Stryker Craniomaxillofacial	750 Trade Centre Way, Suite 200 Kalamazoo, MI 49002
Date	22-Dec-06
Stryker RA Reference Number	[redacted]
Regulatory Agency Reference No	0
Contact Information	
Contact Person	[redacted]
	P: 269-323-4250 F: 269-323-4215
Product Identification	
Product Description	TOM PLUG FOR 01-15400/401
Product Code/Catalogue No from:	01-15407
Product Code/Catalogue No to:	01-15407
Lot Numbers	G4C00F72HN, G5H00F72HN, G7T00F72HN, G8W00F72HN, G9700F72HN
Quantities	52
Expiration date of product	n/a
Expected shelf life/product life	n/a
Issue	
Description of problem	It was identified that the plug's dimension did not meet the specified values. This caused friction with the cutting cylinder during use. A review of the manufacturing records has been performed and it was found that one manufacturing batch of 52 units is affected.
Potential Hazard	Metal shavings come off the plug as a result of the friction between plug and cutting cylinder. The metal fragments will potentially be mixed with the milled bone chips.
Communication Attachments	
Customer response form	
Action to be Taken	
	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 Stryker CMF, attention of [redacted] and quoting reference of the [redacted]**
Product Return Information	
	Contact Stryker Distributor to organise product returns

CUSTOMER RESPONSE 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	[redacted]			
Product Description	*TOM PLUG (01-15407)*			
Product Code/Cat No	From:	01-15407	To:	01-15407
Lot/Serial Numbers	Please Circle: W4 W5 W7 W8 W9			

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		[redacted]	
Contact Title			
Contact Signature			
Contact Phone No.		**Date**	

Completion Instructions

1. Complete and fax back this form to Stryker CMF (269) 323-4215
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