AN INNOVATIVE SMART SOLUTION FOR SPINE SURGERY

Eng. Sara Condino
Current activity

Medical and surgical ad-hoc solutions based on the elaboration of radiological images

THE FUTURE

Surgical templates for spinal fusion surgery
Spinal fusion surgery

- Scoliosis
- Spinal stenosis
- Spinal infections
- Bone tumors
- Spinal cord tumours
- Spinal trauma
- ...

e-SPres3D
An incorrect screw placement can determine the inefficacy of treatment or severe damages to close neurologic structures.
The solution

- Customized surgical templates, radiological images-derived
- The surgeon preoperative plan is transferred to the operative site, guiding the surgical drill to the optimal entry point and along the best trajectory
Business model
Product as a Service

Same model of Materialise
innovators you can count on

The customer
Orthopaedic clinics
Manufacturers of spinal implants

PLANNING

CAD phase

3D PRINTING

STERILIZATION AND PACKAGING

e-SPres3D server

e-SPres3D

server

express
Advantages

• **Improvement in precision**
  - Less Intraoperative complications (−48%)
  - Fewer reoperations (−92%) = −400 K€/year (hospital with 200 cases/year)

• **Reduction of operative time**
  20 min/vertebra vs 60 min/vertebra = −450€/livello

• **Reduction of anesthesia time**

• **Reduction of intra-operative x-ray exposition**

Ref. Kantelhardt 2011
Obtained Results

- In vitro test -> Published results
- Ex vivo test -> Published results, excellent medical feedback
- Ethical Committee approval for the first clinical test
  - Monocentric clinical trial
  - Three patient (12 levels)
  - Evaluation of the template positioning

PATENTED SOLUTIONS:
PCT N° WO2012140569 All claims accepted
National phases started (Europe and China)
# The Competitor

<table>
<thead>
<tr>
<th></th>
<th>Mazor Robotics: Renaissance™</th>
<th>e-SPres3D s.r.l.</th>
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</thead>
<tbody>
<tr>
<td><strong>Precision increase</strong></td>
<td>🟢</td>
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<tr>
<td><strong>X-ray reduction</strong></td>
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<td><strong>Operation time</strong></td>
<td>😐</td>
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<td><strong>Impact on the surgical workflow</strong></td>
<td>😞</td>
<td>😐</td>
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<td><strong>Possibility to perform minimally invasive procedures (max 25%)</strong></td>
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<tr>
<td><strong>Economic Impact</strong></td>
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</table>
The Market

Segmentation of the market:
ICD-9-CM [2011] & DRG codes

Number of interventions/year

ITALY \(\rightarrow\) \(~15000\) a
EUROPE \(\rightarrow\) \(~300000\) b
USA \(\rightarrow\) \(~750000\) c

EU + USA > 700,000 interventions/year

At least 70% with transpedicular screws

MedMarket Diligence (report #M520)
Trending in Spine surgery

a – SDO analysis by the Ministry of Health database
b – European Health for All database (HFA-DB)
c – USA Healthcare Cost and Utilization Project (HCUP)

http://www.salute.gov.it/
http://www.euro.who.int/
https://www.hcup-us.ahrq.gov/
Price

Production cost: **200 Euro**
(assuming a production capacity of 4000 pieces/year)

Price to the final customer ➔ **1200 - 1500 €**
patient kit
## Financial Forecast

<table>
<thead>
<tr>
<th>YEARS</th>
<th>ITALY</th>
<th>EUROPE</th>
<th>EUROPE +USA</th>
<th>EUROPE +USA</th>
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<tbody>
<tr>
<td>1</td>
<td>0 K€</td>
<td>89 K€</td>
<td>369 K€</td>
<td>3.608 K€</td>
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<td>2</td>
<td></td>
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<tr>
<td>3</td>
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<td>4</td>
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<td>5</td>
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<td>Revenue</td>
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<tr>
<td>EBIT</td>
<td>-617K€</td>
<td>-732K€</td>
<td>-961K€</td>
<td>482 K€</td>
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<tr>
<td>Share capital</td>
<td>700 K€</td>
<td>1.000 K€</td>
<td>900 K€</td>
<td>5.225 K€</td>
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<tr>
<td>Procedures Number</td>
<td>59</td>
<td>246</td>
<td>2.406</td>
<td>8.073</td>
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<tr>
<td>Employees</td>
<td>4</td>
<td>5</td>
<td>8</td>
<td>15</td>
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</tbody>
</table>

Possible EXIT
• Acquisition by **Materialise**

• Acquisition by
  - Medtronic
  - DePuy
  - Biomet
  - Stryker
  - ...

Exit
Clinical Advisory Board

**Paolo Parchi** – Orthopaedic Surgeon, Researcher, co-inventor of the patent, Consolidated experience in spine surgery

**Carla Cappelli** – Radiologist, PhD. Consolidated experience radiological images elaboration

**Mauro Ferrari** – General and Vascular Surgeon, Prof. director of a clinical/surgical department

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**Team**

**Marina Carbone** - **CEO (ad interim)**
Biomedical Eng., PhD Biorobotics Scuola Superiore Sant’Anna research and development @ EndoCAS - 5 years experience

**???** – **CEO**
Experience in Marketing and Business Administration

**Sara Condino** - **Certification and Testing**
Biomedical Eng., PhD Health Technologies University of Pisa research and development @ EndoCAS and Scuola Superiore Sant’Anna - 6 years experience

**Vincenzo Ferrari** - **Product Engineering**
Computer science Eng., PhD Health Technologies University of Pisa Technical/scientific coordinator of EndoCAS R&D coordinator @ SW-SCADA e Machine Vision Companies - 5 years experience
la terza dimensione della cura del paziente

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