



Edwards

PRODUCT RECALL

EDWARDS LIFESTENT NT SELF EXPANDING STENT AND DELIVERY SYSTEM

Model Numbers Affected:

**NT186901, NT187901, NT186902, NT187902,
NT356901, NT357901, NT356902, NT357902**

INDICATE ONLY MODELS RELEVANT TO SPECIFIC CUSTOMER!!!

**HOSPITAL
ACCOUNT NUMBER**

DATE

Dear Customer,

In response to recent reports of difficulty in deploying some 6 and 7 mm diameter by 90 mm long LifeStents, Edwards is recalling these specific models of the LifeStent. The affected models are listed above. These models will be unavailable pending additional investigation and corrective action to prevent further deployment issues. It is important to note that only the specified model numbers are being recalled.

The attached sheet lists the products you have received from the recalled models. Please check your inventory immediately and return any unused stents from the list provided.

To return product, please contact **PLEASE FILL IN CONTACT!!!**

Please complete the attached form indicating the results of your stock check.

Fax the completed form to **INSERT FAX NUMBER OR INDICATE HOW FORMS AND SAMPLES WILL BE COLLECTED!!!**. This will allow Edwards Lifesciences to expedite any returns and confirm your awareness of the recall action.

Return product to the following address:

FILL IN ADDRESS IF APPLICABLE !!!

We sincerely regret the inconvenience caused by this recall but greatly appreciate your immediate attention to this matter.

Sincerely,

Rich Shumway
Vice President, Quality
Edwards Lifesciences LLC

Account number: