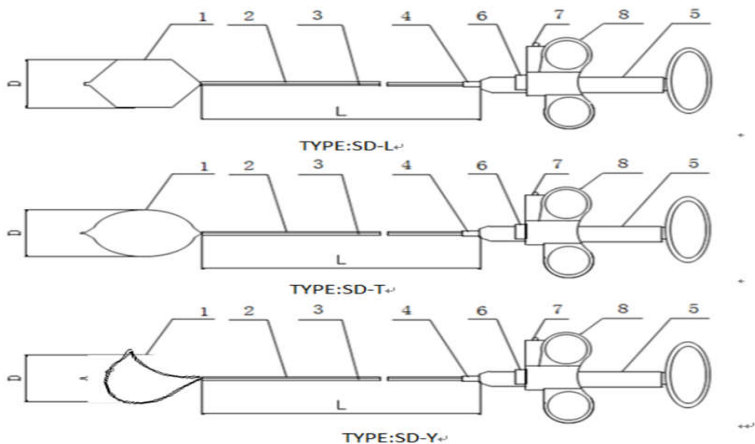


Technical Data Sheet	Electrosurgical snare for single use	
1. Product Name	Electrosurgical snare for single use	
2. Description	Electrosurgical snare for single use Shapes: Oval, hexagonal, crescent Length: 1200mm,1600mm,1800mm,2000mm,2300mm	
3. Characteristics	HOT,it can be use by different techniques including colonoscopy and EGD	
4. Intended use	Electrosurgical Snares for Single Use are used to remove polyps in the gastrointestinal tract.	
5. Instructions for use	See IFU	
6. Sizes & REF numbers	REF NO.	Product Description
	SD-L 1024230	Sheath, Φ2.4mm, L: 2300mm Hexagonal, loop width 10mm
	SD-L 1524230	Sheath, Φ2.4mm, L: 2300mm Hexagonal, loop width 15mm
	SD-L 2024230	Sheath, Φ2.4mm, L: 2300mm Hexagonal, loop width 20mm
	SD-L 2524230	Sheath, Φ2.4mm, L: 2300mm Hexagonal, loop width 25mm
	SD-L 3024230	Sheath, Φ2.4mm, L: 2300mm Hexagonal, loop width 30mm
	SD-L 3524230	Sheath, Φ2.4mm, L: 2300mm Hexagonal, loop width 35mm
	SD-T 1024230	Sheath, Φ2.4mm, L: 2300mm Oval, loop width 10mm
	SD-T 1524230	Sheath, Φ2.4mm, L: 2300mm Oval, loop width 15mm
	SD-T 2024230	Sheath, Φ2.4mm, L: 2300mm Oval, loop width 20mm
	SD-T 2524230	Sheath, Φ2.4mm, L: 2300mm Oval, loop width 25mm
	SD-T 3024230	Sheath, Φ2.4mm, L: 2300mm Oval, loop width 30mm
	SD-T 3524230	Sheath, Φ2.4mm, L: 2300mm Oval, loop width 35mm
	SD-T 1024180	Sheath, Φ2.4mm, L: 1800mm Oval, loop width 10mm
	SD-T 1524180	Sheath, Φ2.4mm, L: 1800mm Oval, loop width 15mm
	SD-T 2024180	Sheath, Φ2.4mm, L: 1800mm Oval, loop width 20mm
	SD-T 2524180	Sheath, Φ2.4mm, L: 1800mm Oval, loop width 25mm

	SD-T 3024180	Sheath, Φ2.4mm, L: 1800mm Oval, loop width 30mm
	SD-T 3524180	Sheath, Φ2.4mm, L: 1800mm Oval, loop width 35mm
	SD-Y 1024230	Sheath, Φ2.4mm, L: 2300mm Crescent loop width 10mm
	SD-Y 1524230	Sheath, Φ2.4mm, L: 2300mm Crescent loop width 15mm
	SD-Y 2024230	Sheath, Φ2.4mm, L: 2300mm Crescent loop width 20mm
	SD-Y 2524230	Sheath, Φ2.4mm, L: 2300mm Crescent loop width 25mm
Technical Information	Component Name	Material
1. List of materials	1.metal loop	Medical grade stainless steel
	2.the sheath	PTFE/PE
	3.wire	Medical grade stainless steel
	4.protecting tube	PE/TPU/PE
	5.core rod	ABS
	6.stop block	ABS
	7.electrical source plug	Cu
	8.slip ring	ABS
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		

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 93/42EEC	
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 20417:2021)
	ISO 15510: 2014	Stainless steels — Chemical composition
	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 60601-1-6: 2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
	EN 60601-2-2:2018	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2017)
	EN 60601-2-18:2015	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
REV	02	Date: 2023/09/15