USA
Customer Adress

[redacted] PRODUCT INFORMATION

Date	19-Nov-07
Stryker RA Reference Number	RA 2007-071
Regulatory Agency Reference No	0
Contact Information	
Contact Person	Name of person within distribution site
Product Information	
Product Description	Locking Screw T7, 2.7x22mm
Product Code/Catalogue No from:	40-27622
Lot Numbers	H8W00F0B41 H9H00F0B41 H9R00F0B41
Quantities	H8W00F0B41 = 70 H9H00F0B41 = 70 H9R00F0B41 = 71
Expiration date of product	n/a
Expected shelf life/product life	n/a
Issue	
Description of problem	The locking thread of the locking screw is missing
Potential Hazard	Screw das not lock in the plate and acts like a standard non-locking screw.
Communications/Attachments	
Customer response form	
Immediate Actions	
	Please quarantine affected product immediately and do not use it any more. Confirm this to your local stryker contact. **If you are not dealing with the affected product directly, please circulate this letter internally to all affected parties.** **In case you have distributed the affected product to other users, please forward this letter appropriately and inform your local stryker contact.** **Return all devices to your local Stryker contact under reference of RA 2007-071**
Product Return Information	
	Contact Stryker Distributor to organise product returns: **Rose Mincieli** **Stryker Orthopaedics** **Regulatory Compliance** **Mahwah, NJ 07430** **Phone (201) 831-5832** **Fax (201) 831-6069**

CUSTOMER RESP0NSE FORM

Please complete this form even if you do not have any product to return. This will preclude the need for future notices

Stryker RA Reference Number	RA 2007-071			
Product Description	*Please give full description of product*			
Product Code/Cat No	From:	40-27622	To:	0
Lot/Serial Numbers				

Please check your inventory for affected product and return completed form to our Quality Department as soon as possible. Please note only the product codes/catalogue numbers specified are affected by this action.

Product Disposition (Completed by Customer)

Product Code/Cat No.	Lot/ Serial No	Qty to be returned	Qty /Used Implanted	Qty Disposed /or destroyed	Qty not located	Upgraded

Customer Details

Response requirements (please complete/delete appropriate section)

I have checked inventory and can confirm that we do not have any affected product at this location.

I have checked inventory and completed the product disposition table. Please arrange for collection of product

I have completed the upgrade/maintenance of all the product listed above in accordance with the regulatory action

Please have Stryker service contact our maintenance department to arrange upgrade of the above listed product

Please sign and return this form to acknowledge receipt of product notice.

Name of Hospital/ Organisation		**Address**	
Contact Name			
Contact Title			
Contact Signature			
Contact Phone No.		**Date**	

Completion Instructions

1. Complete and fax back this form to Stryker .....
2. A Stryker Representative will call you to arrange collection of product/upgrade if necessary

3. Please ensure that the outer package is labelled with Stryker RA Reference number.
4. Ensure that forms are secured in a document wallet on the outer of the package
5. Please ensure that where appropriate a decontamination certificate is returned with product