

Date	24-Nov-07
Stryker RA Reference Number	2007-075
Regulatory Agency Reference No	0

Contact Person	Name of person within distribution site
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Product Description	Gamma Screw Gauge
Product Code/Catalogue No from:	12146000
Product Code/Catalogue No to:	12146000
Lot Numbers	K532495, K532498
Quantities	16
Expiration date of product	n/a
Expected shelf life/product life	n/a

Description of problem	the printing of the depth gauge is reversed and the markings are the opposite way from the op tech
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Potential Hazard	Screw is chosen too long: Tip of screw sticks into soft tissue Screw is chosen too short: A safe force transmission (bone/screw/nail) is not given.
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Customer response form

Immediate Actions

Quarantine product immediately
Return items to Stryker contact
Contact Stryker Distributor to organise product returns

Product Return Information