MEDORAH MEDITEK

PRISM-VIEW™ Cholangioscope (Access and Delivery Catheter)

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

PRISM-VIEW™ Access and Delivery Catheter

Intended Use/ Indications for use:

Intended Use- The access and delivery catheter is intended to provide direct visualization for the diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system, as well as working channels for other accessory devices while using an Image Processor.

Target Population-

- **Age:** Adult patients aged 18 years or older;
- **Sex**: Not limited
- **Weight:** Not limited
- **Health status:** The patient is judged by the clinician to meet the requirements;
- **Clinical symptoms:** According to the intended purpose, indications, contra-indications and judged by professional clinicians.

Device Description

The Access and Delivery Catheter is a sterile, disposable endoscope that enables access and delivery of accessories to targeted pancreatico-biliary anatomy and displays live video while connecting with the Image Processor.

The package contains:

- One (1) Access and delivery catheter
- One (1) Y- Port Adapter
- One (1) Instructions for Use

Ensure the package contains the above components before use.

Performance Specifications PV-11215	
Direction of view	0 degrees (forward viewing)
Field of view	120 degrees in air
Depth of field	5~50mm
Width of insertion portion	3.7 mm
Maximum insertion portion width	4.0 mm
Working length	215 cm
Width of working channel (Inner diameter)	2.0 mm
Minimum Working channel width	1.8 mm
Qty of irrigation channels	2
Auxiliary channel	No

Performance Specifications PV-11215	
Angulation range	≥80° (without accessory device in working channel)

Performance Specifications PV-09215	
Direction of view	0 degrees (forward viewing)
Field of view	120 degrees ±15% in air
Depth of field	5~50mm
Width of insertion portion	3.1 mm
Maximum insertion portion width	3.4 mm
Working length	215 cm
Width of working channel (Inner diameter)	1.2 mm
Minimum Working channel width	1.0 mm
Qty of irrigation channels	2
Auxiliary channel	No
Angulation range	≥80° (without accessory device in working channel)

Performance Specifications PV-11215G	
Direction of view	0 degrees (forward viewing)
Field of view	120 degrees in air
Depth of field	5~50mm
Width of insertion portion	3.7 mm
Maximum insertion portion width	4.0 mm
Working length	215 cm
Width of working channel (Inner diameter)	2.0 mm
Minimum Working channel width	1.8 mm
Qty of irrigation channels	1
Auxiliary channel	Yes
Angulation range	≥80° (without accessory device in working channel)

Indications

The device is recommended for the diagnosis and/or treatment of pancreatico-biliary system diseases, which should be judged by clinicians based on clinical guidelines, expert consensus, clinical diagnosis and treatment experience, and the clinical condition of patients, including but not limited to:

- Biliary Stones
- Pancreatic duct stones
- Biliary Strictures or obstruction
- Primary sclerosing cholangitis (PSC)
- Cholangiocarcinoma
- Pancreatic malignancies

Contraindications

This device is not recommended to be used in the following situations, which need to be judged by clinicians based on clinical guidelines, expert consensus, clinical diagnosis and treatment experience, and the clinical condition of patients, including but not limited to:

- Pharyngeal or esophageal obstruction;
- Acute/active cholangitis or pancreatitis
- Anaphylactic reaction to contrast dye;
- Visceral perforation;
- Severe coagulopathy;
- Small duct, <5 mm in diameter.

Complications

This device is an invasive device used in the surgical diagnosis and treatment of pancreaticobiliary System diseases. This operation may cause the following complications, including but not limited:

- Cholangitis
- Pancreatitis;
- Haemobilia;
- Bile duct perforation.

Clinical Benefits

The clinical benefits of this device mainly include:

- This device can improve the diagnostic efficiency (specificity, sensitivity, accuracy, etc.) of pancreaticobiliary system diseases, including biliary strictures and impacted, Primary sclerosing cholangitis (PSC), cholangiocarcinoma, pancreatic malignancies and so on.
- This device can improve the therapeutic effect of difficult biliary stones and pancreatic duct stones (stone clearance rate, success rate of operation, etc.).
- This device can improve the accuracy and scope of Pancreaticobiliary system duct biopsy.

Warnings

- Please read this instruction manual, the image processor instruction manual and monitor user manual before using the system. Failure to follow any instructions or failure to heed any warnings or precautions may result in harm or injury to patient. Use by untrained clinical users may cause harm to patients.
- Do not use the catheter in the presence of flammable fluids or gases such as detergents, anaesthetics, nitrous oxide (NO), or oxygen. Otherwise, it may cause a fire and burn the operator and the patient.
- Do not insert the catheter through the duodenoscope into the duodenum without a clear endoscopic field of view. Otherwise, it may cause patient injury such as perforation, hemorrhage, or mucous membrane damage.
- Do not perform therapy when an accessory is outside the field of view or force the distal end of the catheter against the mucosa. Otherwise, it may cause patient injury such as perforation, hemorrhage, or mucous membrane damage.
- Do not use irrigation tubing without a single-use, one-way value in place to prevent backflow. Otherwise, it may cause contamination of the device and/or cause patient infection or cross-infection.
- Do not look directly into the light emitted from the catheter, otherwise, it may cause eye injury.
- The surface of the cable connector remains hot for a period of time after disconnection from the processor. Do not touch the surface of the cable connector immediately after removing it from the Processor; otherwise, it will cause skin burns.
- If using the Y-port adapter, open the Y-port adapter before back-loading over a guidewire to ensure that guidewire is not pushed further into the anatomy resulting in perforation.
- The Access and delivery catheter is not intended to be used with coagulation electrosurgical unit, RF cutting and coagulation devices.
- Do not use it if the sterile barrier is damaged; otherwise, it may result in patient infection.
- Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re sterilization may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization 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 infectious disease(s) from one patient to another.
- Do not use the catheter if it exceeds the expiration date.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

PRECAUTIONS

- The catheter can only be used with the image processor. Connecting to the other equipment may cause damage to the device or patient injury.
- Excessive bending of the articulation portion of the catheter with the elevator of the duodenoscope may break or kink the articulation portion. Do not bend the articulation portion excessively with the duodenoscope elevator. If breakage or kinking of the catheter is confirmed under X-ray, stop using the access and delivery catheter immediately.
- Disconnecting the access and delivery catheter cable from the processor before removing the insertion portion from the duodenoscope will result in a loss of visualization. Remove the access and delivery catheter from the duodenoscope before unplugging the cable.
- Damaging the surface of the access and delivery catheter cable connector may result in no visualization or an unexpected loss of visualization. Inspect the surface of the Access and delivery catheter cable connector for damage before use.
- The access and delivery catheter should be used with caution in patients with previous gastric or bile duct surgery, or with ductal strictures. These conditions may prevent passage of the access and delivery catheter.
- Do not insert a wet catheter connector into the catheter cable receptacle; otherwise, it may result in poor video performance or damage to the processor.
- When there is a problem with the catheter during the operation, remove the access and delivery catheter from the duodenoscope".
- Check whether the catheter insertion portion has rough surfaces, sharp edges, or protrusions that may cause hazards before use.
- Properly place the Access and delivery catheter and other accessories connected to it to prevent from tripping the operator.
- The surface temperature of the distal end may exceed 41°C. To avoid burns to the patient's tissue, keep the distal end at a proper distance from the target tissue.
- When the catheters are used with laser equipment, please wear protective glasses.
- When the catheters are used with other medical equipment, it should be operated in accordance with the instructions of the equipment to avoid safety hazards.
- Using a cardiac defibrillator while the access and delivery catheter remains inside the patient may cause damage to the access and delivery catheter. To prevent damage to the access and delivery catheter, remove the access and delivery catheter before using the defibrillator.

Procedure

Use Environment	
Ambient temperature (°C)	5~40
Relative humidity (%)	20~80 (non-condensing)

Atmospheric pressure (hPa)	700~1060
Transportation and storage Environment	
Ambient temperature (°C)	-20~60
Relative humidity (%)	10~90 (non-condensing)
Atmospheric pressure (hPa)	700~1060

Compatibility

The Catheter is compatible with:

Table 1 Compatible equipment and accessories

Equipment/Accessories	**Specifications/Models/Parameters**
Image Processor	PV-200IP
Accessories (via working channel)	Accessory with minimum length of 2.3m and compatible with 2.0mm working channel diameter (inner diameter, applicable to PV11215, PV11215G) Accessory with minimum length of 2.3m and compatible with 1.2mm working channel diameter (applicable to PV09215)
Irrigation Pumps	Maximum transmission pressure：≤400KPa Maximum Flow Rate：≥230ml/min
Suction Source	Limit Negative Pressure: ≥0.09MPa， and with male luer interface device
Duodenoscopes (if applicable)	Minimum working channel diameter: 4.2 mm (for PV11215; PV11215G) or 3.7mm (for PV09215)

Procedure

Below figures show the structure and main components of the **Access and Delivery catheter**.

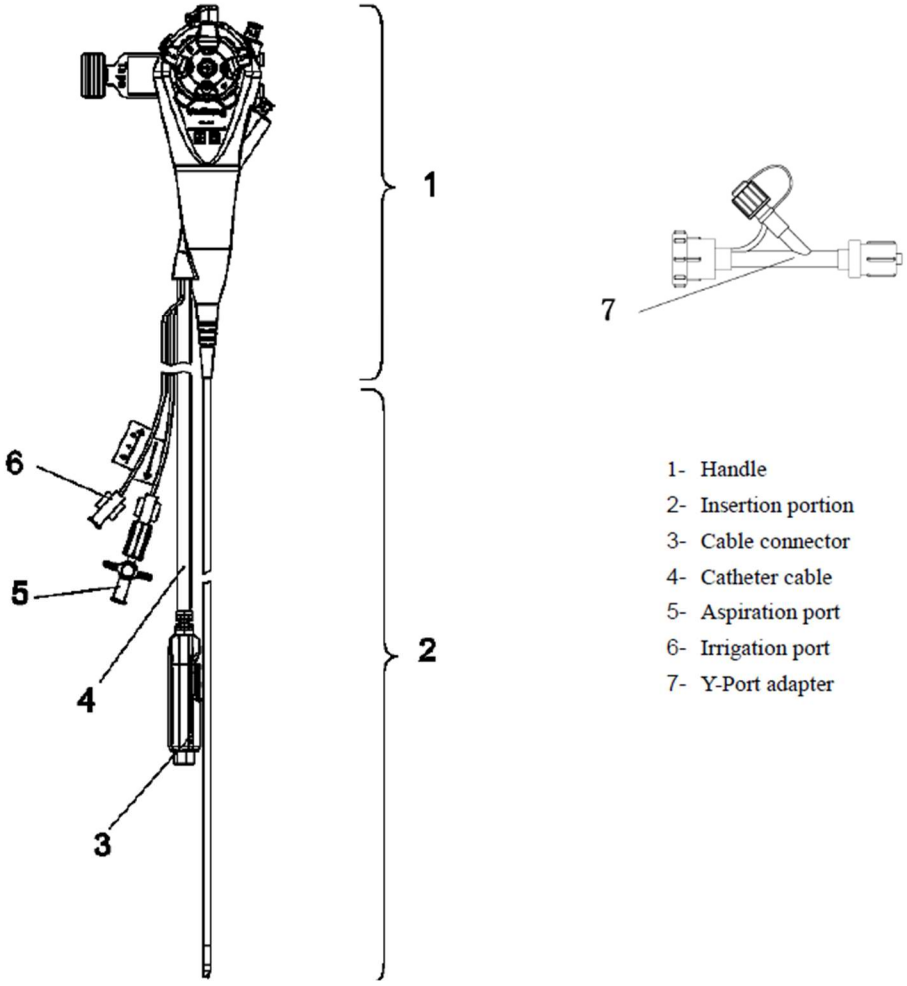


Figure 1 Structure

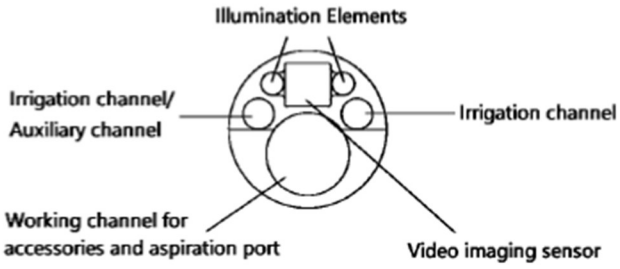


Figure 2 Sectional view of the distal end

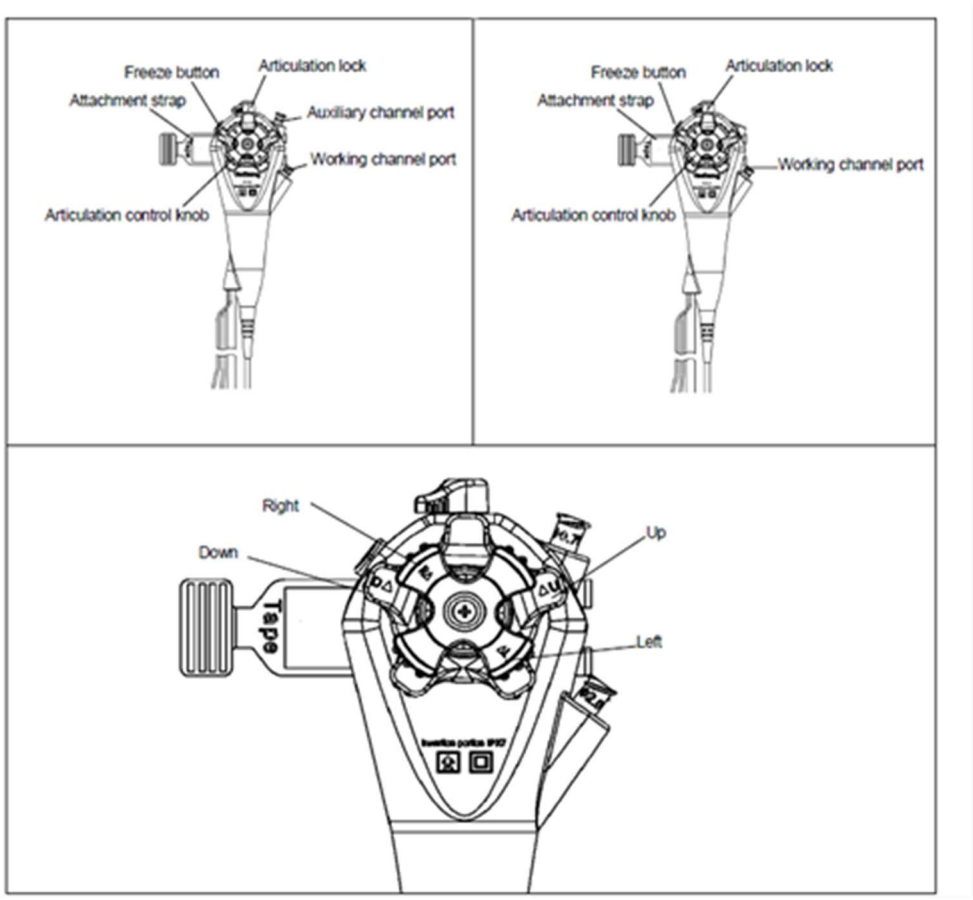


Figure 3 Handle

Unpack and Inspect the Access and Delivery catheter

- Open the shipping package and take out the sterile package.
- Check the expiry date on the sterile package. Do not use the Access and delivery catheter if it exceeds the expiration date.
- Ensure the sterile package is intact without damage, holes, or tears. Otherwise, do not use the catheter.
- Inspect the surface of the insertion portion and ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause harm. Examine the handle, articulation knobs, working channel port, irrigation and aspiration ports and ensure no components are loose or broken.
- Rotate the articulation knobs on the access and delivery catheter handle and confirm it works. Operation should be smooth and precise. Do not force the articulating section into a straight or flexed position while holding the articulation knobs. Otherwise, it may damage the control mechanism. Check the catheter cable and connector are not kinked or damaged.

Connect to the Processor and Check the Image

- Connect the Access and delivery catheter to the processor as shown in Figure 20. While connecting, the lock of the cable connector needs to be upwards. Insert the cable connector

into the connector on the front panel until the lock pushed into place and made a "click" sound.

- Verify an image is presented on the screen.

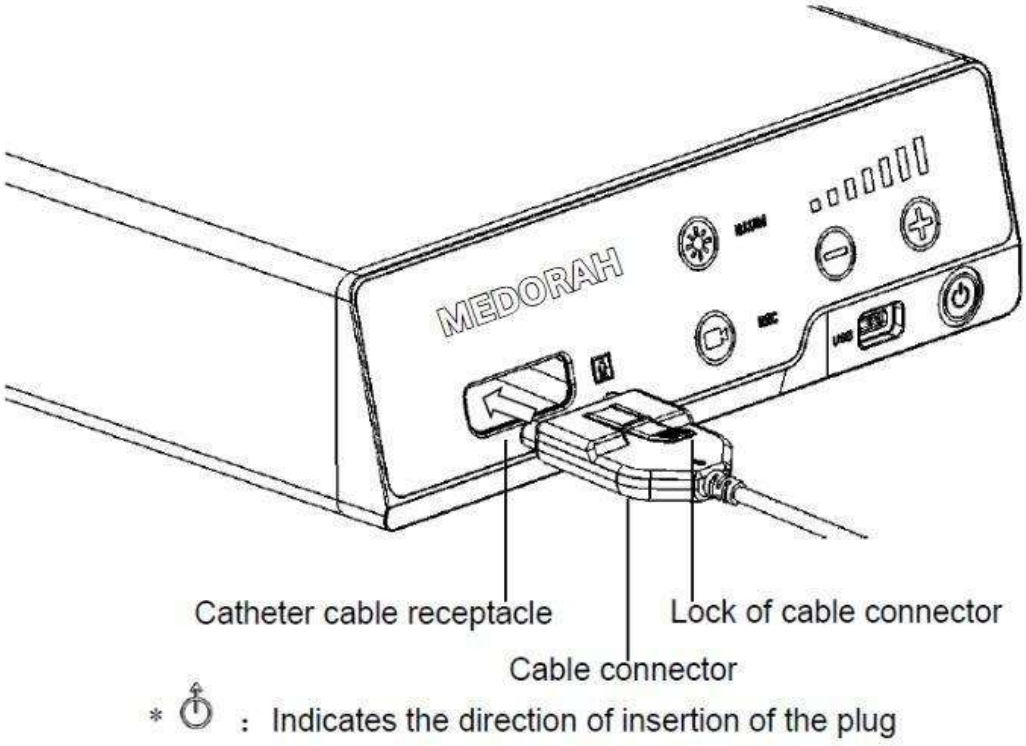
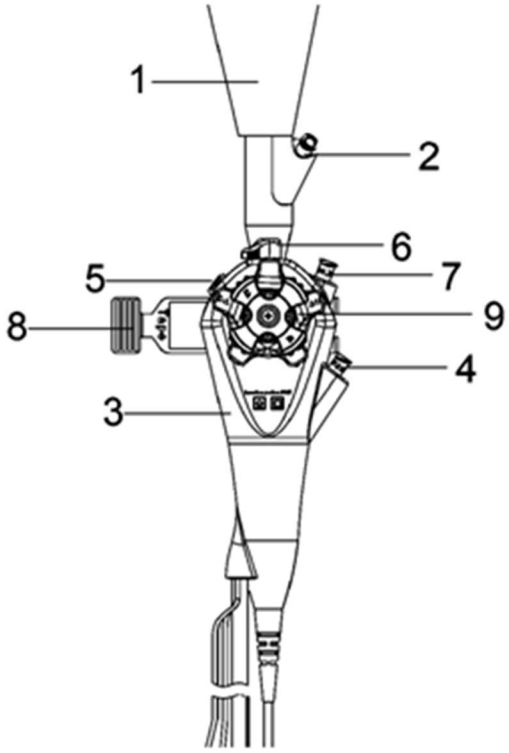


Figure 4 Inserting the cable connector into the Processor

Attach the Access and delivery catheter to the Duodenoscope

Position the Access and delivery catheter so that its articulation knobs are aligned with the duodenoscope's steering knobs and the handle is below the duodenoscope's working channel.



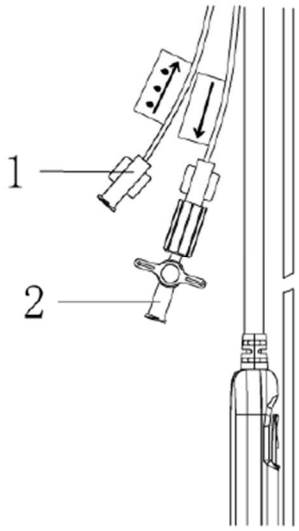
1. Duodenoscope
2. Duodenoscope working channel
3. Access and Delivery Catheter
4. Access and Delivery Catheter working channel port
5. Freeze button
6. Articulation lock
7. Auxiliary channel port
8. Attachment strap
9. Articulation control knob

Figure 5 Positioning the Access and delivery catheter for attachment to the duodenoscope

Attach Irrigation, Aspiration, and Y-port Adapter

- Connect an irrigation pump to the irrigation port of the Access and delivery catheter by the pump's irrigation tubing (Figure 22) following the irrigation pump Instructions for Use.
- If desired, connect a suction source to the Access and delivery catheter aspiration port. The stopcock can be used to control suction flow.
- If desired, attach the Y-port adapter to the Access and delivery catheter working channel port.

Note: *Do not use irrigation tubing without a single-use, one-way valve in place to prevent backflow. Otherwise, it may cause contamination of the device and/or cause patient infection or cross-infection.*



1. Irrigation port
2. Aspiration port

Figure 6 Irrigation and aspiration ports

Insert and position the Access and Delivery catheter

The Access and delivery catheter can be inserted into the working channel of duodenoscope with or without a biopsy cap and with or without a guidewire.

Note: *If inserting Access and delivery catheter through a biopsy cap, ensure the biopsy cap has a sufficient opening to accommodate the Access and delivery catheter flexible insertion section, otherwise puncture the biopsy cap as necessary.*

- Insert the Access and delivery catheter into the duodenoscope.
    a) If using a non-guidewire approach: Insert the distal end of the Access and delivery catheter into the working channel of a duodenoscope
    b) If using a guidewire approach: Leave a cannulated guidewire in the duodenoscope working channel and remove other accessories (tome, cannula, etc.). Back-load the guidewire into the distal end of the Access and delivery catheter working channel. If you use a Y-port adapter, ensure it is in the open position and turn off the light source on the Processor to better see the working channel at the distal end of the Access and delivery catheter if necessary.
- Advance the catheter down to the elevator of the duodenoscope.
- Apply irrigation to flush the catheter irrigation channels with saline until consistent flow is achieved. This will minimize air bubbles when later irrigating in the target duct.
- Advance the catheter through the elevator section of the duodenoscope, lowering the elevator on the duodenoscope as needed.

Note: *Avoid to use the duodenoscope elevator when the blue flexible portion of the Access and delivery catheter is at the elevator.*

- Insert the distal tip of the Access and delivery catheter into the papilla and enter the ampulla of Vater. This may be achieved by using the articulation knobs of the duodenoscope and Access and Delivery catheter. If necessary, partially lock the articulation knobs of the Access and Delivery catheter.

Note: *A previous sphincterotomy may be required in order to advance the Access and delivery catheter into the papilla.*

- If required, adjust the image brightness as necessary to obtain the best image. (See details in the Instructions for Use of the Processor)
- To help clear the field of view throughout the procedure, apply irrigation as needed. If desired, apply suction in addition to irrigation. To apply suction, remove any accessories from the working channel, attach a suction source to the aspiration port, open the aspiration valve and cover the working channel (either with a finger or by tightening the Touhy-Borst on the Y-port adapter). Flush the aspiration port following suction, as needed.
- Continue to advance the Access and delivery catheter through the pancreaticobiliary system towards the target site. This may be achieved by raising and lowering the duodenoscope elevator while simultaneously advancing the Access and delivery catheter and using the articulation control knobs of the Access and Delivery catheter. If desired, partially lock the articulation control knobs.
- Once the Access and delivery catheter is in the desired position, lock the articulating section using the articulation lock as needed.
- If using a guidewire approach, remove the guidewire from the Access and delivery catheter working channel as appropriate to enhance steering control.

Insert an Accessory into the Access and Delivery catheter

- Use an accessory following the accessory instructions.
- While observing the live video and controlling the Access and Delivery catheter, insert the accessory into the Access and delivery catheter working channel using the working channel port.
- Advance the accessory slowly, observing under fluoroscopy as necessary and via live video image for initial entry of the accessory into the field of view at the 6 o'clock position.
- When the accessory emerges from the distal end of the Access and Delivery catheter, direct the distal end of the accessory to the desired location to perform the desired operation.

Note: If resistance is observed when advancing accessories through the Access and Delivery catheter:
(1) ensure the duodenoscope elevator is lowered
(2) ensure the articulation lock on the Access and delivery catheter is disengaged and knobs are in the home position so that the distal end of the Access and delivery catheter is in its straight, default position
(3) ensure the accessory is in the proper configuration for passage through the Access and delivery catheter (e.g. a Biopsy Forceps is closed).
Note: If resistance is still encountered, carefully pull the Access and delivery catheter back and then slowly advance the accessory device. Then the Access and delivery catheter may be moved forward, advancing the accessory device past the point of resistance within the Access and Delivery catheter.

Use auxiliary channel

The Access and delivery catheter has an auxiliary channel, to provide auxiliary irrigation or working channel through the accessory device with a diameter less than 0.75mm according to clinical needs.

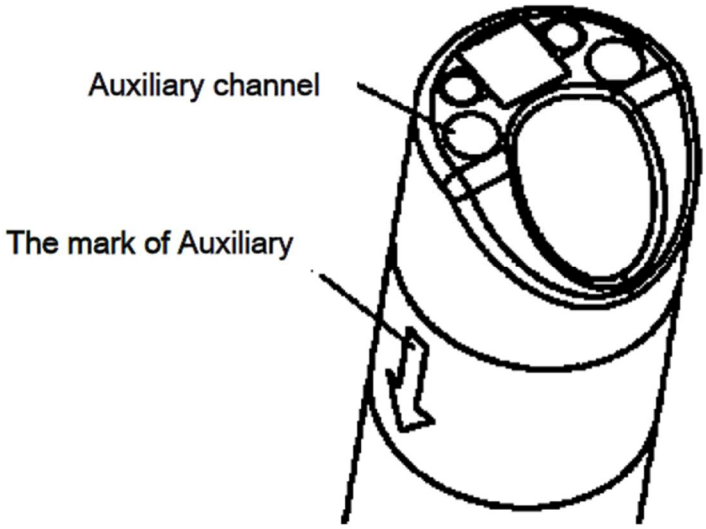


Figure 7 Auxiliary channel and its marking

Freeze and save images

• Press the freeze button on the handle, and the icon will be displayed on the screen, indicating that the image has been frozen;

• Press the freeze button on the handle again, the frozen state on the screen disappears, and the real-time image is restored.

Remove an Accessory from the Access and Delivery catheter

• While observing the live video, withdraw the accessory into the distal end of the Access and Delivery catheter.

• Slowly withdraw the accessory from the Access and Delivery catheter. If you feel resistance, investigate the
source of the resistance before continuing to withdraw the accessory.

• Removal and exchange of accessories is throughout the procedure.

Remove the Access and delivery catheter from the Duodenoscope

Follow these steps to remove the Access and delivery catheter from the duodenoscope:

- Ensure the articulation lock is released and the articulation control knobs are returned to the home position to prevent tissue trauma.

- Remove the accessory from the Access and Delivery catheter.
- Pull the Access and delivery catheter back into the duodenoscope.
- Turn off the LED light on the Image processor.
- Withdraw the Access and delivery catheter flexible portion from the duodenoscope.
- Detach the Access and delivery catheter handle from the duodenoscope by releasing the attachment strap.
- Disconnect irrigation tubing and suction tubing (if necessary) from the Access and Delivery catheter.
- Depress the lock on the Access and delivery catheter cable connector and simultaneously pull the connector outward to release the cable.

Safely Terminate the Operation of Access and delivery catheter during a procedure

- Follow these steps to terminate the operation of the Access and delivery catheter during a procedure:
- Remove any accessory and the Access and delivery catheter from the patient.
- Disconnect the Access and delivery catheter cable from the processor by pushing down on the cable connector lock and pulling it out of the connector.
- Power down the processor by pressing the power button.

Notice for Using Laser Devices

- During laser lithotripsy, the high energy may cause flashes on the display. This is normal and does not mean that the processor or Access and delivery catheter is malfunctioning.
- In advance of laser lithotripsy, the operator shall check the compatibility of laser devices including laser fiber and the Access and Delivery catheter.
- During laser lithotripsy, the laser fiber apex is recommended to stick out the distal of the catheter at least 10mm, otherwise the shockwave of laser will damage the catheter resulting in image loss or other malfunctions.

Notice for using electrohydraulic lithotripsy

During electrohydraulic lithotripsy, the high energy may cause flashes on the display. This is normal and does not mean that the processor or access and delivery catheter is malfunctioning. In advance of electrohydraulic lithotripsy, the operator shall check the compatibility of electrohydraulic devices including electrohydraulic probe and the access and delivery catheter. During electrohydraulic lithotripsy, the probe apex is recommended to stick out the distal of the catheter at least 10mm, otherwise the shockwave of electrohydraulic will damage the catheter resulting in image loss or other malfunctions.

Disposal of the Access and delivery catheter and Packing Materials

- Dispose the Access and delivery catheter as per standard biohazard hospital protocol.
- Dispose the packing materials following the relevant regulations and laws in your

country/region.

APPENDICES

The appendices include:

- Appendix 1: Guidance and Manufacturer's Declaration-Electromagnetic Emissions
- Appendix 2: Guidance and Manufacturer's Declaration-Electromagnetic Immunity
- Appendix 3: Guidance and Manufacturer's Declaration-electromagnetic IMMUNITY-for ME Equipment and ME Systems that are not LIFE-SUPPORTING
- Appendix 4: Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Processor
- Appendix 5: Medical design standards and specifications

Appendix 1 — Guidance and Manufacturer's Declaration-Electromagnetic Emissions

The Access and delivery catheter is intended for use in the electromagnetic environment specified below

Table 2 Guidelines and manufacturer's declaration - electromagnetic radiation IEC60601-1-2

Emission standard	Compliance	Guidance
RF emissions CISPER 11	Group 1	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPER 11	Class A	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPER 11	Class A	

Appendix 2 — Guidance and Manufacturer's Declaration-Electromagnetic immunity

The Access and delivery catheter is intended for use in the electromagnetic environment specified below

Table 3 Guidance and Manufacturer's Declaration-Electromagnetic immunity

Immunity Test	IEC 60601-1-2 4th edition test level	Compliance	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8KV Contact ±2,±4,±8, ±15 KV Air	Same as left	Floors should by be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2KV AC Power lines	Same as left	Mains power quality should be that of a typical commercial
Surge IEC 61000-4-5	±0.5, ±1KV AC power line(s) to line(s) ±0.5, ±1, ± 2KV AC power line(s) to ground	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips: <5% UT(>95% dip in UT) For 0.5 and 1 cycle 70% UT(30% dip in UT) for 25 and 30 cycles Voltage interruptions: <5% UT(>95% dip in UT) For 250 and 300 cycles	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m 50 and 60Hz	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

Immunity Test	IEC 60601-1-2 4th edition test level	Compliance	Guidance
Note — UT is the A.C. mains power supply prior to application of the test level.			

Appendix 3—Guidance and Manufacturers Declaration— Electromagnetic Immunity

The Access and delivery catheter is intended for use in the electromagnetic environment specified below. The

customer or the user of the Processor should assure that it is used in such an environment.

Table 4 Manufacturers declaration—electromagnetic immunity IEC60601-1-2

Immunity Test	IEC 60601-1-2 4th edition test level	Compliance	Electromagnetic Environment (Guidance)
Conducted RF IEC 61000-4-6	3Vrms 150 kHz-80 MHz 6Vrms In ISM band 150kHz-80MHz; 80% AM at 1kHz	3Vrms 150 kHz-80 MHz 6Vrms In ISM band 150kHz-80MHz; 80% AM at 1kHz	**Recommended separation distance** d = 1.2 √P 150KHz-80MHz outside ISM d = 1.2 √P 150KHz-80MHz in ISMa d = 1.2 √P 80MHz to 800MHz d = 2.3 √P 800MHz to 2.7GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) b. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less
Radiated RF IEC 61000-4-3	3V/m 80 MHz - 2.7 GHz	3V/m 80 MHz - 2.7 GHz	
Proximity fields from RF wireless communications equipment IEC61000-4-3	9-28V/m 385 - 6000MHz	9-28V/m 385 - 6000MHz	

Immunity Test	IEC 60601-1-2 4th edition test level	Compliance	Electromagnetic Environment (Guidance)
			than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following Symbol: 
Note 1: At 80MHz and 800MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

A: The ISM (industrial, scientific and medical) bands between 150kHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.

B: The compliance levels in the ISM frequency bands between 150kHz and 80MHz and in the frequency range 80MHz to 2.7GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

C: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Workstation is used exceeds the applicable RF compliance level above, the Workstation should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Workstation.

D: Over the frequency range 150kHz to 80MHz, field strengths should be less than [3] V/m.

Appendix 4-Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Access and Delivery catheter

The Access and delivery catheter is used in a controlled electromagnetic radiation environment. When using portable and mobile RF communication equipment, refer to the recommended separation distance to prevent electromagnetic interference.

Table 5 Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Access and Delivery catheter

Max Output Power (Watts)	Separation distance based on transmitter frequency (m)			
	$d = 1.2\sqrt{P}$ 150KHz-80MHz outside ISM bands	**$d = 1.2\sqrt{P}$ 150KHz-80MHz in ISM bands**	**$d = 1.2\sqrt{P}$ 80MHz-800MHz**	**$d = 2.3\sqrt{P}$ 800MHz-2.7GHz**
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters(m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in matts(W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix 5-Medical design standards and specifications

The Access and delivery catheter meets the medical design standards and specifications

Table 6 Medical design standards and specifications

Design Specifications against Standards	
Type of protection against electric shock	Class I
Degree of protection against electric shock of applied part	TYPE BF applied part
Degree of protection against ingress of materials	IPX7(distal end)
Mode of operation	Continuous operation
Installation and use	Portable Device
Pollution degree classification	2
Overvoltage category	II
Altitude	Less than 3000 meters

Change of performance

If a device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

Shelf life of the Product:
The typical lifespan of the product is three years from the manufacturing date.

Storage

Keep the device under normal room temperature and avoid direct sunlight. Follow the first-in-first-out rules and do not use the device out of expiry date.

Explanation of Symbols

	Date of manufacture		Use-By Date
	Catalogue Number		Do Not re-use

	Consult Instructions for use		Caution
	Type BF Applied Part		Manufacturer
	Serial Number		Keep away from sunlight
	Keep dry		Temperature limitation
	Humidity limitation		Atmosphere pressure limitation
	Sterilized using ethylene oxide		Batch Code
	Do not resterilize		Do not use when package is damaged

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by the appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein which are beyond Medorah Meditek Pvt. Ltd. control such as warranties implied to the application of law, sales or specially purpose suitability after handling over, storage, cleaning and sterilization of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures, and any other details. Medorah Meditek Pvt. Ltd. shall not be liable for any incidental, or consequential loss, damage or expense directly or indirectly arising from the use of this product other than the replacement of it. Medorah Meditek Pvt. Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other persons related to this product.

MEDORAH MEDITEK

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