

**Siège Social**  
Smith & Nephew S.A.S.  
25, Bd Marie et Alexandre Oyon  
72019 LE MANS Cedex 2  
France

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To  
**A l'attention de :**  
**Directeur**  
**CLMV**  
**Pharmacien**  
**SB0**  
Fax :

Date : 9 août 2012

Time

Pages : 13

From Anne-Sophie PINON

Subject : Rappel de produit

Fax 02 43 83 24 45

If you do not receive the fax in full, please contact us at the telephone number above

## **URGENT ! RAPPEL PRODUIT**

### **Dispositifs Médicaux stériles - Implants**

Madame, Monsieur,

Smith & Nephew procède au rappel des **ancres des gammes BIORAPTOR, FOOTPRINT PK, FOOTPRINT Ultra, HEALICOIL, TWINFIX Ti, TWINFIX PK, TWINFIX Ultra Ti, TWINFIX Ultra PK et TWINFIX Quick-T**, références suivantes (tous lots confondus) :

Référence	Description
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72203280	2.3 mm BIORAPTOR™ CURVED PK Suture Anchor, with one ULTRABRAID™ (#2) Suture (COBRAID™-black)
72203281	2.3 mm BIORAPTOR CURVED PK Suture Anchor, with one ULTRABRAID (#2) Suture (COBRAID-blue)
72202403	2.9 mm BIORAPTOR Knotless Suture Anchor
72202397	2.9 mm BIORAPTOR Knotless Suture Anchor
72201541	2.3 mm BIORAPTOR PK Suture Anchor with one ULTRABRAID #2 (COBRAID-blue) suture, sterile
72201542	2.3 mm BIORAPTOR PK Suture Anchor with one ULTRABRAID #2 (COBRAID-black), suture
72201543	2.3 mm BIORAPTOR PK Suture Anchor with one ULTRABRAID #2 (white) suture, sterile
72203378	4.5 mm HEALICOIL™ PK Suture Anchor with two ULTRABRAID (#2) Sutures (blue, COBRAID-blue), suture
72203379	5.5 mm HEALICOIL PK Suture Anchor with two ULTRABRAID (#2) Sutures (blue, COBRAID-blue), sterile
72203380	5.5 mm HEALICOIL PK Suture Anchor with three ULTRABRAID (#2) Sutures (blue, COBRAID-blue, COBRAID-black),sterile
72202901	4.5 mm FOOTPRINT Ultra Suture Anchor
72201826	6.5 mm FOOTPRINT PK Suture Anchor with disposable awl
72201825	5.5 mm FOOTPRINT PK Suture Anchor with disposable awl
72201698	6.5 mm FOOTPRINT PK Suture Anchor

72201697	5.5 mm FOOTPRINT PK Suture Anchor
72202902	5.5 mm FOOTPRINT Ultra Suture Anchor
72200796	2.8 mm TWINFIX™ Ti with 2 DURABRAID™ Sutures Size 2-0
72200763	3.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded DURABRAID sutures, sterile
72202595	4.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (white, COBRAID-blue),sterile
72202623	4.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (COBRAID-blue, COBRAID-black),sterile
72203103	4.5 mm TWINFIX™ Ultra PK Anchor with two #2 sutures (blue, COBRAID™-blue),sterile
72202599	5.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (white, COBRAID-blue), sterile
72202625	5.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (COBRAID-blue, COBRAID-black),sterile
72202600	5.5 mm TWINFIX Ultra PK Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black), sterile
72203104	5.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (blue, COBRAID-blue),sterile
72202605	6.5 mm TWINFIX Ultra PK Anchor with two #2 suture (white, COBRAID-blue),sterile
72202630	6.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (COBRAID-blue, COBRAID-black), sterile

72202606	6.5 mm TWINFIX Ultra PK Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black),sterile
72203105	6.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (blue, COBRAID-blue),sterile
72202893	4.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (white, COBRAID-blue),sterile
72202894	4.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (COBRAID-blue, COBRAID-black),sterile
72202895	5.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (white, COBRAID-blue),sterile
72202896	5.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (COBRAID-blue, COBRAID-black), sterile
72202897	5.5 mm TWINFIX Ultra Ti Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black),sterile
72202898	6.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (white, COBRAID-blue), sterile
72202899	6.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (COBRAID-blue, COBRAID-black),sterile
72202900	6.5 mm TWINFIX Ultra Ti Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black)
72201576	5.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, white ULTRABRAID™), sterile
72201578	5.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, white ULTRABRAID), sterile, with awl
72201681	6.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, white ULTRABRAID),sterile

72201683	6.5 mm TWINFIX PK FT Anchor with two #2 suture (COBRAID-blue, white ULTRABRAID), sterile with awl
72201577	5.5 mm TWINFIX PK FT Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black), sterile
72201579	5.5 mm TWINFIX PK FT Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black), sterile with awl
72201682	6.5 mm TWINFIX™ PK FT Anchor with three #2 sutures (white, COBRAID™-blue, COBRAID-black), sterile
72201684	6.5 mm TWINFIX PK FT Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black), sterile, with awl
72202456	5.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, COBRAID-black)
72202457	5.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, COBRAID-black), with awl
72202458	6.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, COBRAID-black)
72200766	5.0 mm TWINFIX Ti Suture Anchor with two #2 preloaded DURABRAID™ sutures, sterile
72200769	6.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded DURABRAID sutures, sterile
72200755	5.0 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID™ sutures, sterile
72200758	6.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID sutures, sterile
72200687	5.0 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID sutures, sterile Anchor Pack (3 per a box)

72200767	5.0 mm TWINFIX Ti Quick-T Fixation System, sterile
72200764	3.5 mm TWINFIX Ti Quick-T Fixation System, sterile
72200768	5.0 mm TWINFIX Quick-T implant with Quick-T Knot Pusher and Suture Cutter, sterile
72200765	3.5 mm TWINFIX Quick-T implant Quick-T Knot Pusher and Suture Cutter, sterile
72200752	3.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID
72200686	3.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID (3 per a box) sutures, sterile, Suture Anchor Pack
72200685	2.8 mm TWINFIX Ti Suture Anchor with one #2 preloaded ULTRABRAID (3 per a box) suture, sterile, Suture Anchor Pack
72200762	2.8 mm TWINFIX Ti Suture Anchor with one #2 preloaded DURABRAID suture, sterile
72200761	2.8 mm TWINFIX Ti Suture Anchor with one #1 preloaded DURABRAID suture, sterile
72200750	2.8 mm TWINFIX Ti Suture Anchor with one #2 preloaded ULTRABRAID suture, sterile

**Ce rappel est motivé par le motif suivant :** présence éventuelle de micro-perforations dans certains sachets pouvant compromettre la stérilité du produit.

Nos enregistrements indiquent que des produits concernés par ce rappel ont été livrés à votre établissement.

### **INSTRUCTIONS**

Nous vous demandons :

**Siège Social**  
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25, Bd Marie et Alexandre Oyon  
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France

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1. d'identifier tous les produits comportant les références mentionnées ci-dessus, présents au sein de votre établissement et de les **placer en quarantaine** sans délai.
2. de nous **faxer au 02.43.83.24.45 - à l'attention d'Anne-Sophie PINON**, Département des Affaires Réglementaires, la **fiche récapitulative de stock** ci-jointe complétée, dans un délai maximum de 7 jours. Dans le cas où vous n'auriez plus aucun produit à retourner, merci de compléter cette fiche et de nous la faxer en cochant la case « Nous n'avons pas de produits concernés par le rappel ».

A réception de notre formulaire complété, nous procéderons aussitôt à la reprise des produits par un transporteur ainsi qu'à l'échange des produits dans la mesure du possible.

En cas de besoin, vous pouvez contacter votre chargé de clientèle habituel ou joindre le service clients au 02 43 83 24 22.

Nous vous prions de bien vouloir nous excuser pour la gêne occasionnée par ce rappel de produit et vous remercions de l'attention que vous porterez à notre demande.

Nous vous prions d'agréer, Madame, Monsieur, l'expression de nos sincères salutations.

Anne-Sophie PINON  
Pharmacien Responsable Affaires Réglementaires

Tél: 02 43 83 24 58  
Fax: 02 43 83 24 45

anne-sophie.pinon@smith-nephew.com

# Fiche récapitulative de stock



## CLIENT

N° Compte client :

Nom

Adresse

Téléphone

Fax


Référence	Désignation produit	Quantité à faire reprendre*
72203280	2.3 mm BIORAPTOR™ CURVED PK Suture Anchor, with one ULTRABRAID™ (#2) Suture (COBRAID™-black)	
72203281	2.3 mm BIORAPTOR CURVED PK Suture Anchor, with one ULTRABRAID (#2) Suture (COBRAID-blue)	
72202403	2.9 mm BIORAPTOR Knotless Suture Anchor	
72202397	2.9 mm BIORAPTOR Knotless Suture Anchor	
72201541	2.3 mm BIORAPTOR PK Suture Anchor with one ULTRABRAID #2 (COBRAID-blue) suture, sterile	
72201542	2.3 mm BIORAPTOR PK Suture Anchor with one ULTRABRAID #2 (COBRAID-black), suture	
72201543	2.3 mm BIORAPTOR PK Suture Anchor with one ULTRABRAID #2 (white) suture, sterile	
72203378	4.5 mm HEALICOIL™ PK Suture Anchor with two ULTRABRAID (#2) Sutures (blue, COBRAID-blue), suture	
72203379	5.5 mm HEALICOIL PK Suture Anchor with two ULTRABRAID (#2) Sutures (blue, COBRAID-blue), sterile	
72203380	5.5 mm HEALICOIL PK Suture Anchor with three ULTRABRAID (#2) Sutures (blue, COBRAID-blue, COBRAID-black),sterile	
72202901	4.5 mm FOOTPRINT Ultra Suture Anchor	
72201826	6.5 mm FOOTPRINT PK Suture Anchor with disposable awl	



## Fiche récapitulative de stock

72201825	5.5 mm FOOTPRINT PK Suture Anchor with disposable awl	
72201698	6.5 mm FOOTPRINT PK Suture Anchor	
72201697	5.5 mm FOOTPRINT PK Suture Anchor	
72202902	5.5 mm FOOTPRINT Ultra Suture Anchor	
72200796	2.8 mm TWINFIX™ Ti with 2 DURABRAID™ Sutures Size 2-0	
72200763	3.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded DURABRAID sutures, sterile	
72202595	4.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (white, COBRAID-blue),sterile	
72202623	4.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (COBRAID-blue, COBRAID-black),sterile	
72203103	4.5 mm TWINFIX™ Ultra PK Anchor with two #2 sutures (blue, COBRAID™-blue),sterile	
72202599	5.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (white, COBRAID-blue), sterile	
72202625	5.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (COBRAID-blue, COBRAID-black),sterile	
72202600	5.5 mm TWINFIX Ultra PK Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black), sterile	
72203104	5.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (blue, COBRAID-blue),sterile	
72202605	6.5 mm TWINFIX Ultra PK Anchor with two #2 suture (white, COBRAID-blue),sterile	
72202630	6.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (COBRAID-blue, COBRAID-black), sterile	
72202606	6.5 mm TWINFIX Ultra PK Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black),sterile	
72203105	6.5 mm TWINFIX Ultra PK Anchor with two #2 sutures (blue, COBRAID-blue),sterile	

## Fiche récapitulative de stock

72202893	4.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (white, COBRAID-blue),sterile	
72202894	4.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (COBRAID-blue, COBRAID-black),sterile	
72202895	5.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (white, COBRAID-blue),sterile	
72202896	5.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (COBRAID-blue, COBRAID-black), sterile	
72202897	5.5 mm TWINFIX Ultra Ti Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black),sterile	
72202898	6.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (white, COBRAID-blue), sterile	
72202899	6.5 mm TWINFIX Ultra Ti Anchor with two #2 sutures (COBRAID-blue, COBRAID-black),sterile	
72202900	6.5 mm TWINFIX Ultra Ti Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black)	
72201576	5.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, white ULTRABRAID™), sterile	
72201578	5.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, white ULTRABRAID), sterile, with awl	
72201681	6.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, white ULTRABRAID),sterile	
72201683	6.5 mm TWINFIX PK FT Anchor with two #2 suture (COBRAID-blue, white ULTRABRAID), sterile with awl	
72201577	5.5 mm TWINFIX PK FT Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black), sterile	
72201579	5.5 mm TWINFIX PK FT Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black), sterile with awl	
72201682	6.5 mm TWINFIX™ PK FT Anchor with three #2 sutures (white, COBRAID™-blue, COBRAID-black), sterile	

## Fiche récapitulative de stock

72201684	6.5 mm TWINFIX PK FT Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black), sterile, with awl	
72202456	5.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, COBRAID-black)	
72202457	5.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, COBRAID-black), with awl	
72202458	6.5 mm TWINFIX PK FT Anchor with two #2 sutures (COBRAID-blue, COBRAID-black)	
72200766	5.0 mm TWINFIX Ti Suture Anchor with two #2 preloaded DURABRAID™ sutures, sterile	
72200769	6.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded DURABRAID sutures, sterile	
72200755	5.0 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID™ sutures, sterile	
72200758	6.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID sutures, sterile	
72200687	5.0 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID sutures, sterile Anchor Pack (3 per a box)	
72200767	5.0 mm TWINFIX Ti Quick-T Fixation System, sterile	
72200764	3.5 mm TWINFIX Ti Quick-T Fixation System, sterile	
72200768	5.0 mm TWINFIX Quick-T implant with Quick-T Knot Pusher and Suture Cutter, sterile	
72200765	3.5 mm TWINFIX Quick-T implant Quick-T Knot Pusher and Suture Cutter, sterile	
72200752	3.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID	
72200686	3.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID (3 per a box) sutures, sterile, Suture Anchor Pack	
72200685	2.8 mm TWINFIX Ti Suture Anchor with one #2 preloaded ULTRABRAID (3 per a box) suture, sterile, Suture Anchor Pack	

## Fiche récapitulative de stock

72200762	2.8 mm TWINFIX Ti Suture Anchor with one #2 preloaded DURABRAID suture, sterile	
72200761	2.8 mm TWINFIX Ti Suture Anchor with one #1 preloaded DURABRAID suture, sterile	
72200750	2.8 mm TWINFIX Ti Suture Anchor with one #2 preloaded ULTRABRAID suture, sterile	

# Fiche récapitulative de stock

Nous n'avons pas de produits concernés par le rappel (cocher la case).

La personne soussignée reconnaît avoir été informée du rappel des produits et avoir recherché tous les produits concernés : **Ancres des gammes BIORAPTOR, FOOTPRINT PK, FOOTPRINT Ultra, HEALICOIL, TWINFIX Ti, TWINFIX PK, TWINFIX Ultra Ti, TWINFIX Ultra PK et TWINFIX Quick-T (réf ci-dessus)** dans l'établissement et le cas échéant dans les établissements à qui elle a livré ces produits.

\* Lieu d'enlèvement des produits par le transporteur :

Nom et n° de tél de la pers. à contacter pour la reprise :

Date de disponibilité des colis :

Nombre de colis :

Horaires d'ouverture :

Horaires de fermeture :

Nom :

N° de tél.

Fonction :

Signature :

Date :

Cachet de l'établissement :

Formulaire à compléter et à retourner par fax à Smith & Nephew SAS

Département Affaires Réglementaires – Anne-Sophie PINON - Fax : 02 43 83 24 45