided in the withdrawal letter.

I have checked my stock and have quarantined all affected inventory.

Has anyone experienced adverse events associated with this product? Yes No

If yes, please explain:

I plan to:

Return the items for a credit

Arrange for a Pick Up

Name: _____

Company: _____

Address: _____

City/State/Zip: _____

Telephone: _____

Email: _____

PLEASE FAX COMPLETED RESPONSE FORM TO 727-827-1635 or Email to info@exelint.com

Please address any questions to:

Customer Service
EXEL International
Tel. 727-827-1922
Fax 727-827-1635
E-mail: info@exelint.com

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