

URGENT Field Safety Notice: RA 2015-172

22nd January 2016

- Description:** Sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau
- Product Code:** Please refer to the attached list on pages 3-7
- Lot Number:** Please refer to the attached list on pages 3-7

Dear Customer,

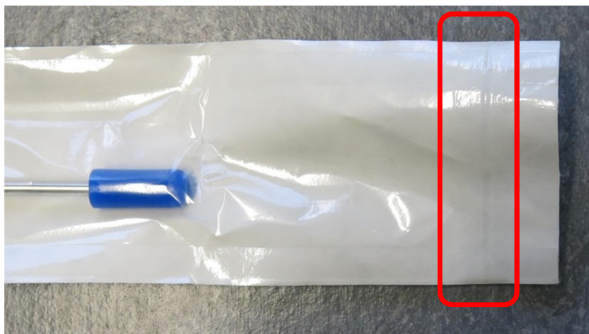
Please find attached details of a voluntary Field Safety Corrective Action that has been initiated by Stryker Trauma GmbH, Trauma and Extremities Division, relating to the sterile packaging of Guide Wire(s), K-Wire(s) and Intramedullary Pin Metaizeau. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue

It was found through a 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 the listed article numbers detailed on pages 3-7 of this document. Given the 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 Required

1. Immediately check your internal inventory to locate subject devices referenced in this notice.
2. Immediately quarantine any subject devices that are located to ensure that they are withdrawn from service.
3. Circulate this Field Safety Notice internally to all interested / affected parties.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility.
5. 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.
6. Complete the attached customer response form and return to Jackie Fripp by fax (01635 262 464) or by e-mail (jacqueline.fripp@stryker.com). Once a completed form has been received, a Stryker Representative will contact you to organise the collection and replacement of any affected devices located on site.
 - a) Please complete this form even if you do not have any products to return. This will preclude the need for Stryker to send any reminder notice.
7. Please inform Stryker of any adverse events concerning the use of the subject devices.
8. Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

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

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours faithfully,



Jackie Fripp
Quality Assurance and Regulatory Affairs

RA 2015-172: Affected Product Codes and Lot Numbers

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, K09CA41, 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, K111472, 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, K394389, 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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12106450S	GAM Kirschner Wire D3.2/L450	K0443F2, K0443F4, K0443F6, K0443F8, K0443FA, K0443FB, K0443FD, K044402, K04C225, K04C226, K04C228, K04C229, K04C22A, K04C22B, K04C22C, K04DCCC, K04DCCC, K04DCCF, K04DCD0, K04DCD1, K04DCD2, K04DCD3, K0CF6E1, K0CF6E2, K0CF6E3, K0CF6E4, K0CF6E5, K0CF6E6, K0CF6E7, K0CF6E8, K0CF6E9, K0CF6EA, K0CF6EB, K0CF6EC, K0CF6ED, K0CF6EE, K0CF6EF, K0CF6F0, K0CF6F1, K0CF6F2, K0CF6F3, K0D278A, K0D278B, K0D278D, K0D278E, K0D278F, K0D2790, K0D2791, K0D2792, K0D2793, K0D2794, K0D2795, K0D4482, K0D4483, K0D4484, K0D4485, K0D4486, K0D4487, K0D4488, K0D448A, K0D4FB7, K0D4FB8, K0D50E5, K0D50E6, K0D50E7, K0D50E8, K0D50E9, K0D50EA, K0D50EB, K0D50EC, K0D50ED, K0D50EE, K0DAC3A, K0DAC3B, K0DAC3C, K0DAC3D, K0DAC3E, K0DAC3F, K0DAC40, K0DAC41, K0DAC42, K0DAC43, K100302, K100303, K100304, K100305, K100353, K100599, K100626, K100643, K104553, K104557, K104560, K104570, K104571, K104586, K108086, K108087, K108088, K108505, K108506, K108507, K108508, K108509, K108510, K109464, K109465, K109466, K109467, K109468, K109472, K115325, K115326, K136475, K136517, K139570, K139571, K139572, K139573, K140461, K140464, K140465, K140470, K153342, K155954, K155955, K155956, K155957, K155958, K155959, K155960, K155961, K164137, K164141, K164142, K164144, K164145, K164265, K177006, K177007, K177008, K177088, K177090, K177829, K188784, K195949, K195950, K195951, K195952, K195953, K195954, K207189, K207215, K207232, K207233, K207234, K207235, K207236, K207238, K207239, K207245, K207768, K207770, K207771, K207772, K229193, K229195, K229196, K229197, K246184, K246185, K246189, K246193, K253564, K253582, K253650, K254303, K254312, K254313, K254331, K254334, K280891, K280892, K388890, K388891, K388892, K388893, K388894, K388950, K398651, K398652, K399435, K399436, K399437, K399438, K399439, K399440, K423424, K423438, K423440, K423441, K423537, K434897, K487798, K487799, K487800, K487802, K487810, K487812, K501500, K501502, K501503, K501504, K501506, K501507, K501508, K501509, K504037, K551100, K551190, K563907, K563916, K563954, K563977, K564003, K564006, K571644, K571657, K571658, K571660, K571671, K571673, K577975, K583492, K628630, K628631, K636902, K636903, K636904, K636905, K636906, K636907, K668647, K668648, K668649, K668651, K668652, K681610, K681612, K681613, K681615, K682548, K682549, K682557, K682558, K714252, K714253, K714255, K714256, K831405, K831408, K831410, K831411, K831412, K831428, K886119, K886122, K886137, K886140, K886143, K889859, K889921, K889922, K889923, K889924, K889933, K890066, K890067, K890068, K890071, K890089, K890090, K895147, K907758, K907759, K907760, K907761, K907763, K907764, K909275, K909276, K909278, K909281, K909283, K909284, K913636, K913639, K913643, K913644, K920825, K920826, K930182, K930183, K930184, K930249, K930250, K930252, K930253, K930261, K962016, K962017, K982610, K982611, K982612, K982613
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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, K0D50FO, 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,

Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
		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
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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, K103034, 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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Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
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Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
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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, K0D8BBAF, K0D8BBB0, 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, K0DCA55, 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, K0C6EF0, K0CB8A7, K0CC1B8, K0CC1B9, K0CE014, K0CE015, K0D063C, K0D1FC2, K0D1FC5, K0D81A7, K0D8467, K0DAC61, K0DAC62, K0DBC90, K0DEEDD, K0DF966, K0E3EB3, K0E690E, K0E6D40, K0E9096, K0ECCDD, K0ECCDE, 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

RA 2015-172: PFA Acknowledgement Form

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

Product Code: Please refer to the attached list on pages 3-7

Lot Number: Please refer to the attached list on pages 3-7

I acknowledge receipt of the Field Safety Notice for RA 2015-172 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
We have further distributed subject devices to the following organisations:			
Facility Name			
Facility Address			

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

**PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO JACQUELINE.FRIPP@STRYKER.COM.**