

Januar 2016

## **HASTER: VIGTIG PRODUKT INFORMATION**

- FSCA-identifikator:** Produktrelateret handling RA2015-172
- Handlingens art:** Sikkerhedsrelateret korrigerende handling
- Beskrivelse:** Steril emballering med guidewire(s), K-wire(s) og Intramedullary Pin Metaizeau
- Katalognr:** Se den vedlagte liste
- Lotkode:** Se den vedlagte liste

Kære kunde

Vedhæftet fremsendes oplysninger om en frivillig sikkerhedsrelateret korrigerende handling, som er påbegyndt af Stryker Trauma GmbH, Division Trauma and Extremities for steril emballage til guidewire(s), K-wire(s) og Intramedullary Pin Metaizeau. Via gennemgang af emballagen blev det fundet, at posens forseglingsintegritet kan være nedsat. Stryker Trauma GmbH, Division Trauma and Extremities tilbagekalder alle ubrugte, ikke-udløbne partier af de ovenfor anførte varenumre. Når man tager den høje omsætning af dette produkt og hyppigheden med hvilken, det har været i restordre i betragtning, forventes det ikke, at der er et betragteligt antal enheder tilbage i markedet, som er genstand for denne information. Ingen kvæstelse eller skade er blevet rapporteret med hensyn til denne hændelse.



Eksempel på emballage – steril pose indvendig (plastik) klar slange



Eksempel på steril pose med potentielt ikke-overensstemmende forsegling

## Potentielle risici

En eventuel kapillær defekt i forseglingen kan potentielt føre til et usterilt produkt.

## Formildende omstændigheder

Den sekundære emballage er et klart (plastik) rør med silikonehætter i begge ender. Skønt det ikke er valideret som en steril barriere, giver det yderligere beskyttelse af den inkluderede poseemballeringskonfiguration.

Ydermere bør det bemærkes, at det er standardpraksis, at kirurger ordinerer antibiotika før operationen for at reducere risikoen for en potentiel infektion, især i situationer, hvor kvæstelsen blev forårsaget af et kraftigt traume.

Vores optegnelser viser, at De har modtaget mindst én af de pågældende anordninger, og at De derfor er berørt af denne handling.

Vi beder Dem læse denne meddelelse omhyggeligt og udføre følgende handlinger:

1. Kontrollér omgående Deres interne lagerbeholdning, og isolér alle berørte anordninger, indtil de kan returneres til Stryker.
2. Lad denne vigtige produktinformation cirkulere internt til alle interesserede/berørte parter.
3. Vær opmærksom på denne produktinformation internt, indtil alle nødvendige handlinger er gennemført på Deres institution.
4. Underret Stryker, hvis en eller flere af de pågældende anordninger er videredistribueret til andre institutioner.
  - a) De bedes give Stryker kontaktoplysninger, så modtagerne kan blive informeret behørigt.
  - b) Hvis De er distributør, bedes De bemærke, at De er ansvarlig for at give deres berørte kunder besked.
5. Informér venligst Stryker om eventuelle utilsigtede hændelser i forbindelse med brugen af de pågældende anordninger.

Vi beder Dem overholde eventuelle lokale bestemmelser vedrørende indberetning af utilsigtede hændelser til Deres nationale, ansvarlige myndigheder.
6. Udfyld det vedlagte kundesvarskema. Det er muligt, at De ikke længere har nogen fysisk lagerbeholdning på stedet. Når De har udfyldt skemaet, kan vi opdatere vores optegnelser, og det vil også eliminere behovet for at udsende yderligere unødvendige meddelelser om denne sag. Vi beder Dem derfor udfylde skemaet, også selvom De ikke længere har nogen af de berørte anordninger på Deres fysiske lager.
7. Returnér det udfyldte skema til Stryker for denne produktrelaterede handling.

Når skemaet er modtaget, vil en Stryker-repræsentant kontakte Dem for at organisere alle relevante, løbende handlinger.

Vi beder Dem besvare denne meddelelse senest 7 kalenderdage fra modtagelsen. Mådatoen for gennemførelse af denne handling er 05 februar 2016, og Deres rettidige svar vil gøre os i stand til at sikre, at vi når dette mål.

Den kontaktperson, De er tilknyttet i forbindelse med denne handling, er opgivet nedenfor. Hvis De har spørgsmål i denne sag, er De meget velkommen til at kontakte vedkommende direkte.

Navn: Christian Troelsen  
Stilling: Sales Manager  
E-mail: christian.troelsen@stryker.com  
Telefon: +45 33 93 60 99

I overensstemmelse med anbefalingerne i MEDDEV.2.12-1 om retningslinjer for et overvågningssystem for medicinsk udstyr kan vi bekræfte, at denne sikkerhedsrelaterede, korrigerende handling er blevet indberettet på behørig vis til de nationale kompetente myndigheder i Deres land.

Vi takker Dem på vegne af Stryker for Deres hjælp og støtte til at gennemføre denne handling inden for tidsfristen, og vi beklager den ulejlighed, som dette måtte medføre. Vi vil gerne forsikre Dem om, at Stryker bestræber sig på at sørge for, at det kun er implantater, der overholder standarderne og lever op til vores høje, interne kvalitetsstandard, der forbliver på markedet.

Med venlig hilsen



Nina Goddard  
Quality Assurance & Regulatory Affairs

## RA2015-172 Berørte produkter og partikoder

Producentens varenummer	Producentens varenavn	Partinumre
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, K0CC1E4, 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
01902000S	MET IM PIN D2xL400	K388843, K849281, K859178
12106450S	GAM Kirschner Wire D3.2/L450	K0443F2, K0443F4, K0443F6, K0443F8, K0443FA, K0443FB, K0443FD, K044402, K04C225, K04C226, K04C228, K04C229, K04C22A, K04C22B, K04C22C, K04DCCC, K04DCCD, K04DCCE, 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, 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, K164143, K164144, 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, K388990, K388991, K388992, K388993, K388994, K389504, K398651, K398652, K399435, K399436, K399437, K399438, K399439, K399440, K423425, 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, K886132, 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
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
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, 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









		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, K179864, K183935, K183940, K183949, K185545, K185563, K185564, K185565, K185566, K194400, K194402, K194403, K194404, K194406, K197524, K197525, K197526, K197527, K202236, K202281, K202282, K202283, K218984, K218989, K219006, K219013, K219014, K219015, K237398, K237593, K237600, K237613, K237614, K237622, K237625, K237626, K239265, K239266, K239284, K239285, K239286, K241070, K241071, K241072, K241073, K241074, K254258, K254277, K254326, K254330, K264963, K264964, K264965, K276018, K276020, K276066, K276067, K276069, K276071, K276072, K276073, K276074, K276790, K278326, K278327, K278328, K281685, K281686, K282169, K282170, K286809, K286812, K286938, K286939, K286940, K286941, K292444, K292445, K292446, K292447, K295104, K295126, K295127, K295140, K295141, K394179, K394180, K394191, K394192, K394193, K398896, K398898, K398899, K398901, K398903, K420471, K420472, K420473, K450333, K450340, K450341, K482329, K482345, K482349, K484578, K484580, K484594, K485287, K486509, K513344, K513346, K513356, K513358, K513359, K524082, K542597, K542598, K542599, K542601, K548947, K548957, K548968, K560994, K560997, K561007, K561011, K569425, K573240, K573242, K573247, K573249, K573453, K578731, K578742, K578746, K578747, K597533, K597535, K597545, K608145, K608185, K608186, K608187, K608191, K610222, K610223, K610224, K610240, K610798, K610801, K610809, K610824, K634775, K634777, K634778, K634779, K634780, K634782, K634783, K634784, K647880, K647881, K647883, K647884, K659283, K659284, K659286, K670666, K671108, K673478, K673481, K673507, K673510, K673782, K674026, K693273, K693480, K694381, K694386, K722519, K722520, K724294, K724297, K724336, K733516, K734034, K734680, K810559, K810564, K810572, K810575, K814641, K814645, K814651, K851536, K851575, K851577, K851593, K909296, K909298, K909302, K909999, K911915, K911928, K911929, K911933, K917721, K917726, K918433, K919721, K919723, K919724, K919726, K919728, K928290, K928319, K928320, K930272, K961997, K961998, K980235, K980273, K980276, K980277, K980280, K980281, K989562, K989563, K989568, K989591, K989592
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, K0C6EF0, K0CB8A7, K0CC1B8, K0CC1B9, K0CE014, K0CE015, K0D063C, K0D1FC2, K0D1FC5, K0D81A7, K0D8467, K0DAC61, K0DAC62, K0DBC90, K0DEEDD, K0DF966, K0E3EB3, K0E690E, K0E6D40, K0E9096, K0ECDDD, 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
-----------	-----------------------------------	---

## KVITTERINGSSKEMA FOR MODTAGELSE AF INFORMATION VEDRØRENDE SIKKERHEDSRELATERET KORRIGERENDE HANDLING

**FSCA-identifikator:** Produktrelateret handling RA 2015-172

**Handlingens art:** Sikkerhedsrelateret korrigerende handling

**Beskrivelse:** Steril emballering med guidewire(s), K-wire(s) og Intramedullary Pin Metaizeau

**Katalognr:** Se den vedlagte liste

**Lotkode:** Se den vedlagte liste

Jeg bekræfter at have modtaget den vigtige produktinformation vedrørende RA 2015-172, og at:

<b>Vi ikke har fundet nogen af disse anordninger på vores lager: (slet, hvis dette ikke relevant)</b>					
<b>Vi har fundet følgende anordninger:</b>					
Produktbeskrivelse	Produktnr.	Lot-nummer	Kvantum	Isoleret kvantum	
<b>Vi har derudover distribueret de omtalte anordninger til følgende organisationer:</b>					
Institutionens navn					
Institutionens adresse					
<b>Skema udfyldt af:</b>					

<b>Kontaktpersonens navn</b>	_____	<b>Kontaktpersons institution</b>	_____
<b>Kontaktadresse</b>	_____	<b>Kontaktpersons stilling</b>	_____
	_____	<b>Kontaktpersons telefonnummer</b>	_____
	_____	<b>Kontaktpersons faxnummer</b>	_____
	_____	<b>Kontaktpersons e-mailadresse</b>	_____

**Udfyld dette skema og fax det til 00 44 1635 262 464  
Eller e-mail det til [nina.goddard@stryker.com](mailto:nina.goddard@stryker.com)**