Unique Device Identification of Surgical Instruments
Summary

- Presentation of Robert Ballanger Hospital
- The evolution of the traceability of sterile medical devices
- The project of Unique Device Identification
- Our next GS1 projects
Robert Ballanger Hospital

- Intercity hospital serving a population of 400,000 persons
- 650 beds
  - 450 beds in acute care (medical, chirurgical and maternity)
  - 200 psychiatry beds
- Outpatient clinic and pharmacy inside Villepinte detention center
- CDG airport hospital
Traceability of Medical Devices in Robert Ballanger Hospital
Sterilization unit

- 120,000 sterilized devices per year
- 20,000 surgery boxes per year
Repartition of the sterilisation unit activity

- Operating Theater: 39%
- Maternity: 9%
- Stomatology: 13%
- Emergency: 6%
- UCSA: 6%
- Others: 27%
Traceability

Pharmacy
- Traceability
  - Implantable Medical Device
- Reception
  - Implantable Medical Device
- Distribution

Operating room
- Surgery intervention

Sterilization unit
- Pre-cleaning
- Cleaning
- Sterilization
- Packaging

Distribution
Traceability of Medical Devices with GS1 Standards

Pharmacy
Reception
Implantable Medical Device
Distribution
Sterilization unit
Distribution of a sterile medical device
Process

GS1

Operating room
Surgery intervention
IT Prescription
Patient traceability
Patient record
Unique Device Identification
The CHIRB choice

DATAMATRIX

Laser

+ Industrial tagging
  Easy reading
  Industrial treatment of instrument

- Time to tag Devices

GS1

Infodot

+ Easy and fast tagging
  Cost

- Deterioration faster than the others
Traceability in year 2009

The Robert Ballanger Hospital choice

<table>
<thead>
<tr>
<th>DATAMATRIX</th>
<th>2009</th>
<th>% Traceability of instruments</th>
<th>% Traceability of sterilisations / year</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFODOT</td>
<td>Clinical services</td>
<td>4 000</td>
<td>35%</td>
</tr>
<tr>
<td>LASER</td>
<td>Operating theater</td>
<td>1 000</td>
<td>10%</td>
</tr>
</tbody>
</table>
DATA MATRIX LASER
Non conformity of surgical boxes

8.7% of No Conformity

- Problem of packaging 5%
  - Can be resolved by UDI

- Quality of Instruments 3.7%
  - Can Not be resolved by UDI
Number of instruments to tag

6 Trays / reference

Tray 1

Tray 2

Tray 3

Tray 4

Tray 5

Tray 6

1 reference

Caesarean Tray

39 instruments / tray

<table>
<thead>
<tr>
<th>Article name</th>
<th>Nº</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOITE INOX 42X18X9 CM</td>
<td>B120</td>
<td>1</td>
</tr>
<tr>
<td>MANCHE DE BISTOURI N° 4</td>
<td>M330</td>
<td>1</td>
</tr>
<tr>
<td>CISEAUX MAYO DROIT 16 CM</td>
<td>C111</td>
<td>1</td>
</tr>
<tr>
<td>CISEAUX MAYO COURBE 18 CM</td>
<td>C112</td>
<td>1</td>
</tr>
<tr>
<td>PINCE DISSECTION A/G 14 CM</td>
<td>P124</td>
<td>1</td>
</tr>
<tr>
<td>PINCE DISSECTION S/G 14 CM</td>
<td>P125</td>
<td>1</td>
</tr>
<tr>
<td>PINCES KOCHER A/G 14 CM</td>
<td>P126</td>
<td>6</td>
</tr>
<tr>
<td>PINCES KELLY DROITES S/G 14 CM</td>
<td>P127</td>
<td>6</td>
</tr>
<tr>
<td>PINCES KELLY COURBES S/G 14 CM</td>
<td>P128</td>
<td>6</td>
</tr>
<tr>
<td>PINCES A CHAMPS BACKHAUSS 12</td>
<td>P129</td>
<td>4</td>
</tr>
<tr>
<td>PINCE A PANSEMENT DROITE 24 CM</td>
<td>P130</td>
<td>1</td>
</tr>
<tr>
<td>PORTE-AIGUILLES MAYO-HEGAR 18</td>
<td>A440</td>
<td>1</td>
</tr>
<tr>
<td>PORTE-AIGUILLES DE DOYEN 14 CM</td>
<td>A441</td>
<td>1</td>
</tr>
<tr>
<td>ECARTEUR DE FARABEUF 12 CM</td>
<td>E550</td>
<td>1</td>
</tr>
<tr>
<td>ECARTEUR FARABEUF 15 CM</td>
<td>E551</td>
<td>1</td>
</tr>
<tr>
<td>VALVES DE KELLY 23 CM</td>
<td>V660</td>
<td>2</td>
</tr>
<tr>
<td>VALVES Vaginales DE DOYEN 90 MM</td>
<td>V661</td>
<td>2</td>
</tr>
<tr>
<td>PINCE DISSECTION S/G 20 CM</td>
<td>D770</td>
<td>1</td>
</tr>
<tr>
<td>PINCE DISSECTION A/G 25 CM</td>
<td>D771</td>
<td>1</td>
</tr>
</tbody>
</table>

234 instruments for the reference “Caesarean Tray”
## Number of instruments to tag

<table>
<thead>
<tr>
<th>Surgical specialities</th>
<th>Orthopedics</th>
<th>Visceral</th>
<th>Obstetric</th>
<th>ORL</th>
<th>Stomato</th>
<th>Urology</th>
<th>Infantil</th>
<th>Ophtalmo</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of references</td>
<td>138</td>
<td>30</td>
<td>15</td>
<td>34</td>
<td>53</td>
<td>32</td>
<td>14</td>
<td>15</td>
<td>331</td>
</tr>
<tr>
<td>Number of trays</td>
<td>222</td>
<td>78</td>
<td>51</td>
<td>72</td>
<td>98</td>
<td>54</td>
<td>25</td>
<td>33</td>
<td>633</td>
</tr>
<tr>
<td>Trays which can not be tagged (implants)</td>
<td>60</td>
<td>2</td>
<td>0</td>
<td>6</td>
<td>18</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>95</td>
</tr>
<tr>
<td>Number of instruments to tag</td>
<td>3270</td>
<td>1899</td>
<td>1107</td>
<td>945</td>
<td>1673</td>
<td>712</td>
<td>672</td>
<td>382</td>
<td>10660</td>
</tr>
</tbody>
</table>
Tag resistance to sterilisation

- Test on 8 different instruments:
  - 95% inox – 5% titanium
  - laser datamatrix, stamping, infodot, RFID

- Result: 100% visibility on Inox laser marked instruments after 200 sterilisation cycles
Resistance of the laser tag
**Number of instruments to tag**

Life time of the tags : 200 cycles

<table>
<thead>
<tr>
<th>Tag life time (LT) in years (based on number of sterilisation cycles / year)</th>
<th>N° references</th>
<th>N° Trays</th>
<th>N° instruments</th>
<th>N° tagging / 10 years</th>
<th>N° tagging / 20 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>LT &lt; 2 years</td>
<td>1</td>
<td>3</td>
<td>30</td>
<td>161</td>
<td>323</td>
</tr>
<tr>
<td>2 years ≤ LT &lt; 5 years</td>
<td>16</td>
<td>97</td>
<td>2 545</td>
<td>5 893</td>
<td>11 787</td>
</tr>
<tr>
<td>5 years ≤ LT &lt; 10 years</td>
<td>66</td>
<td>148</td>
<td>3 438</td>
<td>5 053</td>
<td>10 106</td>
</tr>
<tr>
<td>10 years ≤ LT &lt; 20 years</td>
<td>61</td>
<td>114</td>
<td>2 406</td>
<td>5 656</td>
<td>3 589</td>
</tr>
<tr>
<td>20 years ≤ LT</td>
<td>191</td>
<td>272</td>
<td>2 241</td>
<td>3 899</td>
<td>2 241</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>335</strong></td>
<td><strong>634</strong></td>
<td><strong>10 660</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of markings if life cycle of instruments is 10 years

Number of markings if life cycle of instruments is 20 years

20 663

28 045
Type of Tagged Instruments

N=719 Instruments Tagged
Logistic data

- 360 instruments can be tagged a week
  - Depending on supplier (500 a week for our French supplier)
  - Depending on the numbers of instruments that can be sent per week

- Percentage of code readable: >97%
  - 100% technically readable when tested after their laser marking
  - Our choice: keeping speed of work by not reading very small instruments
Conclusion – Laser Data Matrix

- First results show the easiness of the logistic of tagging
- Laser 2D barcodes are practically all readable and it is possible to tag small instruments
Our next GS1 projects

April 2010

End 2009
End 2010

2010 - 2012

End 2010

2010 - 2012

Ongoing
Link between prescription and material flow (GS1): a focus on drug process

Ward / Nursing unit

1. Prescribe
   - doctor

2. Analysis
   - proposed prescription *
   - prescription + opinions

3. Analysis
   - opinions + exchanges

- Medecine catalog

- Nursing Unit medicine cabinet

- Information

- Dispensation

- Nurse

- Depending on manufacturer

- Ongoing

Pharmacy

1. Prescribe
   - pharmacist

2. Analysis
   - proposed prescription *
   - prescription + opinions

3. Analysis
   - opinions + exchanges

- Medecine catalog

- Pharmacy Computerized Stock Management
  - Semi-automated distribution robot
  - Central pharmacy stocks

- Supplier

- Ongoing

- End 2010

- Data matrix

- GS1

- Ward / Nursing unit

- Pharmacy

(*) : following te protocols established between pharmacists and medical practitioners

Collaborative work - Opinion
What are we all aiming for?

Improving patient safety

• And GS1 standards are helping us ...