

| 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

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

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


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Customer Acknowledgement Form (CAF)

Field Safety Corrective Action FSCA-2020-001	
Date	17.12.2020
Part No.	M2-2016 M-2016, M-2125
Failure Description	<p>The current Instruction For Use (IFU) for Modus and Modus 2 Instruments propose two sterilisation processes:</p> <ul style="list-style-type: none"> - The "Fractionated and Dynamic Prevacuum Process" - The "Flow and Gravitation Process" <p>The previous information contained in the IFU was not specific enough for the following pliers:</p> <ul style="list-style-type: none"> - M2-2016 2.0-2.5 Three-Point Bending Pliers - M-2016 2.0-2.5 Plate Bending Pliers - M-2125 2.5 Plate Bending Pliers <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 this document</p>
Hospital / Clinic / User Information	
Corrective Action From Medartis:	The MODUS and MODUS 2 IFU have been updated. Please read carefully the updated IFUs

Information to user (Field Safety Notice):

I confirm with this document that I am aware of the update made to the MODUS and MODUS 2 IFU initiated by Medartis and that this information has been forwarded to all potentially affected divisions in-house.

	<i>FIRST NAME – NAME - FUNCTION</i>	<i>DATE</i>	<i>SIGNATURE</i>
Filled in by			

Important Informations

➤ Please return this form within 24h at the following email address: return@medartis.com

QF	41405	4	17.12.2020	Nicolle, Erwan	Purga, Johnny; Schweizer, Andrea	Gültig nur aus QM-System
Kategorie	Nummer	Version	Freigabedatum	Verantwortlich für Prozess/Schulung (Freigeber)	Verantwortlich für Qualität/Prüfung (Prüfer)	Seite 1 / 1