


XXXXXXXXXX Customer Address and Contact xxxxxxxxxxxxxxxxxxxxxxxx

| Place/Date: **Basel, 02.01.2020** | Reference: **Urgent Field Safety Notice**

URGENT: Field Safety Notice

Dear Sir or Madam,

On December 19th, Medartis AG has initiated a lot specific product Field Safety Corrective Action (FSCA) for the 2.5 Trilock Screw 14mm, HD7 (A-5750-14/1S).

Product Recall:		2.5 Trilock Screw 14mm, HD7	
Date	19.12.2019		
Part Number	A-5750-14/1S	Lot Number	17169656, 18190766, 19194557, 19200335
FSCA identifier	FSCA-2019-001		
Type of Action	Field Safety Corrective Action: Product Return to supplier (Medartis AG)		
Description of the Problem	<p>Medartis discovered an error on the label of the A-5750.14/1S screws: the mention “<i>not for clinical use</i>” is visible on the label.</p>		
			
	<p>The screw itself has been manufactured within specification. There is no risk for the patient, in case the screw is implanted.</p>		
	<p>The label is incorrect and the error impacts the 4 lots mentioned above.</p>		
Advise on	➤ Please kindly quarantine and return the affected A-5750.14/1S screws		

<p>Actions to be taken</p>	<p>to Medartis.</p> <ul style="list-style-type: none"> ➤ Please kindly fill in and return the attached “Customer Acknowledgement Form” (QF41405). to return@medartis.com ➤ Please kindly forward this notification to all potentially affected divisions in-house. ➤ Please be aware that the current information sent per email will also be sent per mail to your facility.
<p>Medartis Contact person Kontaktperson</p>	<p>XXXXXXX E-Mail: return@medartis.com</p> <p>Medartis AG Hochbergerstrasse 60E 4057 Basel</p>

Swissmedic, our responsible National Authority has been notified on this incident. We kindly apologize for all inconveniences this could cause and remain at your complete disposal for further inquiry.

Kind Regards,

Medartis AG