

19 July 2017

To: Risk Managers
CC: Chairman Medical Board and relevant Head of Departments

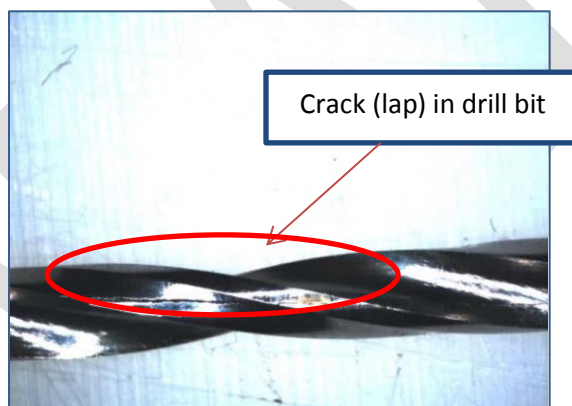
Subject: **URGENT MEDICAL DEVICE RECALL REMOVAL-LOT SPECIFIC**

Affected Product: Various Trauma & Extremity Instruments (Drill bits and Screw taps)

Refer to Attachment 2-Affected Product List for the affected items/lot combinations.

Zimmer Biomet is conducting a medical device field action for various trauma and extremity instruments (drill bits and screw taps). A raw material anomaly was discovered during inspection at Zimmer Biomet, and an investigation by the supplier determined that four lots of raw material could have similar anomalies. The anomaly has the potential to be on or below the surface and can increase the risk of instrument fracture. Accordingly, all products manufactured with the affected raw material are being removed from the field.

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of March 2016 and May 2017.



<i>Risks</i>		
<i>Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	<i>Most Probable</i>	<i>Highest Severity</i>
	<i>Extension of surgery < 30 minutes</i>	<i>Extension of surgery < 30 minutes</i>
<i>Describe long range health</i>	<i>Most Probable</i>	<i>Highest Severity</i>



<i>consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	<i>None</i>	<i>Patient retains piece of fractured instrument leading to patient injury</i>
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Risk Manager Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. Your Zimmer Biomet sales representative will remove the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
 - a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com.
 - b. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your facilities documentation.
5. If after reviewing this notice you have further questions or concerns please call the customer call center at 1-574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of the call center operating hours will receive a prompt to record a voicemail or be transferred to an on-call representative in the case of an emergency. Alternatively, your questions may be sent by email to corporatequality.postmarket@zimmerbiomet.com.

Other Information

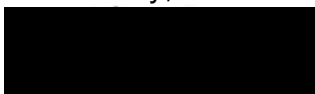
This medical device field action was reported to the U.S. Food and Drug Administration, and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the even. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing zimmer.per@zimmerbiomet.com.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this field action.

Sincerely,





Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement ZFA2017-135

By signing below, I acknowledge that the required actions have been taken in accordance with the Field action Notice.

Hospital Facility

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** () _____ - _____ **Date:** ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ **State:** _____ **ZIP:** _____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: corporatequality.postmarket@zimmerbiomet.com.

ATTACHMENT 2
Affected Product List ZFA2017-135
Extremity

Item Number	Lot number
47430904601	63399406
47430904601	63399407
47430904601	63413258
47430904601	63418122
47430904601	63419454
47430904601	63421749
47430904601	63471169
47430904601	63471170
47430904601	63471171
47430904601	63474753
47430904601	63474754
47430904601	63484232
47430904601	63501370
47430904601	63633540
47430904601	63649266
47430904601	63655091

Trauma

Item Number	Lot number
00115501500	63561678
00115501500	63444450
00115501500	63475217
00129100400	63562128
00129100406	63517946
0200024325	63385956
0200024325	63405774
0200024325	63445667
0200024330	63570344
00225503137	63485033
00225503137	63485036
00225503332	63574676
00225503332	63574677
00225503332	63574678
00225503332	63424385

Item Number	Lot number
00225503332	63451742
00225503332	63493677
00225503332	63493680
00225503337	63505310
00225503550	63329859
00231801100	63574373
00231801100	63622721
00231801100	63398756
00231801100	63415316
00231801100	63444654
00231801100	63462301
00231801100	63474169
00231801100	63485122
00231801100	63485126
00231801100	63496894

Item Number	Lot number
00231801100	63505359
00231801100	63530405
00231801100	63530406
00231801106	63562129
00231801106	63578148
00231801106	63377521
00231801106	63398755
00231801106	63415317
00231801106	63431736
00231801106	63438195
00231801106	63438272
00231801106	63444661
00231801106	63462322
00231801106	63474385
00231801106	63485128

Item Number	Lot number
00231801106	63497202
00231801106	63505360
00231801106	63510813
00231801106	63524432
00231801106	63530407
00231801500	63610789
00231801500	63610790
00231801500	63333727
00231801500	63340530
00231801500	63364066
00231801500	63364067
00231801500	63384623
00231801500	63398757
00231801500	63431747
00231801500	63444664
00231801500	63444666
00231801500	63444667
00231801500	63444668
00231801500	63462334
00231801500	63462340
00231801500	63474387
00231801500	63485135
00231801500	63485138
00231801500	63485141
00231801500	63497203
00231801500	63497204
00231801500	63505361
00231801500	63530409
00231801506	63545279
00231801506	63610791
00231801506	63641572
00231801506	63333729
00231801506	63333730
00231801506	63333732
00231801506	63340531
00231801506	63364064
00231801506	63364065
00231801506	63372902
00231801506	63384626

Item Number	Lot number
00231801506	63384629
00231801506	63444670
00231801506	63444671
00231801506	63457776
00231801506	63457945
00231801506	63462343
00231801506	63462344
00231801506	63474390
00231801506	63497205
00231801506	63497206
00231801506	63505362
00231801506	63510815
00231801506	63535517
00231801506	63535518
00231802000	63545283
00231802000	63578152
00231802000	63578153
00231802000	63584052
00231802000	63358182
00231802000	63358184
00231802000	63364075
00231802000	63384616
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00231802000	63384618
00231802000	63398734
00231802000	63398735
00231802000	63415287
00231802000	63415288
00231802000	63426487
00231802000	63426488
00231802000	63431725
00231802000	63431730
00231802000	63438313
00231802000	63438315
00231802000	63438316
00231802000	63438318
00231802000	63444673
00231802000	63444674
00231802000	63444676

Item Number	Lot number
00231802000	63444677
00231802000	63444678
00231802000	63444680
00231802000	63444681
00231802000	63469895
00231802000	63469897
00231802000	63469898
00231802000	63469901
00231802000	63499636
00231802000	63499638
00231802000	63499640
00231802000	63499641
00231802000	63510882
00231802000	63510883
00231802000	63510884
00231802000	63510885
00231802000	63524433
00231802000	63535519
00231802000	63535520
00231802006	63535521
00231802006	63535522
00231802006	63535523
00231802006	63535524
00231802006	63545285
00231802006	63562130
00231802006	63578154
00231802006	63578156
00231802006	63358058
00231802006	63358059
00231802006	63358060
00231802006	63358061
00231802006	63364050
00231802006	63377480
00231802006	63377481
00231802006	63377482
00231802006	63384605
00231802006	63384606
00231802006	63384607
00231802006	63398721

Item Number	Lot number
00231802006	63398722
00231802006	63398723
00231802006	63398724
00231802006	63398736
00231802006	63398737
00231802006	63398738
00231802006	63415279
00231802006	63415280
00231802006	63415282
00231802006	63415283
00231802006	63415284
00231802006	63415286
00231802006	63426490
00231802006	63426491
00231802006	63431727
00231802006	63431728
00231802006	63431729
00231802006	63438323
00231802006	63438326
00231802006	63444503
00231802006	63444514
00231802006	63444682
00231802006	63444683
00231802006	63444684
00231802006	63444685
00231802006	63444686
00231802006	63457777
00231802006	63457946
00231802006	63457947
00231802006	63457948
00231802006	63469905
00231802006	63469907
00231802006	63510887
00231802006	63510888
00231802006	63517978
00231802006	63517997
00231802006	63518010
00231802006	63524434
00231802500	63545287

Item Number	Lot number
00231802500	63315176
00231802500	63315178
00231802500	63315180
00231802500	63319001
00231802500	63333734
00231802500	63333736
00231802500	63333737
00231802500	63333795
00231802500	63333799
00231802500	63340564
00231802500	63340568
00231802500	63347076
00231802500	63350788
00231802500	63358204
00231802500	63384635
00231802500	63415299
00231802500	63415303
00231802500	63426466
00231802500	63426492
00231802500	63457631
00231802500	63457779
00231802500	63457780
00231802500	63457781
00231802500	63457949
00231802500	63469913
00231802500	63469915
00231802500	63469917
00231802500	63469919
00231802500	63474421
00231802500	63478996
00231802500	63518027
00231802500	63518029
00231802500	63518031
00231802506	63545289
00231802506	63545291
00231802506	63578158
00231802506	63326460
00231802506	63333735
00231802506	63333738

Item Number	Lot number
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00231802506	63340559
00231802506	63340563
00231802506	63347073
00231802506	63347075
00231802506	63350786
00231802506	63350787
00231802506	63358205
00231802506	63358206
00231802506	63384637
00231802506	63384658
00231802506	63384660
00231802506	63398760
00231802506	63415294
00231802506	63415296
00231802506	63426493
00231802506	63444520
00231802506	63457643
00231802506	63457784
00231802506	63457785
00231802506	63457787
00231802506	63457791
00231802506	63457950
00231802506	63469922
00231802506	63469924
00231802506	63469933
00231802506	63474430
00231802506	63478998
00231802506	63518034
00231802700	63556698
00231802700	63630276
00231802700	63630277
00231802700	63358163
00231802700	63364072
00231802700	63372863
00231802700	63415324
00231802700	63415327
00231802700	63426481

Item Number	Lot number
00231802700	63457812
00231802700	63457820
00231802700	63457825
00231802700	63469937
00231802700	63469939
00231802700	63474431
00231802700	63474432
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00231802700	63524435
00231802700	63524436
00231802706	63556699
00231802706	63556701
00231802706	63593922
00231802706	63616886
00231802706	63630279
00231802706	63641603
00231802706	63358167
00231802706	63372864
00231802706	63372865
00231802706	63377514
00231802706	63377516
00231802706	63415331
00231802706	63426482
00231802706	63431757
00231802706	63457850
00231802706	63457853
00231802706	63457856
00231802706	63469884
00231802706	63474434
00231802706	63479002
00231802706	63479004
00231802706	63479006
00231802706	63524437
00231803200	63556702
00231803200	63593924
00231803200	63593925
00231803200	63616888
00231803200	63340538
00231803200	63340539

Item Number	Lot number
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00231803200	63358203
00231803200	63372868
00231803200	63398777
00231803200	63478700
00231803200	63479007
00231803200	63479008
00231803200	63479009
00231803200	63517947
00231803200	63524439
00231803206	63556703
00231803206	63566220
00231803206	63593926
00231803206	63593928
00231803206	63593930
00231803206	63630281
00231803206	63340536
00231803206	63340537
00231803206	63347015
00231803206	63347018
00231803206	63347022
00231803206	63347034
00231803206	63358186
00231803206	63358201
00231803206	63372867
00231803206	63398739
00231803206	63398761
00231803206	63398762
00231803206	63426475
00231803206	63426476
00231803206	63426478
00231803206	63431754
00231803206	63431755
00231803206	63457862
00231803206	63457863
00231803206	63457865
00231803206	63457889
00231803206	63474135
00231803206	63479010

Item Number	Lot number
00231803206	63479011
00231803206	63479013
00231803206	63524442
00231803206	63524443
00231803206	63524445
00231803500	63556745
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00231803500	63457891
00231803500	63479015
00231803500	63479016
00231803500	63524446
00231803506	63556890
00231803506	63630297
00231803506	63358210
00231803506	63431706
00231803506	63444526
00231803506	63457649
00231803506	63457893
00231803506	63479021
00231803506	63524448
00231804000	63557051
00231804000	63451624
00231804000	63451625
00231804000	63451627
00231804000	63457895
00231804000	63517948
00231804000	63524449
00231804006	63457688
00231804006	63474136
00231804006	63524451
00231804500	63641616
00231804500	63457898
00231804500	63478702
00231804500	63479022
00231804500	63479023
00231804500	63524453

Item Number	Lot number
00231804506	63593911
00231804506	63457691
00231804506	63457909
00231804506	63479024
00231804506	63524454
00236015327	63586026
00236015327	63606227
00236015327	63606229
00236015327	63524034
00236015327	63530220
00236015335	63578494
00236015335	63641443
00236015335	63524035
00236017127	63545430
00236017127	63578497
00236017127	63586028
00236017127	63606286
00236017127	63610624
00236017127	63635345
00236017127	63458048
00236017127	63469766
00236017127	63475222
00236017127	63530224
00236017520	63599481
00236017520	63461425
00236017520	63469758
00236017520	63469774
00236017520	63475225
00236017520	63481881
00236020527	63557936
00236020527	63566282
00236020527	63574978
00236020527	63623144
00241001500	63584061
00241001500	63634136
00241002000	63570271
00241002000	63593944
00241002000	63384604
00241002000	63444476

Item Number	Lot number
00241002000	63444477
00241002000	63451591
00241002000	63469943
00241002000	63479045
00241002000	63499653
00241002000	63510892
00241002100	63545295
00241002100	63634139
00241002100	63634141
00241002100	63530410
00241002500	63289918
00241002500	63296044
00241002500	63451593
00241002500	63457958
00241002500	63462349
00241002500	63462351
00241002500	63469945
00241002500	63479047
00241002500	63518080
00241002600	63616893
00241002600	63634147
00241002600	63634148
00241002600	63306445
00241002600	63315168
00241002600	63346870
00241002600	63350727
00241002600	63364046
00241002600	63457951
00241002600	63457952
00241002600	63469948
00241002600	63469950
00241002600	63530411
00241002700	63306444
00241002700	63315170
00241002700	63350728
00241002700	63364047
00241002700	63377460
00241002700	63474111
00241002700	63474113

Item Number	Lot number
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00241002700	63499667
00241003500	63584060
00241003500	63593945
00241003500	63364042
00241003500	63372860
00241003500	63510893
00241004000	63518082
00249004443	63660537
00249004443	63329880
00249004443	63361658
00249004443	63361659
00249004443	63469329
00249004443	63469330
00249004443	63494298
00249004443	63494302
00249004443	63499008
00249004443	63499009
00249004443	63499010
00249004443	63518020
00249004443	63518021
00249006449	63606634
00249007543	63541085
00249007543	63565537
00249007543	63586553
00249007543	63586554
00249007543	63635381
00249007543	63635382
00249007543	63660536
00249007543	63329874
00249007543	63329875
00249007543	63343934
00249007543	63343935
00249007543	63361695
00249007543	63370747
00249007543	63388956
00249007543	63399691
00249007543	63399692
00249007543	63413799

Item Number	Lot number
00249007543	63413801
00249007543	63413803
00249007543	63413804
00249007543	63499022
00480507015	63550419
00480507015	63556696
00480507015	63566195
00480507015	63641526
00480507015	63326478
00480507015	63358155
00480507015	63364056
00480507015	63462112
00480507015	63474138
00480507015	63484940
00480507015	63492343
00480507015	63524430
00480507015	63530361
00480508520	63602805
00480513032	63550421
00480513032	63570257
00480513032	63634090
00480513032	63306459
00480513032	63377487
00480513032	63492354
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00480606011	63630272
00480606011	63530362
00480608515	63570260
00480608515	63574325
00480608515	63584027
00480608515	63451638
00480608515	63451640
00480608515	63457758
00480608515	63457921
00480608515	63478937
00480608515	63478942
00480608515	63478945
00480608515	63484951

Item Number	Lot number
00480608515	63492357
00480608515	63496853
00480608515	63510771
00480610020	63545255
00480610020	63562124
00480610020	63566199
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00480610020	63398778
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00480610020	63431693
00480610020	63431763
00480610020	63444579
00480610020	63444581
00480610020	63444582
00480610020	63444584
00480610020	63444587
00480610020	63451645
00480610020	63451647
00480610020	63451648
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00480610020	63462166
00480610020	63462170
00480610020	63462174
00480610020	63474142
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00480610020	63484966
00480610020	63484973
00480610020	63492362
00480610020	63492363
00480610020	63505347
00480610020	63505348
00480610020	63510772
00480610020	63510773
00480610020	63524431

Item Number	Lot number
00480610027	63545256
00480610027	63550424
00480610027	63457944
00480610027	63462196
00480610027	63462201
00480610027	63469886
00480610027	63474144
00480610027	63484983
00480610027	63492364
00480610027	63496869
00480610027	63505349
00480610027	63510774
00480610027	63530385
00480611025	63545257
00480611025	63545258
00480611025	63451724
00480611025	63451725
00480611025	63451728
00480611025	63451730
00480611025	63451744
00480611025	63451747
00480611025	63451751
00480611025	63451753
00480611025	63451754
00480611025	63462227
00480611025	63478968
00480611025	63478972
00480611025	63478974
00480611025	63485102
00480611025	63530392
00480611025	63530394
00480611035	63562125
00480611035	63574359
00480611035	63584041
00480611035	63596754
00480611035	63634173
00480611035	63364063
00480611035	63426473
00480611035	63431723

Item Number	Lot number
00480611035	63444632
00480611035	63462281
00480611035	63474170
00480611035	63496895
00480611035	63496896
00480611035	63530398
00480614532	63574361
00480614532	63596765
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Item Number	Lot number
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