


EINSCHREIBEN  
 Pro-Motion Medical B.V.  
 Daltonstraat 13  
 3335 LR Zwijndrecht  
 Niederlande

| 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).

<b>Product Recall:</b> 2.5 Trilock Screw 14mm, HD7	
<b>Date</b>	19.12.2019
<b>Part Number</b>	A-5750.14/1S
<b>Lot Number</b>	17169656, 18190766, 19194557, 19200335
<b>FSCA identifier</b>	FSCA-2019-001
<b>Type of Action</b>	Field Safety Corrective Action: Product Return to supplier (Medartis AG)
<b>Description of the Problem</b>	<p>Medartis discovered <b>an error on the label</b> of the A-5750.14/1S screws: the mention <i>"not for clinical use"</i> is visible on the label.</p>  <p>The product label is erroneous. This failure concerns only the article number mentioned above.                  The failure happened during the label release of this product and impacts therefore the 4 lots already produced (see lot numbers mentioned above)</p>

<p><b>Advise on Actions to be taken</b></p>	<ul style="list-style-type: none"> <li>➤ Please kindly quarantine and return the affected A-5750.14/1S screws to Medartis.</li> <li>➤ Please kindly fill in and return the attached “Customer Acknowledgement Form” (QF41405). to <a href="mailto:return@medartis.com">return@medartis.com</a></li> <li>➤ Please kindly forward this notification to all potentially affected divisions in-house.</li> <li>➤ Please be aware that the current information sent per email will also be sent per mail to your facility.</li> </ul>
<p><b>Corrective Action (initiated at Medartis)</b></p>	<ul style="list-style-type: none"> <li>➤ Quarantine of impacted lots currently on stock (done)</li> <li>➤ Initiation of a product recall (FSCA) (initiated). Closure of the FSCA planned until end of February 2020</li> <li>➤ Initiation and implementation of a change request to correct the erroneous label. The change has been initiated and should be completed by end of January 2020.</li> </ul>
<p><b>Preventive Action (initiated at Medartis)</b></p>	<ul style="list-style-type: none"> <li>➤ Preventive measures will be triggered within the Medartis CAPA System (CAPA 11/2019: definition of required measures and associated timelines for their implementation is being defined)</li> </ul>
<p><b>Medartis Contact person</b></p>	<p>Deviation Management E-Mail: <a href="mailto:return@medartis.com">return@medartis.com</a></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

This letter is valid without signature