
URGENT MEDICAL DEVICE REMOVAL

RE: sterile packaging of Guide Wire(s) and K-Wire(s)
ATTENTION: SURGEONS, RISK MANAGER, DIRECTOR or MATERIALS
MANAGER

Date December 22, 2015

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

Product Recalled

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

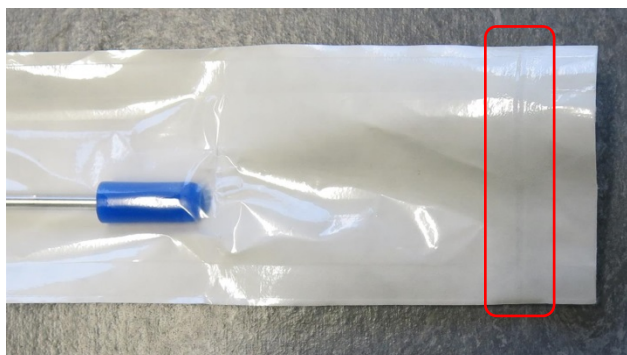
Lot #s: All lots distributed before 10-Nov-2015 with not expired 5 year shelf life (see detailed distribution list).

Product Issue

Please find attached details of a voluntary Product Field 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.

Risk Mitigation

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.

Actions Needed

1. Please inform users of this Medical Device Removal and forward this notice to all those individuals who need to be aware within your organization.
2. Return all affected products available at your location to
Stryker Osteosynthesis
c/o Christie Samsa, Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ, 07430
REF: PFA #2015-068
or
Contact Stryker customer service and refer to PFA #2015-172 for returning the product to us.
3. Complete and sign the enclosed Business Reply Form and fax a copy to: 1-865-252-3635 or email a copy to
4. Keep a copy of the completed and executed Business Reply Form for your records.

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.

Report any adverse events or product quality problems to Stryker Orthopaedics: 1-866-OR-ASSIST. (1-866-627-7747). Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm

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Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to:
MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
Fax: (800) FDA-0178 Phone: (800) FDA-1088

We regret any inconvenience associated with this issue.

As we strive for products that meet your expectations for quality and reliability, please do not hesitate to contact us, in case you have any further questions.

Sincerely,

Christie Samsa
Manager, Regulatory Compliance
Stryker Orthopaedics, 325 Corporate Drive, Mahwah, NJ, 07430
Phone: +1-201-831-5000
Email: christie.samsa@stryker.com

Appendix:

Business Reply Form

AFFECTED PART 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, K114724, 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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12106451S	G3 K-Wire, UNS-Thread D3.2/L450	K0261B1, K02F39C, K041A91, K042ADA, K04E8E9, K05300A, K07CB8A, K08036E, K08270D, K09882E, K09DC48, K09FF4E, K0A3C19, K0B274C, K0C2937, K0DBD03, K0EBF15, K392536, K392537

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12139091S	GAM Guide Pin D4xL400	K01FEA8, K0379C9, K03FD37, K045996, K071156, K0788B7, K084651, K092B62, K0A1467, K0C72A6, K0C72F0, K0CCEC9, K0D1F65, K0DBFB2, K138738, K146099, K168300, K168301, K242631, K242632, K244954, K260758, K637014, K649678, K747613, K763159, K763162, K919161, K919534, K994597
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, K0DF50F1, 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

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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
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Urgent Medical Device Recall – sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau

18060083S	T2 Guide wire ball tipped D2.5xL800	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, K0ECD7F, 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, K398894, 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
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Urgent Medical Device Recall – sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau

18060084S	Guide wire ball tipped D2.5xL1000	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
18060085S	T2 Guide Wire Ball Tip D3xL1000	K0186F2, K01902E, K01909E, K0190D0, K019100, K01913C, K019211, K020BCD, K020BCE, K020BCF, K020BD0, K020BD1, K020BD2, K020BD4, K020BD5, K020BD6, K0210E6, K0210E7, K0210E8, K0210E9, K0210EA, K0210EB, K0210EC, K0225E6, K0225E7, K0225E8, K0225E9, K02260D, K02260E, K02260F, K022610, K022611, K027524, K027525, K027526, K027527, K027528, K02CE61, K02CE62, K02CE63, K02CE64, K02CE65, K0318CE, K0318CF, K0318D0, K0318D1, K0318D2, K032CA3, K032CA5, K032CA6, K032CA7, K032CA8, K03402E, K03402F, K034030, K034031, K034032, K034033, K03D56B, K03D587, K03D588, K03D589, K03D58A, K03D58B, K040FBA, K040FBE, K040FC0, K040FC1, K040FC2, K040FC3, K042A77, K042A78, K042A7A, K042A7B, K042A7D, K042A7E, K043C62, K043C63, K043C64, K043C65, K043C66, K043C68, K0443C2, K0443C3, K0443DB, K0443DE, K0443DF, K0443E0, K0443E1, K0443E2, K0471F2, K0471F3, K0471F4, K0471F5, K0471F6, K048A88, K048A8A, K048A8B, K048A8C, K048A8D, K04C232, K04C233, K04C234, K04C235, K04C236, K04D340, K04D341, K04D342, K04D343, K04D344, K04D345, K04DCD5, K04DCD6, K04DCD7, K04DCD8, K04DCD9, K04DCDA, K04DF0D, K04DF0E, K04DF0F, K04DF10, K04DF11, K04DF12, K057400, K057401, K057402, K057403, K057404, K057405, K057406, K059C56, K059C57, K059C58, K059C59, K059C5A, K059C5B, K05AE78, K05AE7C, K05AE7D, K05AE7E, K05AE7F, K05AE8, K05BEC6, K05BEC7, K05BEC8, K05BEC9, K05BECA, K05BECB, K05D0B1, K05D0B2, K05D0B3, K05D0B4, K068F72, K068F73, K068F74, K068F75, K068F76, K06A9F9, K06A9FA, K06A9FB, K06AA0D, K06AA11, K06ECF8, K06ECF9, K06ECFA, K06ECFB, K06ECFC, K07122E, K07122F, K071230, K071231, K071232, K071233, K07894E, K07894F, K078950, K078951, K078952, K079F8F, K079F90, K079F91, K079F93, K079F94, K079F95, K09422A, K09422B, K09422C, K09422E, K09422F, K094231, K094232, K094234, K097196, K097197, K097198, K097199, K09719C, K09719F, K098834, K098835, K098836, K098837, K098838, K098839, K09883A, K09883B, K09C882, K09C884, K09C885, K09C887, K09C888, K09DC50, K09DC51, K09DC52, K09DC53, K09DC54, K09F653, K09F654, K09F655, K09F656, K09F9C4, K09F9C5, K09F9C6, K09F9C7, K0A0899, K0A089A, K0A089B, K0A089C, K0A77EC, K0A77EE, K0A77F2, K0A77F3, K0A77F4, K0A77F5, K0A77F6, K0A8B8A, K0A8B8B, K0A8B8C, K0A8B8D, K0AC45F, K0AC460, K0AC461, K0AC462, K0AC463, K0ADDE8, K0ADDE9, K0ADDEA, K0ADDEE, K0ADDEF, K0ADF73, K0ADF74, K0ADF75, K0ADF76, K0ADF77, K0B8527, K0B8528, K0B8529, K0B852A, K0B852B, K0C3805, K0C3806, K0C3807, K0C3808, K0C3809, K0C380A, K0C380B, K0C380C, K0C3D87, K0C3D88, K0C3D89, K0C3D8A, K0C3D8B, K0C3D8C, K0C4A94, K0C4A95, K0C4A96, K0C4A97, K0C4A98, K0C4A99, K0C4A9A, K0C7241, K0C7242, K0C7243, K0C7244, K0C7245, K0C7246, K0C7E39, K0C7E3C, K0C7E3E, K0C7E41, K0C7E43, K0C7E45, K0C7ED3, K0C90BA, K0C90BD, K0C90C0, K0C90C4, K0C90C7, K0C90C9, K0C90CB, K0C90D0, K0C90D1, K0C90D2, K0C90D3, K0C90D4, K0C90D5, K0C90D6, K0C90D7, K0C90D8, K0C90D9, K0C90DA, K0C90DB, K0C90DC, K0C90DD, K0C90DE, K0C90DF, K0C90D0, K0CA5E6, K0CA5E7, K0CA5E8, K0CA5E9, K0CA5EA, K0CA5EB, K0CA5EC, K0CAF59, K0CAF5A, K0CAF5C, K0CAF5D, K0CAF5E, K0CC20E, K0CC20F, K0CC210, K0CC211, K0CC212, K0CC213, K0CDF5D, K0CDF5E, K0CDF5F, K0CDF60, K0CDF61, K0CDF62, K0CDF63, K0D8B8E, K0D8B8F, K0D8B90, K0D8B91, K0D8B92, K0DA751, K0DA752, K0DA753, K0DA754, K0DA755, K0DA92A, K0DA92C, K0DA92F, K0DA931, K0DF8E7, K0DF8E9, K0DF8EA, K0DF8EB, K0DF8ED, K0DF8EF, K0DF8F0, K0DF8F2, K0DF8F4, K0E0179, K0E017A, K0E017B, K0E017C, K0E9E1A, K0E9E1C, K0E9E1D, K0E9E1E, K0E9E1F, K0E9E20, K0E9E21, K0E9E23, K0E9E24, K0EC146, K0EC147, K0EC148, K0EC149, K0EC14B, K0ECD36, K0ECD37, K0ECD38, K0ECD39, K0ECD3A, K0ECD3B, K0ECD3C, K0EDF27, K0EDF28, K0EDF29, K0EDF2A, K0EDF2B, K0EDF2C, K108095, K108096, K108097, K108466, K108502, K108504, K109474, K109475, K109973, K109974, K109975, K109976, K109977, K110256, K110260, K110269, K110273, K1110393, K1112330, K113578, K113582, K113598, K113602, K113607, K113612, K114532, K114533, K114534, K114535, K114787, K114788, K114789, K114790, K114791, K114792, K115344, K115345, K115352, K122060, K122062, K122063, K130090, K130091, K130092, K130352, K130354, K130357, K130358, K136841, K136856, K139603, K139605, K139606, K140480, K140481, K170389, K170395, K170396, K177934, K177971, K178102, K178142, K178143, K194520, K194522, K194523, K194525, K214367, K214368, K214369, K214370, K214371, K214372, K214373, K216263, K216264, K220224, K222306, K222307, K222308, K222309, K222310, K223277, K223279, K223280

Urgent Medical Device Recall – sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau

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18060090S	T2 Guide Wire D3xL800 Smooth Tip	K114458, K129451, K129453, K216256, K241547, K241548, K261792, K261793, K261794, K261796, K277504, K280653, K596618, K658004, K885218, K886314, K886347, K913666
18060093S	T2 Guide wire smooth tipped D2.2xL800	K018B4D, K018B6F, K018CE4, K018D81, K018D82, K018D83, K019AC5, K019BC7, K019BC9, K019BCA, K01ABDA, K01B24C, K01B24D, K01B984, K01D3BD, K01D3BE, K01E581, K01E584, K01EDC3, K020337, K020C27, K020C28, K0213DA, K02169E, K021A2C, K0231FC, K023B9C, K023B9D, K023B9E, K024734, K024735, K024736, K025BF3, K025BF4, K026239, K02623A, K02682F, K026830, K026831, K026832, K02888C, K02888D, K02A00D, K02A1AE, K02A1AF, K02A1B0, K02B5E2, K02BA9D, K02BA9E, K02E2B6, K02F22F, K02F230, K02F231, K02F233, K02F5E4, K030205, K030206, K030207, K0307E4, K0307E6, K0340E1, K0340E3, K0343BE, K035255, K0356F4, K035C21, K036A52, K036A53, K036FDB, K037560, K038879, K038B38, K03954E, K03954F, K039550, K03AE9A, K03C33B, K03C371, K03C37D, K03D555, K03EC21, K03FB29, K03FD14, K03FD5C, K03FE05, K040FC8, K041F7C, K043C6C, K044596, K0459E4, K046772, K04720D, K047CBF, K047CC0, K0490C2, K0492AD, K0492AE, K0492AF, K049B40, K04A839, K04A83A, K04A83B, K04B5CF, K04BAF7, K04BAF8, K04C264, K04C45F, K04C460, K04D30E, K04DD74, K04E66A, K04EE33, K04EE34, K04EFF0, K04FF5D, K04FF5E, K05102C, K05102D, K0515FE, K051925, K051C99, K051C9A, K051C9B, K051C9C, K052389, K05266F, K052F65, K053B02, K0560CB, K0587BE, K059CA1, K05AEA1, K05BEFA, K05D1F4, K06148F, K061490, K067CD8, K06BD81, K06D49C, K06D49D, K06D49E, K0712F0, K07136C, K07137B, K0721CB, K0721CC, K0721CE, K073304, K073305, K073306, K073953, K0744F3, K0744F4, K0744F5, K07628D, K07628F, K077640, K07774E, K079F3B, K07B727, K07B728, K07B729, K07C39F, K07C83E, K07C83F, K07C840, K07EF4B, K07EF4C, K07EF4D, K080907, K080908, K080909, K083C1F, K083C20, K083C22, K087AEB, K087AEC, K087AED, K089B57, K089B58, K089B59, K08AC60, K08AC68, K08AC7B, K08C0C3, K08C0C4, K08C0C5, K08CD12, K08CD13, K08CD14, K08FD8F, K08FD90, K08FD91, K0925FE, K0925FF, K092B46, K092B47, K092B48, K0942FF, K094300, K094301, K0976FA, K0976FD, K098707, K098708, K099312, K099313, K099314, K09C8B0, K09C8B1, K09C8B2, K09EEAD, K09EEAE, K09EEAF, K09EEB0, K09F392, K09F393, K09F394, K0A08EC, K0A08ED, K0A08EE, K0A1CD5, K0A1CD6, K0A1CD7, K0A277D, K0A277E, K0A2781, K0A2782, K0A2A79, K0A2A7A, K0A2A7B, K0A3131, K0A4435, K0A4436, K0A62F9, K0A6450, K0A6451, K0AA670, K0AA671, K0AA672, K0AA673, K0AAB2C, K0AAB2D, K0AAB30, K0AAB31, K0AAB4E, K0AAB54, K0ACB6F, K0ACB70, K0ACB71, K0ADB5, K0ADB8, K0ADB9, K0AE02F, K0AE034, K0B278F, K0B2790, K0B6D63, K0B6D64, K0B8614, K0B8615, K0B89B3, K0B89B4, K0B89B5, K0BA360, K0BAB02, K0BAB03, K0BB803, K0BB811, K0BB813, K0BB814, K0BCDC6, K0BCDC7, K0C1666, K0C72BF, K0C72C0, K0C9DA1, K0C9DA2, K0CC25B, K0CC25C, K0CC25D, K0CDF86, K0CDF87, K0CDF88, K0CEAF8, K0CEAF9, K0CEAFA, K0DOCEE, K0D18FA, K0D18FB, K0D18FC, K0D44EC, K0D7D4E, K0D81F3, K0DA971, K0DB599, K0DB59A, K0DB59B, K0DB59C, K0DBC82, K0DC011, K0DC012, K0DC013, K0DCB14, K0DDC66, K0DE2E4, K0DE2E7, K0DE2E8, K0DE2E9, K0DE2EA, K0DE2EB, K0DF962, K0DF963, K0E0BB9, K0E4AE1, K0E4AE2, K0E4AE3, K0E66F7, K0E68D0, K0E8551, K0E8552, K0E8553, K0E9E9F, K0E9EA0, K0EBD50, K0EBD51, K0EBD54, K0EC19F, K0ECD58, K0EDF75, K0EE8C8, K0EE8C9, K0EE8CA, K0EF18D, K0F303C, K0F303D, K0F3677, K0F3678, K0F3679, K0F3C53, K103831, K103832, K103833, K103880, K103881, K109787, K109790, K109812, K109813, K114032, K114033, K114034, K114035, K115374, K115375, K125097, K125099, K125100, K137881, K137898, K137919, K137920, K137921, K141507, K141508, K141509, K141510, K145998, K145999, K146001, K146771, K154090, K154092, K154093, K154097, K159931, K159950, K159960, K159971, K159991, K161982, K161984, K161989, K170734, K170735, K170736, K179719, K179720, K179799, K179800,

Urgent Medical Device Recall – sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau

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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
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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

Urgent Medical Device Recall – sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau

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, K0C6EF0, 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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CUSTOMER RESPONSE ON RECEIPT

We have received your letter, Ref: 2015-172, dated 3 June 2015 concerning the Urgent Medical Device Field Removal Notification of sterile packaging of Guide Wire(s) and K-Wire(s) and will follow your instruction.

We return this page after completion to Paul Jahnke, Recall Coordinator, at Stryker Orthopaedics by email, fax or letter:

email: paul.jahnke@stryker.com

fax: +1 201 831 4154

address: 325 Corporate Drive
Mahwah, NJ 07430

Hospital / Customer Name: _____

Date / Printed Name / Signature: _____