Flexible endoscopy in a robotic world – Challenges?

HONG KONG HOSPITAL AUTHORITY - ADVANCED COURSE FOR INFECTION CONTROL – NOVEMBER 2017

Objectives

1. Provide definitions and applications of robotic surgery

2. Discuss advancements and designs with flexible endoscope robotic surgery

3. Review reprocessing instructions and challenges

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Association for Advancement of Medical Instrumentation (AAMI)
Positions held:

AAMI Board of Directors – Director representing industry since 2015

Member:

- AAMI Finance committee
- Sterilization Standards Committee
- WG 61: Chemical sterilants hospital practices – co-chair
- WG 84: Endoscope reprocessing
- WG 40: Steam sterilization hospital practices
- WG 13: Washer disinfectors; TAG to ISO TC 198 WG 13
- WG 93: Cleaning of reusable devices
- Sterilization of endoscopes stakeholders group
- Task group – HVAC conditions in OR

Robotic Endoscopy = Minimally Invasive Techniques

Technology incorporating automation, microsurgery, engineering, imagery, electronics for minimally invasive surgery that offers better precision, flexibility and control compared to conventional techniques.

Types:

Laparoscopy

- Urology
- Gyn
- Prostate
- Kidney
- Gallbladder
- Cardiothoracic
- Orthopedic

Flexible endoscopy

- Colorectal
- Oncology
- Esophageal

Key innovation: wrist like movement

What is robotic flexible endoscopy?

New MIS technology to allow advanced procedures in natural-orifice transluminal endoscopic surgery (NOTES), with a robotic endoluminal platform, e.g. flexible endoscope enabled by robotics used for:

1. Tissue triangulation – two or three forceps
2. Used for advanced resection techniques, e.g. endoscopic submucosal dissection (ESD)
3. May provide better assessment of resection rate for early cancers
4. Better staging of disease treatment
5. Better access of hard to reach structures
6. Most system require two operators

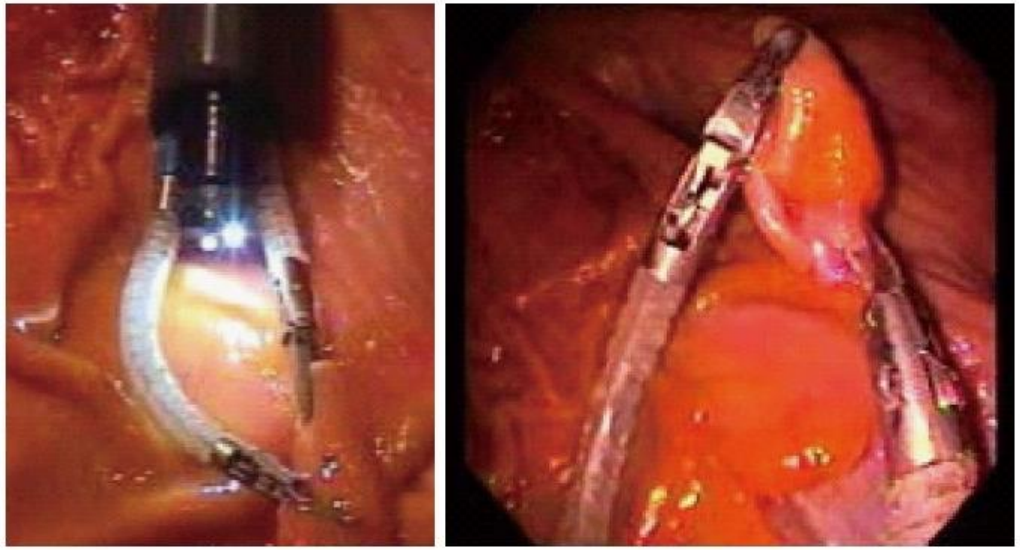
Common types of procedures: esophageal and colonic are ESD most common application

Applications in gastric plication and many others.

Source: Baldwin, 2016

Common Design for Flexible Robotic Endoscopes

Figure 12



On the left, the endoscope and the viacath robotic arms are integrated using an overtube. Abbott et al[75], 2007.

Two mechanical arms attached to a head or conventional endoscope.

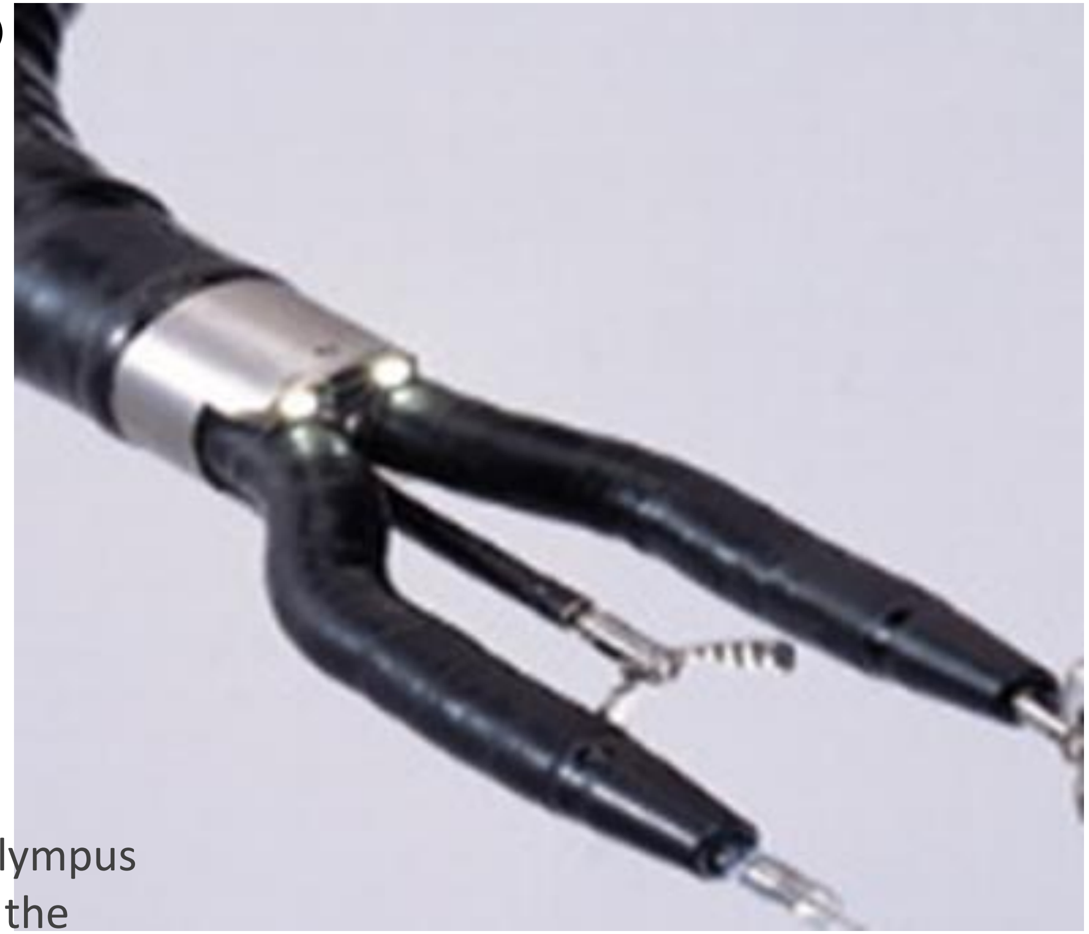
Allows endoscopic manipulations

- Grasping
- Traction
- Incision
- Excision
- Hemostasis

Source: Baldwin, 2016

(a)

(b)



(a) The system of the ENDOSAMURAI™ (by courtesy of Olympus Medical Systems, Tokyo, Japan). (b) The insertion part of the ENDOSAMURAI™ (by courtesy of Olympus Medical Systems, Tokyo, Japan).

Source: Olympus Japan

How do the systems work today?

1. Endoscope connected to mechanically to actuation equipment with mechanically driven cables or levers to move the instrument's arms.
2. Precise movements controlled by endoscopist by joystick or similar control to improve tissue handling in the confined endoluminal space.
3. System allows forward/backward, rotational, up/down, left/right movement of a conventional endoscope.
4. Surgeon views surgical site through microscope and often controls the system from the surgical console.
5. Goal is to improve the procedural performance efficiency.

- New technology with many designs still in trials
- Requires learning curve
- Reported complications:
  - Hemorrhage and perforation
  - May be more of issue with low volume centers
  - System requires expertise
- Multiple designs in trials or use.

Source: Baldwin, 2016

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Table 1

2016

Summary of currently available robotic flexible endoscopic platforms

Platforms	Development status		
Robotic driven locomotion	**FDA**	**CE**	**Sale**
Electromechanical control of a conventional endoscope			
Robotic steering and automated lumen centralization (RS-ALC) (Netherlands)	-	-	-
Endoscopic operating robot (EOR) (Kyushu Institute of Technology, Japan)	-	-	-
Invendoscope (Invendo Medical Gmbh, Germany)	Y	Y	Y
Systems with elements of autonomous locomotion			
Neoguide (Intuitive Surgical, United States)	Y	N	N
Aer-O-scope (GI View Ltd, Israel)	Y	Y	Y
Endotics (ERA Endoscopy SRL, Italy)	N	Y	Y
CUHK double -balloon endoscope (Chinese University of Hong Kong, China)	-	-	-
Robotic driven instrumentation			
MASTER (EndoMASTER Pte, Singapore)	-	-	-
ISIS-Scope/STARS system (Karl Storz/IRCAD, Europe)	-	-	-
Endomina (Endo Tools Therapeutics, Belgium)	Y	-	Y
Scorpion shaped endoscopic robot (Kyushu University, Japan)	-	-	-
Viacath (Hansen Medical, United States)	Y	Y	Y
CUHK robotic gripper (Chinese University of Hong Kong, China)	-	-	-
Imperial College robotic flexible endoscope (Imperial College, United Kingdom)	-	-	-

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Source: Baldwin, 2016

Aeroscope.

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Figure 5

The Aeroscope relies on a balloon at the tip of the endoscope to form a seal with surrounding colonic wall. A computerized pump system generates a pressure gradient proximal and distal to the balloon. This pressure gradient propels the device. Courtesy of GIview Ltd.

- Pump system pressure propels the device.
- FDA cleared

Source: Baldwin, 2016

Invendoscope

Figure 3

Invendoscope. The scope design is akin to a conventional endoscope. The scope is protected by a disposable inverted sheath which unfurls when the endoscope is pushed forward by the actuating wheels (Invendo Medical Ltd).

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- Scope pushed forward with actuating wheels.
- Has sheath that unfurls.
- FDA cleared, CE marked
- Same company has produced a disposable colonoscope.
- Recently acquired by Ambu.

Source: Baldwin, 2016

Endomima System

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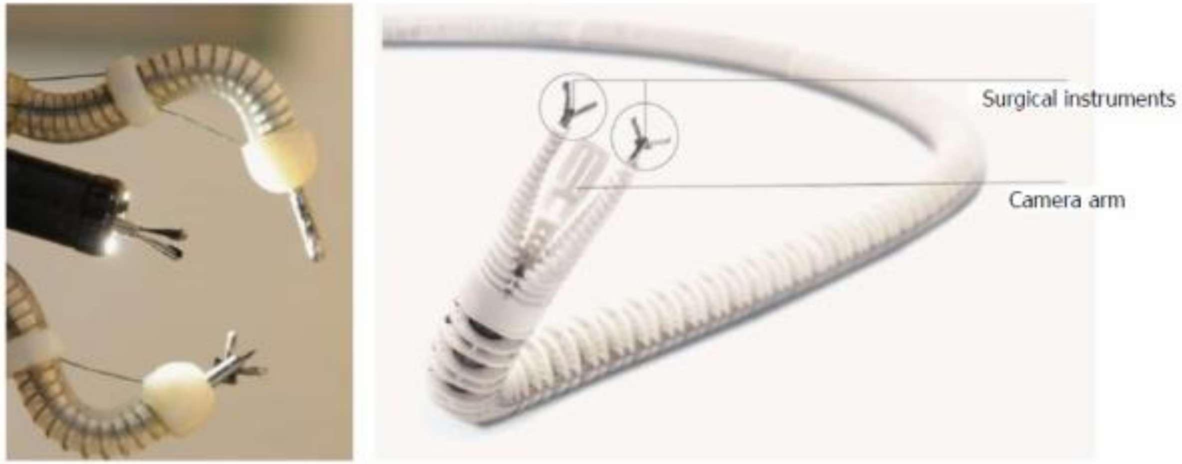
Figure 10



The Endomima system can be mounted onto a conventional endoscope. The arms allow passage of conventional flexible instruments. Each arm has up to 3 DOF of movement (Endotools Therapeutics).

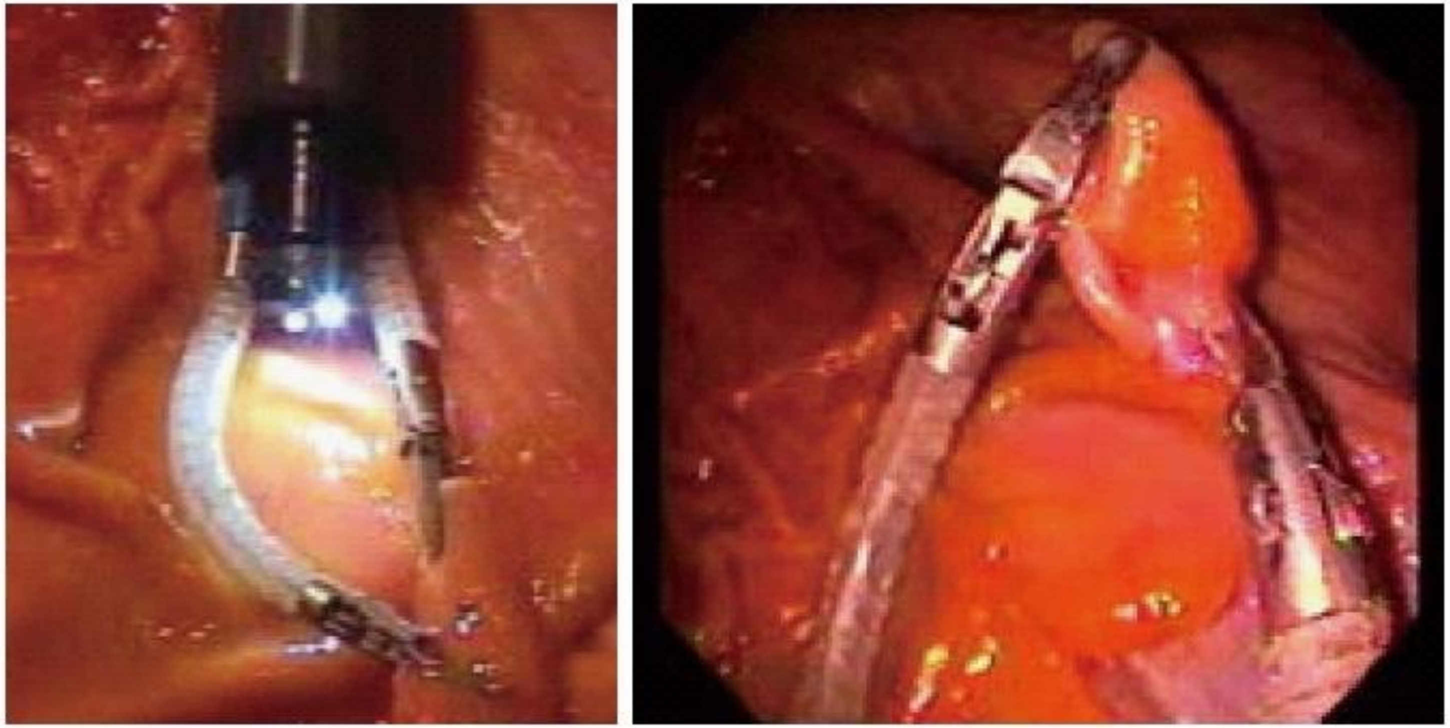
- FDA cleared
- Available for sale.

Source: Baldwin, 2016

Viacath System

- Fits over a conventional endoscope
- FDA cleared, CE marked
- Available for sale

Figure 12



On the left, the endoscope and the viacath robotic arms are integrated using an overtube. Abbott et al[75], 2007.

Source: Baldwin, 2016

Inspection Before Use

⚠ **CAUTION: Inspect the instruments for broken, cracked, chipped, or worn parts. Do not use an instrument if it is damaged.**

Before use, all instruments should be visually inspected for damage or irregularities. Do not use the instrument if damage or abnormalities are observed. Examples of damage include:

- Broken cables or wires
- Scratches, cracks or broken parts on the instrument shaft
- Cracks or missing pieces where the grips attach to the shaft
- Broken, bent, misaligned or gouged instrument tips
- Cracked or broken pulleys near the instrument tips
- Cracks or missing pieces on the outer components surrounding the pulleys
- Loose tip or grips
- Broken lever guards (if applicable)

Source: Intuitive – Da vinci User Manual

Delicate instrumentation must be inspected at point of use

Additional Types of Instruments in Robotic Systems

Graspers, dissectors, needle drivers, scissors
Clip appliers
Suction irrigators

Electrocautery and accessories

Cannulas
Obturators
Seals
Connectors

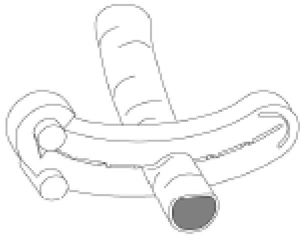


Figure 4.3 Clip applied to vessel

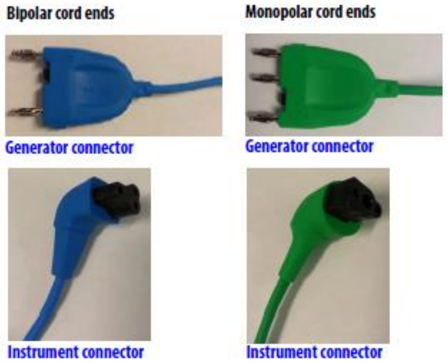


Figure 5.1 Monopolar and Bipolar Cautery Cords

Figure 9.1 8 mm Cannulae, obturators, and cannula seal example

Reprocessing Robotic Instruments

1. Invasive surgical procedures = Terminal Sterilization

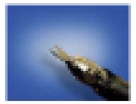
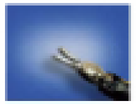
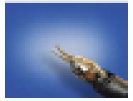
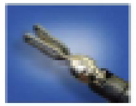
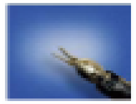
2. Da vinci Endowrists limited reuse – steam or low temperature sterilization

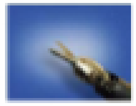
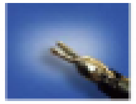
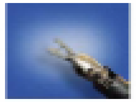
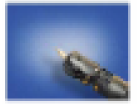
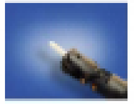
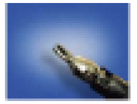
3. Accessories typically steam sterilized

3. Complex precleaning, manual cleaning, ultrasonic followed by automated washer/disinfector cycle. Special attachments for WD.

4. Easily damaged – inspection is important process step.

IAHCSMM Training Video – Reprocessing Robotic Instruments

	**Potts Scissors** Designed for delicate cutting of tissue.
	**Round Tooth Forceps** Designed for atraumatic grasping of tissue.
	**Black Diamond Micro Forceps** Has a delicate instrument tip and is designed to grasp smaller needles as well as tissue.
	**Cadiere Forceps** Designed for atraumatic grasping of tissue.
	**Cautery with Spatula** Designed for blunt dissection and the application of cautery.
	**EndoWrist ProGraspTM** Tissue grasper with greater grasping force than the Cadiere Forceps.
	**Cichon Tissue Forceps** Designed for atraumatic grasping of tissue. The Cichon Tissue Forceps provide similar capabilities as the DeBakey Forceps, but with a much smaller instrument profile that increases the surgeon's exposure to the surgical site.

Instrument Descriptions	
	**Long Tip Forceps** Designed for atraumatic grasping of tissue.
	**Round Tip Scissors** Designed to cut tissue or suture.
	**DeBakey Forceps** Designed for atraumatic grasping of tissue.
	**Small Clip Applier** Specifically designed to apply clips to ligate vessels.
	**Scalpel/Cautery** Designed to hold a 15-degree scalpel blade. The blades are disposable and can be inserted into and removed from the instrument.
	**Scalpel/Cautery** Designed to hold a Beaver blade. The blades are disposable and can be inserted into and removed from the instrument.
	**Large Needle Driver** Has carbide inserts and is specifically designed to grasp and drive needles.

Types of surgical instruments for Da vinci system

Source: Intuitive – Da vinci User Manual

Accessory	Steris®	Sterrad®	EtO	Autoclave (Pre-vacuum)	Enzymatic Cleaner	Ultrasonic Bath
Type 1 Endoscopes (Straight and angled)		✓	✓		✓	
Type 2 Endoscopes (Straight and angled)	✓	✓	✓		✓	
Type 3 Endoscopes (Straight and angled)	✓	✓	✓		✓	
Light Guide Cable			✓a	✓	✓	
Sterile Camera Arm Adapter				✓	✓	✓
Sterile Camera Adapter				✓	✓	✓
Sterile Instrument Arm Adapter				✓	✓	✓
Scope Alignment Targets				✓	✓	✓
Light Guide Cable Adapter				✓	✓	✓
Camera Cannula Mount				✓	✓	✓
Instrument Arm Cannula Mount				✓	✓	✓
Instrument Arm Cannula				✓	✓	✓
Endowrist Instruments				✓	✓	✓

Compatible sterilization process types

Source: Intuitive – Da vinci User Manual

Compatible Process Types and Cycle Parameters

User Manuals provide validated processing instructions

- Types of detergents
- Automated cleaning systems and parameters
  - Ultrasonic
  - Washing
  - Disinfection
- Packaging and technique
- Sterilization process types and parameters
  - Ensure these parameters are available on system in the facility

Process	Restricting Condition
EtO sterilization	Temperature: 55 ± 2°C Relative Humidity: 70 ± 5% Pressure Set Point: 25.4 PSIA Ethylene Oxide Concentration: 600 ± 30 mg/L Gas Exposure Time: 2 hours Detoxification Time: 0 hours Drying time: 0 hours Aeration: 12 hours at 55± 2°C

Autoclave **Note:** Do not autoclave endoscopes.	Cycle: Pre-vacuum Temperature: 270° - 272°F or 132° - 134°C Minimum Exposure Time: 4 minutes* Average Dry Time: 20 minutes
Sterrad® 100 Sterilization System	Vacuum Phase: 5-20 minutes Injection Phase: 6 minutes Diffusion Phase: 44 minutes Plasma Phase: 15 minutes Vent Phase: 5 minutes Total Cycle Time: Approximately 75 minutes
Steris System 1® Sterile Processing System	Sterilant: Peracetic Acid Sterilization time: 12 minutes Process temperature: 50 - 56°C Total processing time: 30 minutes **Note:** Please consult the Steris System 1® Sterile Processing System Operators Manual for detailed instructions for use.

Source: Intuitive – Da vinci User Manual

Summary

1. Advancements in MIS techniques and instrumentation has brought a new wave of technology that will continue to rapidly evolve
2. Robotics incorporated for both rigid, semi-rigid and flexible endoscopy
3. Consolues, carts, instruments and accessories have specific reprocessing instructions
4. Point of use pre-cleaning, manual cleaning and automated cleaning must be effectively performed.
5. Remember – these are invasive surgical techniques using CRITICAL medical devices representing a high risk the patient and the instruments must be terminally sterilized.

References

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3. IEEE Spectrum. Watch 6 of coolest surgical robots in action. https://www.youtube.com/watch?v=2fnv_3qn3Yc

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