Traceability and UDI in the Robert Ballanger Hospital

M. Tournoud, Y. Hassani, J. Mignon, F. Fremont, G. Nicolaos
Summary

- Presentation of the Robert Ballanger Hospital
- Traceability of Sterilized Medical Devices in the Robert Ballanger Hospital
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
Sterilization unit

- 120 000 sterilized devices per year
- 20 000 surgery boxes per year
Definition

Iridectomy scissors
1 product = 1 instrument

Parodontology Set
1 product = 13 instruments
Repartition of the activity of the sterilisation unit

- Operating Theater: 39%
- Others: 27%
- Stomatology: 13%
- Maternity: 9%
- Emergency: 6%
- UCSA: 6%
Traceability in 2008

Pharmacy

Operating room

Sterilization unit

Traceability
Implantable
Medical Device

Reception
Implantable
Medical Device

Surgery intervention

Pre-cleaning

Cleaning

Sterilization

Distribution

Packaging

F. Frémont - G. Nicolaos 13-03-2009
Evolution of Traceability Project – Year 2009

1/ Traceability in the operating room

- Pharmacy
- Reception
- Implantable Medical Device
- Sterilization unit
- Distribution
- Process
- Surgery intervention
- Operating room
- Distribution of a sterile medical device
- Patient record
- Patient traceability
Evolution of Traceability
Project – Year 2009

2/ Traceability of Individual Sterile Medical Device

**Dot-Peening**
- Can be made in the sterilization unit
- Corrosion
- Problem of Reading
- Difficulty with the taging

**Laser**
- Industrial tagging
- Easy reading
- Industrial treatment of instrument
- Time to tag Devices

**DATAMATRIX**

**Infodot**
- Easy and fast tagging
- Cost
- Deterioration faster than the others

F. Frémont - G. Nicolaos 13-03-2009
The Robert Ballanger Hospital choice

<table>
<thead>
<tr>
<th>DATAMATRIX</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFODOT</td>
<td>Clinical services</td>
<td>7000</td>
<td>All</td>
</tr>
<tr>
<td>LASER</td>
<td>Operating theater</td>
<td>4000</td>
<td>3000</td>
</tr>
</tbody>
</table>
DATA MATRIX « Infodot »
Tooth extraction set
Code contained in this infodot
Stomatology

1171 instruments tagged

- Infodot failed: 0.09% (2)
- Infodot cutted: 0.57% (13)

On 729 products returned = 2293 instruments

F. Frémont - G. Nicolaos 13-03-2009
DATA MATRIX LASER
No conformity of surgical sets

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
Kind of Tagged Instruments

N=719 Instruments Tagged

F. Frémont - G. Nicolaos 13-03-2009
Laser Data Matrix 2D barcode
New instrument
Laser Data Matrix 2D barcode
Used instrument
Logistic data

- 360 instruments can be tagged a week

- 100% of codes were readable when they were tested after their laser marking

- >99% are readable in the sterilization unit
  - It is impossible to adapt the scanner parameters during the production
Conclusion

- 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