

14th Oct 2019

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	EIF-000368
Commercial Name	WECK® Auto Endo5® Automatic Hem-o-lok® Clip Appliers
Product Code	Lot Number
AE05ML	See Appendix 2 for list of lots in scope by product code
543965	

Dear Customer,
 Teleflex Medical has issued a recall for the product codes and lot numbers listed above.

Description of the problem & immediate actions required

Teleflex is recalling certain lots of surgical automatic clip appliers due to an increase in misloading and/or jamming related complaints that may be due to a discrepancy in the specification of one of the product components. Misloading and/or jamming may lead to clips falling out of the applier, clip breakage, or the jaws becoming locked in a partially closed position (jammed). In these instances, medical or surgical intervention, or procedural delays, could be required.

Our records indicate you have received products that are subject to this recall.

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities	1
Distributors	2

Action list number 1 – Medical facilities

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and return this form immediately to Customer Service.
3. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.



Action list number 2 – Distributors

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope to Teleflex.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
4. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
5. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs all customers, employees of Teleflex and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice. Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service:

Contact: Nicole Morawiec

FAX: +41 (0) 31 818 40 93

Telephone: +41 (0) 31 818 40 90

Email: info.ch@teleflex.com

Please be advised that all Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex is committed to providing high quality, safe and effective products. We sincerely apologise for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty VP, QA (Manufacturing)

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED
Ref. EIF-000368

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93

Email: info.ch@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and have completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and have completed the required actions contained therein. We confirm our inventory DOES include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. Return Authorisation No: _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number** is **clearly visible** on the returns package
- Please label returns as **“Field Safety Returns”**

Complete this Acknowledgement form and return immediately by using fax number or e-Mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSITIUTION ADDRESS	Phone/FAX
FORM COMPLETED BY:	Stamp
PRINT NAME: _____	
SIGNATURE: _____	
DATE	

Code	Lots				
543965	73J1600836	73C1700518	73D1800018	73H1800233	73A1900664
	73J1600837	73C1700842	73D1800019	73H1800234	73B1900436
	73K1600114	73D1700008	73D1800020	73H1800235	73B1900437
	73K1600115	73D1700009	73D1800558	73H1800236	73B1900438
	73K1600290	73D1700010	73D1800559	73H1800240	
	73K1600515	73D1700068	73D1800560	73H1800496	
	73K1600814	73D1700069	73D1800561	73H1800497	
	73L1600097	73D1700313	73D1800562	73H1800498	
	73L1600098	73D1700314	73D1800563	73H1800499	
	73L1600099	73D1700315	73D1800564	73H1800500	
	73L1600100	73D1700496	73D1800565	73H1800501	
	73L1600101	73D1700497	73E1800526	73H1800502	
	73L1600274	73D1700574	73E1800527	73H1800639	
	73L1600275	73D1700575	73E1800528	73H1800640	
	73L1600276	73F1700209	73E1800529	73H1800641	
	73L1600277	73F1700210	73E1800530	73H1800642	
	73L1600278	73G1700345	73F1800263	73H1800643	
	73L1600279	73G1700346	73F1800264	73H1800820	
	73L1600280	73G1700347	73F1800265	73J1800298	
	73L1600540	73G1700720	73F1800266	73J1800299	
	73L1600792	73G1700721	73F1800267	73J1800300	
	73L1600793	73H1700095	73F1800268	73J1800301	
	73L1600794	73H1700096	73F1800269	73J1800302	
	73L1600795	73H1700097	73F1800270	73J1800303	
	73L1600796	73H1700098	73F1800486	73J1800304	
	73L1600797	73B1800105	73F1800487	73J1800305	
	73L1600798	73B1800106	73F1800759	73J1800306	
	73M1600217	73B1800188	73F1800760	73J1800718	
	73M1600218	73B1800189	73F1800761	73J1800719	
	73M1600219	73B1800190	73G1800089	73J1800720	
	73M1600220	73B1800192	73G1800520	73K1800055	
	73M1600281	73B1800216	73G1800521	73K1800057	
	73M1600282	73B1800217	73G1800522	73K1800058	
	73A1700205	73C1800125	73G1800525	73K1800691	
	73A1700206	73C1800126	73G1800726	73K1800694	
	73A1700207	73C1800127	73G1800727	73K1800700	
	73A1700348	73C1800128	73G1800728	73K1800701	
	73A1700349	73C1800129	73G1800729	73K1800702	
	73B1700226	73C1800130	73G1800730	73K1800703	
	73B1700276	73C1800131	73G1800731	73M1800021	
	73B1700486	73C1800132	73G1800877	73M1800022	
	73B1700487	73D1800013	73G1800878	73M1800023	
	73C1700335	73D1800014	73H1800138	73M1800024	
	73C1700360	73D1800015	73H1800139	73M1800025	
	73C1700361	73D1800016	73H1800231	73A1900662	
	73C1700362	73D1800017	73H1800232	73A1900663	

Code	Lots				
AE05ML	73F1700597	73M1700020	73C1800265	73E1800326	73F1800733
	73F1700598	73M1700074	73C1800266	73E1800327	73F1800734
	73F1700599	73M1700112	73C1800267	73E1800328	73G1800171
	73G1700468	73M1700113	73C1800268	73E1800329	73G1800172
	73G1700469	73M1700114	73C1800515	73E1800330	73G1800264
	73G1700472	73M1700115	73C1800516	73E1800331	73G1800265
	73G1700473	73M1700116	73C1800517	73E1800332	73G1800266
	73G1700554	73M1700286	73C1800578	73E1800333	73G1800267
	73G1700555	73M1700287	73C1800627	73E1800334	73G1800289
	73G1700556	73M1700288	73C1800628	73E1800764	73G1800290
	73G1700557	73M1700289	73C1800629	73E1800765	73G1800291
	73G1700558	73M1700290	73C1800630	73E1800766	73G1800292
	73H1700821	73M1700291	73C1800631	73E1800767	73G1800293
	73H1700835	73A1800244	73C1800632	73E1800768	73G1800294
	73H1700836	73A1800589	73C1800633	73E1800769	73G1800295
	73K1700553	73A1800596	73D1800209	73E1800770	73G1800296
	73K1700567	73A1800597	73D1800210	73E1800771	73G1800868
	73K1700568	73A1800598	73D1800211	73E1800772	73G1800872
	73K1700570	73A1800605	73D1800212	73F1800091	73G1800873
	73K1700571	73A1800742	73D1800213	73F1800092	73G1800874
	73L1700001	73A1800823	73D1800372	73F1800093	73G1800875
	73L1700002	73A1800824	73D1800373	73F1800094	73G1800876
	73L1700004	73A1800825	73D1800374	73F1800095	73H1800071
	73L1700007	73A1800827	73D1800375	73F1800096	73H1800140
	73L1700023	73A1800828	73D1800376	73F1800097	73H1800141
	73L1700107	73B1800286	73D1800377	73F1800098	73H1800142
	73L1700108	73B1800287	73D1800668	73F1800099	73H1800143
	73L1700189	73B1800288	73E1800023	73F1800407	73H1800144
	73L1700190	73B1800289	73E1800024	73F1800408	73H1800145
	73L1700277	73B1800291	73E1800025	73F1800409	73H1800228
	73L1700278	73B1800292	73E1800026	73F1800410	73H1800229
	73L1700280	73B1800468	73E1800027	73F1800411	73H1800638
	73L1700281	73B1800469	73E1800028	73F1800412	73H1800829
	73L1700282	73B1800525	73E1800033	73F1800586	73H1800830
	73L1700351	73B1800526	73E1800034	73F1800587	73J1800030
	73L1700462	73B1800527	73E1800165	73F1800588	73J1800031
	73L1700463	73B1800528	73E1800166	73F1800589	73J1800032
	73L1700464	73B1800529	73E1800167	73F1800590	73J1800033
	73L1700465	73B1800676	73E1800198	73F1800591	73J1800034
	73L1700466	73B1800677	73E1800199	73F1800675	73J1800035
	73L1700467	73B1800678	73E1800200	73F1800727	73J1800036
	73L1700587	73B1800679	73E1800201	73F1800728	73J1800385
	73L1700588	73B1800680	73E1800202	73F1800729	73J1800386
	73L1700589	73B1800681	73E1800203	73F1800730	73J1800387
	73L1700590	73C1800263	73E1800204	73F1800731	73J1800388
	73L1700591	73C1800264	73E1800325	73F1800732	73J1800480

Code	Lots			
	73J1800481	73L1800353	73A1900048	73B1900227
	73J1800482	73L1800354	73A1900049	73B1900228
	73J1800483	73L1800355	73A1900233	73B1900229
	73J1800484	73L1800356	73A1900234	73B1900230
	73J1800485	73L1800357	73A1900235	73B1900231
	73J1800486	73L1800358	73A1900236	73B1900429
	73J1800487	73L1800359	73A1900237	73B1900430
	73J1800488	73L1800541	73A1900238	73B1900431
	73J1800716	73L1800542	73A1900239	73B1900432
	73J1800717	73L1800543	73A1900240	73B1900433
	73K1800059	73L1800544	73A1900241	73B1900434
	73K1800060	73L1800545	73A1900431	73B1900617
	73K1800062	73L1800546	73A1900432	73B1900618
	73K1800063	73L1800547	73A1900433	73B1900619
	73K1800064	73L1800549	73A1900434	73B1900620
	73K1800065	73L1800550	73A1900435	73B1900621
	73K1800132	73L1800728	73A1900436	73B1900622
	73K1800133	73L1800729	73A1900437	73B1900623
	73K1800134	73L1800731	73A1900438	73B1900624
	73K1800336	73L1800732	73A1900439	73B1900625
	73K1800337	73L1800733	73A1900656	73C1900028
	73K1800338	73L1800734	73A1900657	73C1900029
AE05ML (cont.)	73K1800339	73L1800735	73A1900658	73C1900030
	73K1800340	73L1800736	73A1900659	73C1900031
	73K1800341	73M1800226	73A1900660	73C1900032
	73K1800342	73M1800227	73A1900661	73C1900033
	73K1800894	73M1800228	73A1900869	73C1900034
	73K1800895	73M1800229	73A1900870	73C1900035
	73K1800896	73M1800266	73A1900871	73C1900036
	73K1800897	73M1800267	73A1900872	73C1900239
	73K1800898	73M1800268	73A1900873	73C1900240
	73K1800899	73M1800269	73A1900874	73C1900241
	73K1800900	73M1800270	73A1900875	73C1900242
	73K1800901	73M1800271	73B1900050	73C1900243
	73K1800902	73M1800272	73B1900051	73C1900244
	73L1800094	73M1800273	73B1900052	73C1900245
	73L1800095	73M1800474	73B1900053	73C1900437
	73L1800096	73A1900032	73B1900054	73C1900439
	73L1800097	73A1900033	73B1900055	73C1900440
	73L1800098	73A1900041	73B1900056	73C1900442
	73L1800099	73A1900042	73B1900057	73C1900444
	73L1800100	73A1900043	73B1900058	73C1900445
	73L1800101	73A1900044	73B1900223	73C1900446
	73L1800102	73A1900045	73B1900224	73C1900447
	73L1800351	73A1900046	73B1900225	73C1900448
	73L1800352	73A1900047	73B1900226	73C1900609