

June 7, 2017

To: Surgeons

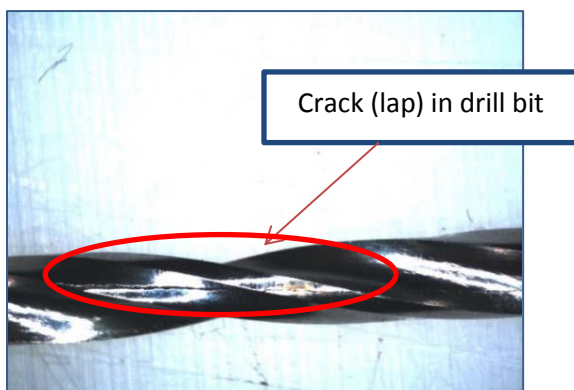
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE- REMOVAL-LOT SPECIFIC**

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 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>None</i> | <i>Patient retains piece of fractured instrument leading to patient injury</i> |

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 support you for the removal the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
 - a. Return a digital copy to fieldaction.emea@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 your local Zimmer Biomet sales representative.

Other Information

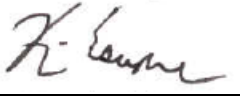
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

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 **Surgeon** (Please check one as applicable)

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: fieldaction.emea@zimmerbiomet.com.

| Product Reference | Lot Reference | Number of returned instruments |
|-------------------|---------------|--------------------------------|
| | | |
| | | |
| | | |
| | | |

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 |
|-------------|------------|
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| 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 |
| 00231802000 | 63384617 |
| 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 |
|-------------|------------|
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| 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 |
|-------------|------------|
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| 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 |
|-------------|------------|
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| 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 | 63340556 |
| 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 |
|-------------|------------|
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| 00231802700 | 63457820 |
| 00231802700 | 63457825 |
| 00231802700 | 63469937 |
| 00231802700 | 63469939 |
| 00231802700 | 63474431 |
| 00231802700 | 63474432 |
| 00231802700 | 63474433 |
| 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 |
|-------------|------------|
| 00231803200 | 63358202 |
| 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 |
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| 00231803206 | 63358186 |
| 00231803206 | 63358201 |
| 00231803206 | 63372867 |
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| 00231803206 | 63426475 |
| 00231803206 | 63426476 |
| 00231803206 | 63426478 |
| 00231803206 | 63431754 |
| 00231803206 | 63431755 |
| 00231803206 | 63457862 |
| 00231803206 | 63457863 |
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| 00231803206 | 63474135 |
| 00231803206 | 63479010 |

| Item Number | Lot number |
|-------------|------------|
| 00231803206 | 63479011 |
| 00231803206 | 63479013 |
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| 00231803206 | 63524445 |
| 00231803500 | 63556745 |
| 00231803500 | 63630284 |
| 00231803500 | 63641610 |
| 00231803500 | 63358212 |
| 00231803500 | 63364073 |
| 00231803500 | 63457891 |
| 00231803500 | 63479015 |
| 00231803500 | 63479016 |
| 00231803500 | 63524446 |
| 00231803506 | 63556890 |
| 00231803506 | 63630297 |
| 00231803506 | 63358210 |
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| 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 |
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| 00231804506 | 63524454 |
| 00236015327 | 63586026 |
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| 00236015327 | 63606229 |
| 00236015327 | 63524034 |
| 00236015327 | 63530220 |
| 00236015335 | 63578494 |
| 00236015335 | 63641443 |
| 00236015335 | 63524035 |
| 00236017127 | 63545430 |
| 00236017127 | 63578497 |
| 00236017127 | 63586028 |
| 00236017127 | 63606286 |
| 00236017127 | 63610624 |
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| 00236017127 | 63458048 |
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| 00236017127 | 63475222 |
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| 00236017520 | 63461425 |
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| 00236017520 | 63469774 |
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| 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 |
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| 00241002700 | 63350728 |
| 00241002700 | 63364047 |
| 00241002700 | 63377460 |
| 00241002700 | 63474111 |
| 00241002700 | 63474113 |

| Item Number | Lot number |
|-------------|------------|
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| 00241002700 | 63499667 |
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| 00241003500 | 63593945 |
| 00241003500 | 63364042 |
| 00241003500 | 63372860 |
| 00241003500 | 63510893 |
| 00241004000 | 63518082 |
| 00249004443 | 63660537 |
| 00249004443 | 63329880 |
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