

Pusignan, le 12 janvier 2016

**NOM CLIENT**  
**ADRESSE 1**  
**ADRESSE 2**  
**CP VILLE**

**A l'attention du Directeur d'établissement**

**Pour diffusion :**

- au Correspondant Matériorvigilance
- au Chef de Bloc opératoire, au personnel médical concerné
- au Responsable Qualité

**URGENT FIELD SAFETY NOTICE: RA2015-172**

**Identifiant FSCA :** Rappel de produits RA2015-172  
**Type d'action:** Field Safety Corrective Action  
**Description :** Emballage stérile de broche-guide, broche de Kirschner et broche intramédullaire de Metaizeau  
**Fabricant légal** Stryker Trauma GmbH, Prof.-Kuentischer-Strasse 1-5, 24232 Schoenkirchen/Kiel, Allemagne

| <b>Réf. catalogue</b> | <b>Nom de produit</b>   |
|-----------------------|---|
| 01520218S             | T2 Kirschner wire (broche de Kirschner T2)                    |
| 01902000S             | MET IM PIN (broche IM MET)                                    |
| 12106450S             | GAM Kirschner Wire (broche de Kirschner GAM)                  |
| 12106451S             | G3 K-Wire, UNS-Thread (broche de Kirschner G3, filetage UNS)  |
| 12139091S             | GAM Guide Pin (broche-guide GAM) D4xL400                      |
| 13200016S             | G3 K-Wire with Washer (broche de Kirschner G3 avec rondelle)  |
| 18060050S             | T2 K-Wire (broche de Kirschner T2)                            |
| 18060051S             | K-Wire Ø3 with Washer (broche de Kirschner Ø 3 avec rondelle) |
| 18060080S             | T2 Guide Wire Ball Tip (broche-guide T2 bout sphérique)       |
| 18060083S             | T2 Guide wire (broche-guide T2)                               |
| 18060084S             | Guide wire ball tipped (broche-guide bout sphérique)          |
| 18060085S             | T2 Guide Wire Ball Tip (broche-guide T2 bout sphérique)       |
| 18060090S             | T2 Guide wire (broche-guide T2)                               |
| 18060093S             | T2 Guide wire (broche-guide T2)                               |
| 18061250S             | Guide Wire Ball Tip (broche-guide bout sphérique)             |
| 18061417S             | Fixations K-Draht (broche de Kirschner de fixation)           |
| 18063030S             | T2 K-Wire Recon (broche de Kirschner T2 Recon)                |
| 18063031S             | T2 K-Wire CoCr Recon (broche de Kirschner T2 CoCr Recon)      |

**Numéros de lots :** Tous les lots distribués avant le 10 novembre 2015 n'ayant pas atteint leur date de péremption (voir la liste de distribution détaillée).

Madame, Monsieur,

Vous trouverez ci-joints les informations détaillées relatives à une action réglementaire produit initiée par Stryker Trauma GmbH concernant les dispositifs dont les références et numéros de lot sont mentionnés ci-dessus. Nos dossiers indiquent que vous avez reçu au moins un des dispositifs cités en objet. Vous êtes donc concerné(e) par cette action. Il est possible que vous n'ayez plus de stock physique de ces dispositifs au sein de votre établissement.

Cette action a été initiée afin de garantir que les utilisateurs sont conscients du degré d'importance des informations relatives aux dispositifs cités ci-dessus. Cette action nécessite que vous lisiez le

document Field Safety Notice joint et que vous preniez les mesures préconisées par le fabricant et détaillées dans cet avis. Nous vous demandons ensuite de bien vouloir compléter et nous renvoyer le formulaire de réponse client, pour confirmer que vous avez reçu cet avis.

Nous vous invitons à compléter le formulaire de réponse client même si vous ne disposez plus de stock pour ces dispositifs dans votre établissement. Votre réponse nous permettra de mettre à jour nos dossiers et d'éviter toute relance inutile à ce sujet. Nous vous demandons de bien vouloir **répondre à cet avis dans les sept jours suivant sa date de réception**. En répondant en temps voulu, vous nous permettrez de garantir que les dispositifs non conformes sont retirés du marché dans les plus brefs délais.

Conformément aux recommandations du document MEDDEV Vigilance Guidance réf. 2.12-1, nous vous confirmons que cette mesure Field Safety Corrective Action a été transmise aux autorités compétentes locales de votre pays.

Nous restons à votre entière disposition pour répondre à vos questions ou vous apporter les éléments complémentaires dont vous auriez besoin. Au nom de Stryker, nous vous remercions sincèrement pour votre aide et votre collaboration dans la mise en œuvre de cette action d'ici la date indiquée et sommes navrés des éventuels désagréments occasionnés. Nous tenons à vous confirmer que Stryker s'engage à ce que seuls des dispositifs conformes, répondant à nos normes internes de qualité les plus strictes, restent commercialisés.

Cordialement,



Anaïs Terebinto,  
Spécialiste Qualité et Affaires Réglementaires  
[FranceRAQA@stryker.com](mailto:FranceRAQA@stryker.com)  
Tel : + 33 (0) 472 453 719  
Fax : + 33 (0) 472 453 665

## URGENT FIELD SAFETY NOTICE: RA2015-172

**Identifiant FSCA :** Rappel de produits RA2015-172  
**Type d'action:** Field Safety Corrective Action  
**Description :** Emballage stérile de broche-guide, broche de Kirschner et broche intramédullaire de Metaizeau  
**Fabricant légal** Stryker Trauma GmbH, Prof.-Kuentzsch-Strasse 1-5,  
24232 Schoenkirchen/Kiel, Allemagne

| Réf. catalogue | Nom de produit  |
|----------------|---|
| 01520218S      | T2 Kirschner wire (broche de Kirschner T2)                    |
| 01902000S      | MET IM PIN (broche IM MET)                                    |
| 12106450S      | GAM Kirschner Wire (broche de Kirschner GAM)                  |
| 12106451S      | G3 K-Wire, UNS-Thread (broche de Kirschner G3, filetage UNS)  |
| 12139091S      | GAM Guide Pin (broche-guide GAM) D4xL400                      |
| 13200016S      | G3 K-Wire with Washer (broche de Kirschner G3 avec rondelle)  |
| 18060050S      | T2 K-Wire (broche de Kirschner T2)                            |
| 18060051S      | K-Wire Ø3 with Washer (broche de Kirschner Ø 3 avec rondelle) |
| 18060080S      | T2 Guide Wire Ball Tip (broche-guide T2 bout sphérique)       |
| 18060083S      | T2 Guide wire (broche-guide T2)                               |
| 18060084S      | Guide wire ball tipped (broche-guide bout sphérique)          |
| 18060085S      | T2 Guide Wire Ball Tip (broche-guide T2 bout sphérique)       |
| 18060090S      | T2 Guide wire (broche-guide T2)                               |
| 18060093S      | T2 Guide wire (broche-guide T2)                               |
| 18061250S      | Guide Wire Ball Tip (broche-guide bout sphérique)             |
| 18061417S      | Fixations K-Draht (broche de Kirschner de fixation)           |
| 18063030S      | T2 K-Wire Recon (broche de Kirschner T2 Recon)                |
| 18063031S      | T2 K-Wire CoCr Recon (broche de Kirschner T2 CoCr Recon)      |

**Numéros de lots :** Tous les lots distribués avant le 10 novembre 2015 n'ayant pas atteint leur date de péremption (voir la liste de distribution détaillée).

Stryker® Trauma GmbH, division Traumatologie et extrémités a initié un rappel de produits concernant les dispositifs référencés ci-dessus.

Lors d'un examen des emballages stérile des broches-guides, broches de Kirschner et broches intramédullaires de Metaizeau, il est apparu que l'intégrité du sellage du sachet pouvait être altérée.

Stryker Trauma GmbH, division Traumatologie et extrémités, rappelle tous les lots inutilisés n'ayant pas atteint la date d'expiration des articles référencés ci-dessus et ayant été distribués avant le 10 novembre 2015. Compte tenu du taux de renouvellement élevé de ce produit et de la fréquence à laquelle il a été remis en commande, il est peu probable qu'une grande quantité du dispositif objet de ce rappel soit encore en circulation. Aucune blessure ni aucun préjudice n'ont été rapportés en lien avec cet événement.



Exemple d'emballage – sachet stérile à l'intérieur d'un tube transparent (en plastique)



Exemple de sachet stérile avec sellage potentiellement non conforme.

### Risques potentiels associés

Un éventuel défaut de capillarité dans le sellage pourrait être à l'origine d'une non-stérilité du produit.

### Facteurs d'atténuation

L'emballage secondaire est constitué d'un tube transparent (en plastique) doté de bouchons en silicone aux deux extrémités. Bien qu'il ne constitue pas une barrière stérile homologuée, il offre une protection supplémentaire au sachet d'emballage qu'il contient.

Rappelons en outre que les chirurgiens prescrivent de manière habituelle des antibiotiques dans la période péri-opératoire afin de réduire le risque d'infection, en particulier dans les cas où un traumatisme important est à l'origine de la blessure.

Nos dossiers indiquent que vous avez reçu au moins un des dispositifs cités en objet. Vous êtes donc concerné(e) par cette action.

Nous vous invitons à lire attentivement le présent avis et à prendre les mesures décrites ci-après.

1. Merci de vérifier immédiatement votre stock et de placer en quarantaine tout dispositif objet du présent rappel de produit avant de le retourner à Stryker.
2. Diffusez le présent avis à toutes les personnes concernées au sein de votre établissement.
3. Restez vigilants en interne par rapport à cet avis jusqu'à ce que toutes les mesures requises soient prises au sein de votre établissement.
4. Informez Stryker si l'un des dispositifs concernés a été distribué à d'autres établissements.
  - a) *Veillez nous en indiquer les coordonnées de façon à ce que Stryker puisse contacter directement les utilisateurs.*
  - b) *Si vous êtes un distributeur, notez que la responsabilité d'avertir vos clients concernés vous incombe.*
5. Informez Stryker en cas d'effet indésirable observé en lien avec avec cette problématique. Nous vous rappelons la nécessité de signaler tout effet indésirable observé avec ces dispositifs à Stryker par fax au 04.72.45.36.65 et à l'Agence nationale de sécurité du médicament et des produits de santé – direction de la surveillance – par mail à l'adresse [materiovigilance@ansm.sante.fr](mailto:materiovigilance@ansm.sante.fr) ou par fax : 01.55.87.37.02.

6. Complétez le formulaire de réponse client ci-joint. Il est possible que vous n'ayez plus de stock physique pour ces dispositifs au sein de votre établissement. Nous vous invitons à compléter le formulaire de réponse client même si vous ne disposez plus de stock pour ces dispositifs dans votre établissement. Votre réponse nous permettra de mettre à jour nos dossiers et d'éviter toute relance inutile à ce sujet.
7. Renvoyez le formulaire rempli à votre représentant Stryker désigné (indiqué ci-après) pour cet avis de rappel produit.  
À la réception de ce formulaire, un représentant Stryker vous contactera pour organiser toute action suivie requise.

Si le retour du produit devait perturber votre capacité à assurer les soins médicaux nécessaires à vos patients, vous pouvez restériliser le produit en suivant les instructions de stérilisation détaillées dans les instructions d'utilisation.

Nous vous demandons de bien vouloir répondre à cet avis dans les 7 jours suivant sa date de réception. La date souhaitée d'achèvement de cette action est le ----- . En répondant en temps voulu, vous nous permettrez de respecter cette date.

Votre interlocuteur désigné pour cette action est indiqué ci-dessous. Si vous avez des questions à ce sujet, n'hésitez pas à le contacter directement.

*Nom* : Anaïs Terebinto

*Fonction* : Spécialiste Qualité et Affaires Réglementaires

*E-mail* : [FranceRAQA@stryker.com](mailto:FranceRAQA@stryker.com)

*Téléphone* : + 33 (0) 472 453 719

*Fax* : + 33 (0) 472 453 665

Conformément aux recommandations du document Meddev Vigilance Guidance réf. 2.12-1, nous vous confirmons que cette action corrective produit a été transmise aux autorités compétentes locales de votre pays.

Au nom de Stryker, nous vous remercions sincèrement pour votre aide et votre collaboration dans la mise en œuvre de cette action d'ici la date indiquée et sommes navrés des éventuels désagréments occasionnés. Nous tenons à vous confirmer que Stryker s'engage à ce que seuls des dispositifs conformes, répondant à nos normes internes de qualité les plus strictes, restent commercialisés.

Cordialement,



Anaïs Terebinto,

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Tel : + 33 (0) 472 453 719

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## RA2015-172 Références des produits et lots concernés

| Référence fabricant | Intitulé fabricant   | Numeros des lots  |
|---------------------|--|---|
| 01520218S           | T2 Kirschner wire (broche de Kirschner T2) 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, 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 (broche IM MET) D2xL400                                     | K388843, K849281, K859178   |
| 12106450S           | GAM Kirschner Wire (broche de Kirschner GAM) D3.2/L450                 | K0443F2, K0443F4, K0443F6, K0443F8, K0443FA, K0443FB, K0443FD, K044402, K04C225, K04C226, K04C228, K04C229, K04C22A, K04C22B, K04C22C, K04DCCC, K04DCD, K04DCCCE, 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, 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, K388890, K388891, K388892, K388893, K388894, K388895, 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, K982610, K982611, K982612, K982613 |
| 12106451S           | G3 K-Wire, UNS-Thread (broche de Kirschner G2, filetage UNS) 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 (broche-guide GAM) 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 (broche de Kirschner G3 avec rondelle) 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 (broche de Kirschner T2) 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 (broche de Kirschner Ø 3 avec rondelle)          | 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 (broche-guide T2 bout sphérique) 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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| 18060083S | T2 Guide wire ball tipped (broche-guide T2 bout sphérique)<br>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, K076CC, 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, KODE2EC, KODE2ED, KODE2EE, KODE2EF, KODE2FO, KODF961, 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, 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 |
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| 18060084S | Guide wire ball tipped (broche-guide bouts sphérique) D2.5x L1000 | 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 (broche-guide T2 bout sphérique) 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, K05AE7G, K05AE7H, K05AE7I, K05AE7J, K05AE7K, K05AE7L, K05AE7M, K05AE7N, K05AE7O, K05AE7P, K05AE7Q, K05AE7R, K05AE7S, K05AE7T, K05AE7U, K05AE7V, K05AE7W, K05AE7X, K05AE7Y, K05AE7Z, K05D0B3, K05D0B4, K068F72, K068F73, K068F74, K068F75, K068F76, K068F77, 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, K094233, K097196, K097197, K097198, K097199, K09719C, K09719F, K098834, K098835, K098836, 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| 18060090S | T2 Guide Wire (broche-guide T2 bout lisse) D3x L800 Smooth Tip | <p>K114458, K129451, K129453, K216256, K241547, K241548, K261792, K261793, K261794, K261796, K277504, K280653, K596618, K658004, K885218, K886314, K886347, K913666</p>  |

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| 18060093S | T2 Guide wire smooth tipped<br>(broche-guide T2 bout lisse)<br>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, K03AEA9, K03C33B, K03C370, K03C371, K03D555, K03EC21, K03FB29, K03FD14, K03FD5C, K03FE05, K040FC8, K041F7C, K043C6C, K044596, K0459E4, K046772, K04720D, K047CBF, K047CC0, K0490C2, K0492AD, K0492AE, K0492AF, K049B40, K04A839, K04A83A, 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| 18061250S | Guide Wire Ball Tip (broche-guide bout sphérique) D3x L1250         | 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 (broche de Kirschner de fixation) Ø 3x285 mm, 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, K0DDBAF, K0DDBB0, K0EE8C6, K0EE8C7  |
| 18063030S | T2 K-Wire Recon (broche de Kirschner T2 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 (broche de Kirschner T2 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 |

## Formulaire de réponse client : RA2015-172

### «NOM\_CLIENT» («CODE\_CLIENT»)

**Identifiant FSCA :** Rappel de produits RA2015-172  
**Type d'action:** Field Safety Corrective Action  
**Description :** Emballage stérile de broche-guide, broche de Kirschner et broche intramédullaire de Metaizeau  
**Fabricant légal** Stryker Trauma GmbH, Prof.-Kuentscher-Strasse 1-5, 24232 Schoenkirchen/Kiel, Allemagne  
**Référence catalogue :** Voir la liste jointe  
**Numéros de lots :** Voir la liste jointe

J'accuse réception de l'avis de sécurité Field Safety Notice RA2015-172 et je déclare que :

| <b>Nous n'avons trouvé aucun des dispositifs concernés dans notre stock</b><br><i>(Barrer si non applicable)</i> |               |   |   |                             |
|--|---------------|---|---|-----------------------------|
| <b>Nous avons trouvé les dispositifs suivants :</b>  |               |   |   |                             |
| Référence Produit  | Numéro de lot | Quantité distribuée à votre établissement | Quantité identifiée en stock et placée en quarantaine | Quantité confirmée utilisée |
|  |               |   |   |                             |
|  |               |   |   |                             |
|  |               |   |   |                             |
| <b>Nous avons également distribué les dispositifs concernés aux organisations suivantes :</b>                    |               |   |   |                             |
| Nom de l'établissement   |               |   |   |                             |
| Adresse de l'établissement   |               |   |   |                             |
| <b>Formulaire complété par :</b>   |               |   |   |                             |
| Nom de la personne à contacter   |               | Cachet de l'Établissement                 |   |                             |
| Fonction de la personne à contacter  |               | N° de téléphone                           |   |                             |
|  |               | N° de fax                                 |   |                             |
| Adresse électronique   |               |   |   |                             |
|  |               | Date                                      |   |                             |

**Veuillez renvoyer le formulaire complété à :**  
**Anais Terebinto - N° FAX : 04.72.45.36.65**  
**ou par e-mail : FranceRAQA@stryker.com**