

AVISO URGENTE DE AÇÃO DE CAMPO: RA 2015-172

Identificador FSCA: Ação de Campo de Produto RA 2015-172

Tipo de Ação: Ação de Campo Corretiva de Segurança

Descrição: Embalagem estéril do(s) Fio guia(s), K-Wire(s) e pino Intramedular Metaizeau

Fabricante Legal: Stryker Trauma GmbH, Prof.-Kuentzsch-Strasse 1-5,
24232 Schoenkirchen / Kiel, Alemanha

Número de catálogo	Nome do produto
1520218S	FIO K 1.8x310MM, PARA PARAFUSOS DE CÔNDILO, ESTÉRIL
12106450S	FIO KIRSCHNER D3.2X450M
12139091S	PINO GUIA ESTERIL. PARACORTADOR CANULADO GAMMA3
18060080S	FIO GUIA BOLA. 3 X 800 MM. STERILE S2
18060083S	FIO GUIA CABECA BOLA. 02.5X800MM T2
18060085S	FIO GUIA BOLA. 3 X 1000MM. STERILE S2
18060090S	FIO GUIA BOLA 3 X 800 MM. STERILE S2
18060093S	FIO GUIA LISO TIPO. 2.2X800MM T2

Lotes: Todos os lotes distribuídos antes de 10-Nov-2015, com prazo de validade não expirado em cinco anos (ver lista detalhada de distribuição).

Caro distribuidor,

Vocês encontrarão os detalhes desta Ação de Campo Corretiva e de Segurança voluntária que foi iniciada pela Stryker Trauma GmbH, divisão de Trauma & Extremidades, para embalagem estéril do(s) Fio guia(s), K-Wire(s) e pino Intramedular Metaizeau nos anexos deste documento.

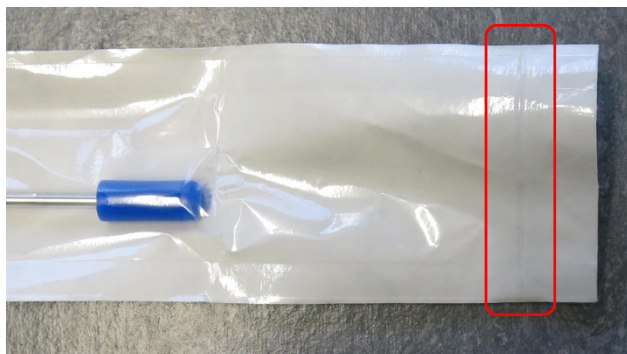
Verificou-se, por meio da avaliação da embalagem, que a integridade da selagem da embalagem pode estar diminuída.

A Stryker Trauma GmbH, divisão de Trauma & Extremidades, está recolhendo todos os lotes não-consumidos e não expirados dos produtos cujos números de catálogo estão listados acima. Dado o alto volume de vendas destes produtos e a frequência de pedidos, acreditamos não haver uma quantidade significativa de unidades sujeita a este aviso ainda em campo.

Nenhuma lesão ou dano foi reportado para este evento.



Exemplo de embalagem - bolsa estéril dentro tubo claro (plástico)



Exemplo de embalagem estéril com selo potencialmente não-conforme

Perigo Potencial

Um potencial defeito na vedação da embalagem pode levar potencialmente a não esterilidade do produto.

Fatores de Mitigação

A embalagem secundária é um tubo claro (plástico) com tampões de silicone em ambas as extremidades. Embora não seja validado como uma barreira estéril, ele fornece proteção adicional para a configuração da embalagem.

Além disso, também deve ser notado que é prática padrão dos cirurgiões prescrever antibióticos pré-operatórios, a fim de reduzir o risco de uma infecção potencial, especialmente em situações em que o ferimento foi causado devido a traumas excessivos.

Nossos registros indicam que você recebeu, pelo menos um dos produtos afetados e, portanto, você é afetado por esta ação.

Nós pedimos que você leia atentamente estas orientações e complete as seguintes ações:

1. Verifique imediatamente em seu inventário interno e em quarentena todos os dispositivos sujeitos a retornar para a Stryker.
2. Circule este Aviso de Ação de Campo de Segurança internamente para todas as partes de interesse/afetadas
3. Tome ciência e mantenha o controle do presente aviso até que todas as ações necessárias forem concluídas dentro de suas instalações.
4. Informar a Stryker se qualquer um dos dispositivos sujeitos foi distribuído para outras organizações.
 - a) Por favor, forneça detalhes de contato para que a Stryker possa informar os destinatários de forma adequada.
 - b) Se você é um Distribuidor, note que você é responsável por notificar seus clientes afetados.
5. Por favor, informe a Stryker de quaisquer eventos adversos sobre o uso dos dispositivos afetados. Cumpra com os regulamentos locais sobre a notificação de eventos adversos para suas autoridades competentes nacionais ou locais.
6. Preencha o formulário de resposta do cliente em anexo. Pode ser que você já não tenha mais um inventário físico no local. O preenchimento deste formulário vai permitir-nos atualizar nossos registros e também irá negar a necessidade de nos enviar quaisquer comunicações desnecessárias sobre este assunto. Portanto, preencha mesmo se você já não tenha mais nenhum dos dispositivos afetados em seu inventário físico.

7. Devolva o formulário preenchido para o Departamento da Qualidade da Stryker do Brasil (indicado abaixo). Após a receber o formulário, um representante da Stryker entrará em contato para organizar todas as ações de devolução aplicáveis.

Nós pedimos que você responda a este aviso no prazo de 7 dias corridos a partir da data de recebimento.

Seu representante para contato designado para essa ação está relacionado abaixo. Se você tiver alguma dúvida quanto a este assunto, por favor, não hesite em contatá-lo diretamente.

Nome: Emilene Bertoldo Martins

Cargo: Coordenadora de Qualidade

E-mail: qualidade@stryker.com

Telefone: (11) 5189-2550

Esta Ação de Campo foi notificada de forma apropriada à Autoridade Competente Nacional (ANVISA).

Em nome da Stryker, agradecemos sinceramente por sua ajuda e apoio na realização desta ação dentro da data estabelecida e lamentamos qualquer inconveniente que possa ser causado. Gostaríamos de tranquilizá-lo que Stryker está empenhada em garantir apenas dispositivos conformes, e em cumprir os nossos padrões internos de alta qualidade, mantendo-se no mercado.

Atenciosamente,



Emilene Bertoldo Martins
Coordenadora da Qualidade
Responsável Técnica Substituta – CRBM: 22752
Stryker do Brasil Ltda.

Produtos afetados e Lotes - RA2015-172

Referência	Nome do produto	Números dos lotes afetados
01520218S	FIO K 1.8x310MM, PARA PARAFUSOS DE CÔNDILO, ESTÉRIL	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, K0A53CE, 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
12106450S	FIO KIRSCHNER D3.2X450M	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, 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, 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, K207239, 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, K930183, K930184, K930249, K930250, K930252, K930253, K930261, K962016, K962017, K982610, K982611, K982612, K982613
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18060080S	FIO GUIA BOLA. 3 X 800 MM. STERILE S2	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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FORMULÁRIO DE CONHECIMENTO DA AÇÃO DE CAMPO CORRETIVA DE SEGURANÇA**Identificador ACCS:** Ação de Campo de Produto RA 2015-172**Tipo de Ação:** Ação de Campo Corretiva de Segurança**Descrição:** Embalagem Estéril do(s) Fio guia(s), K-Wire(s) e Pino Intramedular Metaizeau**Fabricante Legal:** Stryker Trauma GmbH, Prof.-Kuentscher-Strasse 1-5,
24232 Schoenkirchen / Kiel, Alemanha**Número de catálogo:** Consulte a lista em anexo**Lotes:** Consulte a lista em anexo

Recebi o aviso de Ação de Campo de Segurança RA 2015-172 e posso afirmar que:

Não localizamos nenhum destes dispositivos em nosso inventário: <i>(caso esta seja a opção aplicável, coloque um "X" no campo ao lado)</i>				
Localizamos os seguintes produtos em nosso inventário: <i>(caso esta seja a opção aplicável, relacione os itens abaixo)</i>				
Descrição do Produto	Código do Produto	Número do Lote	Quantidade	
Distribuímos os dispositivos sujeitos às seguintes organizações:				
Nome da Instituição				
Endereço da Instituição				
Nome para Contato				
Telefone para Contato				
E-mail				
Formulário preenchido por:				
Empresa:				
Data:				

PREENCHA E ENVIE ESTE FORMULÁRIO POR E-MAIL PARA qualidade@stryker.com