
Urgent Field Safety Notice

Galeo Pro Coronary Guidewire

FSCA-identifier: CM-041116

Device Return

09 November 2016

Concert Medical, LLC Announces voluntary Field Safety Corrective Action of its Galeo Pro Coronary Guidewire

Norwell, MA. - Nov. 09, 2016

Concert Medical, LLC hereby issues this Field Safety Notice requesting the return of certain lots of Galeo Pro Coronary Guidewires.

This voluntary recall is being conducted due to the potential separation and detachment of the polytetrafluoroethylene (PTFE) coating on parts of these devices. Should the PTFE separate from the Coronary Guidewire, PTFE particulate could enter the blood stream of the patient. PTFE in the blood stream, based on the size and quantity, could lead to a thromboembolic event such as a blood clot.

The affected products were manufactured from June 2013 to May 2015. We have received one report of PTFE coating separation from a Galeo Pro Coronary Guidewire that occurred during a procedure. This event did not result in death or serious injury.

Concert Medical is taking this voluntary action as a precaution and has received no reports of patient injuries to date related to this issue. The full list of affected products and lots is itemized below. Other products and lots are not affected by this voluntary Field Safety Corrective Action.

For affected products that have been used successfully, no follow-up action is necessary.

Advice on action to be taken by the customer:

The records of our distributor indicate that you have received Galeo Pro products from the affected lots and we are asking for your cooperation in our efforts to complete this voluntary Field Safety Corrective Action. Therefore, please follow the instructions outlined below.

1. Please discontinue any further use of the affected Galeo Pro lots. Identify and remove all the affected Galeo Pro units from your inventory, store them in a safe place and mark them appropriately.
2. Please read, complete, sign and send the Customer Acknowledgement Form enclosed with this Field Safety Notice. A sales representative will contact you to collect all remaining Galeo Pro from the affected lots. Please hand over all the affected products and the original signed Customer Acknowledgement Form.
3. Please bring this Field Safety Notice to the attention of any health care professional in your organization that needs to be made aware.

77 Accord Park Drive Norwell, MA 02061 Phone: 781-871-7882 Fax: 781-871-6657

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www.concertmedical.com



Assistance

If you have further questions or need assistance with this voluntary Field Safety Corrective Action, please do not hesitate to contact your local sales representative directly or CONCERT MEDICAL, LLC on +1-781-871-7882.

We apologize for any inconvenience this voluntary Field Safety Corrective Action may cause. We appreciate your cooperation in this matter and are committed to maintaining your confidence in the quality of our products.

Respectfully,

Contact reference person:

Timothy S. Powers, Vice President Regulatory Affairs and Operations
 Concert Medical, LLC
 781-871-7882
 Tim.Powers@concertmedical.com

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Timothy S. Powers, VP Regulatory Affairs and Operations
 Concert Medical, LLC

**Voluntary Field Safety Corrective Action
 Concert Medical LLC, Galeo Pro Coronary Guidewires, subset manufactured June 2013 to May 2015, REF and Lot Numbers**

REF Number	389781	389782	389783	389784	389785	389786	389787	389788	389791
Item Description	Galeo Pro 190 HF	Galeo Pro 190 HF-J	Galeo Pro 190 F	Galeo Pro 190 F-J	Galeo Pro 190 M	Galeo Pro 190 M-J	Galeo Pro 190 ES-F	Galeo Pro 190 ES-F-J	Galeo Pro 300 F
	00572887	00572521	00572227	00572233	00572261	00572599	00572231	00572417	00572724
	00573080	00573145	00572229	00572523	00572603	00573029	00572235	00573147	00573378
	00573225	00573705	00572239	00572537	00572900	00573632	00572902	00573690	00574819
	00573456	00573707	00572241	00572912	00572914	00573857	00572904	00574905	00574948
	00573702	00574771	00572713	00573581	00573017	00575096	00572906	00574906	00575710
	00573706	00574939	00572863	00573582	00573019	00575097	00573071	00575095	00576665
	00574106	00574943	00572865	00573835	00573446	00575132	00573076	00575385	
	00574173	00574945	00572871	00574832	00573605	00575137	00573224	00575425	
	00574817	00575173	00572873	00574938	00573611	00575788	00573254	00575426	
	00574824	00575178	00572908	00575094	00573839	00576369	00573455	00576212	
	00574827	00576367	00572910	00575281	00573840		00573645	00576289	

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	00574882	00576959	00573226	00575389	00574568		00573659		
	00574892	00576975	00573289	00576376	00574570		00573880		
	00574895		00573290	00576922	00574840		00574018		
	00574910		00573308	00576932	00574843		00574039		
	00574929		00573332	00577036	00574972		00574759		
	00575030		00573362	00577043	00574991		00574854		
	00575176		00573382	00577047	00575390		00574870		
	00575177		00573424	00577314	00575391		00574880		
	00575275		00573426	00577315	00575551		00574971		
	00575276		00573457	00577425	00575577		00574992		
	00575386		00573458	00577443	00575578		00575098		
	00575387		00573459	00577455	00575606		00575134		
	00575625		00573460	00577478	00575763		00575135		
	00575665		00573580	00577529	00575780		00575138		
	00575924		00573708	00577530	00576028		00575174		
	00576160		00573807	00577531	00576034		00575238		
	00576620		00573879	00577535	00576681		00575238		
	00576621		00573903	00577536	00576983		00575239		
	00576960		00573939	00577537	00576984		00575240		
	00576974		00573940		00576988		00575241		
	00577131		00573973		00576991		00575242		
	00577155		00573981		00576999		00575280		
	00577265		00574128		00577007		00575302		
	00577286		00574380		00577035		00575303		
	00577287		00574391		00577045		00575304		
	00577288		00574535		00577046		00575305		
	00577294		00574546		00577065		00575338		
	00577399		00574788		00577083		00575339		
	00577462		00574811		00577084		00575340		
	00577474		00574835		00577085		00575423		
	00577495		00574897		00577091		00575424		
	00577500		00574907		00577092		00575433		
	00577501		00574970				00575434		
	00577511		00574997				00575435		
	00577519		00575099				00575436		
	00577527		00575133				00575437		
	00577528		00575136				00575438		
	00577532		00575175				00575464		
	00577533		00575179				00575465		
	00577534		00575236				00575466		
			00575237				00575511		
			00575277				00575512		

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			00575278				00575516		
			00575279				00575517		
			00575388				00575519		
			00575427				00575525		
			00575428				00575550		
			00575429				00575553		
			00575432				00575576		
			00575460				00575580		
			00575461				00575589		
			00575462				00575591		
			00575463				00575602		
			00575507				00575638		
			00575508				00575664		
			00575509				00575670		
			00575510				00575703		
			00575513				00575717		
			00575514				00575754		
			00575515				00575762		
			00575518				00575772		
			00575554				00575773		
			00575579				00575785		
			00575616				00575799		
			00575618				00575801		
			00575639				00575804		
			00575645				00575805		
			00575659				00575806		
			00575660				00575807		
			00575663				00575814		
			00575673				00575824		
			00575673				00575861		
			00575674				00575865		
			00575675				00575876		
			00575676				00575898		
			00575690				00575909		
			00575714				00575920		
			00575745				00575925		
			00575748				00575940		
			00575753				00575953		
			00575755				00575997		
			00575758				00575999		
			00575820				00576018		
			00575828				00576019		

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			00575829				00576022		
			00575830				00576027		
			00575837				00576030		
			00575840				00576041		
			00575842				00576056		
			00575850				00576057		
			00575853				00576071		
			00575857				00576072		
			00575859				00576079		
			00575921				00576081		
			00575923				00576093		
			00575933				00576136		
			00575936				00576140		
			00575938				00576144		
			00575968				00576146		
			00576000				00576158		
			00576002				00576182		
			00576007				00576185		
			00576025				00576199		
			00576042				00576203		
			00576043				00576205		
			00576044				00576211		
			00576046				00576257		
			00576051				00576258		
			00576096				00576260		
			00576111				00576273		
			00576112				00576286		
			00576124				00576287		
			00576125				00576288		
			00576173				00576318		
			00576174				00576322		
			00576181				00576323		
			00576186				00576333		
			00576190				00576366		
			00576197				00576374		
			00576225				00576381		
			00576239				00576391		
			00576242				00576404		
			00576244				00576405		
			00576251				00576414		
			00576252				00576442		
			00576292				00576443		

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			00576294				00576464		
			00576296				00576510		
			00576312				00576515		
			00576314				00576545		
			00576377				00576546		
			00576385				00576563		
			00576388				00576564		
			00576403				00576579		
			00576413				00576586		
			00576415				00576600		
			00576433				00576622		
			00576434				00576626		
			00576462				00576655		
			00576463				00576661		
			00576469				00576668		
			00576478				00576689		
			00576499				00576705		
			00576500				00576707		
			00576511				00576716		
			00576512				00576744		
			00576535				00576753		
			00576537				00576777		
			00576547				00576778		
			00576548				00576779		
			00576578				00576780		
			00576598				00576784		
			00576599				00576807		
			00576613				00576808		
			00576614				00576809		
			00576653				00576866		
			00576654				00576888		
			00576662				00576889		
			00576664				00576893		
			00576678				00576913		
			00576695				00576914		
			00576704				00576935		
			00576706				00576936		
			00576708				00576950		
			00576719				00577181		
			00576720				00577208		
			00576736				00577245		
			00576737				00577246		

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			00576752				00577247		
			00576760				00577263		
			00576775				00577267		
			00576776				00577268		
			00576790				00577285		
			00576810				00577357		
			00576856				00577359		
			00576857				00577368		
			00576864				00577395		
			00576865				00577444		
			00576894				00577452		
			00576899				00577458		
			00576917				00577464		
			00576951				00577482		
			00576952						
			00576955						
			00576958						
			00577093						
			00577127						
			00577128						
			00577132						
			00577133						
			00577144						
			00577145						
			00577150						
			00577171						
			00577172						
			00577173						
			00577184						
			00577186						
			00577192						
			00577199						
			00577207						
			00577248						
			00577249						
			00577250						
			00577264						
			00577266						
			00577328						
			00577330						
			00577337						
			00577342						

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			00577343						
			00577352						
			00577353						
			00577405						
			00577422						
			00577463						
			00577497						