A medical device plant journey: from Lean-6 Sigma, through Operational Excellence, to Industry 4.0 vision

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Head of cardiac Surgery Manufacturing and Supply Chain
Agenda

- Who we are: company focused on Head & Heart
- Mirandola site introduction
- Operational Excellence journey
- More to come
We are a $1.0B† focused medical innovator

- Improving quality of patients’ lives
- Strong leadership position in Neuromodulation and Cardiac Surgery
- Targeting underserved and high-growth market segments

†Full-year 2017 net sales
With leading positions in neuromodulation and cardiac surgery

**HEAD**

- Drug-Resistant Epilepsy (DRE)
- Treatment-Resistant Depression (TRD)
- Vagus Nerve Stimulation Therapy (VNS Therapy®)

**40% Neuromodulation (NM)**

**60% Cardiac Surgery (CS)**

**HEART**

- 80% Cardiopulmonary (CP)
- Heart-lung machines (HLM)
- Oxygenators
- Autotransfusion systems (ATS)
- Cannulae

- 20% Heart Valves
  - Sutureless tissue valves
  - Mechanical valves
  - Traditional tissue valves
  - Annuloplasty rings

Numbers are rounded for presentation purposes. 4GNA sales < $1M in 2017 and not included as part of total sales.
manufacturing footprint: global presence with 9 sites
FOCUS ON:

MIRANDOLA PLANT
## Mirandola Plant Profile

<table>
<thead>
<tr>
<th>Criteria</th>
<th>KPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products</td>
<td>Oxygenators (WW), Perfusion Tubing Sets (EU&amp;IC), ATS Disposables, Accessories, Cannulae</td>
</tr>
<tr>
<td>Processes</td>
<td>Injection Molding, PVC Dipping, Assembly (830 equipments with PLC)</td>
</tr>
<tr>
<td>Buildings (sqm)</td>
<td>44,000</td>
</tr>
<tr>
<td>Clean room (sqm)</td>
<td>5,800</td>
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<tr>
<td>Total Ops employees</td>
<td><strong>729</strong></td>
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<tr>
<td>Indirect</td>
<td>185</td>
</tr>
<tr>
<td>Direct</td>
<td>544</td>
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<tr>
<td>Warehouses / DC</td>
<td>In the site</td>
</tr>
</tbody>
</table>

![Plant Layout Diagram](image)
Mirandola core products

INSPIRE Oxygenator

Extracorporeal circulation circuit
Mirandola Product Portfolio

- **Oxygenators**
  - 460,000 units/Y
  - 200 SKUs

- **Perfusion Tubing Sets**
  - 500,000 units/Y
  - 6,000 SKUs

- **ATS KIT**
  - 500,000 units/Y
  - 80 SKUs

- **Cannulae**
  - 250,000 units/Y
  - 380 SKUs
We started our Lean/ 6σ journey in 2010

We began with...
The vision: improving Cost Quality Delivery, enhancing patients experience and saving lives, day by day

- Foundation was built defining Value streams and appointing dedicated interfunctional teams
- Massive training on tools and techniques was launched
- Successful first pilots on single piece flow, U cells, Takt time, WIP and Lead Time reduction…
- 6σ implementation, addressing both molding and Assembly to get breakthrough FPY improvement
- While doing all that, involving continuously people at all level in the plant
Hoshin Kanri & Operational Excellence at work
Some examples of the achievements in the last 2 years ...
Automation: examples in assembly process

- Five separated manual steps into one
- 61" time reduction
- 5 FTE direct labor saving
- Productivity increased from 35 to 29 sec/unit
- Improved quality and safety

- 7 machines integrated by 3 robots
- 48" time reduction
- 4 FTE direct labor saving
- Standardized times and methods
Automation: automatic palletizer and AGV

- reduced manual handling risk
- pallet height from 1.8 m to 2.4 m
- lower number of sterilization cycles
- productivity from 85” to 59” /unit
- SW connection with SCADA and AGV

- connecting CRs, sterilization and FG warehouse
- continuous operation 24 h - 7/7
- 2 FTE indirect labor saving
- improved quality (handling damages reduced.)
Automatic Optical Inspection

- **Starting point**: Several in-process visual checks (solid impurities, welding, gluing, plastic chips, scratches, aesthetic marks) performed by operators.

- Automatic visual inspection successfully implemented (water leak test, IAF gluing).

![Image of oxy during water leak test](image1.png)

![Bowl under analysis](image2.png)

![Welding defect observed during analysis](image3.png)
Predictive maintenance

Infrared camera
- pilot project in 2018 (master thesis UNIMORE)
- Extension to electrical cabinets, drying machines, centrifugal potting

Vibration sensors connected to a supervision system
- pilot project in 2018
- Extension to compressed and sterylized air systems

E-Maintenance Engineering with mobile devices
- real time work orders
- direct request for spare parts by maintenance technician
- enhanced fault tree analysis and preventive maintenance
Digitalization 4.0 + full traceability
Statistical process control

Six sigma implementation to manage automatic components scrap based only on process parameters control (Zero dimensional control)
### Inspire BPU

<table>
<thead>
<tr>
<th>Process</th>
<th>OEE</th>
<th>IE</th>
<th>TCM</th>
<th>Scarto</th>
<th>Rework</th>
<th>Allarme</th>
<th>Pezzi prodotti</th>
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<td>(Rocca Inspire) Roccatura Inspire</td>
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<td>0.0% (0)</td>
<td>0.0% (0)</td>
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<td>0.7% (1)</td>
<td>0.0% (0)</td>
<td>Allarme</td>
<td>136</td>
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Main KPIs available in real time on a web app

OEE real time details

- Availability
- Efficiency
- Quality

Machine alarm: Pareto

CSV file
Lean 4.0: eKanban

- From Excel based eKanban to global Ultriva SW package (paperless implementation)
- Real time collaborative platform → scheduling on shift basis
- Extension to all main suppliers and other Livanova plants planned in 2019
Operators engagement

Driving operational and environmental improvements through:

- 6S
- TQC and TPM
- KAIZEN
- Operators training
- Gemba walk
- Automatic ideas collection

Final award ceremony as a standard for best improvement proposals
Achievements

Suggested/Ideas 2016-2017

<table>
<thead>
<tr>
<th>Area</th>
<th>Suggested activities</th>
<th>Completed activities</th>
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<tr>
<td>A1</td>
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<td>A4-A5</td>
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<td>A9</td>
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<td>321</td>
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<tr>
<td>Total</td>
<td>584</td>
<td>486</td>
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<tr>
<td>% Completed activities</td>
<td>83%</td>
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MIRANDOLA STERILIZATION FACILITY

The Sterilization facility, which uses Ethylene Oxide as sterilant agent, is one of the most fully automated and reliable in the world

- **SAFETY**: No one exposed to EO emissions
- **ZERO products MANUAL handling**: AGV moves pallet from assembly lines to sterilization and then to Finished Good warehouse
- **TRACEABILITY**: Sterilization and degassing process fully traced with RFID technology
- **Parametric release**: remove the biological indicators (Bis) use the process parameters
- **ENVIRONMENT**: Extremely low impact (EO emission lower than 10 times the limits by regulation)
Green campus: tri-generation plant

- Concurrent production of **electrical power, hot water, cold water, steam**
- **30% saving** of primary energy consumption
- Increase the **eco-sustainability** of the site (CO2 emissions)
- **Remote** control and supervision

\[ \eta_{\text{globale}} = \frac{EE + Q + F}{EP_{\text{el}}} \]

(78-82 %)
More to come soon …

What’s in the pipeline
2018-2020: acceleration to Smart factory 4.0

The vision

- Lean 6 Sigma as baseline for continuous improvement together with new technologies
- Enhanced automation
- Digitalization
  - IoT, augmented reality, sensorized machines, M2M interconnection
  - RFID technology expansion (real time control supply chain)
- Zero Handling, internal and external (AGV, automatic pallet creation)
- Zero “human controls”, HANDS OFF
- WORKFORCE 4.0
Cooperative robots application: solvent dispensing

**Today**

- manual solvent dispensing
- need specific DPI
- cycle time and quantity not standardized

**2019**

- solvent dispensing by Cobot
- operator performing other safer activities
- 6 Sigma validation
- real time traceability and in process control
- Lean 4.0 automation system
Automatic visual inspection in molding process

Automatic visual inspection replacing human control with higher accuracy and efficiency
Automatic retrofit process

In-process total quality control (dimensional and aesthetical) and automatic retrofit actions in order to improve process capability.
Thank You