

Single-use Guide Wire



INSTRUCTIONS FOR USE

STERILE EO



CE 0123

Rx ONLY

CAUTION: This device should be sold by or on the order of a physician.

WARNING:

1. Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your ANREI MEDICAL representative.
2. For single use only. **DO NOT REUSE, REPROCESS OR RESTERILIZE.** Reuse, reprocessing or resterilization 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. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and /or cause patient infection or cross-infection, including, but not limited to , the transmission of infections disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
3. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

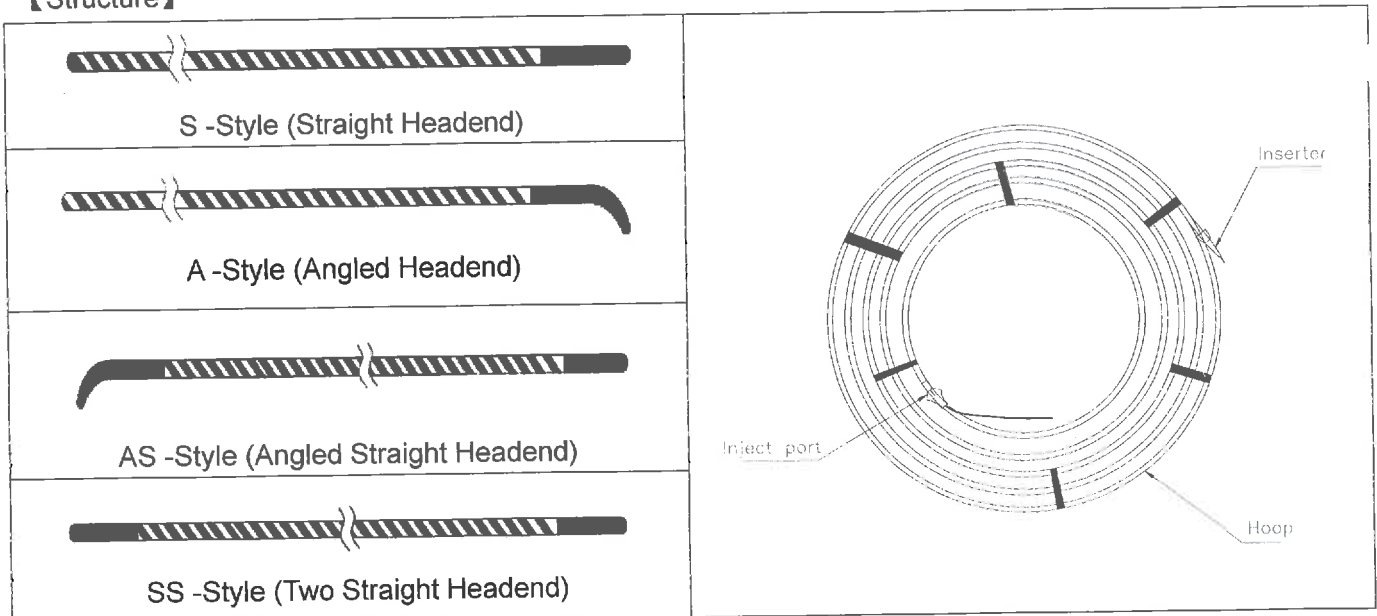
【Device Name】

Single-use Guide Wire

【Intended Use】

This device is intended for use in selective cannulation of the biliary ducts including, but not limited to the common bile, cystic, pancreatic ducts, right and left hepatic ducts. It is designed for use in during endoscopic procedures for catheter introduction and exchanges. This device is supplied sterile and intended for single use only.

【Structure】





AA -Style (Two-Angled Headend)

【Specifications】

Specifications	Headend type	Maximum diameter of the main body (× 10-3Inch)	Length (× 10cm)	Mandrel type	Sheath type steering function
Single-use Guide Wire	S(Straight) A(Angled)、 AS(Angled- Straight)、 SS(Two-Straight) 、 AA(Two-Angled)	18-38	20-50	G (ordinary) S (hardened)	blank(ordinary), P(butting), T(swerve), PT(butting and swerve),U(ultrathin sheath)
GW-SXXXXG	S	18-38	20-50	G	blank
GW-SXXXXS	S	18-38	20-50	S	blank
GW-SXXXXG-P	S	18-38	20-50	G	P
GW-SXXXXS-P	S	18-38	20-50	S	P
GW-SXXXXG-T	S	18-38	20-50	G	T
GW-SXXXXS-T	S	18-38	20-50	S	T
GW-SXXXXG-PT	S	18-38	20-50	G	PT
GW-SXXXXS-PT	S	18-38	20-50	S	PT
GW-SXXXXG-U	S	18-38	20-50	G	U
GW-SXXXXS-U	S	18-38	20-50	S	U
GW-AXXXXG	A	18-38	20-50	G	blank
GW-AXXXXS	A	18-38	20-50	S	blank
GW-AXXXXG-P	A	18-38	20-50	G	P
GW-AXXXXS-P	A	18-38	20-50	S	P
GW-AXXXXG-T	A	18-38	20-50	G	T
GW-AXXXXS-T	A	18-38	20-50	S	T
GW-AXXXXG-PT	A	18-38	20-50	G	PT
GW-AXXXXS-PT	A	18-38	20-50	S	PT
GW-AXXXXG-U	A	18-38	20-50	G	U
GW-AXXXXS-U	A	18-38	20-50	S	U
GW-ASXXXXG	AS	18-38	20-50	G	blank
GW-ASXXXXS	AS	18-38	20-50	S	blank

GW-ASXXXXG-P	AS	18-38	20-50	G	P
GW-ASXXXXS-P	AS	18-38	20-50	S	P
GW-ASXXXXG-T	AS	18-38	20-50	G	T
GW-ASXXXXS-T	AS	18-38	20-50	S	T
GW-ASXXXXG-PT	AS	18-38	20-50	G	PT
GW-ASXXXXS-PT	AS	18-38	20-50	S	PT
GW-ASXXXXG-U	AS	18-38	20-50	G	U
GW-ASXXXXS-U	AS	18-38	20-50	S	U
GW-SSXXXXG	SS	18-38	20-50	G	Blank
GW-SSXXXXS	SS	18-38	20-50	S	Blank
GW-SSXXXXG-P	SS	18-38	20-50	G	P
GW-SSXXXXS-P	SS	18-38	20-50	S	P
GW-SSXXXXG-T	SS	18-38	20-50	G	T
GW-SSXXXXS-T	SS	18-38	20-50	S	T
GW-SSXXXXG-PT	SS	18-38	20-50	G	PT
GW-SSXXXXS-PT	SS	18-38	20-50	S	PT
GW-SSXXXXG-U	SS	18-38	20-50	G	U
GW-SSXXXXS-U	SS	18-38	20-50	S	U
GW-AAXXXXG	AA	18-38	20-50	G	blank
GW-AAXXXXS	AA	18-38	20-50	S	blank
GW-AAXXXXG-P	AA	18-38	20-50	G	P
GW-AAXXXXS-P	AA	18-38	20-50	S	P
GW-AAXXXXG-T	AA	18-38	20-50	G	T
GW-AAXXXXS-T	AA	18-38	20-50	S	T
GW-AAXXXXG-PT	AA	18-38	20-50	G	PT
GW-AAXXXXS-PT	AA	18-38	20-50	S	PT
GW-AAXXXXG-U	AA	18-38	20-50	G	U
GW-AAXXXXS-U	AA	18-38	20-50	S	U

【Direction for Use】

1. According to the requirements of operation, the operator choose appropriate Headend type before use.

2. Prior to removing the guide wire from the holder, flush with 30 cc of saline solution from the injection of joint.
3. Flush the endoscope's accessory channel and/or the lumen of the device with saline solution, and then insert the chosen guide wire Headend.
4. Fluoroscopically monitor guide wire advancement in the digestive system.
5. Proceed with exchange of compatible devices over the guide wire.
6. Upon completion of the procedure, dispose of the device per institutional guidelines for biohazard us medical waste.

【Contraindications】

Contraindications include those specific to ERCP (Endoscopic retrograde cholangiopancreatography, ERCP).

【Potential Complications】

Potential Complications associated with ERCP include, but are not limited to: pancreatitis, cholangitis, perforation, bleeding, infection, and allergic reaction to contrast or medication.

【Caution】

1. Do not use if the package is open or damaged when received.
2. Do not use if an abnormality is detected that would prohibit proper working condition.
3. Do not use if it is expired.
4. The device is a single-use sterile product. Destroy after use. Do not reuse.
5. The device must be operated by trained clinicians.

【Packaging】

Pouch: 1 set per pouch























Box: 10 pouches per box





Carton: 10 boxes per carton

【Date of Manufacture】

Please refer to the label on pouch.

【Symbol Instruction】

	Manufacturer		Authorized representative in the EC
	Date of manufacture		Use-by date
	Batch code		Catalogue number
	Sterilized using ethylene oxide		Do not use if package is damaged
	Fragile, handle with care		Keep away from sunlight
	Protect from heat and radioactive sources		Keep dry
	This way up		Stacking limit by number
	Temperature limit		Do not re-use
	Do not re-sterilize		Caution
	Diameter		EC notified body identification number
	No Natural rubber latex		Consult instructions for use

	Bronchial device		Gastric device
	Colonic device		ERCP device

【storage】

Store the device in a dry, cool (room temperature), clean place and protect it from direct sunlight, heat and/or aggressive chemical substances. Relative Humidity applicable range is less than 80%, temperature applicable range is 10°C - 40°C.

【Sterilization】 Sterilized using ethylene oxide

【Shelf Life】 2 years after sterilization.

【Manufacturer】 Anrei Medical (HZ) Co., Ltd.

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