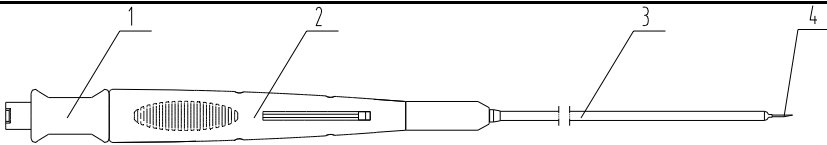


Technical Data Sheet		Endoscopic Injection Needle	
1. Product Name		Endoscopic Injection Needle	
2. Description		Endoscopic Injection Needle Needle size: 19G,20G,21G,22G,23G,25G. Needle length:4mm,5mm,6mm Length: 1200mm,1600mm,1800mm,2000mm,2300mm	
3. Characteristics		Highly transparent sheath and inner tube,Luer connector and system of position fixation	
4. Intended use		Endoscopic Injection Needle is intended for injections in the gastrointestinal area. They are also suitable for stopping bleeding in varicose veins. They should only be used in connections with flexible endoscopes (gastrosopes/coloscopes).	
5. Instructions for use		See IFU	
6. Sizes & REF numbers	REF NO.		Product Description
	IN-A-2423-2004		Neele: 20G*4mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2005		Neele: 20G*5mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2006		Neele: 20G*6mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2104		Neele: 21G*4mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2105		Neele: 21G*5mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2106		Neele: 21G*6mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2204		Neele: 22G*4mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2205		Neele: 22G*5mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2206		Neele: 22G*6mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2304		Neele: 23G*4mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2305		Neele: 23G*5mm sheath: 2.4mm, length 2300mm
	IN-A-2423-2306		Neele: 23G*6mm sheath: 2.4mm, length 2300mm
Technical Information		Component Name	Material
1. List of materials	1. Injection port		ABS
	2. Holder Portion		ABS
	3. Tube		PTFE/PE
	4. Needle		stainless steel
2. Latex free		Yes	
3. PHT/DEHP free		Yes	
4. Shelf life		2 years	
5. Sterilization method		Sterilized using Ethylene Oxide	
6. Packaging specification	6.1 Sales Unit		
	10		Units per middle box
	100		Units per case

7. Technical Drawing	
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Quality & Regulatory Information

1. Quality certificate	Quality Management System according to ISO13485	
2. Product Classification	Class IIa in sterile condition according to Annex II excluding (4) of MDD 93/42/ECC	
3. List of Standards	The product is compliant with the following standards and regulations:	
	Document reference	Title
	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-10:2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	EN ISO 11135:2014+A1	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	EN 1041:2016	Information supplied by the manufacturer of medical devices
	EN ISO 8600-1:2015	Endoscopes- Medical endoscopes and endotherapy devices- Part 1: General requirements
	ISO 7864:2016	Sterile hypodermic needles for single use — Requirements and test methods
REV	01	Date: 2023/04/05