

December 22, 2015

URGENT FIELD SAFETY NOTICE: RA2015-172

FSCA Identifier: Product Field Action RA 2015-172

Type of Action: Field Safety Corrective Action

Description: sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau

Legal Manufacturer Stryker Trauma GmbH, Prof.-Kuentscher-Strasse 1-5,
24232 Schoenkirchen/Kiel, Germany

Catalogue number	Product name
01520218S	T2 Kirschner wire 1p
01902000S	MET IM PIN
12106450S	GAM Kirschner Wire
12106451S	G3 K-Wire, UNS-Thread
12139091S	GAM Guide Pin D4xL400
13200016S	G3 K-Wire with Washer
18060050S	T2 K-Wire
18060051S	K-Wire Ø3 with Washer
18060080S	T2 Guide Wire Ball Tip
18060083S	T2 Guide wire
18060084S	Guide wire ball tipped
18060085S	T2 Guide Wire Ball Tip
18060090S	T2 Guide wire
18060093S	T2 Guide wire
18061250S	Guide Wire Ball Tip
18061417S	Fixations K-Draht
18063030S	T2 K-Wire Recon
18063031S	T2 K-Wire CoCr Recon

Lot #s: All lots distributed before 10-Nov-2015 with not expired 5 year shelf life (see detailed distribution list).

Dear Customer,

Please find attached details of a voluntary Field Safety Corrective Action that has been initiated by Stryker Trauma GmbH, Division Trauma and Extremities for sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau. It was found through review of packaging that the seal integrity of the pouch may be decreased. Stryker Trauma GmbH, Division Trauma and Extremities is recalling all unconsumed, non-expired lots of above listed article numbers. Given high turnover for this product and the frequency with which it had been on backorder it is not expected that a significant quantity of units subject to this notice remain in the field. No injury or harm has been reported for this event.



Packaging example – sterile pouch inside (plastic) clear tube



Example of sterile pouch with potentially non-conforming seal

Potential Hazards

A potential capillary defect in the sealing could potentially lead to unsterile product.

Mitigating Factors

The secondary packaging is a (plastic) clear tube with silicone caps at both ends. While not validated as a sterile barrier, it does provide additional protection to the enclosed pouch package configuration. Furthermore, it should also be noted that it is standard practice for surgeons to prescribe antibiotics peri-operatively in order to reduce the risk of potential infection, especially in situations where the injury was caused due to excessive trauma.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending to return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
 - a) *Please provide contact details so that Stryker can inform the recipients appropriately*
 - b) *If you are a Distributor, note that you are responsible for notifying your affected customers.*

5. Please inform Stryker of any adverse events concerning the use of the subject devices. Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.
6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you longer have any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

If returning the product would adversely impact your ability to provide necessary medical care to patients, you can consider re-sterilizing the product per Sterilization instructions contained in the Instruction for Use.

We request that you respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is ----- and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly

Name:

Position:

Email

Telephone

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,

RA2015-172 Affected Product and Lot Codes

Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
01520218S	T2 Kirschner wire 1p D1.8x310	K019A40, K01AC78, K01BA68, K01BDB5, K01BDD2, K0213D8, K0216AE, K022F76, K02428E, K024A88, K025BF1, K027DFD, K02A2F2, K02ABF5, K02ACE0, K030238, K0307FD, K035253, K035C20, K036ABE, K03891D, K039E67, K03AFDA, K03DAC5, K043D6A, K044645, K045A13, K04696B, K047B0F, K049EF8, K04B3DB, K04C309, K04D3FD, K04FB10, K057518, K05804A, K059D20, K05D1E5, K06064A, K067D41, K06D4ED, K072E41, K073B7E, K077802, K07A941, K07CBF5, K07D658, K07E969, K0827DA, K083CA8, K086BA7, K086BA8, K087B58, K0897B2, K095C20, K0986F1, K09AD68, K09AD69, K09C4A1, K09F5A5, K09FF86, K0A0EAA, K0A2063, K0A5C3E, K0A62F7, K0A66C1, K0A7824, K0B4B54, K0B4CB4, K0B5E75, K0BB7EB, K0BC13C, K0BCA92, K0C2A0B, K0C3898, K0C3AA0, K0CC1C2, K0CC614, K0CC615, K0D21E4, K0D3A2E, K0D5073, K0D6F8B, K0DB5B7, K0DCB37, K0DCB38, K0DE579, K0DE57B, K0E3B4D, K0E4ADB, K0E4CBF, K0E5D78, K0EF68D, K0F0BE8, K0F23DB, K104594, K111169, K1114724, K115187, K119684, K122008, K125044, K132317, K136681, K139722, K163330, K163556, K164819, K164868, K167008, K169793, K173637, K173638, K184013, K184398, K185518, K188039, K188814, K192113, K198568, K201530, K209217, K222494, K225661, K242091, K258074, K267888, K267889, K275949, K278321, K278558, K280749, K283048, K287009, K287793, K288372, K391434, K394399, K394875, K395009, K397943, K398057, K398062, K399344, K434196, K436033, K458902, K481920, K483284, K539363, K548903, K559707, K569492, K572831, K576939, K583444, K583996, K621307, K634652, K638761, K642489, K643429, K649197, K656938, K660722, K665768, K678089, K740904, K748972, K782337, K833224, K862934, K869536, K893048, K897956, K906170, K914086, K918429, K923805, K925945, K931509, K933060, K948906, K953232, K979200
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13200016S	G3 K-Wire with Washer D3.2xL500	K042A89, K04599E, K048240, K061DE1, K06BAE1, K083C97, K0A3DAB, K0B14A8, K0C5F14, K0D31E3, K197105, K397150, K397152, K428732, K428735, K428738, K558182, K681269, K747810, K934212
18060050S	T2 K-Wire D3xL285	K04C22D, K04C22E, K0CF6F9, K0CF6FA, K0CF6FB, K0CF6FC, K0CF6FD, K0CF6FE, K0CF6FF, K0CF700, K0D2796, K0D2797, K0D448B, K0D448C, K0D4FB9, K0D4FBA, K0D50EF, K0D50F0, K0D50F1, K0D50F2, K0D50F3, K0D50F4, K106049, K106051, K108511, K108512, K112316, K112317, K114160, K114161, K114162, K114163, K114164, K114206, K114778, K114779, K114780, K114781, K115327, K115328, K122045, K122046, K122049, K145925, K145926, K157898, K177045, K177053, K195456, K195458, K195459, K195460, K207249, K207280, K207281, K207284, K207811, K207814, K207845, K207848, K216252, K216253, K220248, K220250, K220253, K220256, K231255, K231256, K240762, K240763, K243579, K243582, K251025, K251026, K251074, K251542, K251543, K263873, K263876, K267248, K267260, K267262, K274874, K274875, K274876, K274878, K279217, K279218, K279219, K279220, K279271, K283728, K283729, K283730, K388995, K388996, K390451, K390452, K391997, K391998, K391999, K392000, K393115, K398653, K398654, K421469, K421542, K421551, K421554, K423502, K423506, K423510, K441026, K441027, K441085, K461724, K461725, K461737, K461743, K487813, K487819, K501510, K501511, K501512, K501522, K559033, K559034, K571282, K571298, K571301, K571305, K594419, K594423, K636908, K636910, K647687, K647688, K647689, K647703, K651962, K651965, K651966, K651967, K651968, K651969, K668661, K668662, K668667, K709065, K709066, K714258, K714259, K751037, K751038, K751039, K771128, K771129, K771131, K771132, K886249, K886267, K886276, K886278, K886290, K889956, K889957, K889959, K890093, K890094, K913645, K913646, K913650, K913651, K930052, K932726, K932736
18060051S	K-Wire Ø3 with Washer	K022E5F, K0251F3, K03D5D2, K0500C2, K0500C3, K054720, K0713C3, K072E49, K07A006, K087D3B, K087D3D, K08D900, K08D901, K08D902, K097704, K09EF0A, K09EF0B, K09EF0C, K09F38F, K0B4CB1, K0C4B7A, K0C5CE5, K0C9B6E, K0CD5BD, K0CF191, K0D5419, K0D541A, K0D541B, K0E7BD1, K0E8594, K0EA423, K114142, K159628, K183868, K195487, K218826, K279102, K608197, K920683
18060080S	T2 Guide Wire Ball Tip D3xL800	K0210EE, K03402C, K03402D, K040FB2, K040FB6, K042A75, K042A76, K043C60, K043C61, K04C22F, K04C230, K04D33D, K04D33E, K04DCD4, K07122C, K07122D, K0B72A5, K0B72A6, K0B72A7, K0B72A8, K0CEB5D, K0CEB5E, K0CEB5F, K0CEB60, K0D2798, K0D2799, K0D4FBC, K0D4FBD, K0D4FBE, K0D4FBF, K0D50F4, K0D50F5, K0D50F6, K0D50F7, K0D50F8, K106053, K106054, K108459, K130340, K130341, K130342, K145970, K146258, K151171, K155967, K207286, K207290, K207903, K208139, K214363, K214364, K214365, K214366, K220190, K220191, K220222, K220223, K231257, K238500, K238507, K238511, K238514, K241708, K241709, K243583, K243584, K250129, K250130, K251381, K251407, K255957, K255958, K255991, K277500, K277502, K277503, K282096, K282113, K282557, K282558, K283717, K284474, K284475, K284896, K284897, K284898, K284899, K390252, K390253, K390937, K393878, K393879, K393880, K395670, K395671, K415060, K451893, K451896, K487821, K487822, K500336, K500338, K500340, K509364, K542654, K542746, K542748, K551206, K551232, K571674, K571675, K579612, K579613, K579614, K593811, K593814, K593815, K593816, K607337, K610168, K610172, K610641, K628651, K635099, K635102, K636911, K636913, K642121, K660812, K668641, K668642, K705901, K705902, K714260, K714261, K771134, K771135, K771136, K785076, K785079, K785085, K790908, K847724, K847727, K847734, K847737, K847744, K869896, K869897, K875904, K875905, K879296, K879297, K879298, K885217, K890129, K890131, K901814, K902706, K902708, K905068, K905074, K913652, K913653, K913655, K923004, K923006, K982616, K982617, K982618

18060083S	T2 Guide wire ball tipped D2.5xL800	<p>K018D7E, K018D7F, K018D80, K019A41, K019BC4, K019BC5, K01AC42, K01AF9F, K01B24A, K01B24B, K01E57E, K01E57F, K01EDA7, K020AB7, K020AB9, K020ABA, K020C62, K020C63, K020C64, K0213D9, K021A85, K021A86, K022F78, K023181, K0231FA, K0231FB, K023A85, K023A86, K023BC1, K023BC2, K0246FD, K025EDF, K026237, K026238, K027A20, K027A21, K027A22, K028482, K028CF9, K02977C, K02A235, K02A2E6, K02A2E7, K02AF9E, K02BA9A, K02BA9B, K02C5F5, K02DFE7, K02F234, K030203, K030204, K03043D, K0307E0, K0307E2, K031669, K034082, K03408A, K034099, K0340BF, K035254, K035C22, K0362E8, K0362E9, K0362EA, K036A50, K036A51, K036FDC, K0375EF, K0375F1, K038B4B, K03954D, K03AFDC, K03C312, K03C33C, K03C381, K03C382, K03C384, K03FE02, K03FE03, K03FE04, K040FC7, K043C6B, K045566, K0459E6, K0459E7, K046898, K0490C8, K0490C9, K0492AA, K0492AB, K0492AC, K049B3F, K04A416, K04A417, K04AE0B, K04AE0C, K04D3EA, K04E6CB, K04E6D0, K04E6D3, K04F073, K04F074, K04F075, K051029, K05102A, K05102B, K051694, K051696, K05195D, K05195E, K051C9D, K051C9E, K051C9F, K051CA0, K05238A, K0526E1, K052F63, K052F64, K053B9B, K054704, K058A41, K0594CC, K05BFC3, K05BFC4, K05BFC5, K05D27A, K05D27B, K05D27C, K065D46, K065D48, K065D49, K0665EE, K0665EF, K0665F0, K0665F1, K06BAE9, K06BAEA, K071323, K071324, K071325, K071367, K07136A, K071879, K07187A, K07187B, K0721CF, K072628, K072629, K07262A, K0744F6, K07628A, K07628B, K076CCC, K076CCD, K076CCE, K076CCF, K07763E, K07763F, K07774F, K07A010, K07A011, K07B738, K07B739, K07C83C, K07C83D, K07E876, K07E877, K07E878, K07EF49, K07EF4A, K07F99A, K07F99B, K080AD8, K083C1C, K083C1D, K083C1E, K087924, K087AE6, K087AE7, K087AE8, K087D45, K089B5A, K089B5B, K08C0C2, K08C375, K08C376, K08CD38, K08CD39, K08F054, K0925FA, K0925FB, K092B44, K092B45, K09387E, K09387F, K097E60, K098704, K098705, K098706, K09A621, K09B2D3, K09BB9B, K09C8AD, K09C8AE, K09C8AF, K09CF17, K09E7FD, K09F390, K09F391, K0A1CD3, K0A1CD4, K0A2A76, K0A2A77, K0A2A78, K0A3BA9, K0A3BAA, K0A3BAB, K0A4433, K0A4434, K0A5434, K0A5435, K0A5C56, K0A5C57, K0A5C58, K0A6499, K0A983E, K0A983F, K0AA66E, K0AA66F, K0AAB29, K0AAB2A, K0AAB2B, K0AC9DD, K0AC9DE, K0AF181, K0AF182, K0AF3C8, K0AF3C9, K0B1BFD, K0B278E, K0B6D60, K0B6D61, K0B6D62, K0B8538, K0B89B1, K0B89B2, K0BA364, K0BAAFD, K0BAAFE, K0BB75A, K0BBB10, K0BD541, K0BF5D4, K0C1025, K0C23E4, K0C296C, K0C296D, K0C296E, K0C389A, K0C72BB, K0C72BC, K0C9D9F, K0C9DA0, K0CC255, K0CC256, K0CC257, K0CC258, K0CEB09, K0D18FC, K0D3282, K0D3283, K0D81F1, K0D8824, K0DAC58, K0DB570, K0DB573, K0DB59D, K0DB5A6, K0DBC81, K0DE2EC, K0DE2ED, K0DE2EE, K0DE2EF, K0DE2F0, K0DF961, K0E0BB8, K0E4AE4, K0E4AE6, K0E4AE7, K0E5D79, K0E5D7B, K0E5D7C, K0E8DF0, K0E8DF1, K0E8DF2, K0E9E9D, K0E9E9E, K0ECDFF, K0EE8CB, K0EE8CC, K0EE8CD, K0F050A, K0F312D, K0F3673, K0F3674, K0F3C51, K0F3C52, K101287, K101288, K101289, K101290, K101291, K101293, K101294, K101295, K102850, K102851, K102864, K106055, K106056, K106057, K115356, K115357, K115358, K115373, K115533, K125094, K125095, K125096, K145971, K145997, K151176, K161937, K161940, K161981, K164376, K170730, K170731, K170732, K170733, K173157, K173161, K173162, K173198, K173200, K179691, K179692, K179718, K179884, K184973, K184974, K184976, K185015, K197517, K197519, K197523, K199994, K199995, K199996, K200050, K200081, K200082, K200712, K200713, K200714, K211889, K220445, K220458, K220459, K220464, K220465, K223338, K223339, K223341, K223342, K226739, K226740, K237585, K237592, K237599, K240911, K240912, K240913, K240914, K253653, K253654, K253658, K253854, K267180, K275439, K275452, K275461, K275462, K275463, K276079, K276080, K276084, K276085, K276086, K277572, K277574, K277576, K277578, K280026, K280027, K280029, K280030, K281874, K282165, K282166, K282167, K282168, K284473, K284674, K284675, K284821, K290338, K290341, K290346, K290347, K296298, K296299, K389621, K389622, K389623, K389624, K389625, K390018, K390019, K390037, K390038, K390966, K393645, K393646, K393647, K393648, K394177, K394178, K396123, K398875, K398876, K398877, K398881, K398884, K409290, K409291, K409298, K420204, K420205, K470405, K483062, K528317, K529670, K529932, K530569, K537004, K537023, K537030, K537518, K539220, K539237, K542580, K542593, K542595, K542596, K558065, K558068, K558069, K573236, K573237, K577289, K577290, K577291, K577293, K577294, K586517, K586518, K594149, K594150, K594221, K594222, K597528, K597529, K597530, K610215, K610217, K610218, K610219, K610221, K613921, K613922, K621232, K625011, K625306, K625311, K641301, K641315, K641318, K647845, K647876, K647877, K647879, K657182, K669183, K669184, K683423, K698418, K708869, K714262, K714263, K714339, K714341, K814621, K833117, K833118, K833119, K833120, K849780, K849781, K849782, K849783, K866453, K866566, K872249, K879085, K880464, K880465, K891033, K891035, K902570, K902732, K906294, K911885, K911888, K917718, K917719, K917720, K928697, K928698, K928699, K930422, K930424, K930430, K948798, K953245, K953268, K953434, K953442, K984758</p>
18060084S	Guide wire ball tipped D2.5xL1000	<p>K019BD0, K01B532, K02A030, K02AF9F, K02BA9F, K030208, K0362F1, K036AB7, K04B186, K0523BA, K0523BB, K053373, K0560DC, K07568E, K078A9A, K088521, K08F053, K09AD79, K09CF18, K0ACB75, K0B2782, K0C4B73, K0D063D, K0DE240, K0E1F05, K0E2819, K106497, K120586, K146058, K185176, K243753, K254332, K255983, K278329, K287594, K399645, K411771, K580898, K587978, K588788, K614592, K671960, K781869, K789266, K862942, K874991, K978730</p>

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18061250S	Guide Wire Ball Tip D3xL1250	K01A325, K01E77D, K03094C, K03438A, K03C41E, K03E8C5, K041AA0, K0627FD, K065C72, K0865AE, K086DB2, K0C7E49, K0D18E2, K0D7D1A, K0DAC85, K129408, K163516, K186745, K201488, K231066, K244990, K298228, K501637, K527193, K527200, K562702, K562714, K869902, K930376, K930389
18061417S	Fixations K-Draht Ø3x285mm,SPI	K02EC4E, K02EC4F, K030210, K03789B, K03789C, K03789D, K03789E, K03AE81, K03AE82, K043C55, K045FFC, K049B3A, K050047, K051026, K051027, K054D3F, K054D40, K06582E, K065830, K065831, K065832, K0775DA, K0775DB, K0787D0, K0787D4, K0787D6, K078906, K07F540, K07F55C, K08AC2F, K08AC30, K09421B, K09421C, K09421D, K09B8AC, K09B8AE, K09B8B0, K0A0F51, K0A0F52, K0A0F53, K0A3BB0, K0A98BF, K0A98C0, K0AA628, K0AA62B, K0B36BF, K0B36C0, K0BBAFD, K0BBAFE, K0C0547, K0C0591, K0C0592, K0C0595, K0C165E, K0CB814, K0D50E4, K0DBBAF, K0DBBB0, K0EE8C6, K0EE8C7
18063030S	T2 K-Wire Recon D3.2/L400	K01D37D, K01E5A0, K01ED63, K022612, K022DDD, K022DDE, K023B9A, K024247, K0246B0, K024C76, K029FDD, K02A1AD, K02A64D, K02CA7C, K02D1CA, K032782, K033BD0, K034059, K03405B, K037E9B, K038ABB, K03FAC6, K0420AA, K04338C, K0445F2, K0455EC, K0471F7, K049E5A, K04A302, K04D2CB, K04D2CC, K04E64C, K0511BD, K052F3D, K0546BF, K054D53, K058005, K05D0B5, K05EC23, K061C38, K065C71, K0676AE, K068F77, K06BA41, K070351, K070352, K07129B, K078885, K07998B, K079CAE, K07E7ED, K07E7EE, K07EF06, K081C1E, K083C23, K0859F6, K0865AC, K088A74, K08AC11, K0909EE, K092B43, K0946CA, K097CE1, K09DC58, K09E9AA, K09FF60, K0A538B, K0A5BCF, K0A6476, K0A7DA6, K0A843D, K0B0617, K0B3ADE, K0B53E0, K0B895C, K0BCD2B, K0C0F45, K0C2938, K0C380D, K0C7E48, K0C9B4B, K0C9C2F, K0C9D11, K0C9E26, K0CAF5F, K0CC223, K0CC224, K0CF6F6, K0CF6F8, K0D448D, K0D45E5, K0D6EE4, K0DAC4C, K0DCAC5, K0DE26C, K0DE44E, K0E4C9B, K0E6D07, K0EE408, K0F3282, K0F3B0E, K145985, K178174, K182370, K231065, K250671, K250672, K281817, K281822, K389266, K389267, K394209, K396967, K461761, K494169, K558134, K580646, K624261, K647667, K647668, K676443, K895327, K996491

18063031S	T2 K-Wire CoCr Recon D3.2/L400	K01CCDF, K01D3F1, K020C6D, K020C6E, K0216A8, K0216A9, K023295, K0246F9, K025BEA, K028CEC, K02A02F, K02ABF2, K02B7C9, K02C5FF, K02D1E6, K030233, K03524B, K0359B5, K03A691, K03AFCF, K03AFD0, K03C307, K03DAD9, K03F13D, K042012, K042105, K04555C, K04C030, K04C459, K0500BD, K0500BE, K0508AC, K0533E9, K053BAA, K053BAB, K05BFBA, K060652, K060653, K06287F, K063DBB, K063DBC, K066346, K06D4E3, K06D4E4, K0700EA, K0700EB, K071318, K071319, K071875, K072815, K073B7A, K0789E5, K079A3A, K07B4B4, K07B7ED, K07CC00, K07D654, K07EF54, K081CB1, K0827D2, K0848E2, K0848E3, K085287, K0871E8, K0871E9, K088FB8, K0897A8, K08AC3E, K08DEE6, K09430D, K097753, K0986FB, K0986FC, K098DE5, K09938C, K09ADBA, K09F5A2, K0A08E6, K0A13E6, K0A2A72, K0A66B9, K0A7819, K0A91EC, K0A91ED, K0A9962, K0AE061, K0AF1EF, K0B3AA2, K0B5E93, K0B9DA9, K0B9DAA, K0BCDC2, K0BD0C3, K0C100F, K0C1010, K0C3892, K0C3D75, K0C4B72, K0C6EEF, K0C6EFO, K0CB8A7, K0CC1B8, K0CC1B9, K0CE014, K0CE015, K0D063C, K0D1FC2, K0D1FC5, K0D81A7, K0D8467, K0DAC61, K0DAC62, K0DBC90, K0DEEDD, K0DF966, K0E3EB3, K0E690E, K0E6D40, K0E9096, K0ECDDE, K0F1F6D, K0F4118, K102893, K105916, K106407, K108624, K114718, K119033, K125696, K126411, K128727, K142128, K151732, K154419, K164621, K164626, K164817, K167270, K167449, K174532, K176412, K184373, K197181, K198551, K198552, K209209, K220471, K225652, K225653, K225654, K226760, K238527, K246011, K254823, K279170, K281825, K282807, K283033, K285488, K285492, K292795, K292847, K390869, K395376, K413923, K434145, K462173, K506627, K557355, K567258, K579312, K583618, K607415, K638715, K638921, K649812, K657846, K680553, K680555, K707371, K763761, K771027, K787779, K787780, K810638, K814652, K814653, K834156, K844083, K849308, K862725, K875882, K883063, K891375, K902170, K902171, K902721, K902722, K906148, K906149, K906311, K906312, K912445, K936018, K948748, K953456, K953457, K953666, K978729, K988638
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FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

FSCA Identifier: Product Field Action RA 2015-172

Type of Action: Field Safety Corrective Action

Description: sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau

Legal Manufacturer Stryker Trauma GmbH, Prof.-Kuentscher-Strasse 1-5,
24232 Schoenkirchen/Kiel, Germany

Catalogue #s: Refer to the attached list

Lot #s: Refer to the attached list

I acknowledge receipt of the Field Safety Notice for RA2015-172 and can confirm that:

We have not located any of these devices in our inventory: <i>(please delete if not applicable)</i>				
We have located the following devices:				
Product description	Product Reference	Lot Number	Qty	Qty Quarantined
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				
Form completed by:				

Contact Name _____ **Contact Facility** _____

Contact address _____ **Contact Position** _____

_____ **Contact Tel No** _____

_____ **Contact Fax No** _____

_____ **Contact e-mail** _____

**PLEASE COMPLETE AND FAX THIS FORM TO X
OR EMAIL TO X.**