April 25, 2024

URGENT: MEDICAL DEVICE RECALL

Customer Information:
CIMed Healthcare Sdn Bhd
C-6-1 & C-6-3A Lobby C , Melawati Corporate Centre ,
Lot 29242, Jln Bandar Melawati, Taman Melawati,
53100 Kuala Lumpur

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Anika Therapeutics, Inc. is voluntarily recalling one manufacturing lot of **Tactoset® Injectable Bone Substitute**, a synthetic, biocompatible bone graft substitute material that hardens and converts to a semi crystalline hydroxyapatite at body temperature. It is indicated for filling bone voids or defects of the skeletal system (i.e. extremities and pelvis) that are not intrinsic to the stability of bony structure. The device is an injectable, self-setting, osteoconductive bone graft substitute that resorbs and is replaced by the growth of new bone during the healing process and may be combined with autologous bone marrow aspirate. Tactoset can also be used to augment hardware and support bone fragments during a surgical procedure. The cured material acts only as a temporary support media and is not intended to provide structural support during the healing process.

Anika has received two reports of situations where Tactoset did not set (harden) within the timeframe specified in the product's Instructions for Use (IFU). Anika has determined that both reports involved Tactoset from a single manufacturing lot.

No adverse patient outcomes, serious injuries or deaths have occurred or are expected to occur due to the delayed material setting time.

If Tactoset does not set within the expected timeframe, there could be a delay to the procedure in which it is being used, potentially exposing the patient to increased time under tourniquet or anesthesia. Usage of Tactoset which is not fully set may result in migration of the material into soft tissue surrounding the implantation site. In the worst-case scenario, this may lead to additional follow up by the surgeon to evaluate incomplete bone formation or lack of bone formation in the desired location, delayed union, or non-union.

How to recognize that the device may fail:
Failure of Tactoset to set within the specified time in the IFU (approximately 10 minutes at 37ºC (98ºF)) is discernable to the surgeon and should result in disposal of the device and selecting a substitute. In the event that the surgeon proceeds to use a device that has not fully set, there could be a potential delay to the procedure necessitating an alternate surgical plan to reduce patient risk.

For any patient that may have been implanted with recalled product, we recommend that healthcare providers use their judgement regarding patient follow-up. If the patient shows signs of incomplete bone formation or lack of bone formation, delayed union, or nonunion, the appropriate clinical measures should be taken based on the individual patient circumstances. If the patient experienced adequate healing, there is no reason to believe that there would be any additional concerns with the product.

Actions to be taken by the Customer/User:

Anika is requesting customers to do the following:

1. Please locate and remove the impacted product as specified in the table below from normal storage locations. Do not use product from this lot.
2. Complete the enclosed Recall Return Response Form and return via fax to 781-305-9720, via e-mail to TactosetRecall@anika.com, or certified mail to the address provided on the form.
3. Return product in accordance with the instructions provided on the Recall Return Response Form. If there is no product to return, please complete the form noting a quantity of zero.

Product Distribution Information				
Product Names, Unique Device Identifier	Manufacturer's Product Number/ Catalog Number	Lot/Serial Number	Manufacturing Dates	Expiration Date DD-Mon-YY
Tactoset 00817337000074	6000041	0000010390	12-Jul-23	12-Jul-26

Action by the Company:

Anika has implemented corrective actions to ensure Tactoset product performs as intended and will be reporting this recall to FDA in accordance with all applicable guidance and regulations. Adverse reactions or quality problems experienced with the use of this product may be reported to Anika by emailing globalcomplaints@anika.com. They may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Please visit http://www.fda.gov/MedWatch/report.htm for more information.

Authorized by:

Mira Leiwant,
Vice President, Regulatory, Quality and Clinical Affairs
Anika Therapeutics, Inc.
mleiwant@anika.com +1 (781) 457-9204

Attachment: Customer Confirmation Form

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer Information:
CIMed Healthcare Sdn Bhd
C-6-1 & C-6-3A Lobby C , Melawati Corporate Centre ,
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53100 Kuala Lumpur

TACTOSET®
INJECTABLE BONE SUBSTITUTE

Lot/Serial numbers: 0000010390

If there have been any adverse events associated with recalled product, please explain. If not, check 'Not Applicable'. **NOT APPLICABLE** ☐	**Details:**

Affected Product Information: Please complete the following information for the Tactoset product that you have received.

Affected Product Information Table				
Product/Brand Names, UDI	Manufacturer's Product Number/Catalog Number	Lot/Serial Number(s) shipped to Customer	Quantity Received	Quantity / returned
Tactoset 00817337000074	6000041	0000010390		

Return Response Box:

Please return all product from the specified lot numbers to Anika. A Returns Good Authorization (RGA) is attached. A return label is included in this package. A credit will be issued to your account. Please submit a new purchase order if you wish to replace the product.

ANIKA THERAPEUTICS, INC.
32 Wiggins Avenue
Bedford, MA 01730
www.anika.com

Anika customer service:
1-888-721-1600
customerservice@anika.com

ACKNOWLEDGEMENT COMPLETED BY

Name/Title	
Telephone	
Email address	

COMPLETED FORM TO BE RETURNED TO ANIKA:

Email	TactosetRecall@anika.com
Fax	781-305-9720
Mail	Anika Therapeutics, Inc. Attn: Tactoset Recall Acknowledgement 32 Wiggins Avenue Bedford, MA 01730