R&D in Italy, issues for commercializing medical robots

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Ekymed spa
Biorobotics Institute, Scuola Superiore Sant’Anna
Based on the experience gained in medical device R&D, we have built up some solid collaborations with spin-off companies for helping to cover the gap between academia research and industry.

In this presentation, we provide a paradigmatic example of this collaboration, by illustrating a recent case of study for the development of a robot for single port surgery in the framework of a European project (ARAKNES, 7FP)
ARAKNES Integrated 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

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

**Imperial College London (ICL), UNITED KINGDOM**

**Universität di Pisa (UNIPI), ITALY**

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

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

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

**ST Microelectronics (STM), ITALY**

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

**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
The ultimate goal of ARAKNES is to integrate the advantages of traditional open surgery, laparoscopic surgery (MIS), and robotics surgery into a deeply innovative system for bi-manual, tethered, visible scarless surgery.

Main intended interventions:
**Gastric and abdominal surgery**
- Single-port access/transluminal bariatric surgery (both with restrictive procedures and malabsorptive procedures)
User Console

Bimanual Controller

Autostereoscopic Display

Additional Displays

ARAKNES robotic unit for umbilical access

ARAKNES robot for oesophageal access

Patient Support System
Medical robotics projects @ SSSA

(Milords, Regione Toscana; MicroVast, Fondazione CARIPisa; Stiff-Flop, European Commission)
Medical device industry in Italy

2,735 companies, over 52,000 employees and a total turnover in Italy of 16.8 billion euros, compared to a domestic market of medical devices that is estimated at 8.6 billion euros*

* Report Assobiomedica May 2012
Ekymed spa Business Model

**R&D activities:** starting from KOL surgeons ideas we develop new medical devices for minimally invasive surgery

**Marketing activities:** Ekymed offers products and services in the healthcare field in Italy and abroad through specialized sales network

- Floseal GI catheter
- STAR SYSTEM
- SURFASOFT
- ALKANTIS
- NOVACOL
Italian surgical robotics at research level 1/2

- **Alf-X**

  Joint Research Centre (JRC) + SOFAR

  - haptic feedback
  - independent arms
  - trocars can be located anywhere on the patient
  - eye-tracking system to efficiently control the endoscopic view

International Workshop on Medical Robots
• **Surgenius beta**

Altair Robotics Laboratory of University of Verona

- 6 DOF tip-force sensors providing haptic feedback
- independent arms
- the wrist has 3 DOF
- **Surgenius BETA** is compliant with the applicable EU regulations (CE mark approved in May, 2012).
A market that initially reached $1 billion in 2008, surgical robotics equipment is forecasted to reach $14 billion by 2014 (Piribo).

In Italy: 58 installs (2012)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of robotic surgical procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>7000</td>
</tr>
<tr>
<td>2012 (first 3 months)</td>
<td>1500 (+40%)</td>
</tr>
</tbody>
</table>
Robotic surgery at clinical level in Tuscany

Tuscany, with 8 DaVinci robots, is one of the most technological advanced regions of Italy in the field of robotic surgery. The first regional robotic surgery centre was founded in Tuscany and it is coordinated by Franca Melfi, director of the Multidisciplinary Centre Of Robotic Surgery of the Pisa Hospital and winner of the first award “Bio WomenTech”.

A fertile region for Da Vinci Surgical System

- 2 in Pisa
- 2 in Florence
- 2 in Grosseto
- 1 in Siena
- 1 in Arezzo

International School of Robotic Surgery where testing novel robotic tools for future surgical procedures
The rules for safe and effective surgical robotics innovation

1- Identify JOC*
2- Submit Idea
3- Review Idea
4-CO-INVENT
5- Develop
6- LAUNCH

**Commercialization:**
- Distributor
- Marketing
- Advertising

**Industrialization:**
- Technical file and Certification
- Quality system
- Risk analysis

**Pre-industrial prototype design**
- Materials
- Ergonomics
- Manufacturing Processes

**Changes based on suggestions of the surgeon**
- Participatory observation
- Patenting
- Feasibility study
- Business plan

**Job Outcomes and Constraints:**
- Anatomical and physiological knowledge
- Analysis of medical literature
- State of the art: commercial systems and methods

**Preliminary:**
- Business plan
- Market analysis
- Risk analysis
- Feasibility study

**Preliminary prototype implementation:**
- Proposed Solution to the surgeon
- Comparison and ideas

Spin Off
Impresa Spin-Off della Scuola Sant’Anna

www.ekymed.com
The Strategy of ARAKNES
What surgeons need today

• Better (or at least same) and new capabilities with respect to DaVinci
• Same dependability as DaVinci
• Lower cost (purchase, maintenance, consumable, personnel in the OR, etc.)
What surgeons need today

• Better (or at least same) and new capabilities with respect to DaVinci
• Same dependability as DaVinci
• Lower cost (purchase, maintenance, consumable, personnel in the OR, etc.)
SPRINT (Single-Port laparoscopy bimanual robotic) application

Laparoscopic Surgery

Technical constraints, such as instrument collisions, lack of triangulation and cross-handing have hampered the SILS approach from fully emerging.

Need of new instrumentation for future development: robotic surgery can help.

70 years for reaching success from the origin: lack of instrumentation at the beginning

Single port robot technical needs

1. Faster initial setup
2. Easy change of setup during intervention
3. Easy port placement
4. Less bulky robot: both internally and externally
5. Dexterity
6. No stress for surgeon (ergonomics)
7. No instrument collision
8. Good triangulation as laparoscopy
External and internal manipulators for Single Port Surgery

Moving the introducer using a 4 DOF parallel robot (developed by EPFL) → additional workspace and degrees of freedom

6+6+2 DOF + 4 DOF = 18 DOF
The SPRINT - evolution

**the introducer**, enabling simple changes of tools and insertion of additional sensors
The SPRINT evolution in the last 6 months: complete delivery through the introducer

SPRINT v01

SPRINT v02
SPRINT ROBOTIC PLATFORM: first set up

Master Console

Slave Manipulator
In-Vivo tests: results

Small bowel enteroenterostomy

Ligation of a mesenteric vessel bundle

Current activity: integration with the multifunctional teleoperated console

- Sensor acquisition and display
- Eye tracking for visualization functionalities (e.g. zooming and activation of different monitors)
- Integration of the surgical planning module
- Integration of the surgical navigation module
Our strategy
Research vs Industry

- **Regulatory aspects**: marketing technological innovations in compliance with the high standards of the medical equipment industry requires high qualifications and competencies.
  - Regulations and standards
  - Risk analysis

- **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, IPR, 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.
## PROCEDURES

Please fill the green cells with **Y** (Yes) if the SPRINT robot could be used to perform the procedure and **N** (No) otherwise.

### 2. OPERATIONS ON THE ENDOCRINE SYSTEM (06-07)

<table>
<thead>
<tr>
<th>07</th>
<th>Operations on other endocrine glands</th>
<th>FEASIBLE WITH SPRINT</th>
</tr>
</thead>
<tbody>
<tr>
<td>07.2</td>
<td>Partial adrenalectomy</td>
<td></td>
</tr>
<tr>
<td>07.21</td>
<td>Excision of lesion of adrenal gland</td>
<td>Y</td>
</tr>
<tr>
<td>07.22</td>
<td>Unilateral adrenalectomy Adrenalectomy NOS</td>
<td></td>
</tr>
<tr>
<td>07.29</td>
<td>Other partial adrenalectomy Partial adrenalectomy NOS</td>
<td>N</td>
</tr>
<tr>
<td>07.3</td>
<td>Bilateral adrenalectomy Excision of remaining adrenal gland</td>
<td></td>
</tr>
</tbody>
</table>

### 3A. OTHER MISCELLANEOUS DIAGNOSTIC AND THERAPEUTIC PROCEDURES (17)

<table>
<thead>
<tr>
<th>17</th>
<th>Other miscellaneous procedures</th>
<th>FEASIBLE WITH SPRINT</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.1</td>
<td>Laparoscopic unilateral repair of inguinal hernia</td>
<td></td>
</tr>
<tr>
<td>17.11</td>
<td>Laparoscopic repair of direct inguinal hernia with graft or prosthesis Laparoscopic repair of direct and indirect inguinal hernia with graft or prosthesis</td>
<td>Y</td>
</tr>
<tr>
<td>17.12</td>
<td>Laparoscopic repair of indirect inguinal hernia with graft or prosthesis</td>
<td></td>
</tr>
<tr>
<td>17.13</td>
<td>Laparoscopic repair of inguinal hernia with graft or prosthesis, not otherwise specified</td>
<td>Y</td>
</tr>
<tr>
<td>17.2</td>
<td>Laparoscopic bilateral repair of inguinal hernia</td>
<td></td>
</tr>
<tr>
<td>17.21</td>
<td>Laparoscopic bilateral repair of direct inguinal hernia with graft or prosthesis</td>
<td>Y</td>
</tr>
</tbody>
</table>
## SPRINT Market evaluation

### Source:

HCUP Nationwide Inpatient Sample (NIS), 2009, Agency for Healthcare Research and Quality (AHRQ):

http://hcupnet.ahrq.gov/

### Budget plan

### Table

<table>
<thead>
<tr>
<th>ICD-9-CM all-listed procedure code and name</th>
<th>Total number of discharges</th>
</tr>
</thead>
<tbody>
<tr>
<td>07.22 Unilateral Adrenalectomy</td>
<td>9,972</td>
</tr>
<tr>
<td>07.29 Part Adrenalectomy Nec</td>
<td>829</td>
</tr>
<tr>
<td>17.11 Lap Dir Ing Hern-Graft</td>
<td>957</td>
</tr>
<tr>
<td>17.12 Lap Indir Ing Hern-Graft</td>
<td>1,350</td>
</tr>
<tr>
<td>17.13 Lap Ing Hern-Graft Nos</td>
<td>1,209</td>
</tr>
<tr>
<td>17.21 Lap Bil Dir Ing Hm-Graft</td>
<td>266</td>
</tr>
<tr>
<td>17.22 Lap Bi Indir Ing Hm-Gfr</td>
<td>392</td>
</tr>
<tr>
<td>17.23 Lap Bi Dr/Ind Ing Hm-Gr</td>
<td>322</td>
</tr>
<tr>
<td>17.24 Lap Bil Ing Hern-Gfr Nos</td>
<td>497</td>
</tr>
<tr>
<td>17.31 Lap Mul Seq Res Lo Intes</td>
<td>258</td>
</tr>
<tr>
<td>17.32 Laparoscopic Cecectomy</td>
<td>4,436</td>
</tr>
<tr>
<td>17.33 Lap Right Hemicolectomy</td>
<td>32,334</td>
</tr>
</tbody>
</table>

### Graph

- **Home market (IT)**
- **Germany**
- **EU without IT and GER**
- **USA**
- **Japan**
- **ROW**
- **Total**
What surgeons need today

• Better (or at least same) and new capabilities with respect to DaVinci
• Same dependability as DaVinci
• Lower cost (purchase, maintenance, consumable, personnel in the OR, etc.)
# Regulatory issues

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>(EMDD) European Medical Device Directive</td>
<td>2007/47</td>
</tr>
<tr>
<td>Application of risk management to medical devices</td>
<td>ISO 14971</td>
</tr>
<tr>
<td>Quality management systems - Requirements for regulatory purposes</td>
<td>ISO 13485</td>
</tr>
<tr>
<td>Biological evaluation of medical devices</td>
<td>ISO 10993</td>
</tr>
<tr>
<td>Clinical evaluation of medical devices for human subjects</td>
<td>ISO 14155</td>
</tr>
<tr>
<td>Electrical safety</td>
<td>ISO 60601</td>
</tr>
<tr>
<td>Fundamental aspects of safety standards for medical electrical equipment</td>
<td>IEC/TR 60513</td>
</tr>
<tr>
<td>Medical device software – Software life cycle processes</td>
<td>IEC 62304</td>
</tr>
<tr>
<td>Packaging for terminally sterilized medical devices</td>
<td>ISO 11607</td>
</tr>
<tr>
<td>Sterilization of medical devices</td>
<td>ISO 11135, 11137, 11138, 11140</td>
</tr>
</tbody>
</table>
## Intended Use

Here intended use

Bimanual, single access robotic platform for single port surgery. The system is inserted through a 34 mm insertion port with panoramic view camera. It comprises a stereoscopic HD camera and 2 robotic internal arms with 4 dof per arm. At the distal end standard laparoscopic instrumentation is provided.

## Classification

### Reference Directive

2007/47/EEC (new amendment of 93/42)

### Annex IX (CLASSIFICATION CRITERIA)

#### Short term

1.1 Normally intended for continuous use for not more than 30 day

#### Surgically invasive device

1.2 An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices

### Definitions

2.3. Rule 7

(All surgically invasive devices intended for short-term use are in Class IIa unless they are intended for..)

### CLASS

IIa
A safe product is one that has reasonable risks, given the magnitude of the benefit expected and the alternatives available.

All parts of the health care delivery chain try to maintain this benefit-risk balance by making sure that products are developed, tested, manufactured, labeled, prescribed, dispensed, and used in a way that maximizes benefit and minimizes risk.

Questions that can be used to identify medical device characteristics that could impact on safety

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the intended use and how is the medical device to be used?</td>
<td>This medical device is intended to be used to perform surgical tasks in laparoscopic single site interventions.</td>
</tr>
<tr>
<td>Is the device intended to be implanted?</td>
<td>NO</td>
</tr>
<tr>
<td>Will the device be in (direct) contact with patient or other persons?</td>
<td>Yes: direct contact with the patient (the device is invasive in phase of surgical laparoscopic interventions) and direct contact with the surgeon (manual control).</td>
</tr>
<tr>
<td>What are the materials or components used?</td>
<td>Factors that should be considered include:</td>
</tr>
<tr>
<td></td>
<td>– compatibility with relevant substances;</td>
</tr>
<tr>
<td></td>
<td>– compatibility with tissues or body fluids;</td>
</tr>
<tr>
<td></td>
<td>– whether characteristics relevant to safety are known;</td>
</tr>
<tr>
<td></td>
<td>– is the device manufactured utilizing materials of animal origin?</td>
</tr>
<tr>
<td></td>
<td>NOTE See Annex I and also the ISO 22442 series of standards[19].</td>
</tr>
<tr>
<td>Is some kind of energy given or detracted to the patient?</td>
<td>yes bipolar energy</td>
</tr>
<tr>
<td>Is some kind of matter given or detracted to the patient?</td>
<td>NO</td>
</tr>
</tbody>
</table>
Risk identification:

HACCP (Hazard Analysis and Critical Control Points)

Hazard Analysis is the detailed qualitative examination of the device from the perspective of the user. It considers the interface of the device with the user. It ignores the internals of the device and what may happen internally in the device to cause an external hazard.

FMEA (Failure mode and effects analysis) will follow in a later stage.
# Device Risk analysis

<table>
<thead>
<tr>
<th>Analyzed element: Biocompatibility</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials</td>
<td></td>
</tr>
<tr>
<td>Biodegradation of materials</td>
<td>Exposure of tissues to degradation products</td>
</tr>
<tr>
<td>Bioincompatibility: use of non biocompatible materials</td>
<td>Infection</td>
</tr>
<tr>
<td>Toxicity of chemical constituents</td>
<td>Presence of solvent residue</td>
</tr>
</tbody>
</table>
## SWOT analysis:
Customer Surgeons/hospital/patient point of view

### Internal Analysis/Factors

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>− No fulcrum constraint</td>
<td>− Still Big incision</td>
</tr>
<tr>
<td>− Less invasive comparing to the main competitor</td>
<td>− Missing high frequency coagulation system</td>
</tr>
<tr>
<td>− Less bulky</td>
<td>− Changeable End effectors</td>
</tr>
<tr>
<td>− Good combination between precision and gross movement</td>
<td>− Stapling</td>
</tr>
<tr>
<td>− Integrated vision system</td>
<td>− Lack of Pneumoperitoneum</td>
</tr>
<tr>
<td>− 2 vision systems</td>
<td></td>
</tr>
<tr>
<td>− Application of diagnostic sensors intraoperatively through the working channel</td>
<td></td>
</tr>
</tbody>
</table>

### External Analysis/Factors

<table>
<thead>
<tr>
<th>Threats</th>
<th>Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>− Big new training sessions for the surgeons and assistants</td>
<td>− New surgical procedures can arise</td>
</tr>
<tr>
<td>− New procedures for cleaning, sterilization, set-up, to be defined</td>
<td>− Collect new incomes (new patients coming to the hospital)</td>
</tr>
<tr>
<td>− Not yet defined outcome for all the surgical procedures</td>
<td>− Hospital /surgeons participating to leading edge research projects</td>
</tr>
<tr>
<td></td>
<td>− Improve healthcare delivery</td>
</tr>
<tr>
<td></td>
<td>− Advantages in suturing</td>
</tr>
<tr>
<td></td>
<td>− Use new technologies/reputation/marketing chance for their resume</td>
</tr>
</tbody>
</table>
# SWOT Analysis: Producing Company

## Internal Analysis/Factors

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Bimanual robot with high dexterity</td>
<td>- Technological constraints (miniaturization, electrical insulation,..)</td>
</tr>
<tr>
<td>- Less invasive comparing to the main competitor</td>
<td>- Cleaning and sterilization</td>
</tr>
<tr>
<td>- Less bulky externally</td>
<td>- Limited workspace</td>
</tr>
<tr>
<td>- More dofs</td>
<td>- Integration of standard instrumentation</td>
</tr>
<tr>
<td></td>
<td>- Safety issues</td>
</tr>
</tbody>
</table>

## External Analysis/Factors

<table>
<thead>
<tr>
<th>Threats</th>
<th>Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>- IP</td>
<td>- Big market</td>
</tr>
<tr>
<td>- Big competitors</td>
<td>- No real competitor on the market of robotic single port surgery</td>
</tr>
<tr>
<td>- Long time to market (need for cashflow coverage)</td>
<td></td>
</tr>
</tbody>
</table>
## SPRINT robot competitor analysis

<table>
<thead>
<tr>
<th>Brand</th>
<th>Picture</th>
<th>Status</th>
<th>Target surgical field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intuitive Surgical Inc.</td>
<td><img src="image1" alt="Intuitive Surgical Inc." /></td>
<td>on the market</td>
<td>Cardiothoracic, General Surgery, Gynecology, Urology</td>
</tr>
<tr>
<td>Titan Medical Inc.</td>
<td><img src="image2" alt="Titan Medical Inc." /></td>
<td>FDA submission in late 2014, Market Launch 2015</td>
<td>General surgery, ENT and thoracic with additional applications in urology and gynecology</td>
</tr>
<tr>
<td>Sofar-EC JRC</td>
<td><img src="image3" alt="Sofar-EC JRC" /></td>
<td>received CE mark in December 2011</td>
<td></td>
</tr>
<tr>
<td>Surgica Robotica</td>
<td><img src="image4" alt="Surgica Robotica" /></td>
<td>Received CE mark in March 2011, and now the beta prototype is getting ready for clinical trials</td>
<td>Abdominal surgery</td>
</tr>
</tbody>
</table>
What surgeons need today

- Better (or at least same) and new capabilities with respect to DaVinci
- Same dependability as DaVinci
- Lower cost (purchase, maintenance, consumable, personnel in the OR, etc.)
Best/worst competitor

- Certified only for colecystectomy
  - Too bulky
  - Too expensive

Budget araknes project: 8.1 M€
List of R&D expenses

Research and development expenses include:

– amortization of purchased intellectual property
– costs associated with co-development R&D licensing arrangements
– costs of prototypes
– salaries
– benefits
– other headcount related costs, contract and other outside service fees, and facilities and overhead costs
SPRINT pre-launch costs

Total planned budget: 15.321.500€ in 5 years
SPRINT robot: Road to Market

Estimated overall cost: 15M€
industrialization

Estimated trials cost:
from 200 to 500 k€

Preclinical (safety and effectiveness)
Bench testing
Animal testing

2012
SPRINT pre-industrial prototype

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

2016
SPRINT industrial prototype

Investors and funding search

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

Patient Monitoring and data collection
Phase III trials

Continuous Monitoring and updating of Business Plan

2017-2018
Market launch

International Workshop on Medical Robots
## Sprint Market model

<table>
<thead>
<tr>
<th>Market over all</th>
<th>Home market (IT)</th>
<th>Germany</th>
<th>EU without IT and GER</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>349,515</td>
<td>477,670</td>
<td>2,085,437</td>
<td>1,000,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cases per year</th>
<th>Home market (IT)</th>
<th>Germany</th>
<th>EU</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market for Item</td>
<td>349,515</td>
<td>477,670</td>
<td>2,085,437</td>
<td>1,000,000</td>
</tr>
<tr>
<td>Total</td>
<td>349,515</td>
<td>477,670</td>
<td>2,085,437</td>
<td>1,000,000</td>
</tr>
</tbody>
</table>

### Market Assumption

- **Reachable market**: 20%
- **Achievable market share**: 6%
- **Annual market growth**: 1%

### Market share

<table>
<thead>
<tr>
<th>Year after Product Launch</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramp-Up Home market</td>
<td>10%</td>
<td>25%</td>
<td>50%</td>
<td>100%</td>
</tr>
<tr>
<td>Ramp-Up Germany</td>
<td>10%</td>
<td>25%</td>
<td>50%</td>
<td>100%</td>
</tr>
<tr>
<td>Ramp-Up EU</td>
<td>10%</td>
<td>25%</td>
<td>50%</td>
<td>100%</td>
</tr>
<tr>
<td>Ramp-Up USA</td>
<td>10%</td>
<td>25%</td>
<td>50%</td>
<td>100%</td>
</tr>
<tr>
<td>Ramp-Up Japan</td>
<td>10%</td>
<td>25%</td>
<td>50%</td>
<td>100%</td>
</tr>
</tbody>
</table>

- **Market Share Home market**: 0%
- **Market Share Germany**: 0%
- **Market Share EU**: 0%
- **Market Share USA**: 0%
- **Market Share Japan**: 0%
Sprint Business plan

Months after market launch (month 30)

International Workshop on Medical Robots
Critical evaluation of budget plan

if we want to be competitive we should:

1. Reduce cost per procedure
   1. Reducing the cost of reusable components
   2. Augmenting number of use per instrument (new design which allows it)

Scenario 1: 10 uses
Scenario 2: 15 uses

Pay attention to cumulative need for money needed!
Critical evaluation of budget plan

- With a bottom up price strategy of 150% of costs vs 130% we have less necessity of cumulative

Scenario 1: 130%

Scenario 2: 150%
Italian market

Stakeholders:
1. Good inventors
2. Skilled customers for robotic surgery
3. Big market
4. Good manufacturing companies

What do we need?

• Work on the management of the big business of robotic surgery
• Integration between actors
• Investments in R&D
Thanks for your attention!

Questions?

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