


AA112	Arbeitsanweisung Druck Bedienungsanleitung durch Kunden <i>Work Instruction</i> <i>Printing of IFUs through customers</i>	
Rev: 0		
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1 Zweck / Purpose

This Work Instruction (WI) is written in English to address the international audience of this WI.

This WI serves to describe the piggy-back process of printing instructions for use (IFU) and attaching the IFUs to MediceL products.


This process applies to IOL Injectors only.

All Phaco Accessories i.e. Phaco Accessory Sets and I/A Handpieces are equipped with a printed IFU.

2 Geltungsbereich / Scope

This WI is applicable to all customers, distributors or logistic providers that need to attach country specific printed IFUs to MediceL products.

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3 Begriffe / Definitions and Abbreviations

IFU	Instruction for Use
WI	Work Instruction
Piggy-back	Attaching an IFU to the box of the product's sales unit


4 Verantwortlichkeiten / Zuständigkeiten / Responsibilities

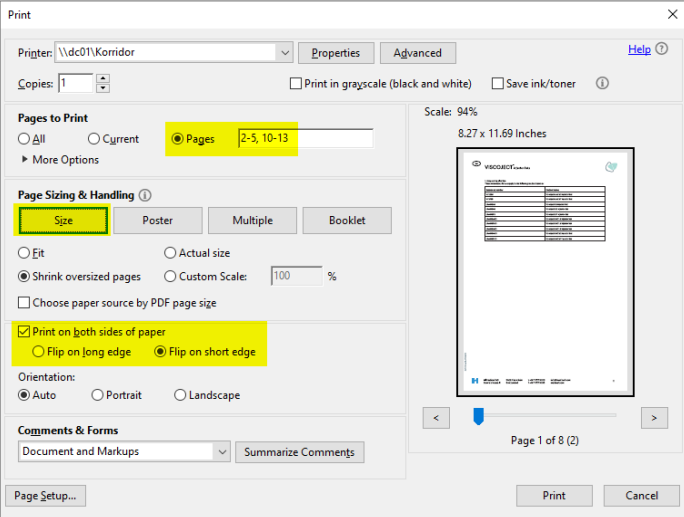
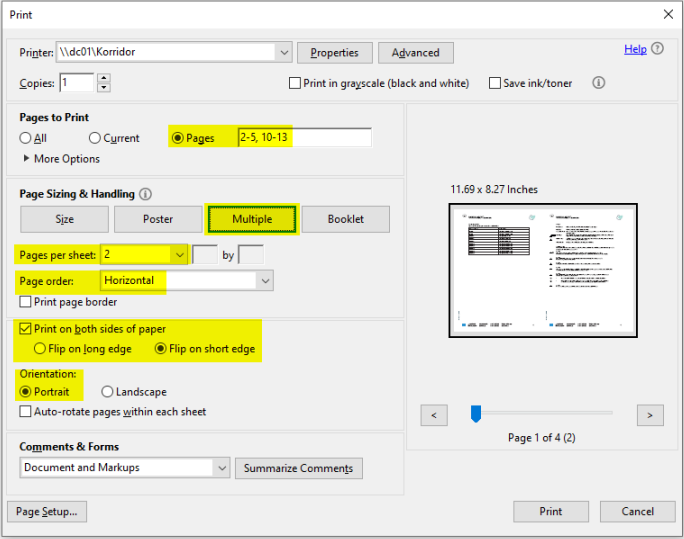
It's the responsibility of the customer and / or logistic provider to follow this procedure.

5 Beschreibung des Arbeitsablaufs / Description of the process


No	Arbeits- bzw. Prüfschritt <i>Working / inspection step</i>	Beschreibung der Arbeits- bzw. Prüfaktivitäten <i>Description of working / inspection activities</i>	Erforderliche Hilfsmittel <i>Required tools</i>	Begründung, Hinweise <i>Reasoning, remarks</i>
1.	Download of IFU	Download the correct IFU for the product from the Medicel website (https://www.medicel.com/IFU)	PC, internet connection, web browser	Scroll down to section "Instructions for Use", sub section "IOL Injectors and Cartridges"
2.	Printing of IFU	Each language of the IFU consists of four or five pages. At the bottom left of each page of the IFU the IFU name, version and release date can be found. The cover page of the IFU does not need to be printed. For example: If English needs to be printed, print pages 2-5 of the document. 1 st step: Set "pages to print" if multiple languages shall be printed at once separate by comma. E.g. "2-5, 10-13" 2 nd step: Print front- and backside of the sheet so one IFU language fits one sheet. To do so set "print on both	PC, PDF-viewer, printer, paper (preferably DIN A4 format, alternatively US letter)	All IFUs have a Table of Content indicating the section where the required language(s) can be found

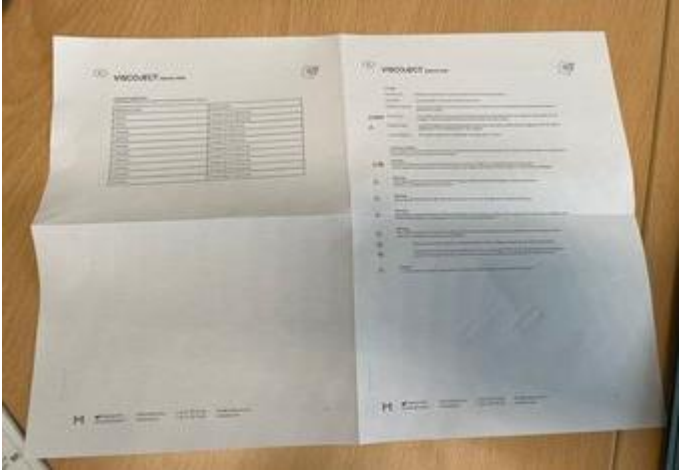


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	<p>sides of paper”, “flip on short edge”</p>  <p>3rd step: Set printing options “Page Sizing & Handling”, “Multiple” the printer to 2 pages per sheet, page order to “horizontal” and “orientation” to “portrait”.</p> 		
3.	Folding of IFU	Fold the IFU(s) vertically once and horizontally once.	n/a

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4.	Attaching the IFU to the box	Use 2 adequately sized rubber rings (one horizontally, one vertically) to attach the IFU(s) to the box 		

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6 Mitgeltende Unterlagen und Dokumentation / *Applicable documents and documentation*

IFUs accessible through download from MediceI's website.

7 Erläuternde Hinweise und Besonderheiten / *Explaining remarks and specialties*

N/A

8 Verteiler / *Distribution*

Quality Management

Product Management

9 Änderungen / *Change history*

Ausgabe <i>Version</i>	Datum <i>Date</i>	Änderungsgrund / geändertes Kapitel <i>Reason for change / changed chapter</i>
00	16.08.2023	Initial release

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