PEGASUS

INSTRUCTIONS FOR USE

Wireless Endoscopy System

*Read **all** instructions prior to use*

Caution: Federal (US) Law Restricts this device to sale by or on the order of a physician.

1. Introduction

Intended Use

Pegasus is intended to be used in an operating room during endoscopic and arthroscopic procedures.

Indications for Use

Pegasus is indicated for use in diagnostic and operative endoscopic and arthroscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

Device Description

The AM Surgical Pegasus Wireless Endoscopy System is a sterile, disposable, endoscopic device that consists of a wireless camera and receiver. The endoscopy unit incorporates a transmitter that delivers an uncompressed analog video signal to a receiver module. The receiver module is connected to a video display using a standard TV composite cable. An integrated LED light source eliminates the need for a separate light source and light cable, and the camera is powered by battery.

The Pegasus device includes the endoscopy unit with the LED light source and camera embedded in the shaft, a wireless receiver, a composite video cable, and power cords. Refer to **Figure 1** on the following page.

Contraindications

None known.

Warnings

- Do not dispose of camera device without first powering it off to avoid interference.
- Do not attempt to modify or disassemble the Pegasus camera device, receiver, or any other component. Doing so may damage the device or create a safety hazard.
- Do not use if handling causes device to become non-sterile or if packaging has been damaged.

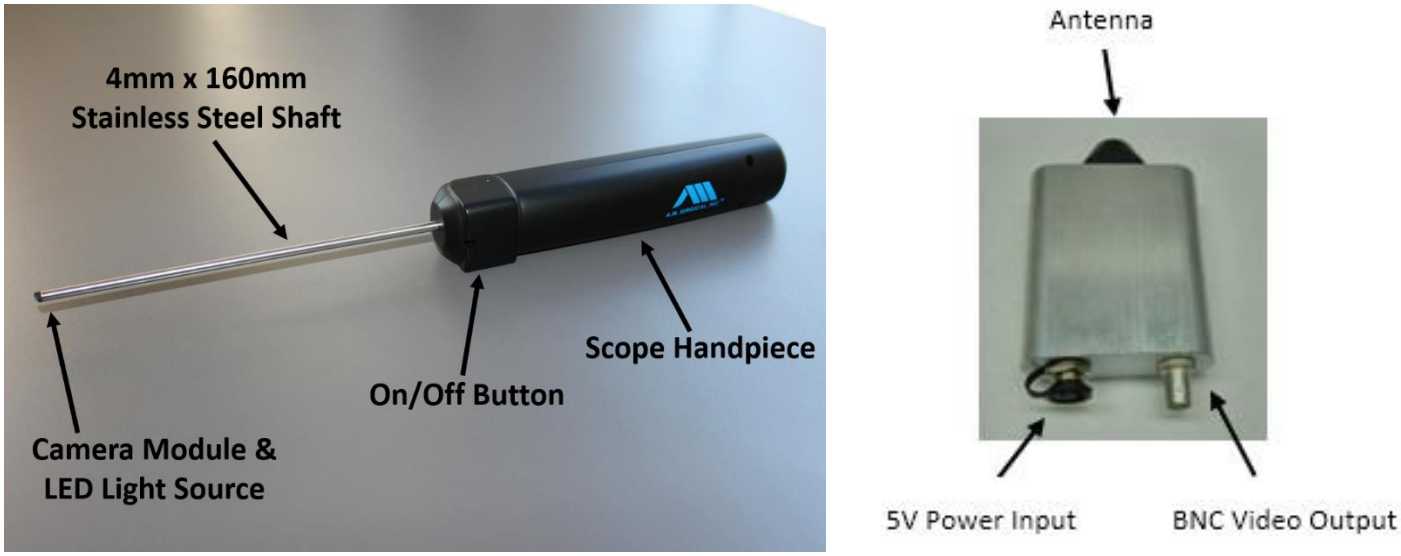

Figure 1 - A.M. Surgical Pegasus Wireless Endoscopy System (Catalog Number XXX-XXX)

Precautions

- Do not reuse the Pegasus unit. One-time use only. Receiver may be reused after disinfection.
- Do not submerge or allow liquids to enter the body of the Pegasus, as it is only water resistant and this may damage the electronics within the device.
- Use only the supplied cables and components with the Pegasus Camera System. Test the system prior to any procedure to ensure functionality.
- Do not stare directly at the LED light source or point it directly at anyone's eyes while illumination is active.

Recommended Supplies & Compatible Equipment

The following supplies and/or equipment are not provided but are required to use the Pegasus Camera System:

- Compatible video monitor with composite input
- Lint-free cloths

Care and Handling

The Pegasus camera system is constructed of sensitive electronics and optical components. Special care must be taken to prevent damage to the device and to maintain functionality. Negligent care and/or handling may void warranty.

2. Instructions for Use

Preparation & Installation of Receiver

1. Place the receiver in an area such that it is no more than 15 feet away from the endoscopy unit for the duration of the procedure. Ensure wires are clear of any walking path to minimize risk of tripping.
2. Connect the composite cable from the output of the receiver module to the composite input on the video monitor.
3. Connect the barrel connector of the AC power supply to the 5V input on the receiver.

Preparation & Use of Camera Module

Once the receiver has been successfully set up, the endoscopy unit may be used to provide visualization for minimally invasive endoscopic and arthroscopic surgical procedures.

1. To begin, press the On/Off button once on the unit. This button is found on the side of the plastic housing. When the device is turned on, the LED will illuminate.
2. Check the video monitor to confirm that the receiver is obtaining a clear, uninterrupted signal from the camera. White balance and brightness are automatically adjusted.
3. If the signal is blurry, ensure that there is no dust or other particulate matter blocking the camera lens by wiping it with a sterile lint-free cloth. If the signal is cutting out or the picture is grainy, double check to make sure the receiver is less than 15 feet from the camera or move the receiver closer. If problems persist, remove objects from the path between the endoscopy unit and receiver.
4. Once the procedure has concluded, press the On/Off button once more to shut down the endoscopy unit and dispose of the device. Confirm LED light is off to ensure device is completely off prior to disposal. **Warning: Do NOT reuse. Endoscopy unit is NOT re-sterilizable.**

3. Cleaning, Disinfection, & Maintenance

The A.M. Surgical Pegasus Wireless Endoscopy unit is delivered sterile. The unit is designed for one-time use only and cannot be re-sterilized. The receiver is reusable after disinfection between procedures. To clean the receiver, wipe it down with a disinfecting wipe. Visually inspect the package for integrity prior to use. Do not use if the pouch is breached.

4. Storage & Disposal

The unit and components may be stored at normal room temperature. There are no special storage requirements. Ensure device is turned off prior to disposal to avoid interference. Follow local governing ordinances and recycling plans regarding the recycling or disposal of the device or components. Lithium batteries may have specific regional requirements for recycling or disposal.

5. Maintenance of Quality of Service & Security

6. Troubleshooting, Technical Specifications, & Compliance

Troubleshooting

Problem	Possible Cause	Action
Endoscopy unit will not power up	Battery has died	Defective or expired unit. Replace with new unit.
No Image	No power to receiver	Ensure that power is connected to the receiver and that wall outlet is providing power.
	Receiver not connected to monitor	Check the composite video connection on the receiver and the monitor to ensure the composite connector is fully seated in the input.
	Monitor set to incorrect input	Check the monitor to ensure the correct composite video input is selected
	Camera not powered on	Turn the camera module on by pressing the power button. An image should appear on the screen within 5 seconds of powering on the device
Image freezes on screen/"choppy" video quality	Distance between camera and receiver too great	Move the camera closer to the receiver to see if this corrects the issue. It is recommended that the camera be operated no more than 15 feet from the receiver.
	Objects between camera and receiver obstructing signal	Remove objects from the path between the endoscopy unit and receiver.
Loss of light from LED light source	Battery or LED has died	Defective or expired. Replace with new unit
Image not in focus	Camera lens is dirty	Gently rub tip of endoscopy unit shaft with a lint-free cloth in the sterile field until image is clear.

Technical Specifications & Compliance

Item	Specification
Depth of Field	5mm-50mm
Field of View	120°
Direction of View	30°
Wireless Signal Type	Analog RF
Frequency Band	5.8 GHz
Image Latency	<100ms
Weight (Unit)	100 grams
Camera Native Resolution	400x400
Supported Video	NTSC
Video Output	Composite Video
Expected Service Life	Minimum of 120 min per device
Battery Type	CR123A
Mode of Operation	Continuous
Battery Life at Full LED Power	Minimum of 120 minutes
Safe operating ambient temperature range	59-91 Degrees Fahrenheit
Safe storage and transport temperature range	32-122 Degrees Fahrenheit
Safe operating, storage, & transport relative humidity range	0-95% RH
Complies with industrial electrical standards	IEC 60601-1, IEC 60601-2-18
Complies with medical safety standards	IEC 60601-1, IEC 60601-2-18
Complies with medical EMC standard	IEC 60601-1-2:2007
Complies with FCC standard	FCC Part 15C, FCC sDoC,

Electromagnetic Compatibility (EMC)

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section. Portable and Mobile RF communications equipment can affect Medical Electrical Equipment.

7. FCC Warnings

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTICES TO USER:

This equipment complies with the requirements of IEC 60601-1-2 and has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

7. Warranty & Repair Service

Limited Warranty

A.M. Surgical Inc. warrants for a period of one (1) year following purchase of the product that the product will be free from defects in material and workmanship. Within the warranty period, upon receipt of Customer's prior written notice, A.M. Surgical may either repair or replace defective parts/products at no charge to Customer. A.M. Surgical Inc. warrants that reasonable care has been used in the design and manufacture of this device. A.M. Surgical Inc. excludes all other warranties, whether expressed or implied, by operation of law or otherwise including, but not limited to, any implied warranties of merchantability or fitness since handling and storage as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond A.M. Surgical's control directly affect the device and the results obtained from its use. A.M. Surgical Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. A.M. Surgical Inc. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this device. Refer to A.M. Surgical Inc., Inc. Standard Terms and Conditions.

Warranty Assessment / Return for Service

Customers have the option of purchasing repair and replacement coverage for the Pegasus system, which will provide certain repair and/or replacement benefits in the event that the system has been damaged.

Contact Customer Service for Details:

Phone: (631) 979-9777

Fax: (631) 980-4369

Email: info@amsurgical.com (Inquiries)

service@amsurgical.com (Sales)

Note: If returning devices for assessment, all products must be cleaned and disinfected prior to shipping per one of the approved methods described within this document. Documentation must be provided stating the device has been reprocessed prior to shipping. If disposing devices, discard devices and all waste products according to appropriated environmental health safety guidelines.

8. Symbol Descriptions & Manufacturer Information

STERILE EO Sterilized by Ethylene Oxide	Caution	Consult IFU	Do Not Resterilize	Manufactured Date	Do Not Reuse	FCC Registered	IP54 Dust/Splash Resistance	
LATEX No Latex	Do not use if package is broken	Non-Ionizing Radiation	REF Reference Number	LOT Lot Number	QTY Quantity	Do not stare at bright light	Use-by date	Rx Only Prescription use only

Symbols Reference

ISO 15223-1:2012 – Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements

IEC 60417:2002 – Graphical symbols for use on equipment

IEC/TR 60878:2015 – Graphical symbols for electrical medical practice

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