



PRODUCT TECHNICAL FORM

Device name : Adapt Endoscopic Ultrasound Aspiration Needle

Trade name:

Areus™ Adapt Endoscopic Ultrasound Aspiration Needle

Trident™ Adapt Endoscopic Ultrasound Aspiration Needle

Description: The device is divided into Class IIa according to MDR 2017/745

References:

EUS-19-0-F; EUS-22-0-F; EUS-19-1-F; EUS-22-1-F

Intended Use: This device is designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope.

Indication	This device is designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope.
Security of use	1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed. 2. Do not use this instrument for any purpose other than its intended use. 3. This instrument is intended for use by physicians or medical personnel who have received appropriate training, in accordance with the applicable laws. This product can only be used by well-trained doctor or with her/his supervision. As an accessory of ultrasound endoscope, the product shall be used by professionals familiar with the operation technique of ultrasound endoscope. 4. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view, do not use it. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhages or mucous membrane damage. It may also damage the endoscope and/ or instrument. 5. The product is intended for adult. 6. The product is not used for the heart or vascular system. 7. The product should only be used to sample tissue where possible hemorrhage will not present a danger to patients. The device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies. 8. The product contains cobalt, which may cause cancer, may damage fertility, is suspected of causing genetic defects. Although migration test for cobalt had been carried out and the result shows that it does not migrate, please do not use this instrument for any purpose other than its intended use. In case of incident, get medical advice/attention if you feel unwell.
Recommendations	PRODUCT DISPOSAL After use dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Device Description:

PHOTOS, DRAWINGS

Product Drawing

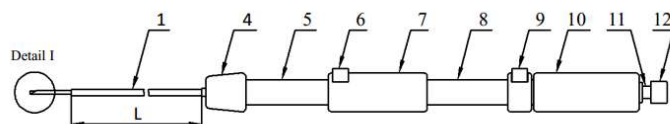


Fig a Front view of product

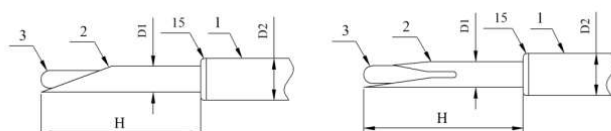


Fig b Detail view I - needle type

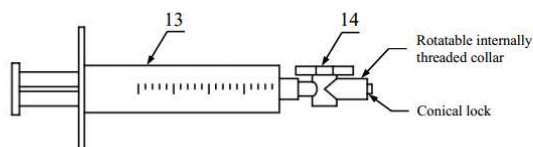


Fig c Negative Suction Device

No	Item	No	Item
1	Sheath	9	Needle lock
2	Needle	10	Upper handle
3	Stylet	11	Proximal connector
4	Scope connector	12	Stylet lock
5	Sheath indicator	13	Syringe
6	Sheath lock	14	Stopcock
7	Lower handle	15	Protecting tube
8	Needle indicator	/	/

PHOTOS, DRAWINGS

Device Illustration –proposed device in package



Device Illustration –proposed device out of package



Device Illustration- needle tip design



Bevel needle



Trident needle

Device Illustration-negative suction device



Invasive device / non invasive device: Invasive device

Long term / short term: Short-term



PRODUCT TECHNICAL FORM

Components: *materials of components*

1. Product

Materials for

No.	Component		Material	Material Grade Name
1	Sheath		Polytetrafluoroethylene	PTFE
2	Needle	Needle	Nitinol, Stainless steel 304	Nitinol, SUS304
		Heat shrinkable tube	Polytetrafluoroethylene	PTFE
		Silicone Oil	Silicone Oil	Silicone Oil
3	Stylet		Nitinol	Nitinol
4	Scope connector		Acrylonitrile - butadiene - styrene + polycarbonate	ABS+PC
5	Sheath indicator		Acrylonitrile - butadiene - styrene + polycarbonate	ABS+PC
6	Sheath lock		Acrylonitrile - butadiene - styrene + polycarbonate	ABS+PC
7	Lower handle		Acrylonitrile - butadiene - styrene + polycarbonate	ABS+PC
8	Needle indicator		Acrylonitrile - butadiene - styrene + polycarbonate, Thermoplastic elastomer	ABS+PC, TPE
9	Needle lock		Acrylonitrile - butadiene - styrene + polycarbonate	ABS+PC
10	Upper handle		Acrylonitrile - butadiene - styrene + polycarbonate, Thermoplastic elastomer	ABS+PC, TPE
11	Proximal connector		Acrylonitrile - butadiene - styrene + polycarbonate	ABS+PC
12	Stylet lock		Acrylonitrile - butadiene - styrene + polycarbonate	ABS+PC
13	Syringe		Acrylonitrile - butadiene - styrene, polycarbonate, silicone rubber	ABS, PC, SR
14	Stopcock		Polycarbonate, polyethylene	PC, HDPE
15	Protecting tube		Stainless steel 303Cu, Stainless steel 304	SUS303Cu, SUS304

2. Packaging

- A. Inner packing (a pouch and a fixed board): CR27-1073B +35791-E (MPTP), PETG
- B. Case box: Cardboard
- C. Carton: Double layer corrugated paper
- D. Shipper box: Double layer corrugated paper

Presence of:

	YES	NO		YES	NO
Active substances		✓	Phtalate and DEHP		✓
PVC:		✓	Bisphenol A		✓
Product of animal or biological origin		✓	Latex		✓



PRODUCT TECHNICAL FORM

Manufacturer

Manufacturer name	Micro-Tech (Nanjing) Co., Ltd.
Manufacturing location(s)	No.10 Gaoke Third Road, Nanjing National Hi- Tech, Industrial Development Zone Nanjing 210032, Jiangsu Province PEOPLE'S REPUBLIC OF CHINA
Manufacturer Quality Assurance System	EN ISO 13485: 2016

Sterilisation

Sterilisation method	EO
Sterilisation location(s)	No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech Industrial Development Zone, Nanjing 210032, Jiangsu Province, PRC.
Sterilisation control(s)	BI testing, EO Residue Test
Shelf Life	2 years

Storage conditions

1. The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.
2. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

CE Mark Number	CE2797
Notified body	BSI Group - The Netherlands B.V Say Building, John M. Keynesplein 9, K1066 EP Amsterdam, The Netherlands
European representative (full name, address and unique identification n°)	Shanghai International Holding Corp.GmbH(Europe) Eiffestrasse 80,20537 Hamburg Germany
Class of the device (I,Ia,Ib,II,III)	Class IIa
EMDN Code	A01020199
GMDN Code	10403

Labeling:

Individual product label	Case box of 1 unit label	Carton of 10 units label
PHOTO Areus™ Adapt Endoscopic Ultrasound Aspiration Needle Maximum Needle Length H 80 mm Maximum Insertion Portion Diameter D1 2.5 mm Working Channel 2.8 mm Working Length 1375~1415mm REF EUS-19-0-F 2022-12-05 LOT ME1111111111 2024-12-04 STERILIZED MD 2797 CAUTION, DESTROY IT AFTER USING Micro-Tech (Nanjing) Co., Ltd. No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, PRC Tel: +86-25-58609879 Fax: +86-25-58744269 E-mail: info@micro-tech.com.cn http://www.micro-tech-medical.com Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany EUEUS-19-0-F 1-103399 REV 0 11/22	PHOTO Areus™ Adapt Endoscopic Ultrasound Aspiration Needle Maximum Needle Length H 80 mm Maximum Insertion Portion Diameter D1 2.5 mm Working Channel 2.8 mm Working Length 1375~1415mm REF EUS-19-0-F 2022-12-05 LOT ME1111111111 2024-12-04 STERILIZED MD 2797 CAUTION, DESTROY IT AFTER USING Micro-Tech (Nanjing) Co., Ltd. No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, PRC Tel: +86-25-58609879 Fax: +86-25-58744269 E-mail: info@micro-tech.com.cn http://www.micro-tech-medical.com Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany EUEUS-19-0-F 1-103399 REV 0 11/22	PHOTO Areus™ Adapt Endoscopic Ultrasound Aspiration Needle Maximum Needle Length H 80 mm Maximum Insertion Portion Diameter D1 2.5 mm Working Channel 2.8 mm Working Length 1375~1415mm REF EUS-19-0-F 2022-12-05 LOT ME1111111111 2024-12-04 STERILIZED MD 2797 CAUTION, DESTROY IT AFTER USING Micro-Tech (Nanjing) Co., Ltd. No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, PRC Tel: +86-25-58609879 Fax: +86-25-58744269 E-mail: info@micro-tech.com.cn http://www.micro-tech-medical.com Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany EUEUS-19-0-F 1-103399 REV 0 11/22



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	Areus™ Adapt Endoscopic Ultrasound Aspiration Needle REF: EUS-19-0-F LOT: ME1111111111 2024-12-04 	<table><tr><td>Maximum Needle Length H</td><td>80 mm</td></tr><tr><td>Needle Diameter D1</td><td>19G</td></tr><tr><td>Maximum Insertion Portion Diameter D2</td><td>2.5 mm</td></tr><tr><td>Working Channel</td><td>2.8 mm</td></tr><tr><td>Working Length</td><td>1375~1415mm</td></tr></table>	Maximum Needle Length H	80 mm	Needle Diameter D1	19G	Maximum Insertion Portion Diameter D2	2.5 mm	Working Channel	2.8 mm	Working Length	1375~1415mm
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Barcode type	(01)x6902284xxxxxx (17) xxxxxx(10)MExxxxxx	PHOTO  (01)26902284550135(17)241204(10)ME1111111111
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Packaging:

Pouch of 1 product (Length x width cm)	Case box of 1 unit (Height x width x depth cm)	Carton of 5 units (Height x width x depth cm)	Shipper box of 10 units (Height x width x depth cm)
PHOTO 70×34 cm	PHOTO 58.3×29.3×3 cm	PHOTO 59×16.3×30 cm	PHOTO 60.8×36×33.1 cm
			

Simple or double	1 piece simple
Number of units per sterile packaging unit	1pc/pouch, 1 pouch/ case box, 5 case boxes/ carton, 2 cartons/ shipper box
Final packaging	Shipper box
Product conservation	Packed as the packaging.



PRODUCT TECHNICAL FORM
Description

Revision

Date

Initial

A/0

2023-01-17