GS1 Healthcare Provider Advisory Council (HPAC) Webinar

Surgical Instruments Traceability and scanning

GS1 Global Office

10th April 2014

Centre Hospitalier Intercommunal Robert Ballanger

HPAC Case Study Webinars

This is the THIRD Webinar

- Patient security and supply chain optimization:
  - Surgical Instruments Traceability and scanning
- It will be recorded!
- Webinars will take place monthly

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HPAC Case Study Webinars

Planning following webinars

The following topics and dates will be as follow:

Date	Speaker	Webinar theme
8 May 2014	Thomas De Rijdt UZ Leuven, Belgium	The missing link in patient safety
12 June 2014	Michael Innes & Kirk Metzger Kaiser Permanente	Achieving supply chain efficiencies, delivery of patient care and product utilisation. HPAC Award Winning Case Study
10 July 2014	HTG representative	HTG Update

Previous Webinars:

- 13th February 2014: **The link between Traceability and Patient Safety**
  - View recording (please note it takes a couple of minutes to load before viewing)
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- 13th March 2014: **Implementation in a hospital pharmacy in Argentina**
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Details here: http://www.gs1.org/healthcare/hpac_webinars

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C.H.I Robert Ballanger
Frédérique Frémont

Patient security and supply chain optimization

Surgical Instruments Traceability and scanning

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Hi! Robert Ballanger Hospital

- Intercity hospital serving a population of 400,000 persons
  - 650 beds
    - 450 beds in acute care (medical, chirurgical and maternity)
    - 50 beds physical Medecine and rehabilitation
    - 170 psychiatry beds
  - Outpatient clinic and pharmacy inside Villepinte detention center
  - CDG airport hospital

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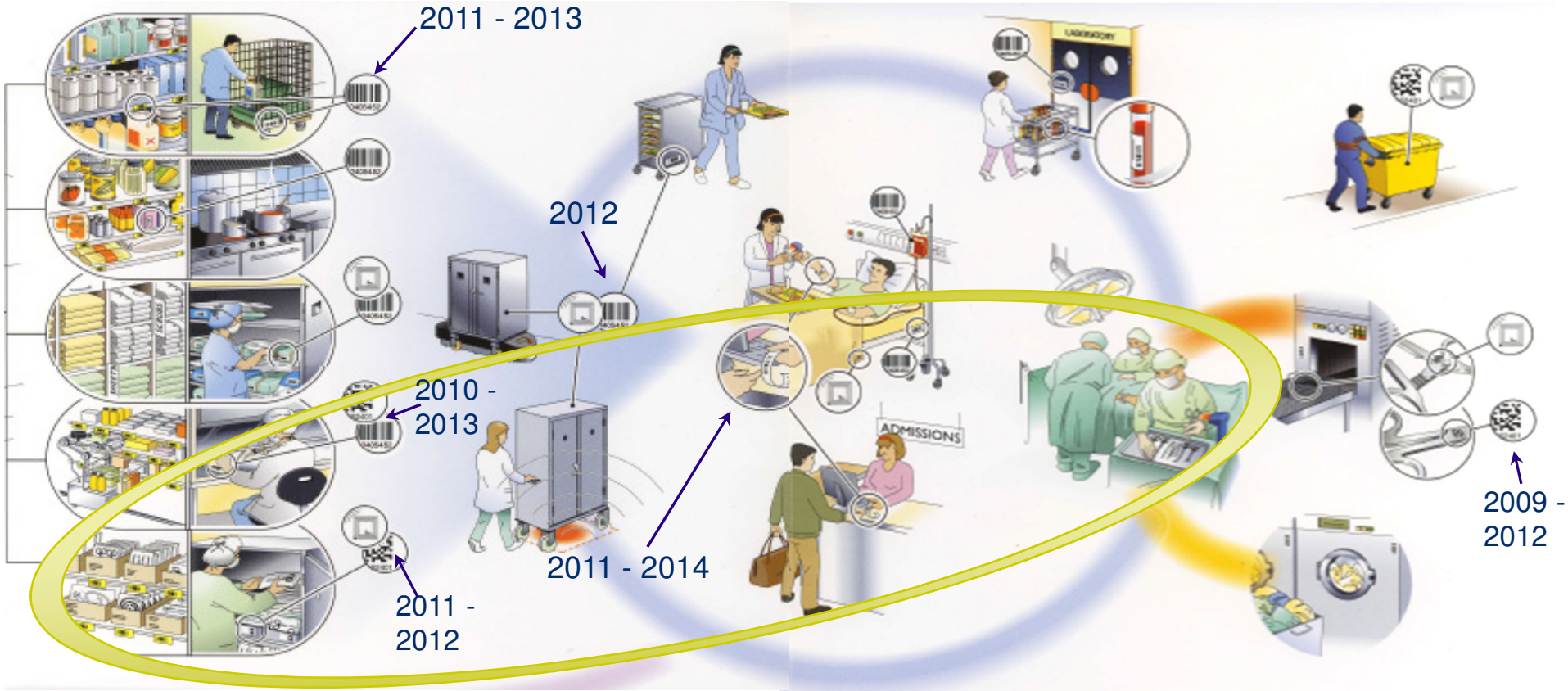
Overview of instrument and implant traceability



Goal: Full traceability as it is mandatory and French Pharmacists are personally liable for Drugs and Sterile Medical Devices

Challenges : Managing the projects which are fundamentally linked together with too few resources (pharmacists, IT, ;..)

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Global Project : Medical Devices Traceability and scanning

- **Initial Business Issue** : Surgical Instruments
  - Due to Creutzfeldt-Jakob risk, the last 5 patients on which the instruments have been used must be known
  - Applies to hospital owned or loaned instruments
- **Secondary Business Issue** : Surgical Instruments
  - Contracting for taking in the sterilization of another hospital (same level of activity, different surgical procedures)
- **Business Issue :** Implants and high value Medical Devices
  - Implants : traceability is mandatory
  - Itemized billing to the patient (not included in the hospital bundled payment)
- **Who?** The head of the pharmacy has been the leading sponsor but it took 2 years to convince the top management to go to a full GS1 hospital

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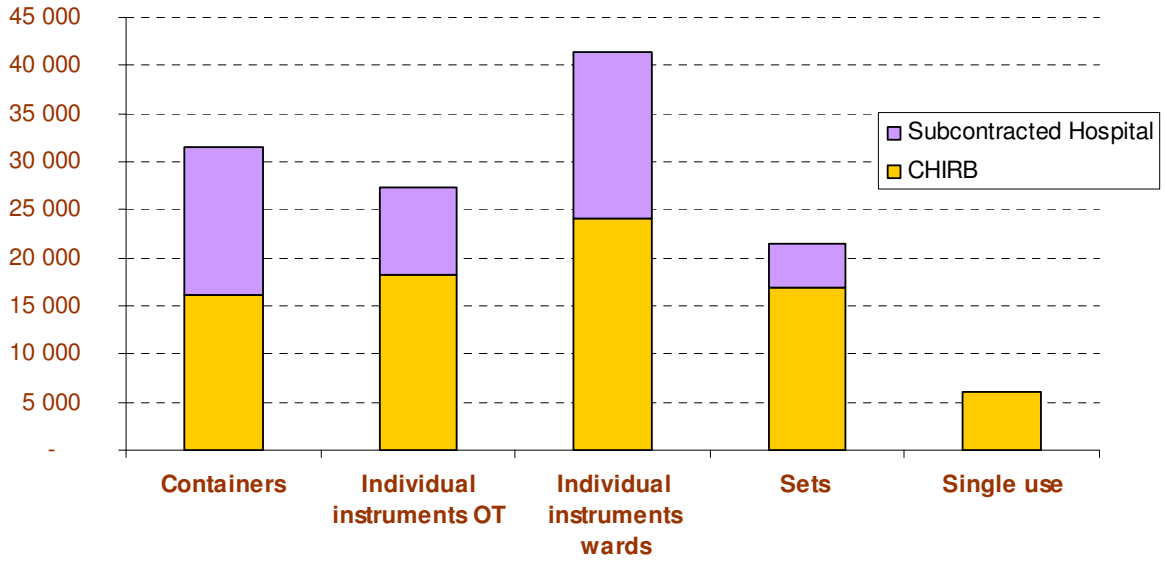
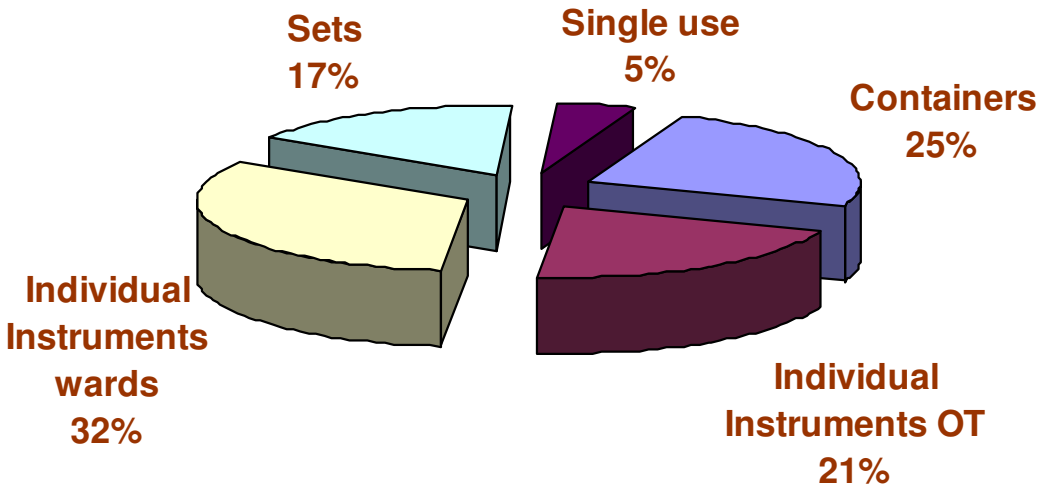
Focus : Surgical Instruments Traceability and scanning



	CHIRB	Subcontracted Hospital	Total
Containers	16 188	15 399	31 587
Individual instruments OT	18 186	9 175	27 361
Individual instruments wards	24 069	17 389	41 458
Sets	16 937	4 477	21 414
Single use	6 016		6 016
Total produits	81 396	46 440	127 836



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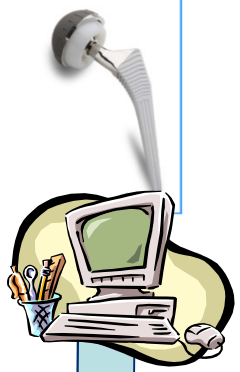
Process and instrument traceability

Pharmacy

Traceability
Implantable
Medical Device

Reception
Implantable
Medical Device



Distribution

Operating Theater

intervention

Sterilization Unit

Pre-cleaning

Cleaning

Packaging

Sterilization

Distribution

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Surgical Instruments Traceability and scanning : Preliminaries

- **Marking : Data Matrix**
  - Two carriers could be used in the operating theatre and sterilization units : RFID tags and DataMatrix 2D bar codes
  - Choice of the most pragmatic system of identifying the surgical instruments with a DataMatrix 2D bar codes.
    - Ease of laser marking existing or branded new Instruments
    - Cost of this kind of marking. a single lasermark costs between 2 and 3 Euros, whilst an RFID tag costs approximately 7 Euros
    - Existence of software that enables this kind of traceability

- **Standard : GS1**
  - Will to buy new instruments already marked by the supplier
  - Existing French supplier marking its instruments with GS1 DataMatrix
  - Knowledge of GS1 in the hospital and help by our MO

Implementation of DATAMATRIX and follow-up

- **1st step (2009 – mid 2012) : 1 engraving subcontractor in France**
  - **Our choice**
    - Laser engraving for Operating Theater instruments
    - Infodot for wards instruments
  - **Challenge : Logistics**
    - 360 instruments could be tagged per week
      - Depending on supplier (500 a week for our French supplier)
      - Depending on the numbers of instruments that can be sent per week

Laser

GS1

+

Industrial tagging
Easy reading
Industrial treatment of instrument

-

Time to tag Devices

Infodot

+

Easy and fast tagging
Cost

-

Deteriorate faster than the others

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Implementation of DATAMATRIX and follow-up

cont.

- Codification :
  - 1 GTIN for all instruments engraved under our responsibility + serial number (automatic incrementation)
  - Links with the article number in the IT system (T-Doc)
  - Each packaging unit has its own supplier code and is labeled with a unique number for each sterilization process
- Traceability at the instrument level is done in the packaging area : instrument to container
- Traceability is done to the packaging unit (container, tray,…) in the other area of the sterilization unit and in the operating theater

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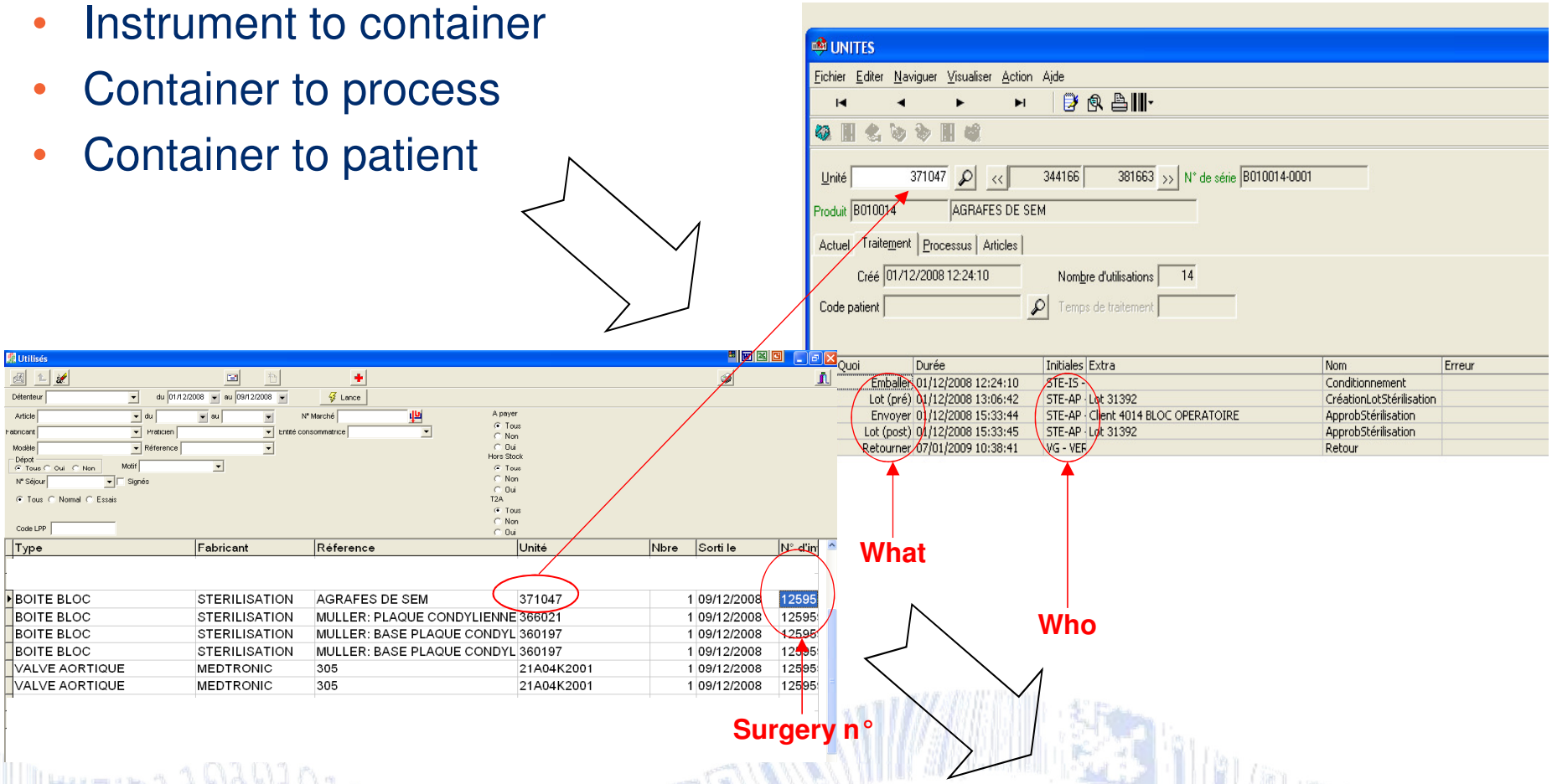
Implementation of DATAMATRIX and follow-up

cont.

- Traceability :
  - Instrument to container
  - Container to process
  - Container to patient



Link : Patient – Container – Instrument - Process

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Surgical Instruments Traceability and scanning : How it works

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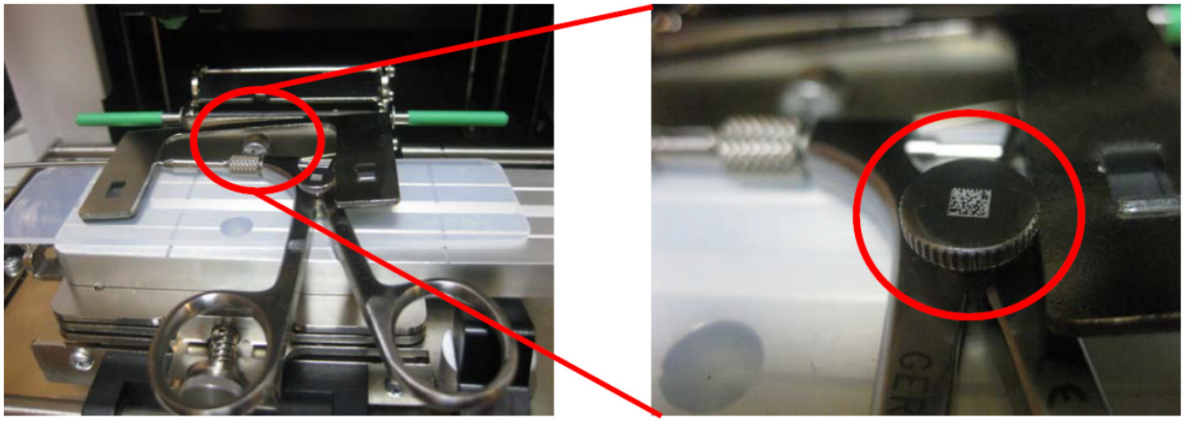
Implementation of DATAMATRIX and follow-up

cont.

- **2st step (mid 2012 – mid 2013) : new subcontractor**
  - **On spot engraving by the subcontractor employees**
    - Micro-dot (new technology) or laser engraving depending on the alloy
    - All instruments are engraved
    - Outside Hospital instruments engraved with their own GS1 numbers



Engrave the Screw Head

Data Matrix

Data matrix size :

- Depending on the instrument
- Smallest size : 1,2 x 1,2 mm

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Implementation of DATAMATRIX and follow-up

cont.

- **2st step (mid 2012 – mid 2013) : new subcontractor**
  - **Benefit : Logistics**
    - Instruments tagged alongside the sterilization process

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Implementation of DATAMATRIX and follow-up

cont.

- **3st step (end 2013 - …) : 100 % instruments on stock engraved**
  - **Marking needed for :**
    - Worn-off data matrix (eg. instruments used daily)
    - New instruments (if not engraved by the supplier)
  - **How :**
    - Acquisition of the dot engraving machine
    - Training of 3 sterilization operators
    - If needed, laser engraving on site by the subcontractor
  - **Purchasing : GS1 marking including in bid to tender terms**
    - OK for Operating Room Quality instruments
    - Reduced number of suppliers for others
- **Remaining challenge : ancillaries on loan**
  - No engraving done by the suppliers
  - Need of a common request by the Health Providers
  - UDI legislation will help

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Surgical Instruments Traceability and scanning

- **Business benefits**
  - **Cost reduction : ROI around 24 weeks**
    - Decrease in non-conformance and decrease of cost per box per surgical procedure
    - Decrease in the number of Operating Theater nurses needed : 2 as team leaders and referents

Type of surgery	Number of instruments	Price for engraving
Total	**10 063**	**35 221 €**

Without engraving

Type of surgery	Number of containers per week	Average sterilization cost per container	Cost per week	Non conformity - Resterilization of **8%** of containers	Total cost
Total containers / week	**558**		**18 275 €**	**1 462 €**	**19 737 €**

With engraving

Type of surgery	Number of containers per week	Average sterilization cost per container	Cost per week	Non conformity - Resterilization of **1%** of containers)	Total cost
Total containers / week	**558**		**18 275 €**	**183 €**	**18 458 €**

Difference per week
1 279 €

Difference per year
66 508 €

maintenance / year (new engraving) - *3 522 €*

No more operating theater nurses needed in sterilization unit (1 FTE) replace by 1 sterilization operator

Difference in salary per year
13 315 €

ROI (weeks)
24

Total **76 301 €**

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Surgical Instruments Traceability and scanning

- **Acceptance and Change Management**
  - Great sponsorship by the Sterilization Department Pharmacist
    - No prior knowledge of GS1 but had the will to learn and understand
    - Became a strong project leader and helped convince the top management
    - Recognized as a team leader by his operators
  - Newly refurbished sterilization unit
    - Operators participated in the new design and new organization
    - Young team, used to scanning (their ID, containers)
    - Were kept informed and participated since the beginning of the project
    - Proud of being among the first to implement such a project

Immediate acceptance and even enthusiasm

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Surgical Instruments Traceability and scanning

- **What were the key implementation challenges experienced?**
  - At first, only one engraving supplier (second entered the market in 2012)
  - Scanners are one of the biggest challenge in instrument engraving (reading of very small data matrix, 2mm x 2mm or 1.3mm x 2.8mm)
    - With a good scanner, processing time is not significantly different (can be lower)
  - Interoperability with IT process traceability
    - 4 IT systems :
      - Pharma® in the Pharmacy Department : Management of Drugs and Medical Devices and Electronic Prescription)
      - T-Doc ® in the Sterilization Department : Process Management and Traceability
      - Bloqual/Sedistock in the Operating Theater : OT Management and Traceability
      - McKesson : Patient Medical Record
    - Data Base integration : 1 849 references for Reusable Medical Devices had to be entered by hand in the Operating Theater IT system
- **What next?**
  - Tracing the implants and manage the operating theater stock with the WMS we have now implemented in a new Medical Devices warehouse
  - Link with automated dispensing cabinets in the operating rooms through GS1 Datamatrix or bar code reading

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Next step : Traceability of Medical Devices with GS1 Standards

Pharmacy

Reception
Implantable Medical Device

GS1

Distribution

Sterilization unit

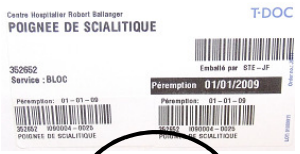
Process

Distribution of a sterile medical device

GS1

Operating room

GS1



GS1

Surgery intervention

IT Prescription

Patient traceability

Implemented

Patient record
Implementation in progress

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Thank You!

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