

Urgent: Field Safety Notice

[Customer Name
Hospital Name
Street Address
City, State, Zip Code]

Affected Product: Epix® Universal Clip Applier

Manufacturer Single Registration Number: US-MF-000000764

8 February 2024

Dear Valued Customer,

Applied Medical is conducting a Field Safety Corrective Action of specific lot numbers of its Epix® Universal Clip Applier due to a nonconformance that may result in a clip not loading into the jaws after the trigger is actuated. The nonconformance does not impact the functionality of the clip when applied to a structure. The clip itself will be properly formed and applied to the structure when the clip is loaded into the jaws of the device. Out of an abundance of caution for patient safety and a commitment to provide only the highest quality products, Applied Medical has decided to conduct a FSCA of all potentially affected units.

We regret this inconvenience and assure you that maintaining high-quality standards continues to be our highest priority. **All CA500 Epix® Universal Clip Appliers (UDI: (01)00607915125318) from the lots listed below should be returned to Applied Medical. Please see Pages 7-10 for kits including CA500 Epix® Universal Clip Appliers with impacted lots.**

Lot #(s)									
1475580	1478017	1479969	1484005	1487790	1489531	1491059	1493421	1495270	1495838
1475581	1478018	1479971	1484021	1487791	1489532	1491060	1493422	1495807	1495839
1477351	1478019	1482641	1484022	1487792	1489874	1491910	1493423	1495808	1495840
1477352	1478089	1482644	1484023	1488875	1489895	1491914	1493568	1495809	1495841
1477353	1478155	1482645	1484024	1488876	1489896	1491916	1493569	1495830	1495842
1477354	1478925	1482646	1484025	1488877	1489897	1492220	1493590	1495831	1495843
1477355	1478926	1482647	1484026	1488878	1489898	1493194	1493591	1495832	1495844
1477356	1478927	1482648	1486035	1488910	1490284	1493195	1494324	1495833	1495845
1477357	1479771	1482649	1486036	1488967	1490315	1493196	1494470	1495834	
1477358	1479772	1482954	1486037	1488968	1490523	1493197	1494471	1495835	
1477359	1479773	1484000	1486038	1488969	1490524	1493198	1495262	1495836	
1478016	1479774	1484004	1486039	1489421	1491058	1493420	1495263	1495837	

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Our records indicate that you have received units from one or more of the affected lots. For FSCA effectiveness, we ask that you please complete the following actions:

- Check your inventory for recalled product.
- Complete the attached Customer FSCA Notification Confirmation Form (Page 3) to acknowledge the FSCA and indicate if your facility is returning or has already used the lots listed above. **Please note that you must return the form even if you have no devices in inventory.**
 - If no product is being returned, please indicate on the Customer FSCA Notification Confirmation Form (Page 3).
- Complete the attached Distributor FSCA Notification Confirmation Form (Page 4) to acknowledge the FSCA and indicate if your facility is returning or has already used the lots listed above.
 - If no product is being returned, please indicate on the Distributor FSCA Notification Confirmation Form (Page 4).
 - Please notify any facilities to which you distributed the affected product. Please also complete the Distributor FSCA Notification Confirmation Report (**Page 5**).
- Return the Customer FSCA Notification Confirmation Form to Applied Medical by email at Reply-Europe@appliedmedical.com.
- Return affected product and a copy of the Customer FSCA Notification Confirmation Form to Applied Medical. Product Return Instructions are on **Page 6**.


We apologize for any inconvenience this action may cause. Your immediate attention is appreciated.

Applied Medical will ensure that the appropriate Regulatory Agencies have been notified.

For product return questions, please contact Customer Service at 0800 0347 333 or by email at Reply-Europe@appliedmedical.com.

For regulatory questions, please contact Regulatory Affairs at +31 (0) 33422 90 40 (Option 5) or by email at RA-QA@appliedmedical.com.

Sincerely,



Nesma Bishara
Director, Regulatory Affairs
Applied Medical Europe B.V.

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Customer FSCA Notification CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:

Email: Reply-Europe@appliedmedical.com

The form must be returned even if you have zero devices in inventory.

Applied Medical "Sold To" Account Number: XXXXX

Applied Medical "Ship To" Account Number: XXXXX

If you have transferred devices to another facility, please send them a copy of this FSCA letter. If possible, list the facility information, including contact information. Also, please add a note if you received the devices from another facility.

INFORMATION FOR CUSTOMER FACILITY RESPONDING TO FSCA:

Hospital Name: _____

Hospital Address: _____

If products were supplied to you by a distributor other than Applied Medical, please also provide:

Distributor's Name: _____

RETURNING PRODUCT INFORMATION:

If no products are being returned, please check here:

(If no products are returning, it is assumed that all products were previously used and/or are no longer available.)

Model Number	Lot Number	Qty of Units Being Returned

Please select credit or replacement: Credit Replacement

If requesting replacement product, please include a No-Charge P.O.# _____

Please note:

1. Customers who purchased directly from Applied Medical will receive replacement or a credit when product is returned.
2. Customers who received recalled product from a distributor other than Applied Medical may request credit through their original distributor by returning the recalled product to that distributor.

INFORMATION ABOUT INDIVIDUAL COMPLETING THIS FORM:

Name: _____ Date: _____

Title: _____ Telephone: _____

Email: _____ Fax: _____

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Distributor FSCA Notification CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:

Email: Reply-Europe@appliedmedical.com

The form must be returned even if you have zero devices in inventory.

Applied Medical "Sold To" Account Number: XXXXX

Applied Medical "Ship To" Account Number: XXXXX

If you have transferred devices to another facility, please send them a copy of this FSCA letter. If possible, list the facility information, including contact information. Also, please add a note if you received the devices from another facility.

INFORMATION FOR DISTRIBUTOR FACILITY RESPONDING TO FSCA:

If you are a distribution facility, please provide the below information and fill out Page 5:

Distributor Name: _____

Distributor Address: _____

RETURNING PRODUCT INFORMATION:

If no products are being returned, please check here:

(If no products are returning, it is assumed that all products were previously used and/or are no longer available.)

Model Number	Lot Number	Qty of Units Being Returned

Please select credit or replacement: Credit Replacement

If requesting replacement product, please include a No-Charge P.O.# _____

Please note:

1. Customers who purchased directly from Applied Medical will receive replacement or a credit when product is returned.
2. Customers who received recalled product from a distributor other than Applied Medical may request credit through their original distributor by returning the recalled product to that distributor.

INFORMATION ABOUT INDIVIDUAL COMPLETING THIS FORM:

Name: _____ Date: _____

Title: _____ Telephone: _____

Email: _____ Fax: _____

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Distributor FSCA Notification CONFIRMATION REPORT
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DISTRIBUTOR, PLEASE COMPLETE THIS FORM AND SEND TO:

Email: Reply-Europe@appliedmedical.com

**Information about Distributor's Units Sent to
Other Distribution Centers and/or Other Customers:**

Lot Number	Name and location of Distribution Centers or Other Customers who received recalled product	Number of units distributed	Has this facility been notified of the FSCA?	Date this facility was notified of FSCA

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Product Return Instructions

Collection of the recalled units will be arranged by our Customer Service team after receipt of the Customer FSCA Notification Confirmation Form.

Please write the provided RGA Number on the outside of the package.

Please include a copy of the completed Customer FSCA Notification Confirmation Form with your returned product(s).

If you have questions about the Customer FSCA Notification Confirmation Form or how to return product, please contact the Customer Services team at:

Telephone: 0800 0347 333
Email: Reply-Europe@appliedmedical.com

If you have any regulatory questions, please contact:

Regulatory Affairs Department
Telephone: +31 (0) 33422 90 40 – Option 5
Email: RA-QA@appliedmedical.com

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Model Description	Lot #(s)						
GK1003, AME KIT 54562	1493930	1499051	1505559	1509312	1510944		
GK1004, KIT LAP CHOL DEN HOED 2	1498012	1498814	1507422	1510192			
GK1005, K2550 - HÉPATECTOMIE ERASME	1503416						
GK1011, K-19459	1492258	1494291	1496830	1501491	1503409	1505119	
	1506824	1509999	1512086				
GK1014, K-18031 STANDARD KIT	1492615	1498019	1500346				
GK1018, K-20735 STANDARD KIT	1490830	1493458	1493663	1496834	1499821	1504146	
	1504513	1507714	1509639	1512094	1512095		
GK1033, AME STANDARD KIT 21-023	1490821	1490903	1491315	1491731	1493162	1495246	
	1497709	1498010	1498633	1500231	1501062	1503405	
	1504625	1505118	1505796	1507783	1509737	1510306	
	1511132	1511807	1512088	1512551	1513276		
GK1044, KE39830 COLE	1493549	1495781	1498030	1499053	1499054	1502937	
	1505126	1507642	1511155	1512771			
GK1047, AME STANDARD KIT 22-003	1491880	1499686	1499951	1500927	1501554	1503255	
	1503730	1505549	1507423	1510193	1511011		
GK1063, AME STANDARD KIT 22-022	1495826	1503999					
GK1068, AME STANDARD KIT 22-027	1490822						
GK1071, AME STANDARD KIT 22-030	1490896	1493870	1493926	1493929	1494174	1494306	
	1494579	1494701	1494741	1494859	1494864	1495044	
	1495045	1499068	1499069	1499071	1499078	1499096	
	1499099	1499130	1499172	1499176	1499198	1499205	
	1499206	1500087	1500088	1500093	1500097	1500099	
	1500100	1500114	1500117	1500156	1500159	1500160	
	1500161	1500163	1500164	1500169	1500170	1500173	
	1500174	1500230	1500234	1500235	1500236	1500237	
	1500238	1500241	1500244	1500246	1501735	1501921	
	1501924	1501925	1503849	1503851	1503854	1503856	
	1503859	1503860	1503863	1503865	1503986	1503989	
	1504282	1508813					
	GK1083, AME STANDARD KIT 22-045	1491732	1493101	1494231	1495454	1495765	1496937
		1497677	1498634	1498819	1500175	1501091	1502639
1502820		1503434	1504140	1505968	1507476	1508265	
1508951		1510018	1510964	1512407	1512539		
GK1094, AME STANDARD KIT 23-015	1499055						
GK1096, AME STANDARD KIT 23-017	1500172	1503414	1504111	1510746			
GK1101, AME STANDARD KIT 23-033	1511803						
GK131, LAP CHOLE PROCEDURE PACK	1490908	1491620	1492157	1493081	1493274	1493407	
	1493781	1493950	1494389	1495122	1496843	1496956	

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	1497191	1497708	1498055	1498292	1498600	1500385
	1501791	1502201	1509780			
GK153, TOTAL 5mm SOLUTION KIT 11	1499020					
GK168, 10mm ACCESS/LIGATION/RETRIEVAL PK	1490209					
GK258, AME STANDARD KIT 44	1511252					
GK260, STANDARD SET 360 Z	1490828	1494576	1500777	1503355		
GK307, CHOLE KIT 1	1501293	1504075	1509317			
GK308, CHOLE KIT 15	1501490	1505192				
GK320, CHOLE KIT 24	1501240					
GK358, CHOLE KIT 22	1500915	1503540	1505884			
GK360, CHOLE KIT 18	1508997					
GK363, CHOLE KIT 31	1502619	1506447				
GK364, CHOLE KIT 30	1502328	1506137	1508889			
GK365, CHOLE KIT 28	1500608	1502439	1507417			
GK368, CHOLE KIT 33	1501332	1501898	1509610			
GK401, TOTAL 5mm SOLUTION KIT 41	1508770					
GK402, TOTAL 5mm SOLUTION KIT 42	1501460	1505435				
GK736, LAP. CHOLECYST. CLIP	1493043	1495458	1498596	1500866	1502123	1504004
	1506444	1508809				
GK738, STANDARD SET 112 F	1491619	1492686	1495110	1496948	1499485	1501463
	1503811	1506649	1507715	1510023	1510304	1512403
GK739, STANDARD SET 397 F	1503064	1506643	1510180			
GK834, K100796	1495822	1497787	1500923	1505281	1505798	1506319
	1508517	1508522	1510441	1510848	1511410	1511421
	1512467					
GK835, KIT AME 55003	1497788	1510292	1513554			
GK837, KIT K86656	1491037	1491748	1495253	1501352	1505282	1508523
	1511262	1511420	1512787			
GK857, KIT CHOLECYSTECTOMIE LOBBES	1492683	1494234	1496978	1501086	1505205	1508565
GK858, KIT KE284	1495118	1502633	1509709	1509710	1510437	
GK861, KIT VESICULE 11MM CHA	1492048	1500239	1501353	1507706	1509061	
GK874, LAP CHOLE KIT Z-THREAD	1491303	1493161	1498017	1502935	1502946	1503343
GK877, LAP CHOL KIT 5	1490819	1493865	1496824	1498444	1500768	1503071
	1505441	1507713	1510974	1511789	1513551	
GK878, SSMC LAP, CHOLE, KIT NO.1	1498018	1500420				
GK879, SSMC LAP, CHOLE, KIT NO. 2	1509554					
GK891, LAP-GALLE-SET	1490823	1494238	1497179	1499066	1500930	1501340
	1501920	1504307	1509067	1510640	1511342	
GK895, KIT HERES LAP CHOL 5MM	1497622	1505551				
GK905, GALLKIT TORSBY SJUKHUS	1491032	1494692	1499499	1503063	1504306	1506452

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	1508714	1509732	1510742	1511012	1512772	
GK920, K57569	1502805 1509055	1502807 1509057	1502808	1505558	1505957	1505960
GK921, K57526	1498103	1500166	1514370			
GK924, K65251	1491750	1493149	1493363	1500343		
GK962, LAP CHOL BOOM	1501922	1507421	1510191			
GK965, URO-VARIKOCELEN+LYMPHEKTOMIESE	1507007	1513790				
GK969, KIT LAP CHOL TOORENVLIEET	1494155 1513851	1497999	1505547	1507414	1510014	1510186
GK980, KE78892 LAP PROSTATECTOMY 2	1491757 1510015	1492402	1495452	1499493	1505198	1505829
GK983, KIT KE 111515	1493037 1508706	1493623	1494298	1500108	1506320	1507005
GK987, LAP. CHOLE-SET LKH MURTAL	1494571	1497181	1498913	1500344	1505286	1508525
GK988, LAPCHOLE KIT ERASME VERSION 4	1493447 1507172	1493450 1507173	1495439 1509556	1498111 1512553	1502003 1512554	1505144
GK992, K8056 - KIT COLE	1494299 1514298	1496688	1500107	1505741	1508705	1508713
GK993, K116634	1493144	1495814	1497178	1506142	1510016	1514437
GK998, GALLEKIT VOSS	1491047 1505443	1493868 1505444	1494278 1508942	1494279 1511428	1494493 1512392	1502349 1512393
JK001, OLYMPUS KIT 1 (2XCTF03,1XCA500)	1493487	1501078				
JK003, OLYMPUS KIT 3 (2XCFF05, 1XCA500)	1501079 1505454	1501225	1501226	1501227	1501228	1501229
JK004, OLYMPUS KIT 4 (2XCTR05, 1XCA500)	1509579					
K0880, DR. THAMES-LAP CHOLE	1486916 1502306	1490807	1490880	1498695	1500633	1501933
K0924, DR. COMPTON'S LAP CHOLE PACK	1486919	1502629	1506861	1507605		
K2212, DR. MILLER LAP CHOLE KIT	1487879 1505154	1490193	1491626	1493218	1493564	1503006
K2440, LAP CHOLE KIT	1493093	1496700	1497686			
K2607, BORLAND GASTRIC SLEEVE	1486309	1495945	1505585			
K2640, LAP CHOLE KIT	1490307 1511062	1493094	1499070	1499683	1503358	1509534
K2656, SOUTH SUNFLOWER LAP CHOLE KIT	1488898					
K2703, DR. AZAR LAP CHOLE PACK	1486917 1506843	1493201	1493565	1498694	1499047	1506330
K2705, DRS.GIROD & INGRAM LAP CHOLE PACK	1486300 1508455	1486918	1491050	1492698	1493566	1502628
K2797, LAP CHOLE PROCEDURAL PACK 1	1489703 1506927	1492619 1507969	1499716 1509808	1501351 1513390	1504311	1506681
K2903, LAP CHOLE KIT	1486930	1490129	1490565	1492645	1492745	1494199

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	1497562	1498943	1499046	1499254	1499731	1501016
	1501527	1501934	1505701	1509335		
K2922, KIT CLIP APPLIER	1487883	1488001	1489540	1490187	1490569	1491394
	1492062	1492063	1493045	1493861	1494210	1495447
	1495788	1496076	1497811	1500066	1501114	1501569
	1502309					
K2924, CLIP KIT A	1486342	1486353	1490902	1500396	1503806	1505008
	1510770					
K2925, CLIP KIT F	1499021	1499752	1500035			
K2927, CLIP KIT B	1489362	1495924	1497522	1501165	1503808	1505009
K2928, LAP CHOLE KIT	1504637					
K2929, LAP CHOLE KIT	1486931	1495448				
K2933, AM MENAT KIT # 0001	1503833					
K2934, AM MENAT KIT # 0002	1501854	1501980	1502018	1502170	1502200	1502401
	1502586	1502587	1502588	1502589	1502590	1502591
	1502592	1502882	1502883	1502884	1503120	1503121
	1503135	1503136	1503137	1503138	1503141	1503142
	1503231	1503839	1503840	1503841	1503843	1504521
	1504522	1504523	1504524			
K2926, CLIP KIT F	1487882	1489361	1490901			