

## URGENT PRODUCT INFORMATION

### Recall

Date	7-Jan-09
Stryker RA Reference Number	2008-136
Regulatory Agency Reference No	0

#### Contact Information

Contact Person	Name of person within distribution site
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#### Product Information

Product Description	GAMMA3 OP-Techniques Trochanteric Nail (170 +180)
Product Code/Catalogue No from:	B0300008 (180), B0300020 (170)
Product Code/Catalogue No to:	n/a
Lot Numbers	all
Quantities	approx. 10.500
Expiration date of product	n/a
Expected shelf life/product life	n/a

#### Issue

Description of problem	There is no issue. However, as part of monitoring of device usage and based on use experience a revision of the operative technique and more specifically to the warnings and precautions section was decided. Some of the events that led to these changes were routinely reported under the medical device reporting regulation such as missdrilling. As a consequence the drill can miss the nail and the distal locking screw also will miss the nail.
Potential Hazard	Distal missdrilling may elongate the surgery time or cause a revision procedure or weaken the bone with a stress riser close to the implant

#### Communications/Attachments

[Customer response form](#)

#### Immediate Actions

**For customers who use the Global version (english) version of the OP-Technique:**  
**Please scrap the old one and further use the new one instead. The Product Information Sheet includes specific steps of the surgery where the surgeon should pay special attention regarding prevention of distal missdrilling.**

**Please fill out the customer response form and return it to Stryker.**

**For customers who use a version in local language:**  
**Please continue to use your current version together with the information provided in the Product Info Sheet until the new version will be available in local language. As soon as you have received the new version in local language, please scrap you old copy and further use the new one instead.**

**Please fill out the customer response form and return it to Stryker.**

#### Product Return Information

**It is not necessary to return the old OP-Technique. Simply scrap your old copy.**