



Doc. Ref. FSN 201701

TO WHOM IT MAY CONCERN

Urgent: Field Safety Notice ref. FSCA 201701

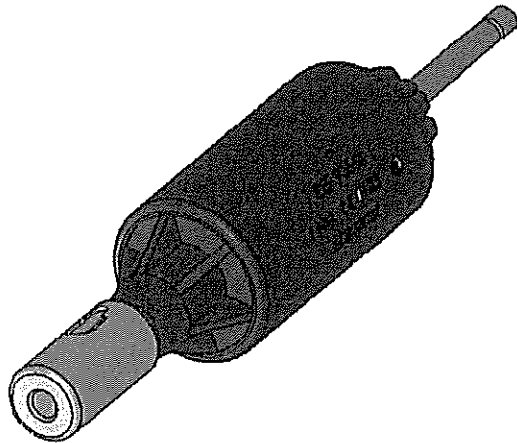
Subject: POWER DRILL TORQUE LIMITER, code 99-93568 included in the sale configurations listed in the table below

Details of the FSCA																			
Date	June 28, 2017																		
Reference Contact	Orthofix Customer Service Orthofix Srl Via delle Nazioni, 9 - 37012 Bussolengo (Verona) Italy e-mail: customerservice@orthofix.it – tel.+39 045 6719000 – fax.+39 045 6719380																		
Affected Products	<table border="1"> <thead> <tr> <th>Product code</th> <th>Product Description</th> </tr> </thead> <tbody> <tr> <td>99-93568</td> <td>POWER DRILL TORQUE LIMITER</td> </tr> <tr> <td>99-93506</td> <td>GALAXY UNYCO DIAPHYSEAL TIBIA STERILE KIT</td> </tr> <tr> <td>99-93509</td> <td>GALAXY UNYCO MINI KIT INSTRUMENTS STERILE</td> </tr> <tr> <td>99-93790</td> <td>GALAXY UNYCO DIAPHYSEAL FEMUR BOX</td> </tr> <tr> <td>99-93791</td> <td>GALAXY UNYCO KNEE BRIDGING BOX</td> </tr> <tr> <td>99-93792</td> <td>GALAXY UNYCO ANKLE BRIDGING BOX - UNILATERAL FRAME</td> </tr> <tr> <td>99-93793</td> <td>GALAXY UNYCO ANKLE BRIDGING BOX - DELTA FRAME</td> </tr> <tr> <td>99-93794</td> <td>GALAXY UNYCO DIAPHYSEAL TIBIA BOX</td> </tr> </tbody> </table>	Product code	Product Description	99-93568	POWER DRILL TORQUE LIMITER	99-93506	GALAXY UNYCO DIAPHYSEAL TIBIA STERILE KIT	99-93509	GALAXY UNYCO MINI KIT INSTRUMENTS STERILE	99-93790	GALAXY UNYCO DIAPHYSEAL FEMUR BOX	99-93791	GALAXY UNYCO KNEE BRIDGING BOX	99-93792	GALAXY UNYCO ANKLE BRIDGING BOX - UNILATERAL FRAME	99-93793	GALAXY UNYCO ANKLE BRIDGING BOX - DELTA FRAME	99-93794	GALAXY UNYCO DIAPHYSEAL TIBIA BOX
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Details of the FSCA	This is a precautionary action initiated to avoid that potentially defected “power drill torque limiters” cause the disruption of the surgical procedure. The potentially defective “power drill torque limiters” are included in the sale configurations listed above. A defective “power drill torque limiter” may break during use in surgery application. <i>Please see the picture attached to the present FSN which show the power drill torque limiter involved in this action</i>																		
Risk for patient	Disruption of DCO procedure with delay of procedure in emergency circumstances Gradual loss of fixation stability as a consequence of incorrect application of Galaxy Unyco fixator																		
Immediate Actions Required – PLEASE REPLY WITHIN JULY 3RD, 2017																			
For Distributors	<p>Immediately identify the products in Your warehouse which are involved in this action, quarantine them in your warehouse and communicate the quantity to Orthofix Srl for the replenishment of the additional torque limiters. (see contact details above).</p> <p>Please ensure that all who received, or who may have received, affected units from You are provided immediately with this Field Safety Notice.</p> <p>Please fill in the REPLY FORM with all the above information and send to Orthofix.</p>																		
For Hospitals	Immediately identify the products in Your warehouse involved in this action, quarantine them in your warehouse and communicate the quantity to your local distributor or directly to Orthofix Srl for the replenishment of the additional torque limiters (see contact details above)																		



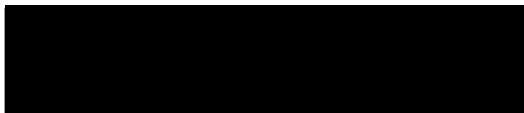
Products on patient Orthofix recommends continuing prescribed post-operative activities and follow-up

Picture of the power drill torque limiter



The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Respectfully,



Roberto Donadello
Managing Director – VP Operations Intl
Orthofix Srl