

Urgent: Field Safety Notice ref. FSCA201803

Subject: VOLUNTARY RECALL OF SOME BATCHES OF ORTHOFIX DRILL BITS.
 In Attachment A is reported the list of codes and batches involved in this action.

Details of the FSCA	
Date	September 24, 2018
Reference Contact	Orthofix Srl Customer Service Department 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	Please kindly refer to Attachment A for the list of the affected products
Details of the FSCA	<p>Orthofix has received some complaints from the market of a lower cutting performance of drill bits.</p> <p>Orthofix Srl conducted an investigation by performing technical analysis, medical evaluations and a review of the risk analysis.</p> <p>The result of the investigation determined that some production batches of drill bits, manufactured in a limited period of the years 2017/2018, show a lower cutting performance compared to drill bits historically manufactured.</p> <p>Orthofix determined that all drill bits manufactured in that limited period of time be withdrawn from the market.</p> <p>This problem can be detected during:</p> <ul style="list-style-type: none"> - intra-operative phase. The problem can be detected by the Surgeon during the drilling phase as he experiences slower advancement of the drill tip and necessity of higher force to complete the drilling. The problem does not compromise the possibility to complete the drilling step.
Risk for patient	<p>The hazards identified are:</p> <ul style="list-style-type: none"> - prolongation of surgery time - possible complications secondary to heat necrosis - damage of bone during screw insertion - bone screw and fixator loosening and subsequent additional surgery
Immediate Actions Required – PLEASE REPLY WITHIN SEPTEMBER 30TH, 2018	
For Distributors	<p>Immediately cease any further distribution of the affected devices.</p> <p>Immediately identify the products in Your warehouse which are involved in this action, remove them from inventory and return to Orthofix Srl (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	Do not use any products involved in this action and immediately return to your local distributor or directly to Orthofix Srl (see contact details above)
Products already used on patient	For patients who have undergone surgery using a drill bit involved in this action, we recommend continuing their prescribed post-operative activities and follow-up.

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

Respectfully,

A handwritten signature in blue ink, appearing to read 'Roberto Donadello', with a stylized flourish at the end.

Roberto Donadello
Managing Director – VP Operations Intl
Orthofix Srl

ATTACHMENT A

Table 1 - List of lots reported on the label of the devices involved in the FSCA201803

Product code	Product Description	Label Lot
11007	DRILL BIT KIT DIAMETER 4.8 MM LENGTH 280 MM	B1200908
13550	DRILL BIT KIT DIAMETER 2.7 MM LENGTH 127 MM	B1200674
13550	DRILL BIT KIT DIAMETER 2.7 MM LENGTH 127 MM	B1209688
1100101	DRILL BIT DIAMETER 4.8 MM LENGTH 180 MM	B1208414
1100101	DRILL BIT DIAMETER 4.8 MM LENGTH 180 MM	B1218188
1100201	DRILL BIT DIAMETER 4.8 MM LENGTH 240 MM	B1200779
1100201	DRILL BIT DIAMETER 4.8 MM LENGTH 240 MM	B1206265
1100201	DRILL BIT DIAMETER 4.8 MM LENGTH 240 MM	289818
1100301	DRILL BIT DIAMETER 3.2 MM LENGTH 200 MM	B1202045
1100301	DRILL BIT DIAMETER 3.2 MM LENGTH 200 MM	B1206643
1100301	DRILL BIT DIAMETER 3.2 MM LENGTH 200 MM	B1218524
1100701	DRILL BIT DIAMETER 4.8 MM LENGTH 280 MM	B1200720
1355001	DRILL BIT DIAMETER 2.7 MM LENGTH 127 MM	B1215075
1-1100101	DRILL BIT D.4,8 MM L.180 MM TIN COATED - QUICK CONNECT	B1200713
1-1100101	DRILL BIT D.4,8 MM L.180 MM TIN COATED - QUICK CONNECT	289813
1-1100101	DRILL BIT D.4,8 MM L.180 MM TIN COATED - QUICK CONNECT	289813
1-1100101	DRILL BIT D.4,8 MM L.180 MM TIN COATED - QUICK CONNECT	300237
1-1100201	DRILL BIT D.4,8 MM L.240 MM TIN COATED - QUICK CONNECT	B1205238
1-1100201	DRILL BIT D.4,8 MM L.240 MM TIN COATED - QUICK CONNECT	B1205760
1-1100201	DRILL BIT D.4,8 MM L.240 MM TIN COATED - QUICK CONNECT	B1213842
1-1100201	DRILL BIT D.4,8 MM L.240 MM TIN COATED - QUICK CONNECT	289814
1-1100301	DRILL BIT D.3,2 MM L.200 MM TIN COATED - QUICK CONNECT	B1203608
1-1100301	DRILL BIT D.3,2 MM L.200 MM TIN COATED - QUICK CONNECT	B1210965
1-1100301	DRILL BIT D.3,2 MM L.200 MM TIN COATED - QUICK CONNECT	B1211752
1-1100301	DRILL BIT D.3,2 MM L.200 MM TIN COATED - QUICK CONNECT	B1214172
1-1100301	DRILL BIT D.3,2 MM L.200 MM TIN COATED - QUICK CONNECT	B1218793
1-1100701	DRILL BIT D.4,8 MM L.280 MM TIN COATED - QUICK CONNECT	B1199835
1-1100701	DRILL BIT D.4,8 MM L.280 MM TIN COATED - QUICK CONNECT	289815
1-1300301	DRILL BIT D.3,2 MM L.140 MM TIN COATED - QUICK CONNECT	B1209082
99-36501	RADIOLUCENT WRIST FIXATOR KIT COMPLETE SYSTEM - STERILE	B1200654
99-36501	RADIOLUCENT WRIST FIXATOR KIT COMPLETE SYSTEM - STERILE	B1205554
99-36501	RADIOLUCENT WRIST FIXATOR KIT COMPLETE SYSTEM - STERILE	B1208340
99-36501	RADIOLUCENT WRIST FIXATOR KIT COMPLETE SYSTEM - STERILE	B1215045
99-36501	RADIOLUCENT WRIST FIXATOR KIT COMPLETE SYSTEM - STERILE	B1215995
99-36501	RADIOLUCENT WRIST FIXATOR KIT COMPLETE SYSTEM - STERILE	B1232424
99-91600UE	UE XCALIBER METADIAPHYSEAL COMPLETE KIT	B1207402
99-91600UE	UE XCALIBER METADIAPHYSEAL COMPLETE KIT	B1209817

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Product code	Product Description	Label Lot
99-91600UE	UE XCALIBER METADIAPHYSEAL COMPLETE KIT	B1211407
99-91600UE	UE XCALIBER METADIAPHYSEAL COMPLETE KIT	B1212676
99-91600UE	UE XCALIBER METADIAPHYSEAL COMPLETE KIT	B1229618
99-91600UE	UE XCALIBER METADIAPHYSEAL COMPLETE KIT	B1232423
99-91600UE	UE XCALIBER METADIAPHYSEAL COMPLETE KIT	B1233324
99-91600UE	UE XCALIBER METADIAPHYSEAL COMPLETE KIT	B1233663
99-91647	US XCALIBER ANKLE COMPLETE KIT	B1201157
99-91647	US XCALIBER ANKLE COMPLETE KIT	B1203789
99-91647	US XCALIBER ANKLE COMPLETE KIT	B1226060
99-91647UE	UE XCALIBER ANKLE COMPLETE KIT	B1206515
99-91647UE	UE XCALIBER ANKLE COMPLETE KIT	B1206561
99-91647UE	UE XCALIBER ANKLE COMPLETE KIT	B1209206
99-91647UE	UE XCALIBER ANKLE COMPLETE KIT	B1211406
99-91647UE	UE XCALIBER ANKLE COMPLETE KIT	B1212677
99-91647UE	UE XCALIBER ANKLE COMPLETE KIT	B1215964
99-91647UE	UE XCALIBER ANKLE COMPLETE KIT	B1233839
99-92501	PREFIX II DIAPHYSEAL COMPLETE KIT STERILE SHORT SCREWS	B1207286
99-92501	PREFIX II DIAPHYSEAL COMPLETE KIT STERILE SHORT SCREWS	B1207428
99-92501	PREFIX II DIAPHYSEAL COMPLETE KIT STERILE SHORT SCREWS	B1211384
99-92501	PREFIX II DIAPHYSEAL COMPLETE KIT STERILE SHORT SCREWS	B1215263
99-92502	PREFIX II DIAPHYSEAL COMPLETE KIT STERILE NO SCREWS	B1209789
99-92503	PREFIX II DIAPHYSEAL COMPLETE KIT STERILE LONG SCREWS	B1207287
99-92504	PREFIX II ANKLE COMPLETE KIT STERILE	B1207288
99-92504	PREFIX II ANKLE COMPLETE KIT STERILE	B1215312
99-92504	PREFIX II ANKLE COMPLETE KIT STERILE	B1228971
99-92504	PREFIX II ANKLE COMPLETE KIT STERILE	B1233730
99-93501	PELVIS STERILE KIT	B1200694
99-93501	PELVIS STERILE KIT	B1204116
99-93501	PELVIS STERILE KIT	B1224715
99-93501	PELVIS STERILE KIT	B1232315
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1202055
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1225324
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1225854
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1226694
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1228037
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1228211
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1228361
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1228547
99-93501JP	PELVIS STERILE KIT (STERILE GAMMA)	B1231459
99-93501US	PELVIS STERILE KIT	B1225391
99-93502	LOWER LIMB DIAPHYSEAL STERILE KIT	B1200709
99-93502	LOWER LIMB DIAPHYSEAL STERILE KIT	B1204115



Product code	Product Description	Label Lot
99-93502	LOWER LIMB DIAPHYSEAL STERILE KIT	B1206439
99-93502	LOWER LIMB DIAPHYSEAL STERILE KIT	B1225414
99-93502	LOWER LIMB DIAPHYSEAL STERILE KIT	B1233729
99-93502JP	LOWER LIMB DIAPHYSEAL STERILE KIT (STERILE GAMMA)	B1202062
99-93502JP	LOWER LIMB DIAPHYSEAL STERILE KIT (STERILE GAMMA)	B1224660
99-93502JP	LOWER LIMB DIAPHYSEAL STERILE KIT (STERILE GAMMA)	B1227924
99-93502JP	LOWER LIMB DIAPHYSEAL STERILE KIT (STERILE GAMMA)	B1231700
99-93502US	TIBIA FEMUR DIAPHYSEAL STERILE KIT	B1225603
99-93503	ANKLE STERILE KIT	B1200695
99-93503	ANKLE STERILE KIT	B1224714
99-93503US	ANKLE TRANSFIX PIN STERILE KIT	B1225407
99-93504	ELBOW STERILE KIT	B1203702
99-93504	ELBOW STERILE KIT	B1205553
99-93504	ELBOW STERILE KIT	B1209103
99-93504	ELBOW STERILE KIT	B1212944
99-93504	ELBOW STERILE KIT	B1215607
99-93504	ELBOW STERILE KIT	B1219056
99-93504	ELBOW STERILE KIT	B1212544
99-93601	GALAXY WRIST STERILE KIT	B1213075
99-93601	GALAXY WRIST STERILE KIT	B1215044
99-93601	GALAXY WRIST STERILE KIT	B1216539
99-93601	GALAXY WRIST STERILE KIT	B1217847
99-93601	GALAXY WRIST STERILE KIT	B1234691

Table 2 - List of lots marked on the drill bits involved in the FSCA201803 (if unpacked from their original package)

Product code	Product Description	Lot number
1100101	DRILL BIT DIAMETER 4.8 MM LENGTH 180 MM	289817
1100101	DRILL BIT DIAMETER 4.8 MM LENGTH 180 MM	273349
1100201	DRILL BIT DIAMETER 4.8 MM LENGTH 240 MM	289818
1100201	DRILL BIT DIAMETER 4.8 MM LENGTH 240 MM	273350
1100301	DRILL BIT DIAMETER 3.2 MM LENGTH 200 MM	273351
1100701	DRILL BIT DIAMETER 4.8 MM LENGTH 280 MM	289819
1100701	DRILL BIT DIAMETER 4.8 MM LENGTH 280 MM	273352
1100901	DRILL BIT DIAMETER 4.0 MM LENGTH 280 MM	273353
1300301	DRILL BIT DIAMETER 3.2 MM LENGTH 140 MM	273356
1355001	DRILL BIT DIAMETER 2.7 MM LENGTH 127 MM	303106
1355001	DRILL BIT DIAMETER 2.7 MM LENGTH 127 MM	289822
1355001	DRILL BIT DIAMETER 2.7 MM LENGTH 127 MM	273357
1-1100101	DRILL BIT D.4,8 MM L.180 MM TIN COATED - QUICK CONNECT	300237
1-1100101	DRILL BIT D.4,8 MM L.180 MM TIN COATED - QUICK CONNECT	300238
1-1100101	DRILL BIT D.4,8 MM L.180 MM TIN COATED - QUICK CONNECT	289813
1-1100101	DRILL BIT D.4,8 MM L.180 MM TIN COATED - QUICK CONNECT	273342
1-1100201	DRILL BIT D.4,8 MM L.240 MM TIN COATED - QUICK CONNECT	300239
1-1100201	DRILL BIT D.4,8 MM L.240 MM TIN COATED - QUICK CONNECT	289814
1-1100201	DRILL BIT D.4,8 MM L.240 MM TIN COATED - QUICK CONNECT	273343
1-1100301	DRILL BIT D.3,2 MM L.200 MM TIN COATED - QUICK CONNECT	300241
1-1100301	DRILL BIT D.3,2 MM L.200 MM TIN COATED - QUICK CONNECT	300240
1-1100301	DRILL BIT D.3,2 MM L.200 MM TIN COATED - QUICK CONNECT	273169
1-1100701	DRILL BIT D.4,8 MM L.280 MM TIN COATED - QUICK CONNECT	289815
1-1100701	DRILL BIT D.4,8 MM L.280 MM TIN COATED - QUICK CONNECT	273344
1-1300301	DRILL BIT D.3,2 MM L.140 MM TIN COATED - QUICK CONNECT	273347
1-1355001	DRILL BIT D.2,7 MM L.127 MM TIN COATED - QUICK CONNECT	300244
1-1355001	DRILL BIT D.2,7 MM L.127 MM TIN COATED - QUICK CONNECT	300243
1-1355001	DRILL BIT D.2,7 MM L.127 MM TIN COATED - QUICK CONNECT	289816
1-1355001	DRILL BIT D.2,7 MM L.127 MM TIN COATED - QUICK CONNECT	273348