### 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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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.
Outline

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

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Medical Robotics: an increasingly successful clinical and industrial field
A success story in surgical robotics: the “Da Vinci” system

The main reasons for success:

- VERY HIGH SURGICAL PRECISION
- Minimal invasiveness
- Intuitive control
A success story in surgical robotics: the “Da Vinci” system

- 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)

HOWEVER
Robots in 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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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

- Open Surgery
- Laparoscopic Surgery
- Robotic Surgery
- N.O.T.E.S.
- SPL

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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

**Consortium**

**Coordinator**
Scuola Superiore Sant'Anna (SSSA), ITALY

**Imperial College London**

**Università di Pisa (UNIPI), ITALY**

**Ecole Polytechnique Fédérale de Lausanne (EPFL), SWITZERLAND**

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

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

**University of Barcelona (UB), SPAIN**

**Laboratory of Computer Sciences, Robotics and Microelectronics (CNRS), FRANCE**

**ST Microelectronics (STM), ITALY**

**University of St. Andrews (USTAN), UNITED KINGDOM**

**Ecole Polytechnique Fédérale de Lausanne (EPFL), SWITZERLAND**

**novineon Healthcare Technology Partners GmbH (NVN), GERMANY**

- **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
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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 bi-manual, tethered, scarless surgery based on microrobotic instrumentation.

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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- ARAKNES exploitation
Surgical scenario and System Architecture

- User Console
- Bimanual Controller
- Autostereoscopic Display
- Additional Displays
- Patient Support System
- ARAKNES robotic unit for umbilical access
- ARAKNES robotic unit for esophageal access

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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.
### ARAKNES access port: Prototypes

<table>
<thead>
<tr>
<th>Picture</th>
<th>Vision System</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="2nd prototype" /></td>
<td>2nd prototype</td>
<td>Vision system Housing</td>
</tr>
<tr>
<td><img src="image2" alt="2nd prototype" /></td>
<td>Vision system Housing</td>
<td>Flexible multilumen tube (oval section)</td>
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<tr>
<td></td>
<td></td>
<td>Closing Handle (Stability for the vision system)</td>
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<tr>
<td></td>
<td></td>
<td>Insulation: O-ring</td>
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<tr>
<td></td>
<td></td>
<td>Insufflation throughout a dedicated lumen</td>
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<td></td>
<td></td>
<td>Balloon fixing mechanism</td>
</tr>
<tr>
<td><img src="image3" alt="Integration of the 2nd Prototype" /></td>
<td>2nd prototype</td>
<td>No Vision and Illumination System</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HD panoramic Camera and Illumination</td>
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<td></td>
<td></td>
<td>Intra-gastric and Trans-gastric approaches</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Components:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Multilumen tube has been realized by extrusion of a silicone medical grade PE600</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Handle(3D printed) contains the connection to the supply tube (vision, air, water)</td>
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<tr>
<td></td>
<td></td>
<td>Balloon fixing mechanism</td>
</tr>
<tr>
<td></td>
<td></td>
<td>22 mm OD and 14 mm ID</td>
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<tr>
<td></td>
<td></td>
<td>Length 90 cm</td>
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<td></td>
<td></td>
<td>Inserted in the oesophagus trough a guiding endoscope</td>
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</tbody>
</table>
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ARAKNES Optical System

Image acquisition systems

**Vision system for access ports**
- **Flexible Oesophageal access port (MT)**
  - Fully integrated in tube wall (MT)
  - HD-resolution
  - 2D
  - LED illumination
- **Rigid Umbilical access port (SSSA)**
  - Fully insertable in the umbilical access port (MT)
  - No hindrance for other instruments
  - HD-resolution
  - 2D
  - LED illumination

**Vision system for robotic modules**
- **Fixed panoramic vision system (KST)**
  - Fully insertable in the umbilical access port (MT)
  - No hindrance for other instruments
  - HD-resolution
  - 2D
  - LED illumination
- **Swing-out panoramic vision system (KST)**
  - Fully insertable in the SPRINT-introducer (SSSA)
  - No hindrance for other instruments
  - HD-resolution
  - 3D
  - LEDs + Light-fibres
- **Fixed stereo vision system (KST)**
  - 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

**Steerable stereo vision system (SSSA)**

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Double access approach (the “HYBRID” APPROACH), from the oesophagus and through the abdomen.
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ARAKNES robot - Short term and long term approaches

Clinical Platform (Single Port umbilical access)

Research Platform (trocar/NOTES access)
Clinical Platform (Single Port umbilical access)

Short term and long term approaches

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SPRINT: Single-Port lapaRoscopy bImaNual roboT

Operative Tool

Assistive Tool

Stereoscopic Camera

Bimanual ARAKNES Robot

Umbilical Access Port

Panoramic Camera
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The SPRINT robot

- Single Port External Diameter: 30 mm
- External Diameter of the robot arms: less than 20 mm

- Insertion tube
- Stereoscopic camera
- Grippers
- Left arm
- Right arm
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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
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:


G. Basili, G. Pietroni, A. Menciassi, D. Pietrasanta, M. Niccolini, O. Goletti
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ARAKNES External manipulator: DIONIS system

- 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

DIONIS manipulator
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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
ARAKNES Photonic-based and chemical-based devices
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.
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.
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ARAKNES Console

- Autostereoscopic Display
- Bimanual Controller with Haptic Feedback
- Additional Display
SPRINT ROBOTIC PLATFORM

Master Console

Slave Manipulator
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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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
We know our COMPETITORS ...

Sofie system from Eindhoven 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

Endoluminal Platform

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

Surgical research emphasizing NOTES

2009
1st ARAKNES Review Meeting

2009
Surgical research emphasizing SPL

2009
Intuitive’s fourth quarter 2008
Revenue: $231.5 million

Release of the Da Vinci Si

2010
2nd ARAKNES Review Meeting

2010
First ARAKNES Working robot prototype

Pre-clinical (effectiveness trials)
Bench testing
Animal testing

2011
3rd ARAKNES Review Meeting

2011
ARAKNES Robot final prototype

2012
End of Project

2012
ARAKNES System full working prototype

Joint venture between industrial partners for producing the system

Business plan
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Estimated overall cost: from 10 to 20 mil. €

Estimated trials cost: from 200 to 500 k€

Estimated trials cost: from 2 to 3 mil. €

ARAKNES System:
Road to Market

Preclinical (safety and effectiveness)
- Bench testing
- Animal testing

First pilot trials
- Phase I (mono-centric)
- 20-50 patients

Pivotal trials
- Phase II (multi-centric)
- Min. 20 patients per kind of intervention

Patient Monitoring and data collection
- Phase III trials

2011
ARAKNES pre-industrial prototype

2012
ARAKNES industrial prototype

2014
Production of first lot

2015
Serial manufacturing

Continuous Monitoring and updating of Business Plan

10% interventions/year in EU

Market

Industrialization

Production

Funding

Investors

Distributors
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.
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
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.
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
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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)
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 Contacts

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