A.R.A.K.N.E.S.
Array of Robots Augmenting the KiNematics of Endoluminal Surgery

May 3-4 May, 2012,
Athens, Greece

A novel platform for Scarless Robotic Surgery: the ARAKNES (*Array of Robots Augmenting the KiNematics of Endoluminal Surgery*) Integrating Project

ARAKNES Project Coordinator

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Speaker:

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www.araknes.org

The ARAKNES (Array of Robots Augmenting the KiNematics of Endoluminal Surgery) Project has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

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Outline

- Motivations and strategy
- A novel platform for Scarless Robotic Surgery: ARAKNES Project
  - Objectives
  - Key results
  - Progress status
- ARAKNES first prototype
- ARAKNES exploitation

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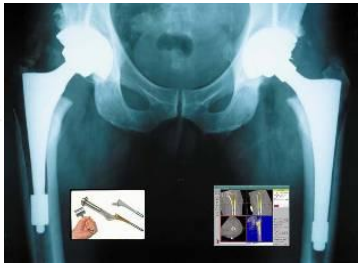
Medical Robotics: an increasingly successful clinical and industrial field

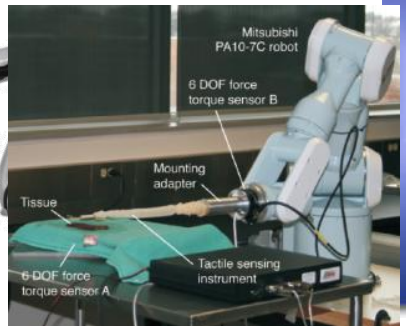


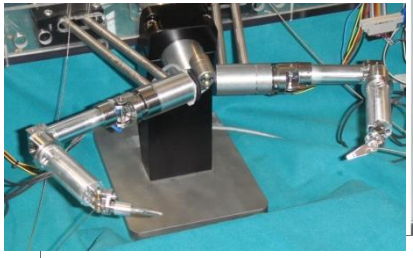
















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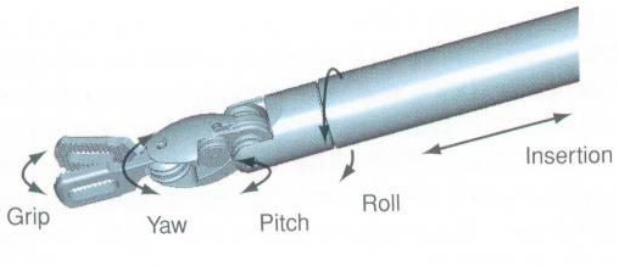
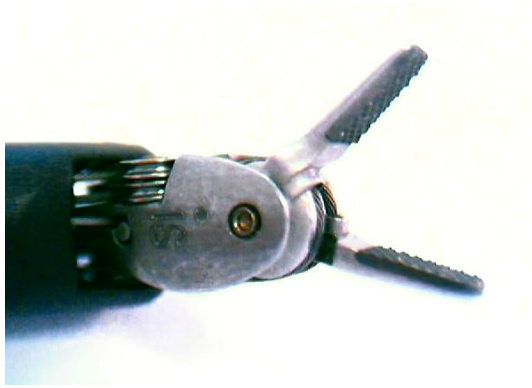
A success story in surgical robotics: the "Da Vinci" system





The main reasons for success:

- **VERY HIGH SURGICAL PRECISION**
- **Minimal invasiveness**
- **Intuitive control**

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A success story in surgical robotics: the "Da Vinci" system

HOWEVER

- System console is too much immersive
- 4 12-mm diameter accesses + 1 additional 5-mm service access
- Very expensive (1.5+M€ system, plus disposables and servicing)

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Robotics Surgery: Lessons Learned

Problems to be solved for full acceptance of robots in surgery:

- Real application domains and procedures that benefit
- Cost/benefit clearly proved
- Time of intervention
- Time and complexity for set up

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ARAKNES Project

Open Surgery

Laparoscopic Surgery

Robotic Surgery

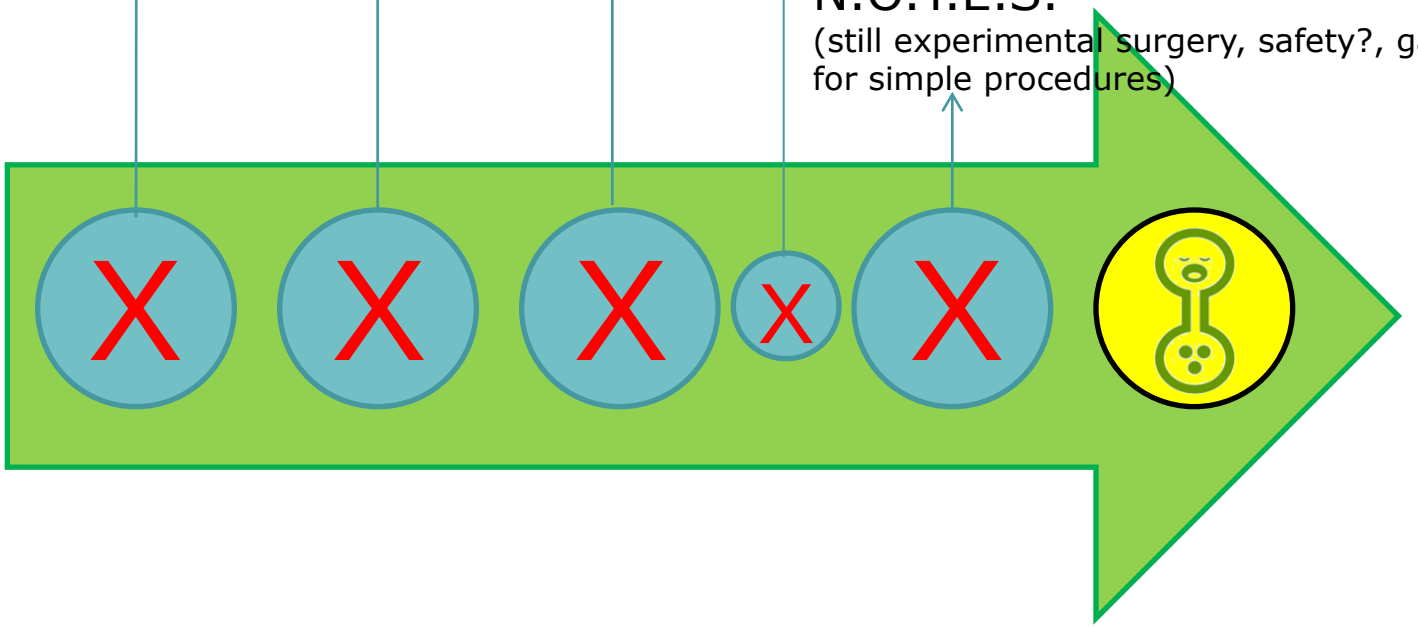
(costs, more invasive than std laparoscopic, for selected cases)

SPL

(triangulation, ergonomics)

N.O.T.E.S.

(still experimental surgery, safety?, gastric hole, not reproducible, for simple procedures)



ARAKNES the future gold standard for MIS

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ARAKNES Integrating Project

- **Grant Agreement number:** 224565
- **Project acronym:** ARAKNES
- **Project title:** Array of Robots Augmenting the KiNematics of Endoluminal Surgery
- **Funding scheme:** Large-scale integrating project (IP), FP7-ICT-Challenge 3: Components, systems and engineering/Micro/nano systems
- **Project website address:** www.araknes.org
- **Start date of project:** 01/05/2008
- **Duration:** 48 Months + 6 Extension months
- **Total budget:** € 11.100.000,00
- **EU contribution:** € 8.100.000,00

Consortium

Coordinator
Scuola Superiore Sant'Anna (SSSA), ITALY

MicroTech S.r.l. (MT), ITALY

University of Barcelona (UB), SPAIN

Imperial College London (ICL), UNITED KINGDOM

KARL STORZ GmbH & Co. KG (KST), GERMANY

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Università di Pisa (UNIPI), ITALY

ST Microelectronics (STM), ITALY

Ecole Polytechnique Fédérale de Lausanne (EPFL), SWITZERLAND

University of St. Andrews (USTAN), UNITED KINGDOM

novineon Healthcare Technology Partners GmbH (NVN), GERMANY

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The ARAKNES team

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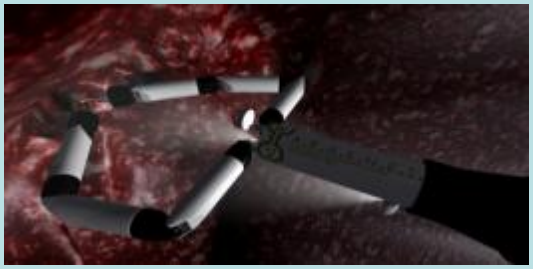
ARAKNES Project: objectives

To integrate the advantages of traditional open surgery, laparoscopic surgery (MIS), and robotics surgery into a deeply innovative system for <u>bi-manual, tethered, scarless surgery based on microrobotic instrumentation</u>







Main intended interventions: *Gastric and abdominal surgery*

- Single-port access/transluminal bariatric surgery (both with restrictive procedures and malabsorptive procedures)
- Cholecystectomy (a *de facto* benchmark for surgical devices)

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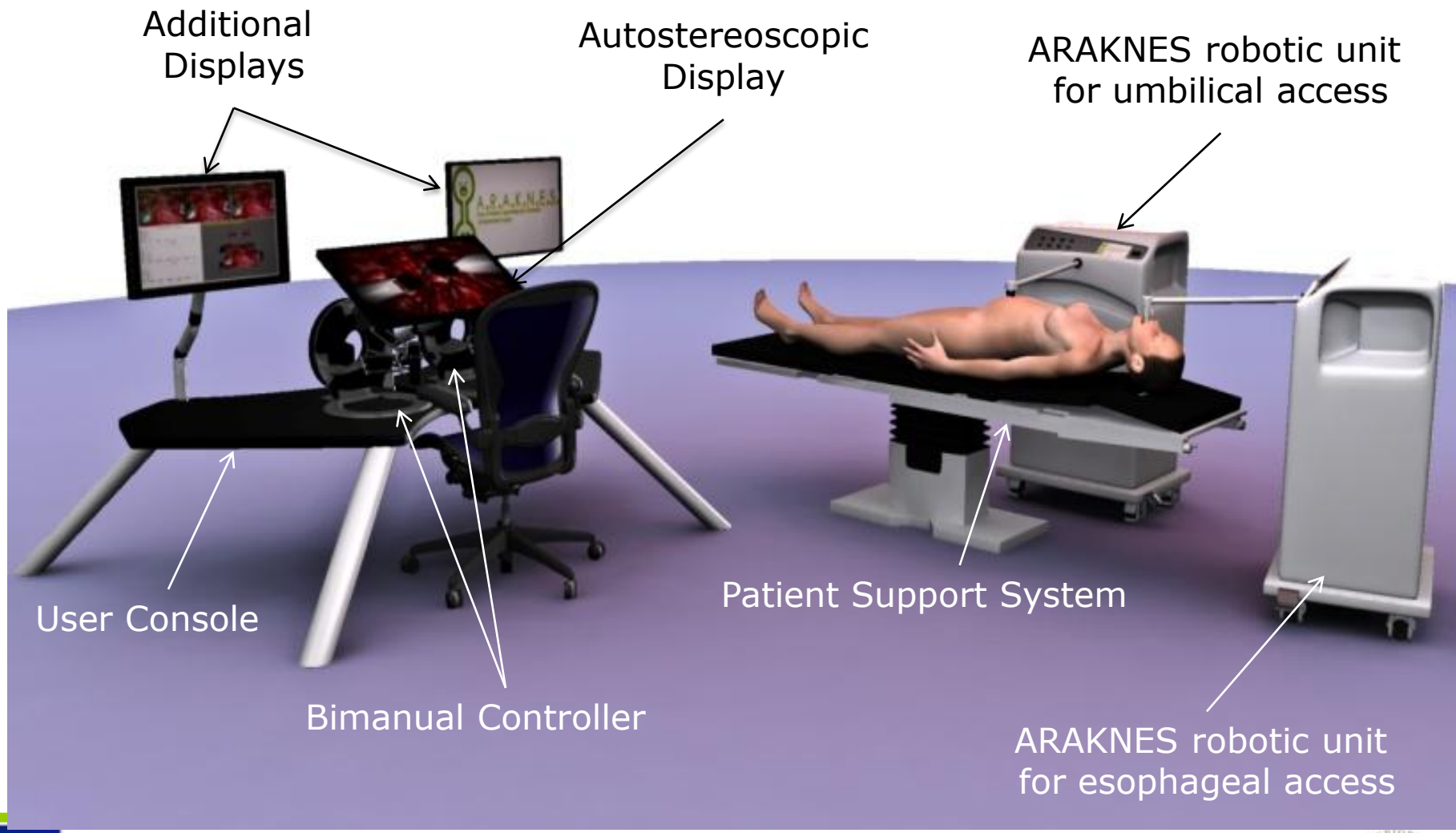
Surgical scenario and System Architecture



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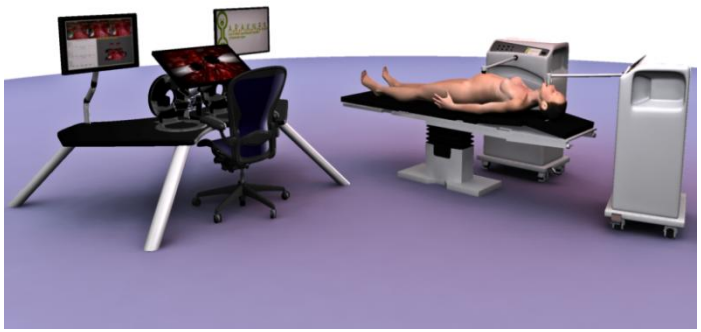
The ARAKNES platform includes:

- A flexible oro-pharyngo-oesophageal access port and an umbilical access port;
- A set of assistive and operative miniaturized robots allowing a bi-manual operation inside the abdomen or the stomach;
- An imaging system consisting of
  - ✓ endoscopic stereo-cameras at the distal end of the robotic platform, to restore depth perception, combined with panoramic cameras embedded in the access ports;
  - ✓ additional vision modules for increasing points of view and surgical operations safety and flexibility;
- Photonic-based and chemical-based devices;
- The operating console, haptic interfaces and augmented reality solutions.



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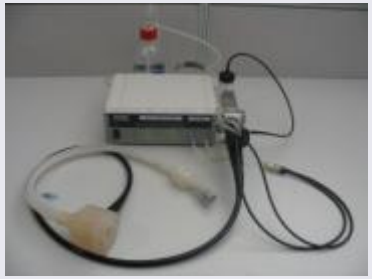
ARAKNES access port: Prototypes

Picture		Vision System	Features
	2nd prototype	Vision system Housing	• Flexible multilumen tube (oval section) • Closing Handle (Stability for the vision system) • Insulation: O-ring • Insufflation throughout a dedicated lumen • Balboon fixing mechanism


 
	2nd prototype
	Integration of the 2nd Prototype
		No Vision and Illumination System
		HD panoramic Camera and Illumination
			• Intra-gastric and Trans-gastric approaches
			• Components:
			  • Multilumen tube has been realized by extrusion of a silicone medical grade PE600
			  • Handle(3D printed) contains the connection to the supply tube (vision, air, water)
			  • Balloon fixing mechanism
			• 22 mm OD and 14 mm ID
			• Length 90 cm
			• Inserted in the oesophagus trough a guiding endoscope

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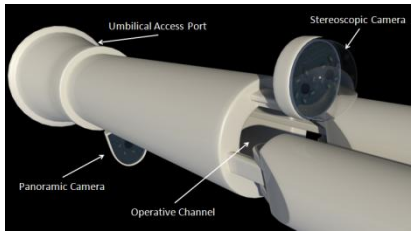
ARAKNES Optical System

Image acquisition systems



Vision system for access ports

Vision system for robotic modules

Flexible Oesophageal access port (MT)

Rigid Umbilical access port (SSSA)

Fixed panoramic vision system (KST)

- Fully integrated in tube wall (MT)
- HD-resolution
- 2D
- LED illumination

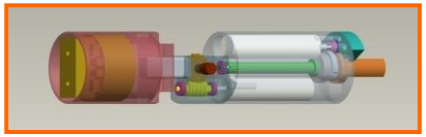
Swing-out panoramic vision system (KST)

- Fully insertable in the umbilical access port (MT)
- No hindrance for other instruments
- HD-resolution
- 2D
- LED illumination

Fixed stereo vision system (KST)

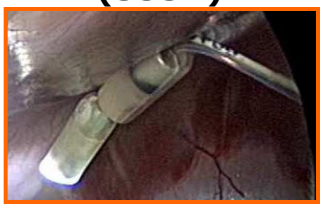
- Fully insertable in the SPRINT-introducer (SSSA)
- No hindrance for other instruments
- HD-resolution
- 3D
- LEDs + Light-fibres

Steerable stereo vision system (SSSA)



- Fully insertable in the access port
- No hindrance for other instruments
- Pan and Tilt DOFs
- HD resolution
- 3D
- LED illumination

Steerable stereo vision system (SSSA)



- Fully insertable
- Magnetic internal mechanism (MIM)
- Up to 5 DOFs (external and internal actuation)
- HD resolution
- 3D
- LED illumination

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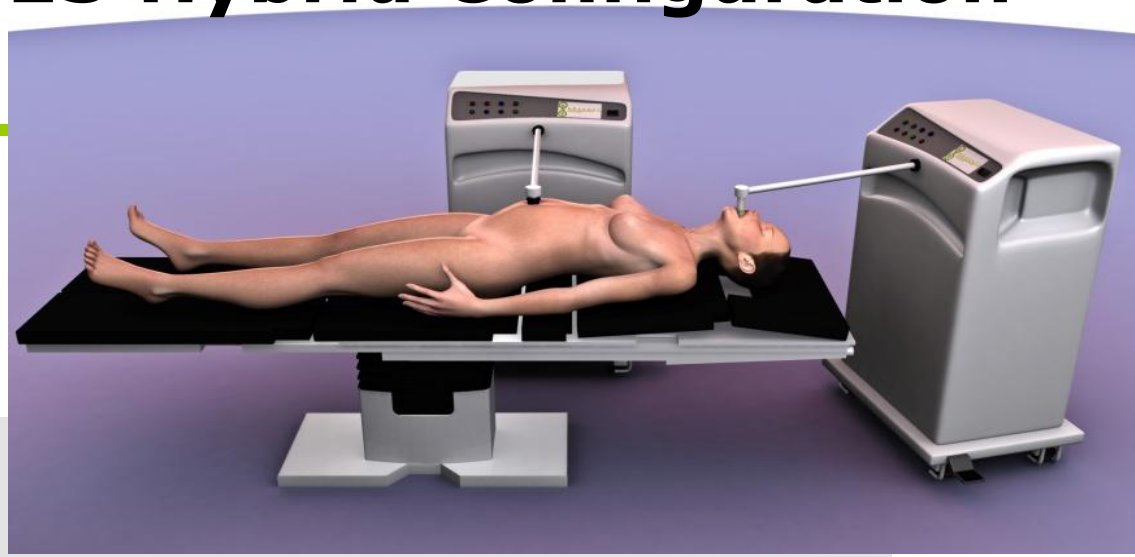
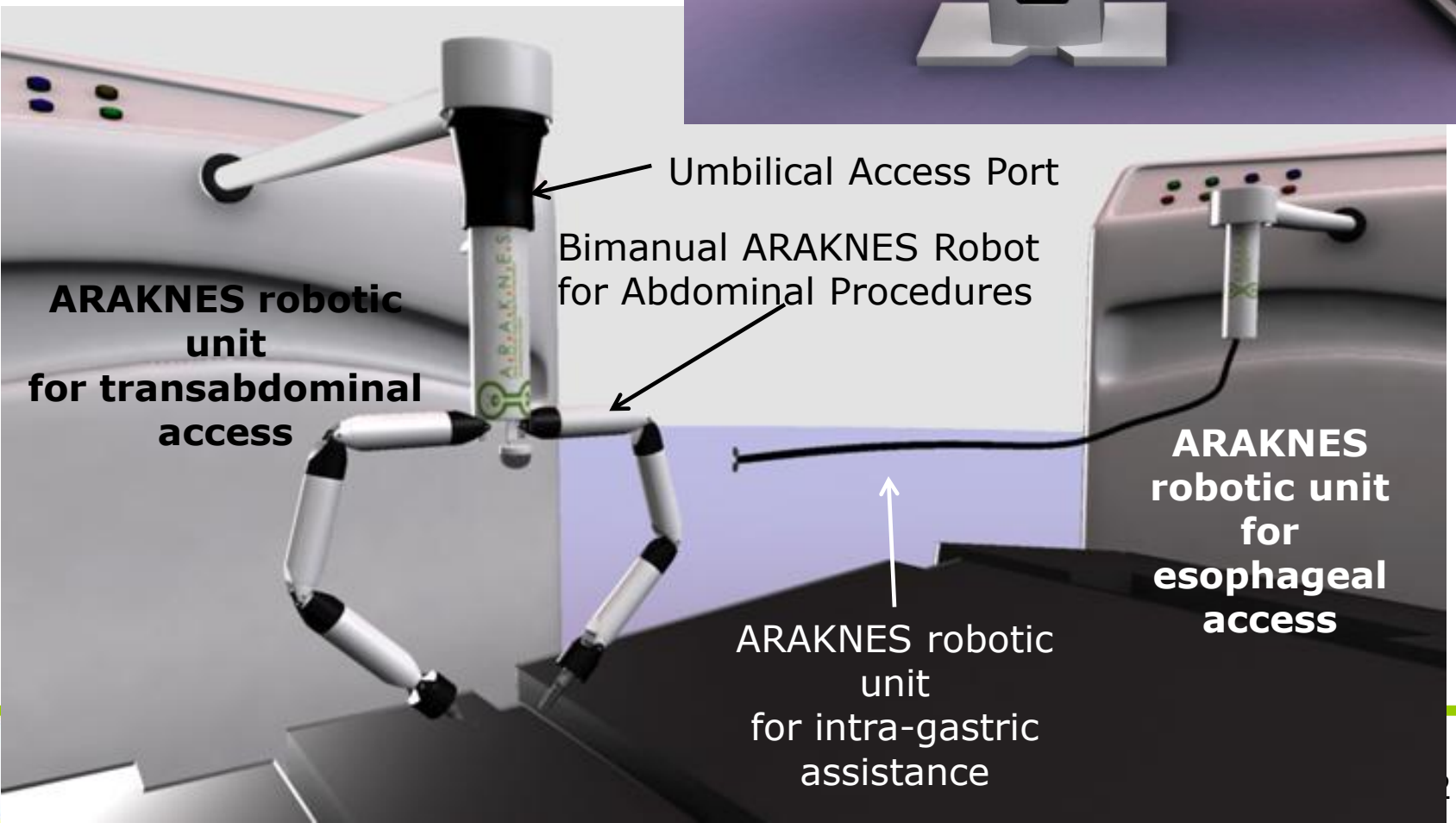
ARAKNES Hybrid Configuration

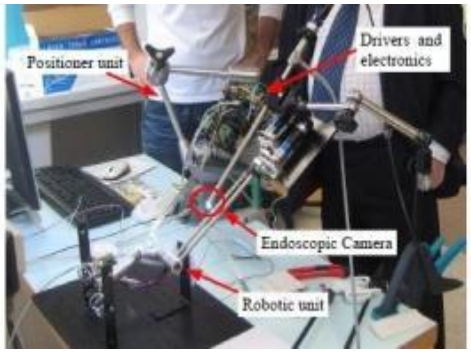
Double access approach (the "**HYBRID" APPROACH**), from the oesophagus **and** through the abdomen

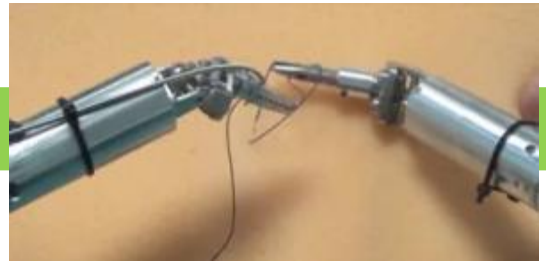




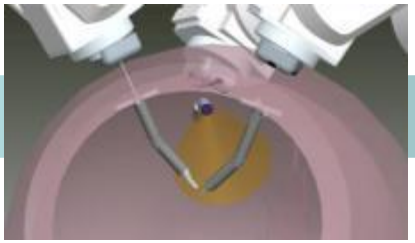
ARAKNES robot - Short term and long term approaches

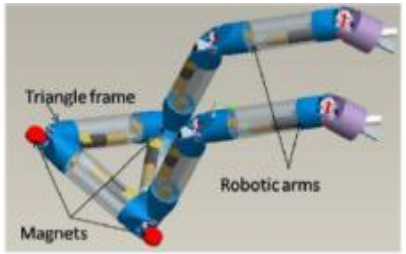
Clinical Platform (Single Port umbilical access)

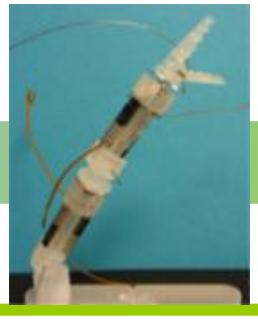




Research Platform (trocar/NOTES access)







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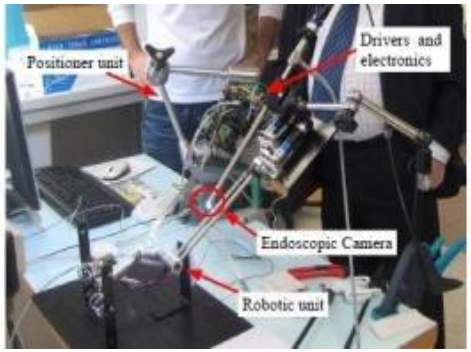
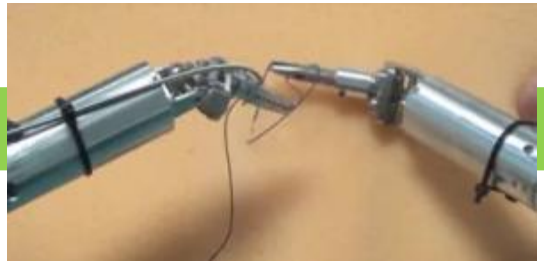
Short term and long term approaches

Clinical Platform (Single Port umbilical access)





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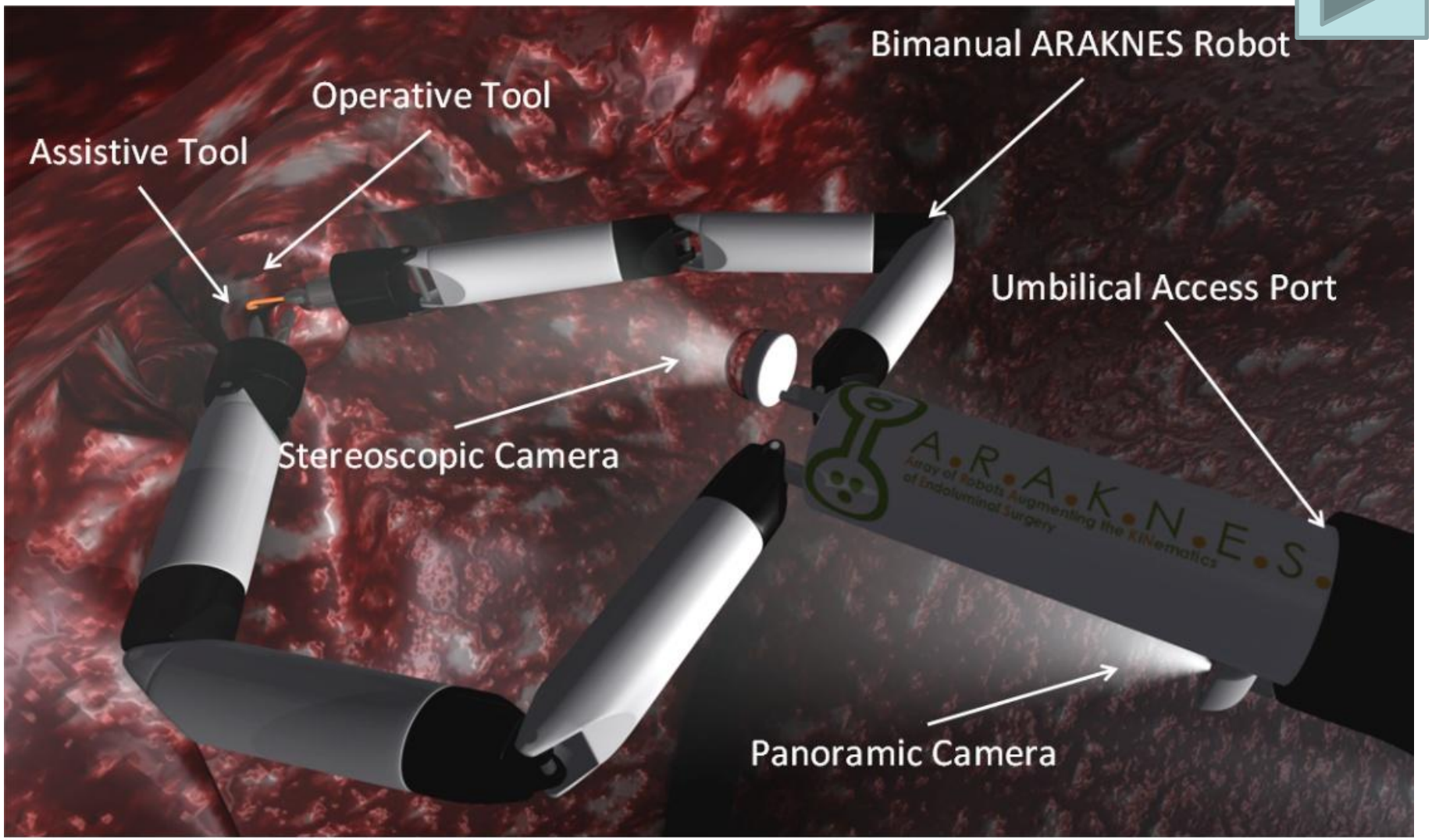
SPRINT: Single-Port lapaRoscopy bImaNual roboT



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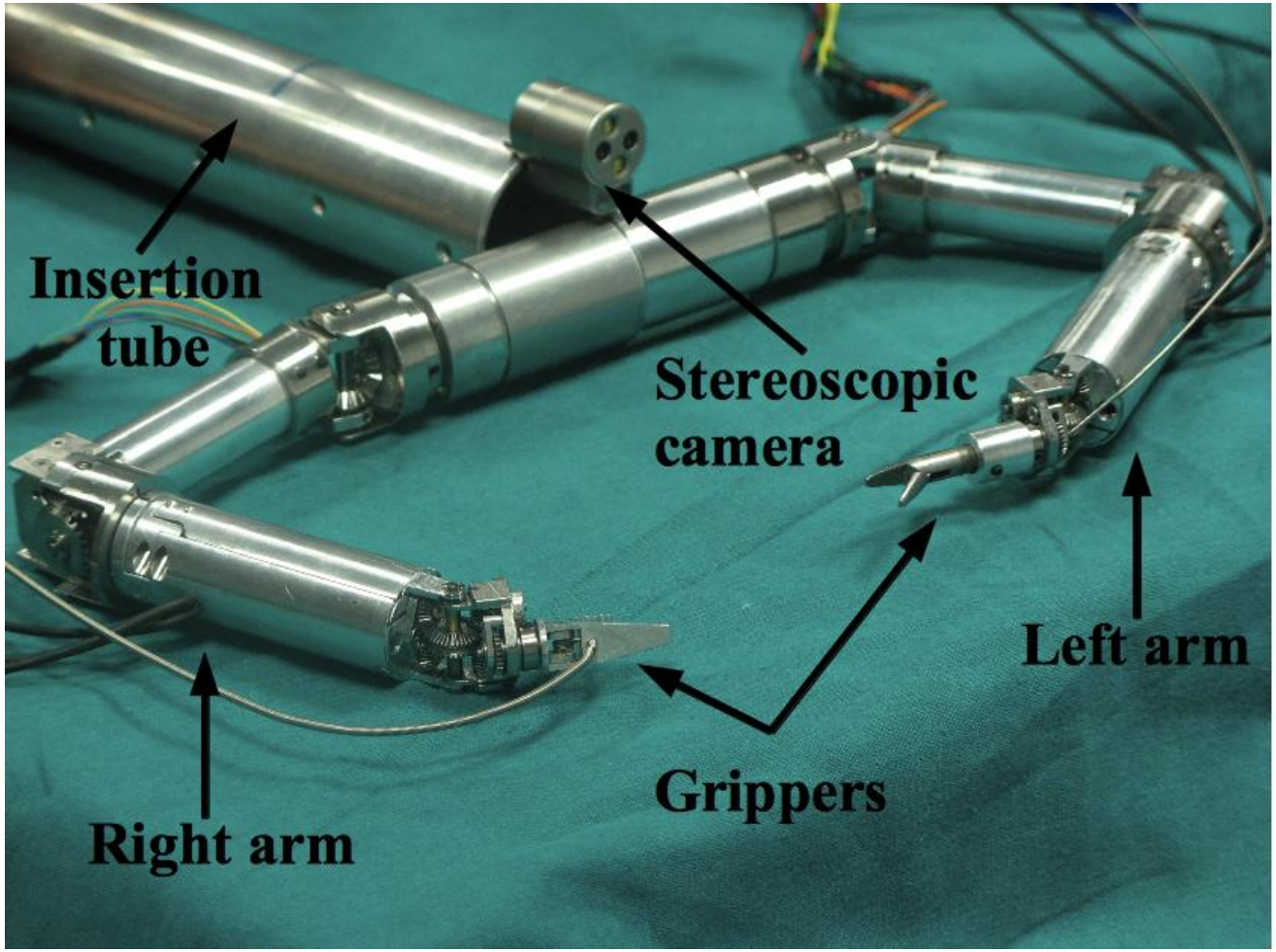
The SPRINT robot



Single Port External Diameter: 30 mm

External Diameter of the robot arms: less than 20 mm

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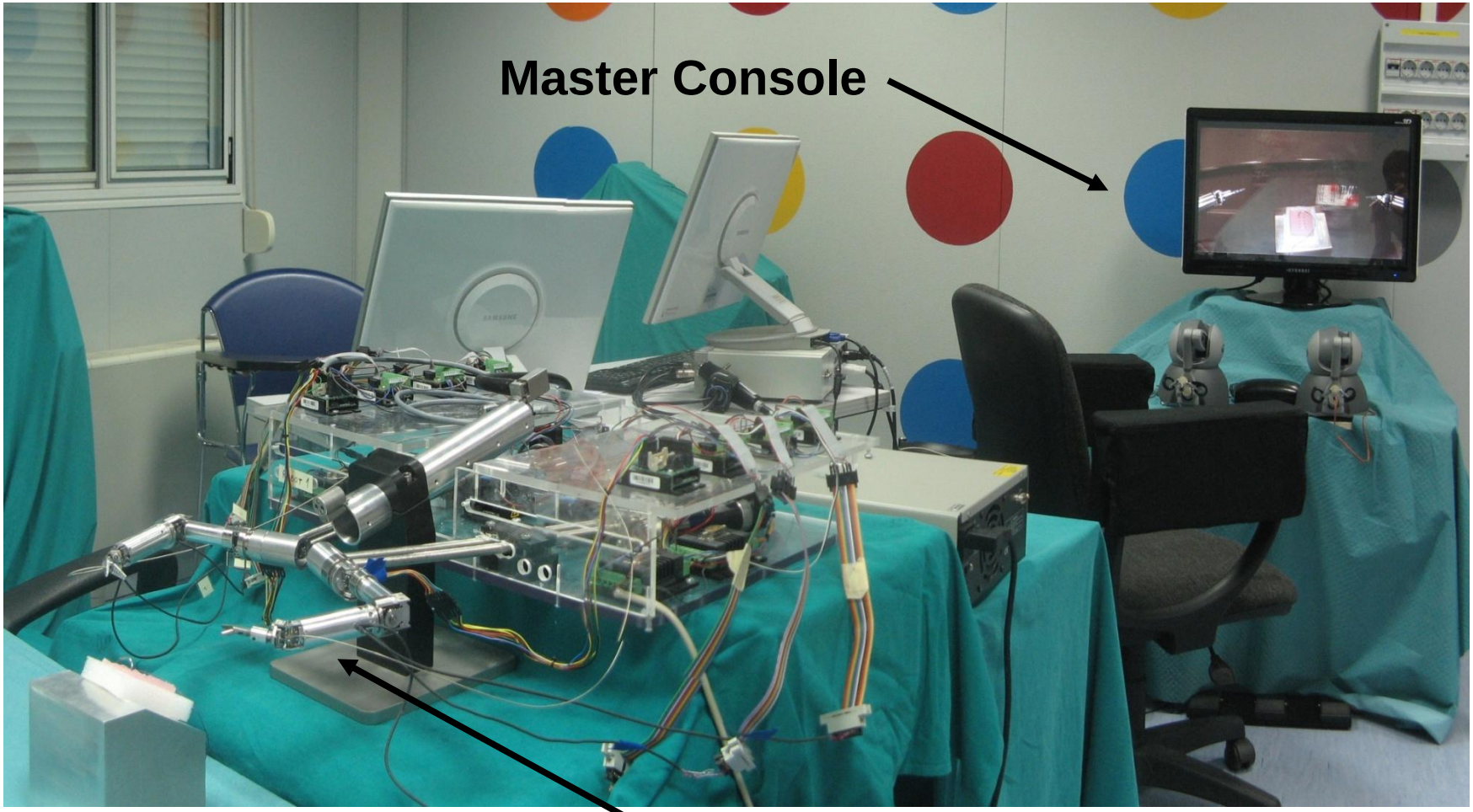
SPRINT ROBOTIC PLATFORM



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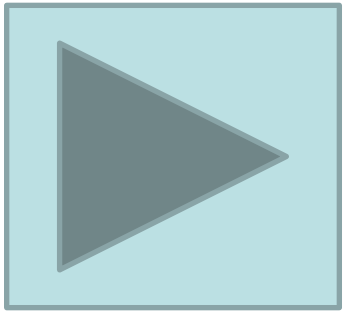
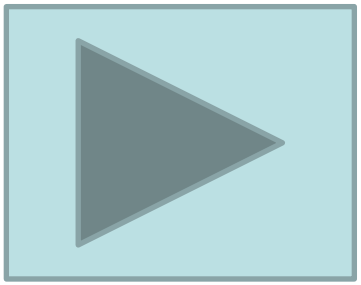
SPRINT System: simulated pick and place tasks



SPRINT System: simulated suturing tasks



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SPRINT robot In-Vivo Tests

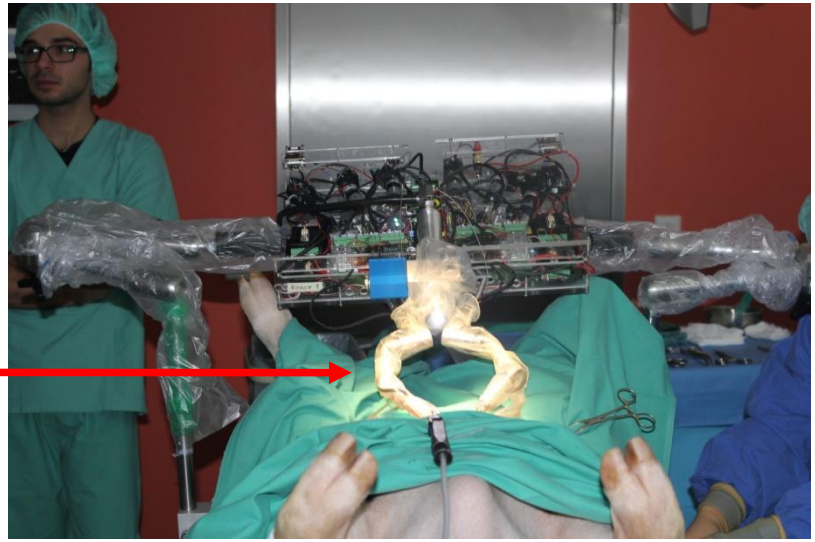
Master Console

3D Monitor

Haptic Interfaces

Slave Manipulator

SPRINT robot



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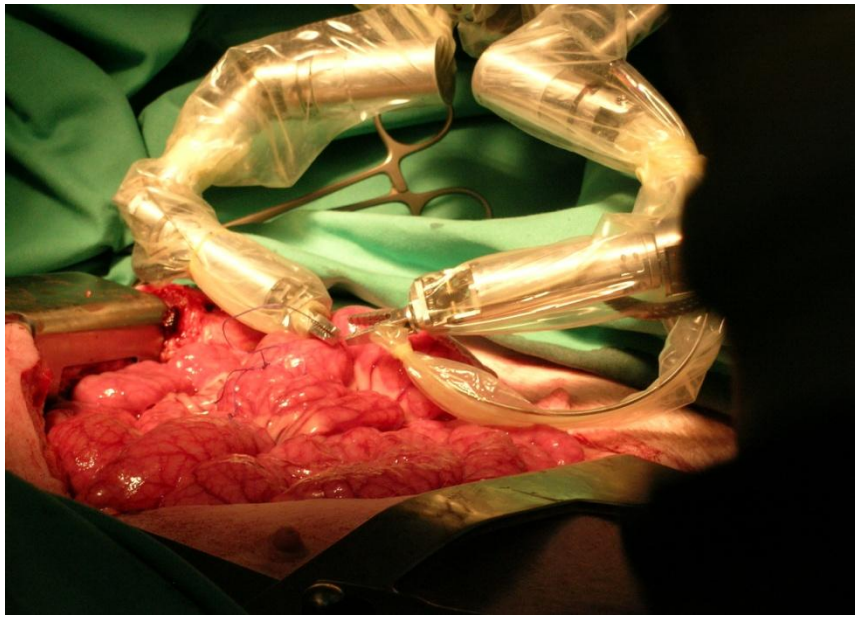
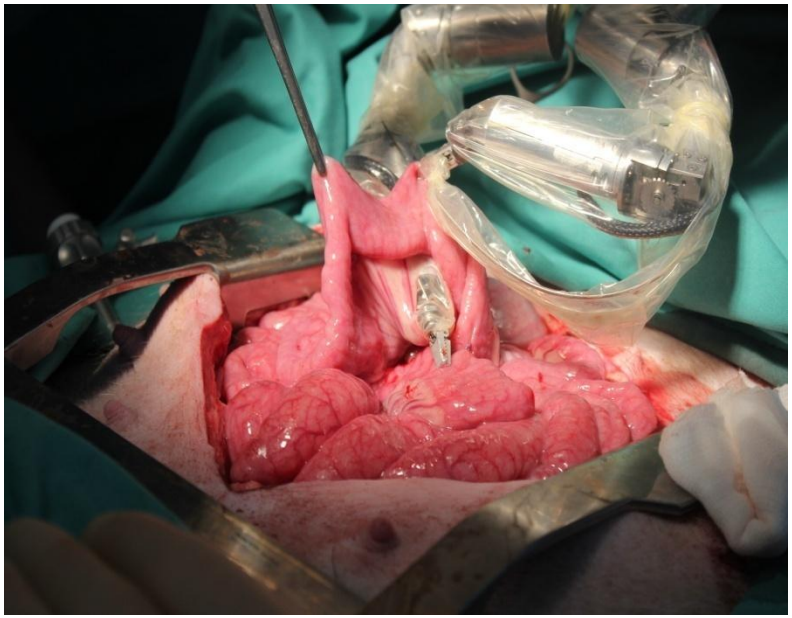
In-Vivo Tests: Results

Small bowel entero-enterostomy



Ligation of a mesenteric vessel bundle



Results of In-Vivo Tests presented at **SAGES 2012** Annual Meeting:

A New Robotic System for Single-Incision Laparoscopic Surgery: Preliminary Experience.

G. Basili, G. Pietroni, A. Menciassi, D. Pietrasanta, M. Niccolini, O. Goletti

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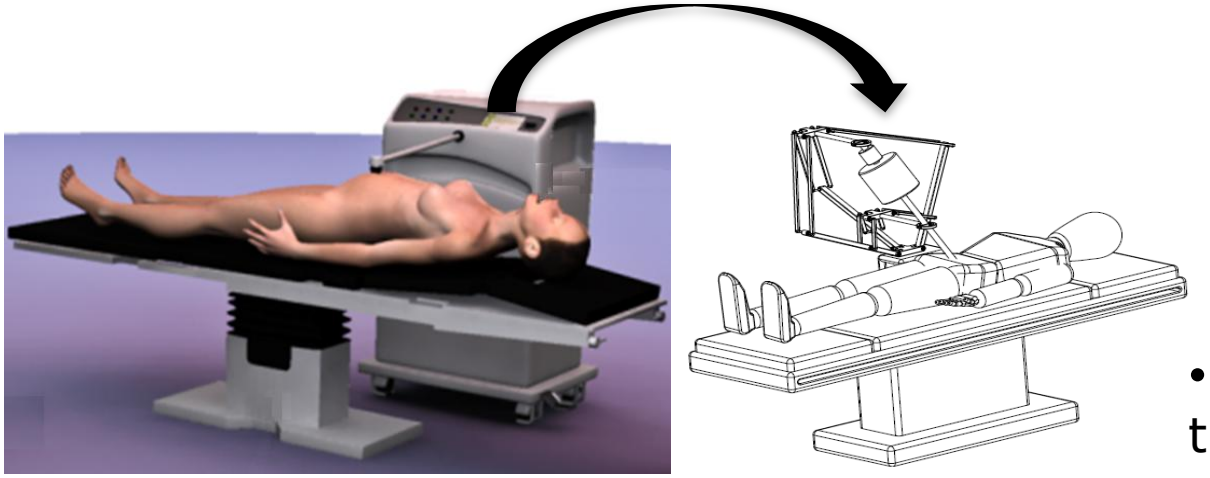
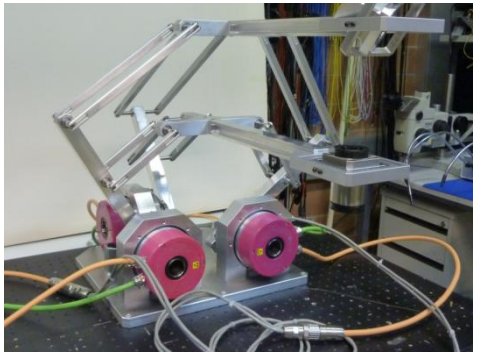
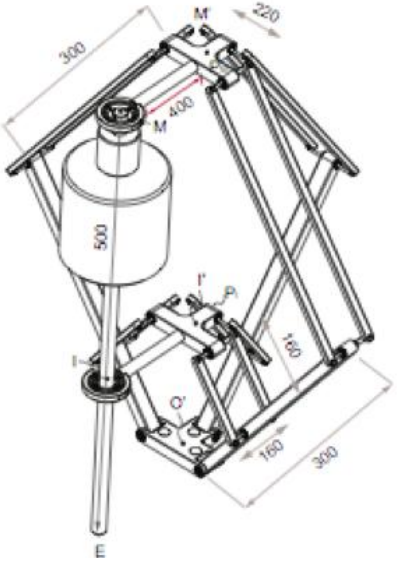
ARAKNES External manipulator: DIONIS system



DIONIS manipulator





- External DOF to position the micro-arms in the abdominal cavity
- Novel parallel kinematics, able to provide 3 rotations and 1 translation
- Axes intersect at a remote centre of rotation in the MIS entry port

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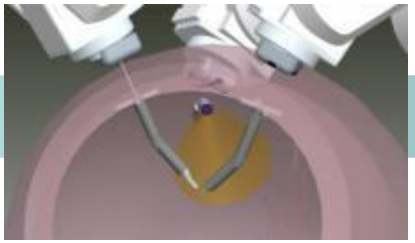
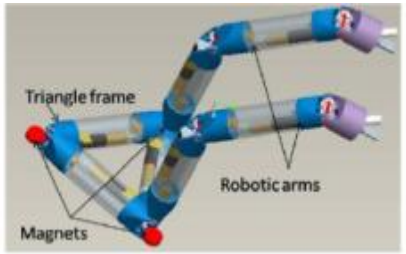
ARAKNES Research platform

Approach preserving the oesophageal access

Research Platform (trocar/NOTES access)





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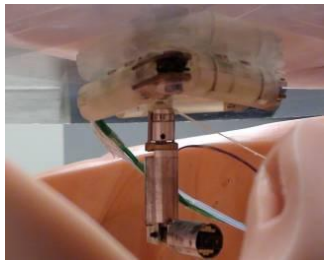
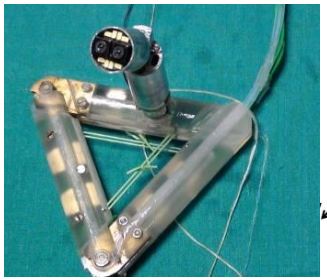
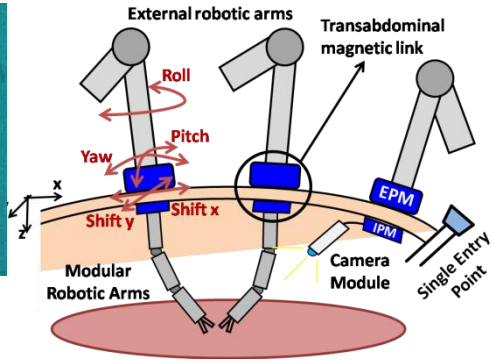
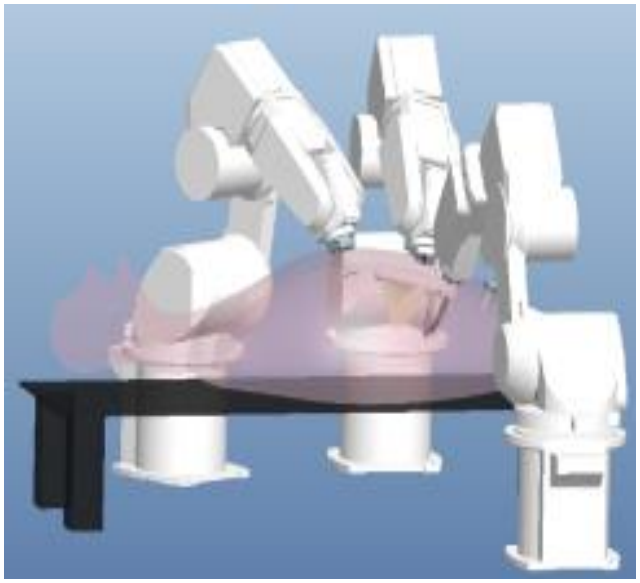
ARAKNES Research platform

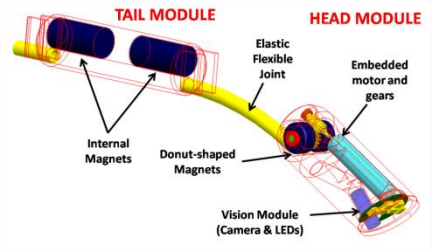
- **Magnetic frame** for robot positioning or for auxiliary device supporting
- **Robotic miniature manipulators** for dedicated tasks in MIS surgery
- **Magnetic levitation camera**

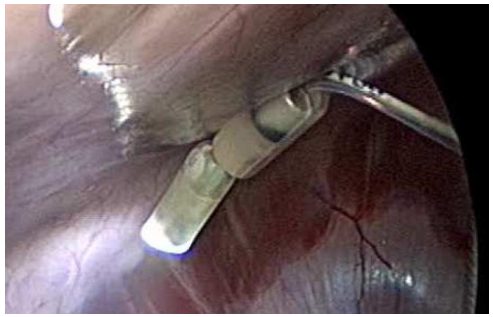












- **Trans-abdominal magnetic link**
  - Passive link
  - Active magnet rotation
  - Active magnet translation

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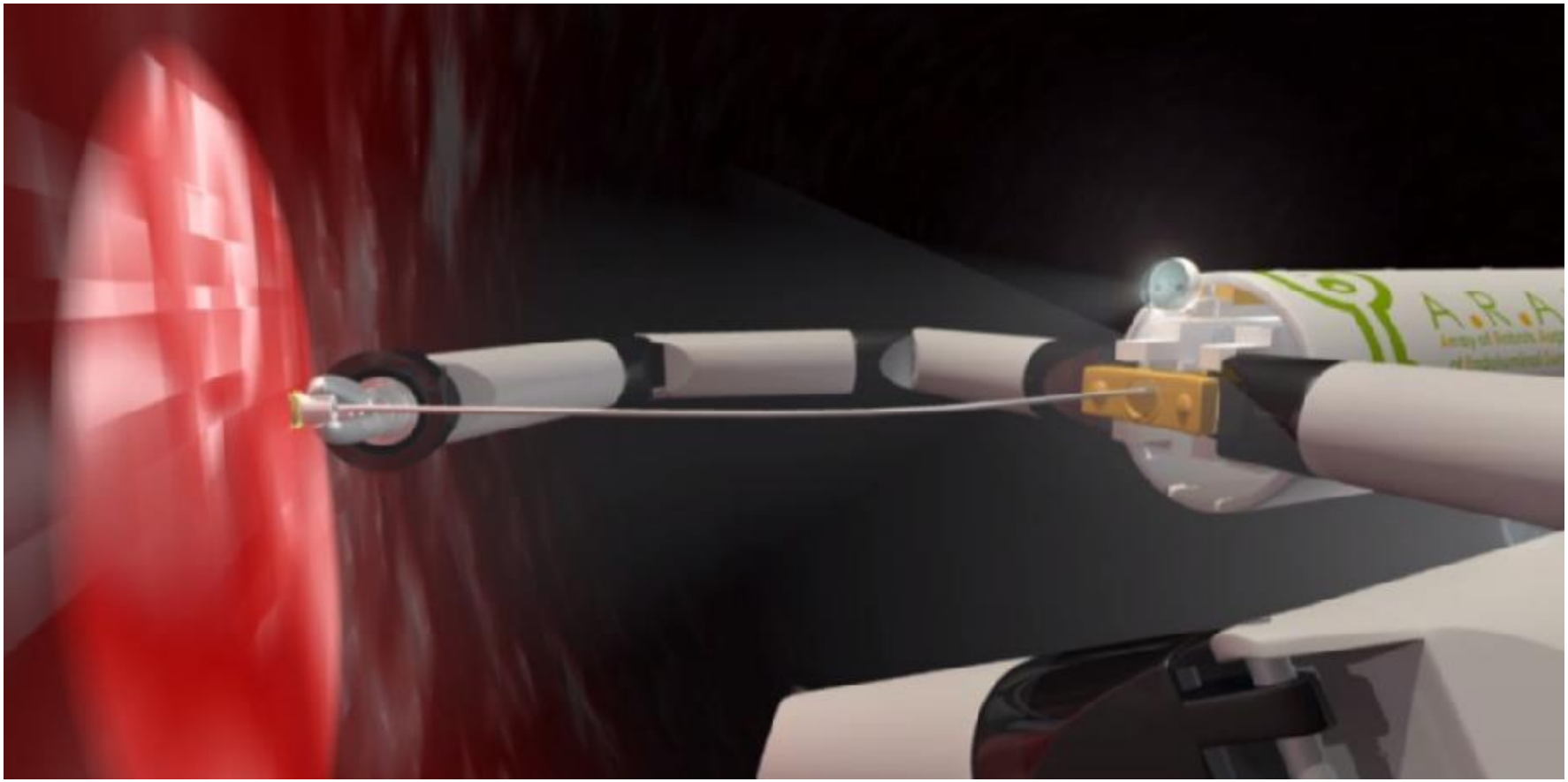
ARAKNES Photonic-based and chemical-based devices



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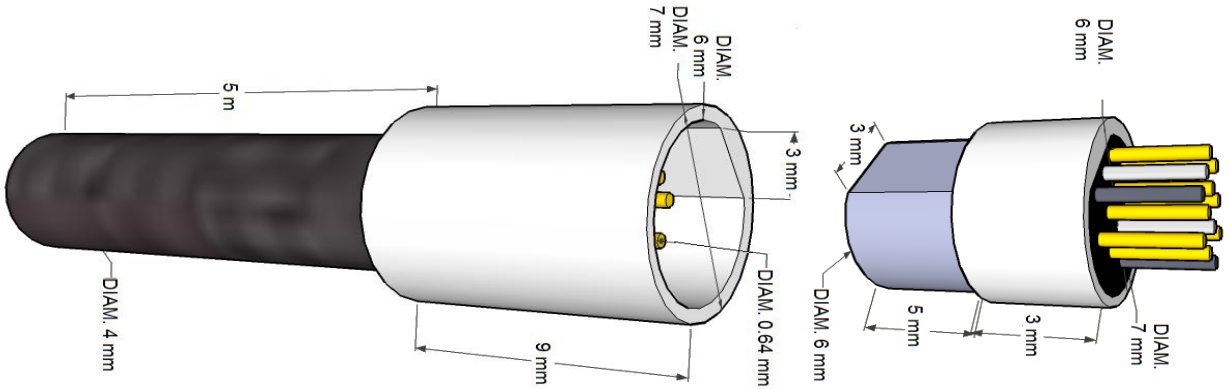
ARAKNES Micro and nano-systems for endoluminal monitoring & therapy

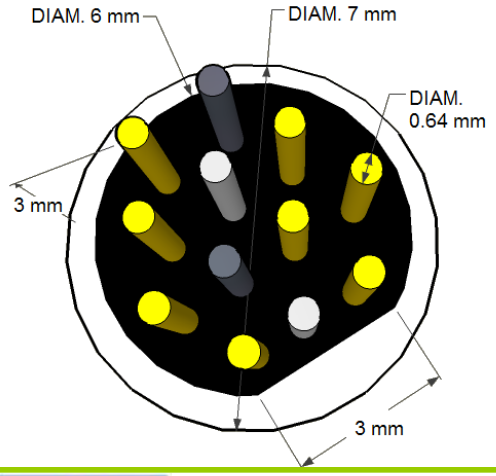
Electrochemical Multi-sensor array for ischemia monitoring in tissue.

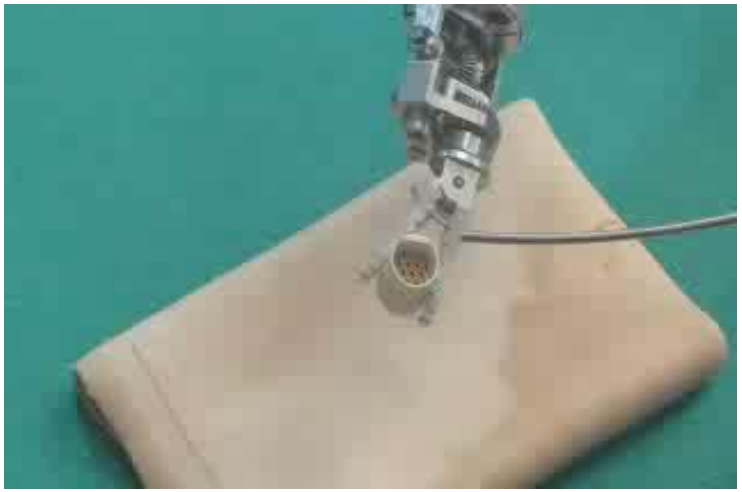
Array Design:

Needle array for the electrochemical detection of pH, K^+, pO_2 and pCO_2 in tissue has been developed by UB



Designed to be reusable, and with appropriate size for the endoscope and robot manipulation





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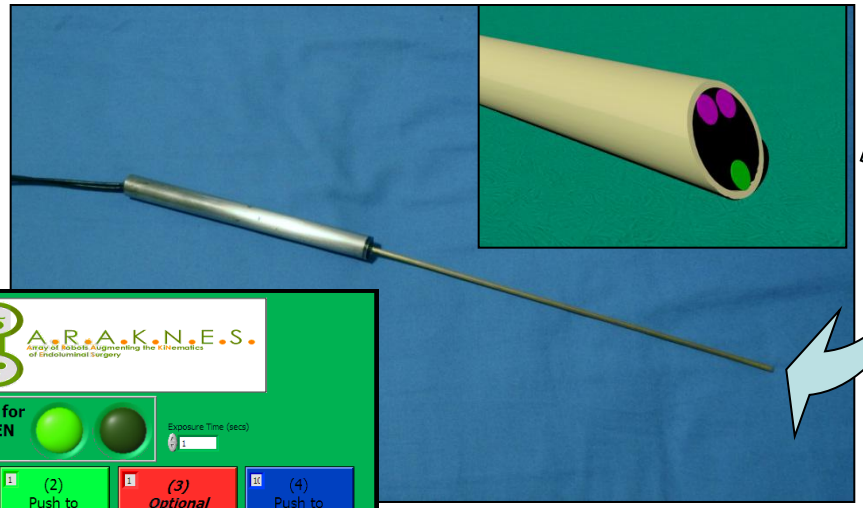
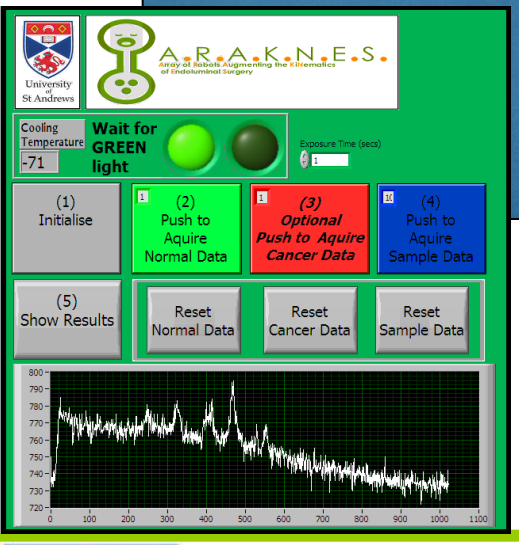
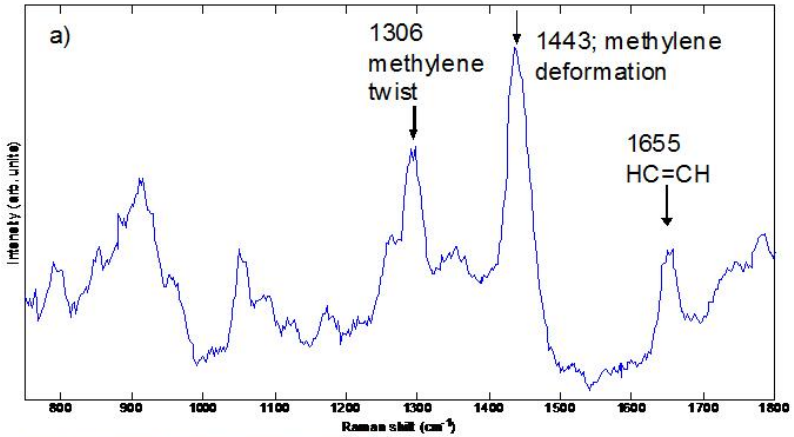
ARAKNES Optics & Photonics technologies

Optics & photonics for monitoring, diagnostics and therapy

- ✓ **Raman spectroscopy**
- ✓ **OCT system – optical coherence tomography**
- ✓ **NIRS laparoscopy**







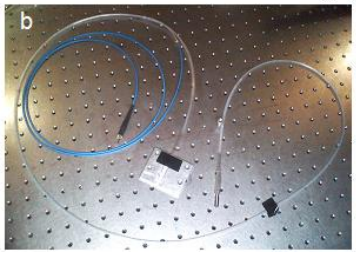


Fig1. a) Raman spectrum of porcine tissue taken with b) disposable Raman probe designed and constructed at USTAN. Acquisition time was 5s and power 30 mW at sample. Distinctive Raman peaks obtained match with literature[1]

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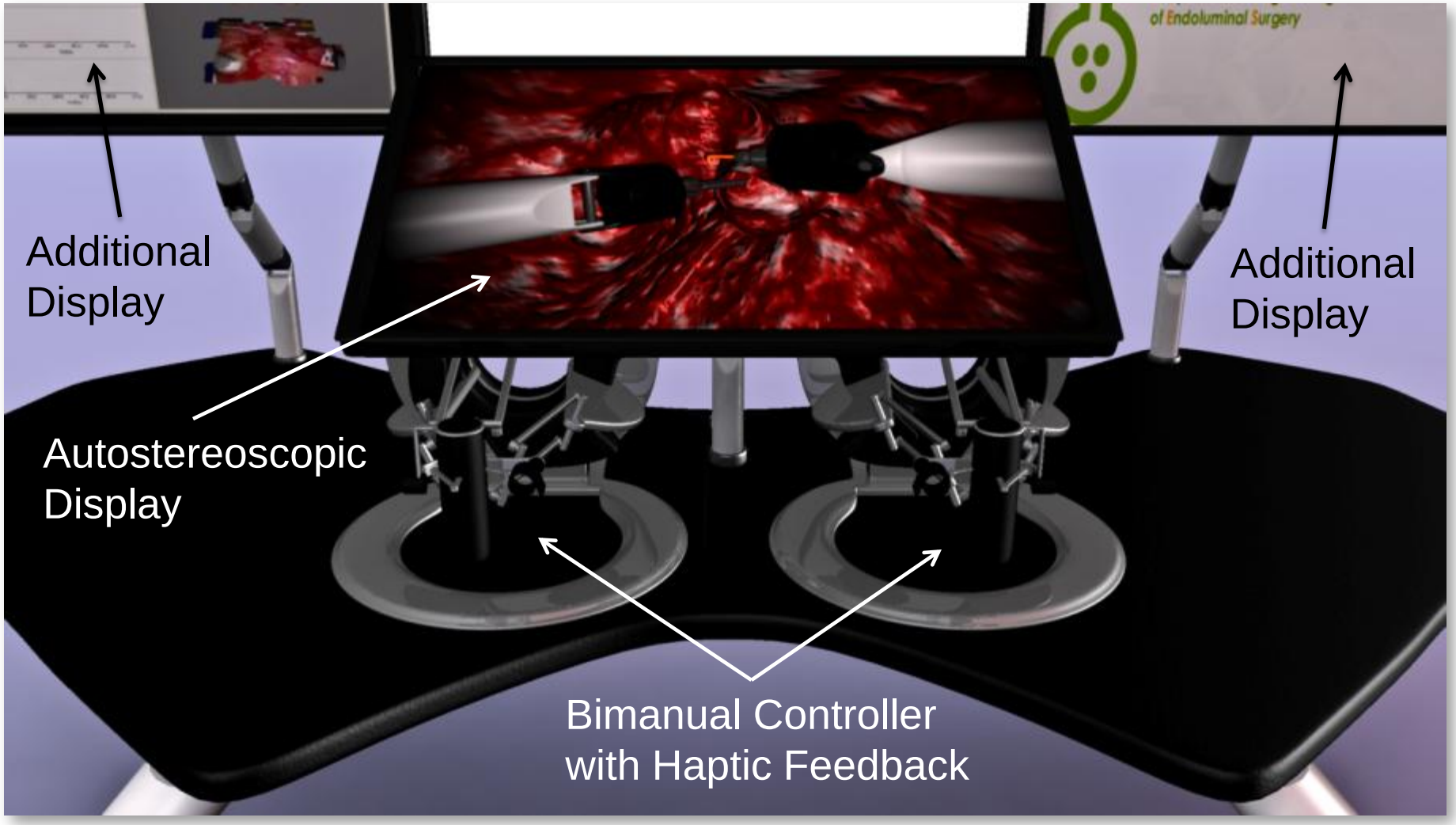
ARAKNES Console



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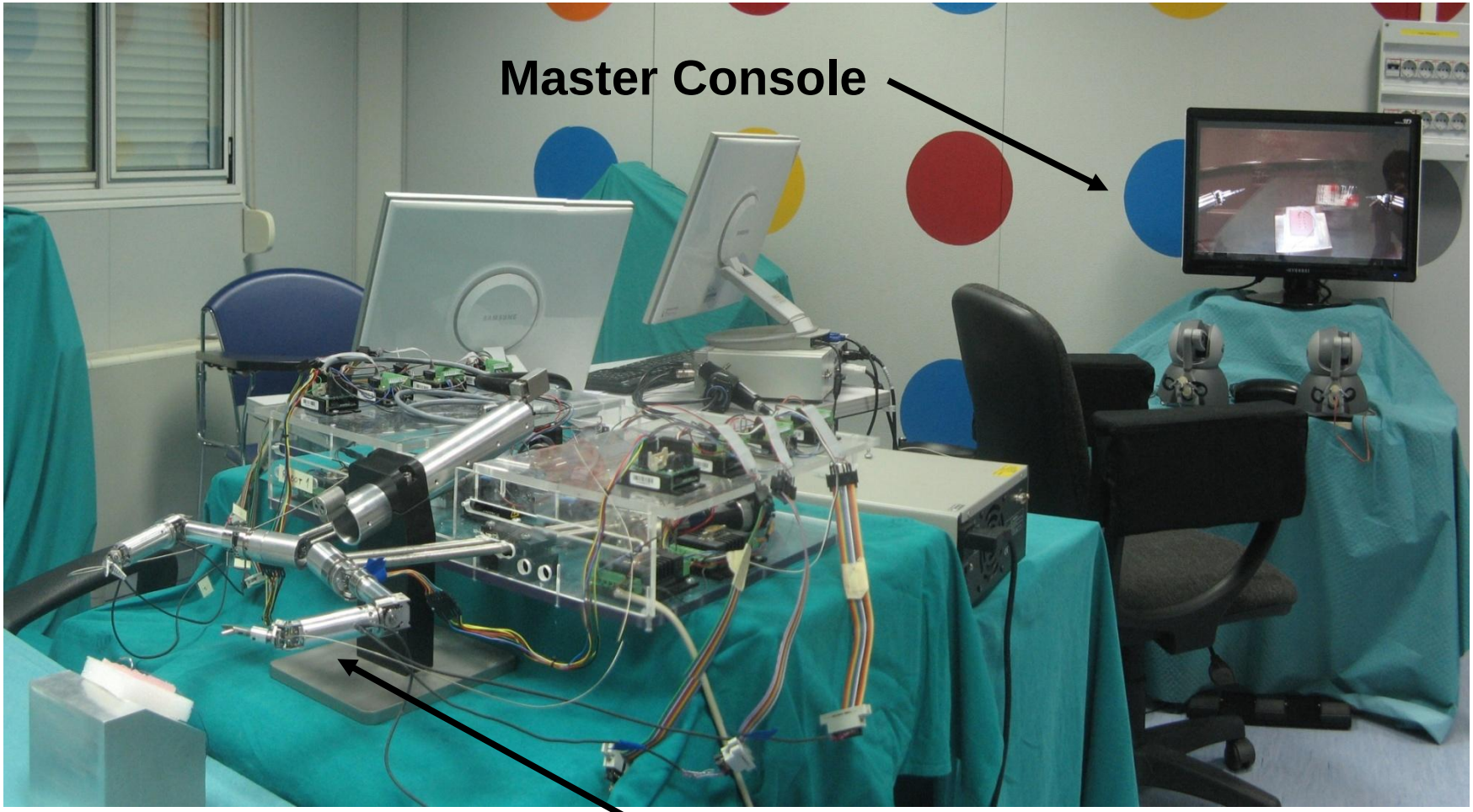
SPRINT ROBOTIC PLATFORM



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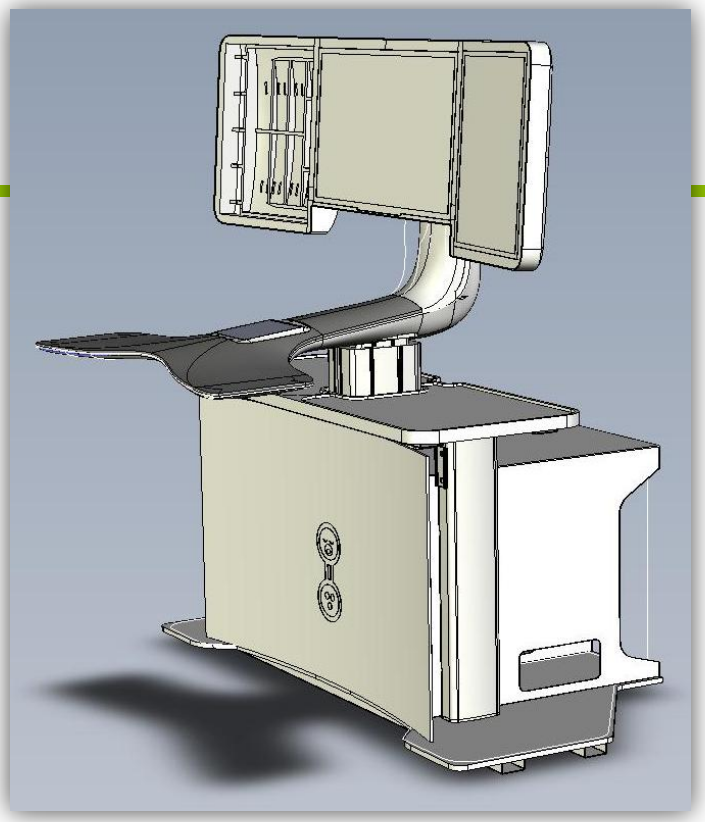
ARAKNES console



- ✓ Ergonomic design
- ✓ Fully user adjustable (height, screen tilting)
- ✓ 3D visualisation
- ✓ Eye-tracking enabled
- ✓ Generic haptic manipulators can be accommodated
- ✓ Ergonomic display of all data involved
- ✓ Setup, pre-op, intra-op phases

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Outline

- Motivations and strategy
- A novel platform for Scar-Less Robotic Surgery: ARAKNES Project
  - Objectives
  - Key results
  - Progress status
- ARAKNES platform
- ARAKNES exploitation

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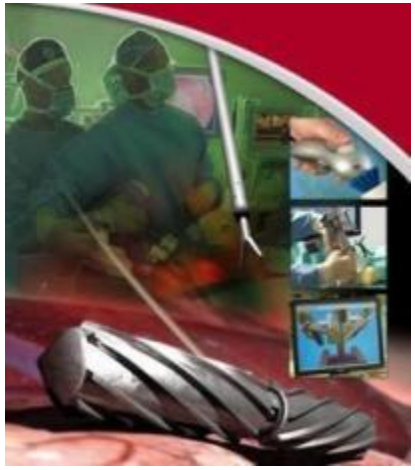
We know our COMPETITORS …

Other Relevant Competitors

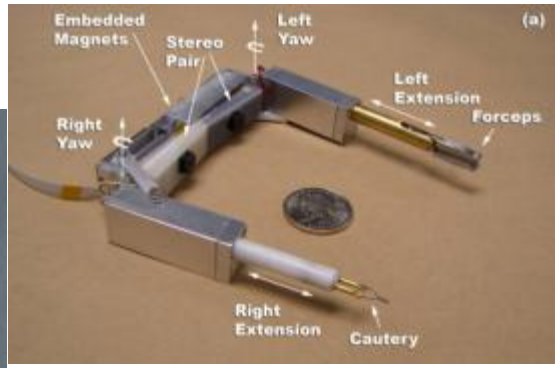
- Olympus Surgical
- Fujinon
- Boston Scientific
- Ethicon Endo-Surgery
- Covidien

EndoWrist Instruments
Intuitive Surgical, Inc.
USA

DaVinci Surgical System
Intuitive Surgical, Inc.
USA



Nebraska Surgical Solutions, Inc., USA



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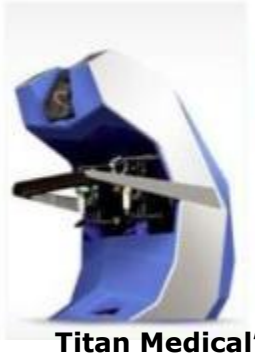
We know our COMPETITORS …

Sofie system from Eindoven University of Technology

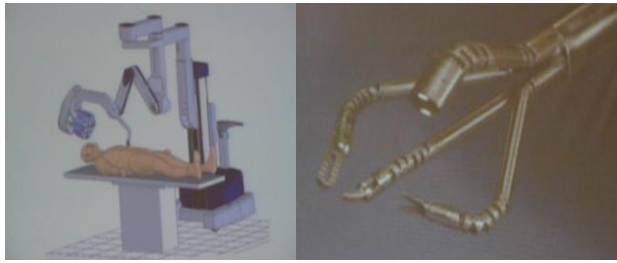
MiRO robot

I-SNAKE robot



Titan Medical's Amadeus Platform with KUKA Lightwieght robot

Intuitive Surgical's robotic instrumentation for single-site surgery (VeSPA)



Intuitive Surgical prototype for single-hole surgery. (left) single robotic arm, (right) articulated end-effectors

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ARAKNES Timeline

2008
Beginning of the ARAKNES Project

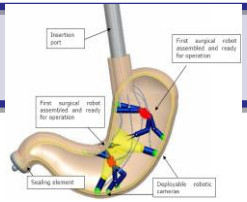
2009
1st ARAKNES Review Meeting

2010
2nd ARAKNES Review Meeting

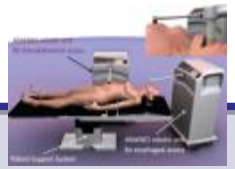
2011
3rd ARAKNES Review Meeting

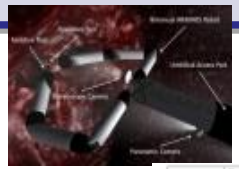
2012
End of Project

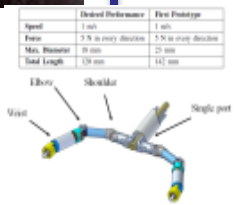
Endoluminal Robotic Platform



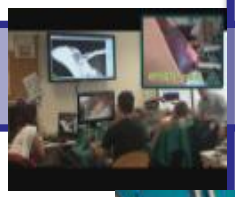
The hybrid approach

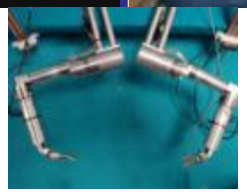






Pre-clinical (effectiveness trials)
Bench testing
Animal testing





Joint venture between industrial partners for producing the system

Business plan

2008
Intuitive's fourth quarter 2007
Revenue: $189.4 million

2008
Surgical research emphasizing NOTES

2009
Surgical research emphasizing SPL

2009
Intuitive's fourth quarter 2008
Revenue: $231.5 million
-
Release of the Da Vinci Si

2010
First ARAKNES Working robot prototype

2011
ARAKNES Robot final prototype

2012
ARAKNES System full working prototype

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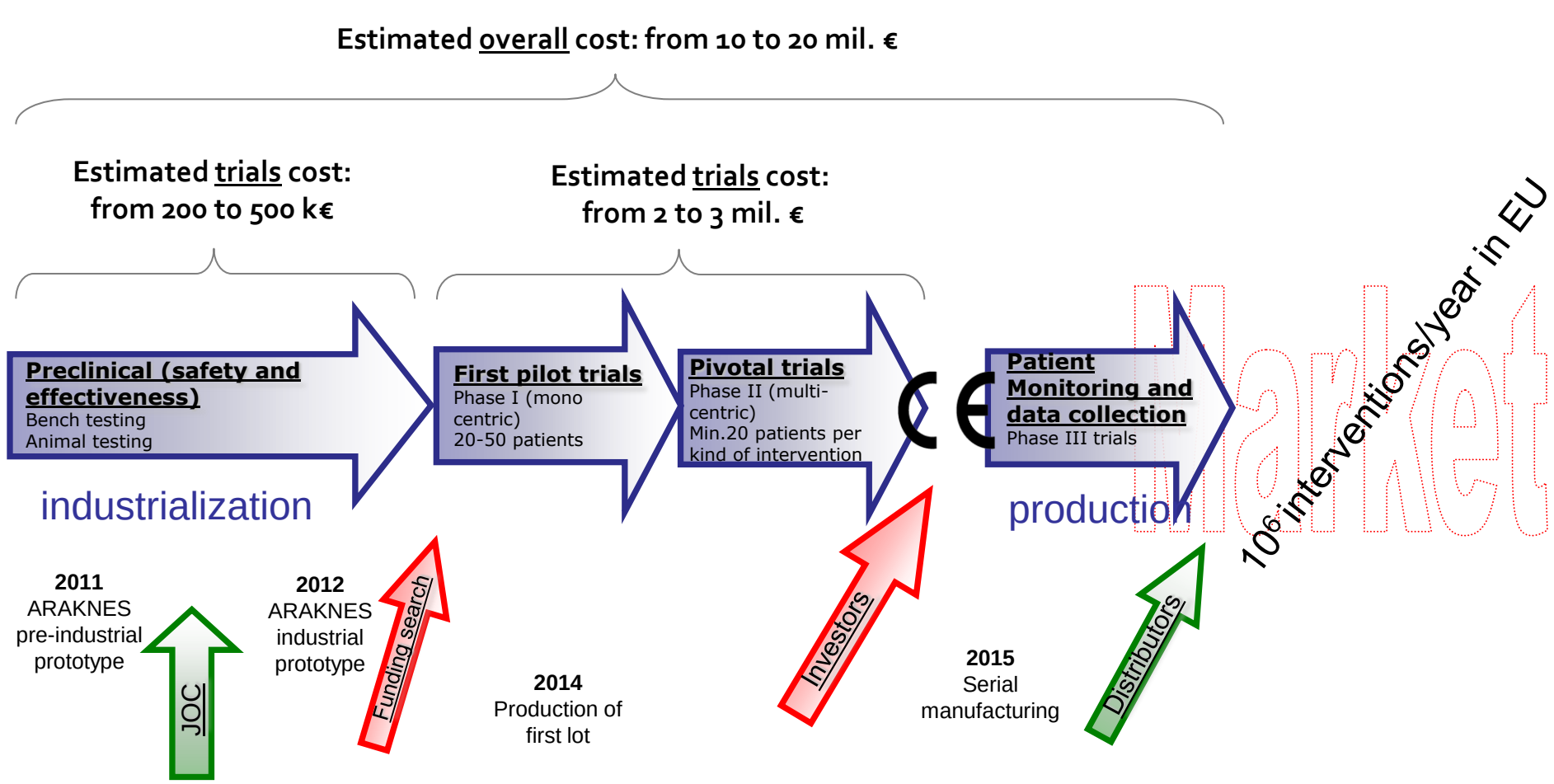
ARAKNES System: Road to Market



Continuous Monitoring and updating of Business Plan

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ARAKNES exploitation: problems

- In the medical field investments required (assets and machinery, electronic components and software, testing and trials) are large. A big problem is represented by **the lack of complementary resources,** especially for devices developed by academic institutes, such as investment capital, sales infrastructure and financial support.

- Established manufacturing firms are deterred by the high **technological and market uncertainties** associated with these opportunities. For disruptive technologies the volume, market share and growth rates of the prospective markets are still unknown, and the medical application is just emerging.

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The aim of Exploitation

- To guide the transition from a result of research activities to the ultimate commercialization of innovations
- The aim is to attract investors and it could be done by:
  - Proving the market potential of the innovation (marketability)
    - to find resources needed to transform solutions into products
  - Developing prototypes (to demonstrate the technical feasibility)
    - to convince investors of the technological potential of the innovation

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Research vs Industry

- **Regulation aspects**: marketing technological innovations in compliance with the high standards of the medical equipment industry requires high qualifications and competencies.
  - Regulations and standards
- **Market Potential:** to recognize the actual potential and impact of these innovations in the respective field of application and the market and to show and stress the degree of innovativeness of new product
  - Competitors analysis, Recent state-of-the-art reviews and market analysis
  - Definition Target application (Interview and questionnaire to surgeons)
  - Definition of market dimension (DRG analysis)
  - Business Plan (Costs, Swot analysis, Pricing strategy....)
- **Networking and promotion activities:** demonstration activities bring to a substantial reduction of the technological and market uncertainties associated with the new devices and helps to gain a sense of the emerging market for innovations.

Eky Med

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Consortium activities

- PEC (Project Exploitation Committee) meetings focused on:
  - Identification of derivative devices
  - Development plans
  - IP activities
- Templates to partners:
  - Classification(2007/47 and 93/42/EEC)
  - Intended use
  - Risk analysis (ISO 14971)
- Consultants assistance
  - Business plan and SWOT analysis

Eky Med

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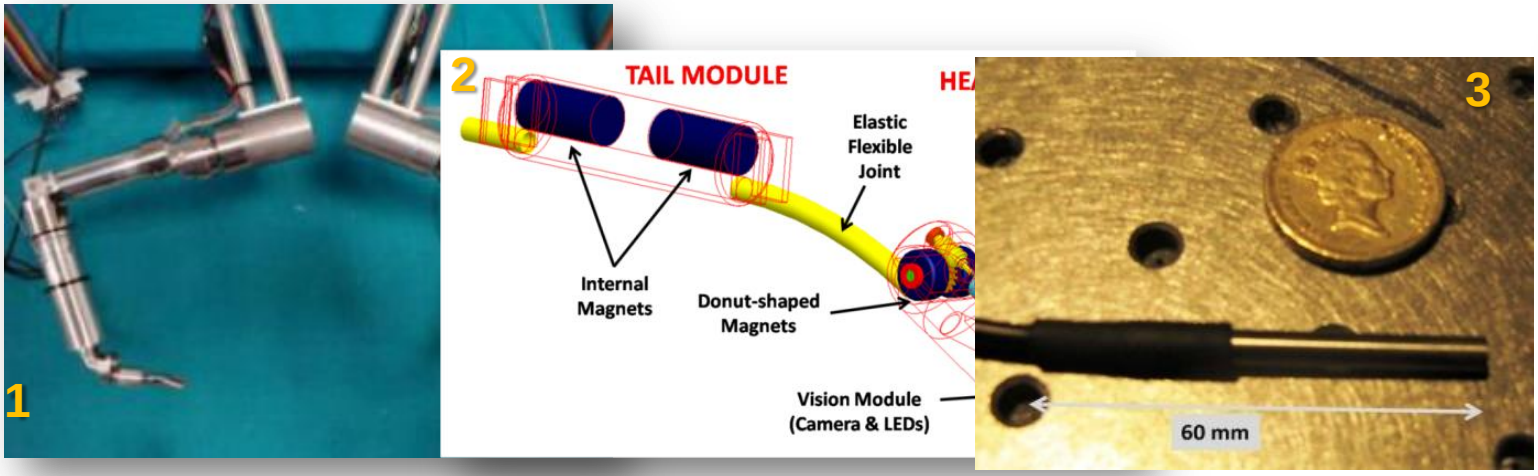
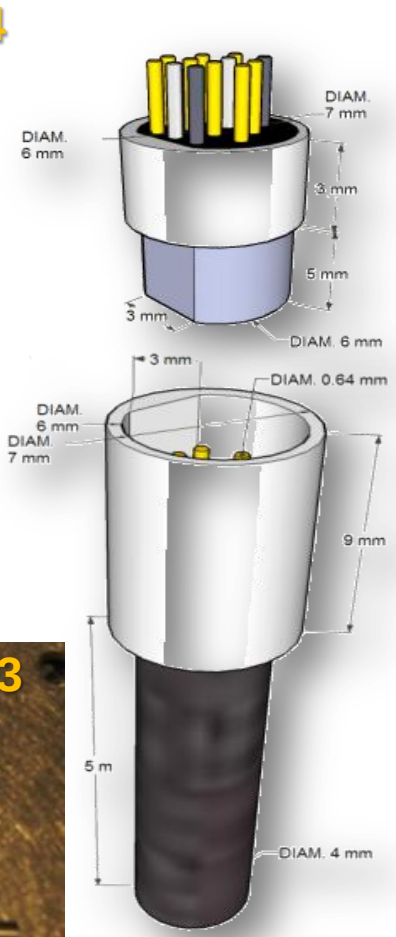
Most promising devices chosen for exploitation analysis

1. ARAKNES SPRINT (SSSUP, Scuola Superiore Sant'Anna)
2. MIM camera (SSSUP)
3. Optical Sensors (USTAN, University of St. Andrews)
4. Electrochemical sensor (UB, University of Barcelona)





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Conclusions

- A disruptive new technology being developed for scarless surgery
- Driven and oriented by surgical needs
- Exploring new engineering paradigms in miniaturization, reconfigurability, dexterity, intuitive control and operation, actuation, sensorization of surgical instruments
- A (potentially) high performance/low cost EU alternative to dominating US surgical products
- A platform for investigating and developing means for accurate, local, endoluminal diagnosis and therapy using microsystems technology

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Thank you!











ARAKNES Project
MNBS 2012 – Athens – 3th May 2012

SCUOLA SUPERIORE SANT'ANNA PISA

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