



## URGENT MEDICAL DEVICE RECALL NOTIFICATION

Date:

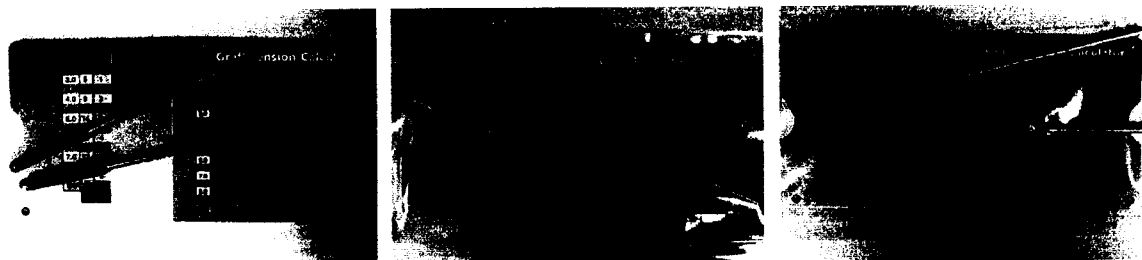
### SAMPLE

**Product:** ConMed Linvatec C9054 SE™ Graft Tensioner Breakaway Pins with Graft Tension Calculator, Sterile, Single-Use, Box of 5 Pouches. Each pouch contains 2 Breakaway Pins and 1 calculator.

**Lot Number(s):** See attached listing of affected lots distributed to your account.  
**Attention:** Risk Manager or Materials Manager

Our distribution records indicate your facility received one or more of the ConMed Linvatec C9054 SE™ Graft Tensioner Breakaway Pins with Graft Tension Calculator ("product"). ConMed Linvatec has determined there is a possibility that pin protective tip caps may come off of the pins and cause the pin(s) to puncture the poly pouch package, thereby potentially compromising the sterility of the device, and/or potentially causing an injury while handling the pouch. **Warning: Due to the nature of this problem, use extreme caution and care while handling the pouches to avoid injury by the sharp pins.** This recall is being conducted to the distributor and user level. Please do not use the product.

### Example of Product Packaging Problem



Please check your facility's inventory **immediately** for this product. If you have the product, please return the product to your ConMed Linvatec Distributor, for a credit. Please follow the instructions below. Your Distributor will collect any affected product and reply forms and will return them to ConMed Linvatec, Largo, FL.

1. Please complete the REPLY FORM and mail or fax to your distributor. Please return the product and reply form to your ConMed Linvatec Distributor.
2. Please use extreme care in handling the pouches. Please package all loose pouches in a box to return to ConMed Linvatec.
3. If there is no product to be returned, the reply form must be filled out and mailed or faxed to your ConMed Linvatec Distributor.



Replacement product is currently estimated to become available in June 2006.

Please accept our sincere apology for any inconvenience this action may have caused. Should you have any additional questions, please contact me at 727-399-5276, fax at 727-399-5264, email at [dmahoney@linvatec.com](mailto:dmahoney@linvatec.com) or contact customer service at 800-237-0169, email at [Custserv1@linvatec.com](mailto:Custserv1@linvatec.com)

Sincerely,

A handwritten signature in cursive script, appearing to read 'Deborah Mahoney'.

Deborah Mahoney  
Recall Coordinator  
Linvatec Corporation  
(International Customer letter)

**MEDICAL DEVICE RECALL NOTIFICATION  
REPLY FORM  
(Return to ConMed Linvatec Distributor)**

**FROM:**

**Date:**

**Product:** ConMed Linvatec C9054 SE™ Graft Tensioner Breakaway Pins with Graft Tension Calculator, Sterile, Single-Use, Box of 5 Pouches. Each pouch contains 2 Breakaway Pins and 1 calculator.

**Lot Number(s):** See attached listing of affected lots distributed to your account.

**International Customer Notification  
Linvatec RG Number: BA2000**

**CHECK/TICK:**

**Please check/tick all that apply.**

\_\_\_\_\_ I verify that our facility does not have any of the affected lot numbers remaining in inventory of the ConMed Linvatec C9054 SE™ Graft Tensioner Breakaway Pins with Graft Tension Calculator.

\_\_\_\_\_ The following product(s) are being returned for Credit \_\_\_\_\_.  
(Please attach additional sheets if necessary.)

Lot Number _____	Number of Pouches _____
Lot Number _____	Number of Pouches _____
Lot Number _____	Number of Pouches _____
Lot Number _____	Number of Pouches _____
Lot Number _____	Number of Pouches _____

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Telephone

\_\_\_\_\_  
Fax

**Please return the completed REPLY FORM and product to:**  
ConMed Linvatec  
International Distributor

**RG No. BA2000**

C9054 - List of Affected Lot Numbers, Manufacture Dates and Quantities Manufactured

CAT	LOT NO	QTY	DATE
C9054	00467996	20	12/20/02
C9054	00468997	20	01/02/03
C9054	00476484	21	01/30/03
C9054	00479127	37	02/10/03
C9054	00489287	13	03/14/03
C9054	00500100	25	04/23/03
C9054	00500101	25	05/07/03
C9054	00503594	20	05/13/03
C9054	00513622	24	07/25/03
C9054	00536458	50	09/15/03
C9054	00536459	50	09/29/03
C9054	00542023	20	10/07/03
C9054	00545300	50	10/16/03
C9054	00545301	50	10/30/03
C9054	00551020	50	12/03/03
C9054	00557370	50	12/09/03
C9054	00562646	25	01/22/04
C9054	00565800	25	01/22/04
C9054	00573830	50	01/29/04
C9054	00573831	50	01/30/04
C9054	00577089	50	02/06/04
C9054	BBB35599	50	03/09/04
C9054	BBB36106	50	03/12/04
C9054	BBB37122	45	03/23/04
C9054	BBB38744	50	03/31/04
C9054	BBB39280	50	04/06/04
C9054	BBB40892	50	04/20/04
C9054	BBB42869	50	05/03/04
C9054	BBB42870	50	05/04/04
C9054	BBB42942	50	05/04/04
C9054	BBB44437	25	05/18/04
C9054	BBB45893	50	05/25/04
C9054	BBB45895	35	05/25/04
C9054	BBB46813	100	06/03/04
C9054	BBB48228	65	06/11/04
C9054	BBB52252	100	07/16/04
C9054	BBB52253	100	07/19/04
C9054	BBB53242	100	07/30/04
C9054	BBB53599	100	08/04/04
C9054	BBB55558	50	08/09/04
C9054	BBB56118	50	08/18/04
C9054	BBB56731	50	08/23/04
C9054	BBB62064	50	09/28/04
C9054	BBB62369	50	09/29/04
C9054	BBB62708	50	09/29/04
C9054	BBB62848	50	10/04/04
C9054	BBB65271	50	10/13/04
C9054	BBB63035	50	10/15/04
C9054	BBB66237	50	10/22/04
C9054	BBB71060	50	11/24/04
C9054	BBB72840	50	12/17/04
C9054	BBB76468	100	01/04/05
C9054	BBB76474	50	01/06/05
C9054	BBB78965	50	01/18/05
C9054	BBB79719	50	02/01/05

C9054 - List of Affected Lot Numbers, Manufacture Dates and Quantities Manufactured

CAT	LOT NO	QTY	DATE
C9054	BBB81949	50	02/03/05
C9054	BBB84304	50	02/18/05
C9054	BBB85710	50	02/23/05
C9054	BBB85711	50	03/04/05
C9054	BBB88207	40	03/14/05
C9054	BBB88479	50	04/02/05
C9054	BBB93406	50	04/08/05
C9054	BBB94524	50	04/14/05
C9054	BBB95183	50	04/14/05
C9054	BBB95088	50	05/19/05
C9054	BBC00884	50	05/23/05
C9054	BBC01039	50	05/24/05
C9054	BBC02177	50	06/01/05
C9054	BBC03183	50	06/07/05
C9054	BBC03518	50	06/14/05
C9054	BBC05054	65	06/23/05
C9054	BBC08345	50	07/14/05
C9054	BBC08492	35	07/14/05
C9054	BBC11047	50	07/28/05
C9054	BBC11048	50	07/28/05
C9054	BBC11225	50	08/01/05
C9054	BBC11224	50	08/05/05
C9054	BBC12161	50	08/08/05
C9054	BBC12164	50	08/10/05
C9054	BBC13432	50	08/19/05
C9054	BBC13819	50	08/19/05
C9054	BBC15791	95	09/06/05
C9054	BBC16885	50	09/09/05
C9054	BBC16886	50	09/09/05
C9054	BBC17640	50	09/15/05
C9054	BBC18334	50	09/19/05
C9054	BBC18915	50	09/23/05
C9054	BBC20730	10	10/05/05
C9054	BBC21310	50	10/12/05
C9054	BBC21510	50	10/17/05
C9054	BBC22707	50	10/19/05
C9054	BBC22706	50	10/20/05
C9054	BBC24546	100	11/03/05
C9054	BBC24726	50	11/07/05
C9054	BBC31657	50	12/22/05
C9054	BBC32163	50	01/11/06
C9054	BBC32398	50	01/11/06
C9054	BBC33508	50	01/11/06
C9054	BBC32164	50	01/13/06
C9054	BBC34788	50	01/13/06
C9054	BBC37291	50	01/25/06
C9054	BBC37704	50	01/25/06
C9054	BBC37705	50	01/25/06
C9054	BBC37707	50	01/27/06

Total QTY = 5190