

Medartis AG | Hochbergerstrasse 60E | CH-4057 Basel

| Place/Date: **Basel, 17.12.2020**| Reference: **Urgent Field Safety Notice****URGENT: Field Safety Notice**

Dear Sir or Madam,

On December 17th, Medartis AG has initiated a product Field Safety Corrective Action (FSCA) for the MODUS and MODUS 2 pliers M2-2016, M-2016 and M-2125

<b>Field Safety Corrective Action: MODUS and MODUS 2 pliers M2-2016, M-2016 and M-2125</b>			
<b>Date</b>	17.12.2020		
<b>Part Number</b>	<p><b>M2-2016</b> 2.0-2.5 Three-Point Bending Pliers</p> <p><b>M-2016</b> 2.0-2.5 Plate Bending Pliers</p> <p><b>M-2125</b> 2.5 Plate Bending Pliers</p>	<b>Lot Number</b>	<p><b>IFU Modus 2</b> - The revision for each specific language is detailed below:</p> <ul style="list-style-type: none"> <li>- German (DE): MODUS2_00000100_Rev.C</li> <li>- English (EN): MODUS2_00000101_Rev.C</li> <li>- French (FR): MODUS2_00000102_Rev.C</li> <li>- Italian (IT): MODUS2_00000105_Rev.C</li> <li>- Polish (PL): MODUS2_00000104_Rev.C</li> <li>- Spanish (SP): MODUS2_00000103_Rev.C</li> </ul> <p><b>IFU Modus</b> - The revision for each specific language is detailed below:</p> <ul style="list-style-type: none"> <li>- German (DE): MODUS_00000100_Rev.L</li> <li>- English (EN): MODUS_00000101_Rev.L</li> <li>- French (FR): MODUS_00000102_Rev.L</li> <li>- Italian (IT): MODUS_00000105_Rev.L</li> <li>- Polish (PL): MODUS_00000104_Rev.L</li> <li>- Spanish (SP): MODUS_00000103_Rev.L</li> </ul>
<b>FSCA identifier</b>	FSCA-2020-001		

<b>Type of Action</b>	Field Safety Corrective Action: <b>Field Safety Notice and update of the IFU</b>
<b>Description of the Problem</b>	<p>The current Instruction For Use (IFU) for Modus and Modus 2 Instruments propose two sterilisation processes:</p> <ul style="list-style-type: none"> <li>- The “Fractionated and Dynamic Prevacuum Process”</li> <li>- The “Flow and Gravitation Process”</li> </ul> <p>The previous information contained in the IFU was not specific enough for the following pliers:</p> <ul style="list-style-type: none"> <li>- M2-2016 2.0-2.5 Three-Point Bending Pliers</li> <li>- M-2016 2.0-2.5 Plate Bending Pliers</li> <li>- M-2125 2.5 Plate Bending Pliers</li> </ul> <p>These three instruments shall be sterilized with the <u>“Fractionated and Dynamic Prevacuum Process”</u>.</p> <p>The user shall confirm in writing to Medartis that the information has been read und understood while filling in and returning the “Customer Acknowledgement Form” (CAF)</p>
<b>Advise on Actions to be taken</b>	<ul style="list-style-type: none"> <li>- The MODUS and MODUS 2 IFU have been updated. Please read carefully the updated IFUs</li> <li>- Please kindly forward this notification to all potentially affected divisions in-house.</li> <li>- Please kindly fill in and return the attached “Customer Acknowledgement Form” at the following email address: <a href="mailto:return@medartis.com">return@medartis.com</a></li> </ul>
<b>Medartis Contact person</b> Kontaktperson	<p>Erwan Nicolle            Group Manager – Deviation Management            Tel: +41 61 633 34 34            E-Mail: <a href="mailto:return@medartis.com">return@medartis.com</a>            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 inquiries.

Kind Regards  
 Erwan Nicolle

17.12.2020  
