

Teleflex Medical s.a.s
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S.A.S au capital de 1 031 471 €
R.C.S. Toulouse B 347 479 883
Siret 347 479 883 00030

Urgent : Rappel de dispositifs médicaux Premier avis

Le Faget, 11 septembre 2008

Très cher client de Teleflex Medical,

Teleflex Medical a entrepris un retrait volontaire de clips de ligature de la marque Weck portant sur les produits Hem-o-lok, Horizon, Hemoclip Traditional et Hemoclip Plus car des trous ont été détectés dans le plateau thermoformé de certains conditionnements stériles, ce qui signifie que leur stérilité ne peut être garantie.

Les inspections de produits de Teleflex Medical ont mis en évidence 317 brèches sur les 1 478 631 conditionnements inspectés (fréquence de survenue = 0,0214 %). Le rappel s'applique aux produits qui ont été fabriqués entre janvier 2006 et juillet 2008. **Les produits fabriqués en août 2008 ou ultérieurement ne sont pas concernés par ce retrait.** La FDA (Food and Drug Administration) et l' AFSSAPS ont été avisées de cette mesure.

Produits concernés par le retrait :

La pièce jointe A fournit une liste des codes et numéros de lot des produits concernés par ce retrait et devant être renvoyés à Teleflex Medical sans autre intervention de votre part.

La pièce jointe B fournit une liste des codes et numéros de lot des produits concernés par ce retrait mais pour lesquels une partie des lots a été identifiée dans nos centres de distribution européens et a été soumise à une inspection intégrale. Afin de déterminer si le produit en votre possession a été inspecté, il convient d'ouvrir la boîte d'expédition. Si le produit qu'elle contient porte une étiquette indiquant **OK**, le produit a effectivement été soumis à une inspection intégrale et peut être conservé par vos services. Si le produit ne porte pas l'étiquette **OK**, il doit être renvoyé conformément aux instructions ci-dessous.

Nos registres indiquent que vous avez reçu un produit concerné par ce retrait :

Selon les produits que nous vous avons livrés, vous trouverez ci-joint la liste A et/ou la liste B.

Afin d'offrir à nos clients des produits de qualité optimale, nous vous engageons à prendre les mesures suivantes :

- 1. Interrompez toute utilisation et distribution ; placez immédiatement en quarantaine tous les produits concernés. Si le produit est répertorié dans la pièce jointe A, il doit être maintenu en quarantaine. Si le produit est répertorié dans la pièce jointe B, ouvrez la boîte d'expédition afin de déterminer si les produits qu'elle contient portent l'étiquette OK. Placez en quarantaine tout produit répertorié dans la pièce jointe B ne portant pas d'étiquette OK.**

2. Remplissez le formulaire d'accusé de réception joint pour le(s) produit(s) identifié(s), signez le formulaire et renvoyez-le immédiatement par fax à :

Teleflex Medical S.A.S
Service qualité – Clips

Fax : 05 62 18 79 82

Ceci permettra de confirmer que vous avez bien reçu cet avis et d'établir le nombre de produits en votre possession devant être renvoyés.

3. Si vos stocks comportent des produits concernés par ce retrait, veuillez les retourner, accompagnés du numéro de retour suivant : 0809CPN10050

à

Teleflex Medical S.A.S
Service qualité – Clips
31460 – Le Faget

4. Nous vous prions de nous excuser pour la gêne occasionnée et pour toutes informations complémentaires, merci de bien vouloir contacter notre service clients au :05 62 18 79 40.

Cordialement,

Dominique Giulioli
Responsable assurance qualité
Et affaires réglementaires

Liste A	
Type client	Client Export (Interco)

					Boites			
N° Client	Nom	Pays	Référence	N° de Lot	Quantité			
Customer code	Customer name	Country	Product code	Lot number	Qty			
700025	TELEFLEX MEDICAL BV	PAYS-BAS	HZ1201	T1219269	2			
700101	TELEFLEX MEDICAL BE sprl	BELGIQUE	HZ1200	01A0800045	40			
				01B0800210	49			
				01B0800381	26			
				01K0700193	7			
				01K0700292	25			
				01L0700001	89			
				01L0700089	35			
				01L0700250	26			
				01L0700332	12			
				T1219268	150			
				T1221287	30			
				T1222951	118			
				T1223070	42			
				T1224976	62			
				T1225863	22			
				T1226772	31			
				T1227726	18			
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				T1252517	38			
				T1254473	8			
				T1258343	35			
				T1260338	34			
				T1261020	94			
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				T1264226	54			
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	01L0700252	138
	01L0700334	148
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	T1230587	166
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	T1236596	58
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	T1241609	48
	T1244725	80
	T1246548	45
	T1248473	52
	T1249599	11
	T1250516	165
	T1251541	27
	T1252519	47
	T1256400	127
	T1256401	127
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	T1258345	25
	T1259832	144
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	T1246173	1
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T1266963	21
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HZ5200

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T1247398	8
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WK523100

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WK523135

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T1207485	37
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T1244224	10	
T1244667	4	
T1247447	69	
T1248348	43	
T1250498	22	
T1256391	183	
T1259112	61	
T1260617	5	
T1261796	61	
T1264926	20	
T1268385	10	
T1270369	30	
T1272880	4	
T1276885	27	
T1278109	10	
WK523835	T1195699	23
	T1213974	46
	T1217528	27
	T1224083	23
	T1241601	23
	T1248347	15
	T1249519	58
	T1261006	51
	T1264922	23
	T1268381	23
	T1268816	20
	T1275782	120
	T1277293	15
WK523860	T1195700	6
	T1201399	8
	T1202198	4
	T1203610	8
	T1206016	12
	T1213980	8
	T1226600	5
	T1230384	10
	T1234308	23
	T1240292	25
	T1248343	32
	T1253535	10
	T1256384	10
	T1261791	25
	T1264104	1
WK523870	01L0700014	6
	01L0700184	19
	T1192809	1
	T1202221	9
	T1212660	16
	T1220113	27
	T1225876	18
	T1227701	17
	T1230386	25
	T1236585	48
	T1238444	2

			01C0800254	41
			01D0800002	10
			01D0800198	37
			01D0800277	16
			01E0800057	61
			01L0700021	41
		WK544250	01A0800436	9
			01B0800082	32
			01B0800294	19
			01B0800375	24
			01C0800304	29
			01D0800141	21
			01K0700209	29
			01L0700022	29
			01L0700191	8
			T1195768	103
			T1203690	36
			T1208603	2
			T1210246	1
			T1211617	3
			T1216058	64
			T1226768	68
			T1227722	5
			T1231592	29
			T1233413	10
			T1238493	29
			T1244680	29
			T1247431	16
			T1249598	13
			T1252511	47
			T1253547	10
			T1256395	29
			T1257305	29
			T1258320	29
			T1262900	5
			T1266956	32
			T1273797	68
			T1275793	34
			T1276892	29
			T1279068	49
	Total			107 109

Liste B	
Type client	Client Export (Interco)

N° Client	Nom	Pays	Référence	N° de Lot	Quantité
Customer code	Customer name	Country	Product code	Lot number	Qty
700101	TELEFLEX MEDICAL BE sprl	BELGIQUE	WK533800	01K0700204	16
700241	TELEFLEX MEDICAL UK	ROYAUME-UNI	HZ1201	01K0700293	4
				01L0700180	59
			WK533800	01A0800392	45
				01K0700204	155
			WK533860	01A0800101	23
	01B0800169	1			
700280	TELEFLEX MEDICAL S.r.l	ITALIE	WK533860	01A0800101	6
Total					309

Teleflex Medical s.a.s
31460 Le Faget - France
Tél.: 33+ (0)5.62.18.79.00
Fax: 33+ (0)5.61.83.34.57
www.teleflex.com

Formulaire d'accusé de réception
Avis à prendre en compte immédiatement

Veillez contrôler vos produits et renvoyer immédiatement ce formulaire par FAX à :
Teleflex Medical S.A.S - Service qualité - Clips
Numéro de Fax : 05 62 18 79 82

- Nos stocks ne comportent aucun produit concerné par ce retrait.
- Notre établissement est en possession du produit suivant, concerné par le retrait. Nous avons cessé d'utiliser le produit en question et l'avons placé en quarantaine.

RÉFÉRENCE	NUMÉRO DE LOT	QUANTITÉ	AVOIR / ECHANGE

Renvoyez tout produit concerné à :

Teleflex Medical S.A.S
Service qualité – Clips
31460 – Le Faget

Afin de faciliter le traitement commercial des produits rappelés, merci de nous fournir votre numéro de client
Teleflex Medical : _____

(Nom en majuscules)	(Date)
(Signature)	(Numéro de téléphone)
(Nom de l'établissement)	(Adresse e-mail)
(N° de rue, nom de rue de l'établissement)	<u>Autre adresse de correspondance</u>
(Ville et code postal de l'établissement)	(Adresse)
(Pays)	(Ville, code postal)

Merci d'écrire lisiblement, en majuscules.