Materiovigilance : Daily implant traceability

EAHP 2018 – Gothenburg
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Cliniques universitaires
SAINT-LUC
UCL BRUXELLES

Disclosure

Relevant Financial Relationship
None

Off-Label Investigational Uses
None

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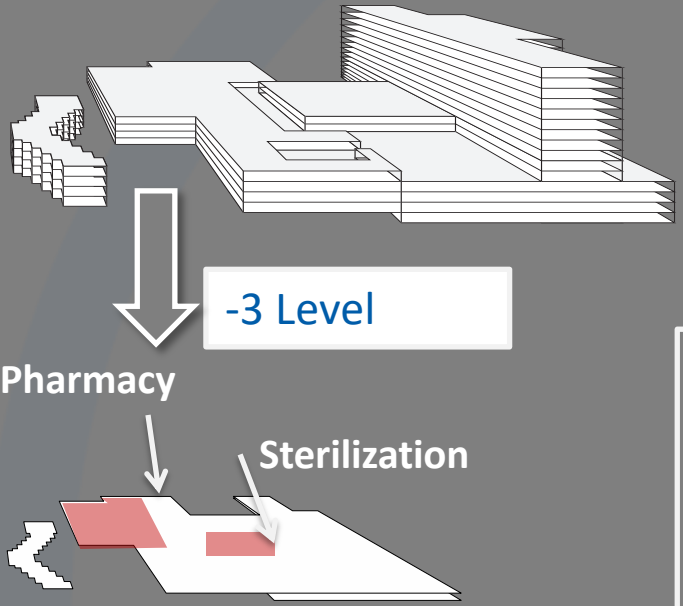
Self assessment questions

1. Current implant packaging barcodes use uniform traceability data format ?
- False
- True

2. The communication frequency used in RFID technology for implants is :
- Low frequencies
- Ultra high frequencies

3. Which type of RFID tag reading is best suited for daily practice in a surgical ward ?
- 1D reading
- 3D reading

Cliniques Universitaires St-Luc : an overview



- ✓ 481.000 Consultations
- ✓ 235.000 Standard hospitalization days
- ✓ 72.000 Emergency admissions
- ✓ 43.000 Day time hospitalisations and dialysis
- ✓ 21.000 Surgeries including 200 transplants
- ✓ 1.780 Births
- ✓ 979 Accredited hospital beds
- ✓ 30.000 referenced medical devices

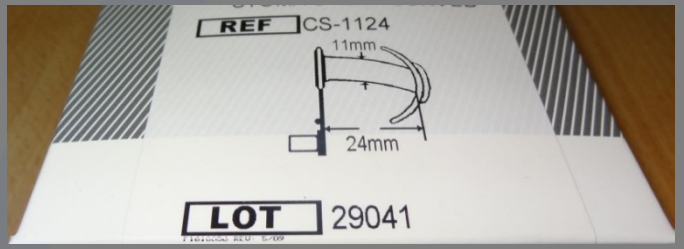
Traceability cycle

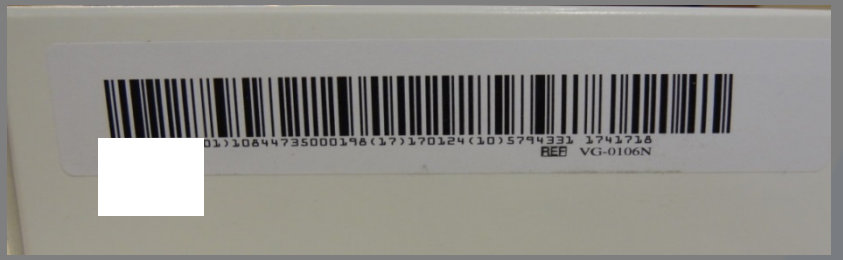
2008 : new Pharmacy software

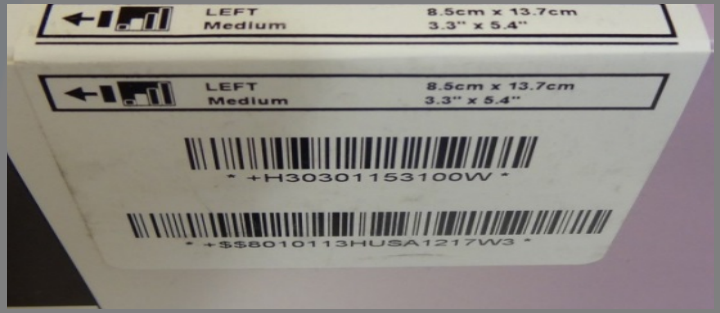
- Pharmaceutical specialties
- Sterile medical devices
- Implants

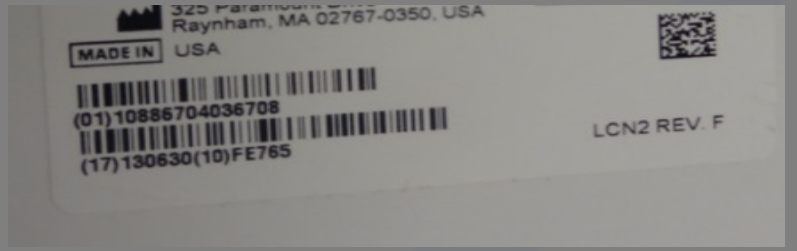
- Creation of a system for the traceability of consigned items
- Objective ?
  - Trace each implant within the hospital
  - Improve pharmaceutical material vigilance
- How ?
  - Industry bar codes are not standardized
  - Creation of a yellow traceability tag

Implant packaging





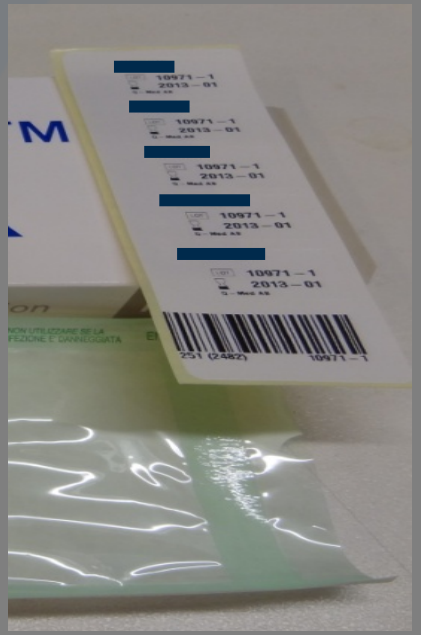




Solution : UDI

Implant packaging

Traceability tags

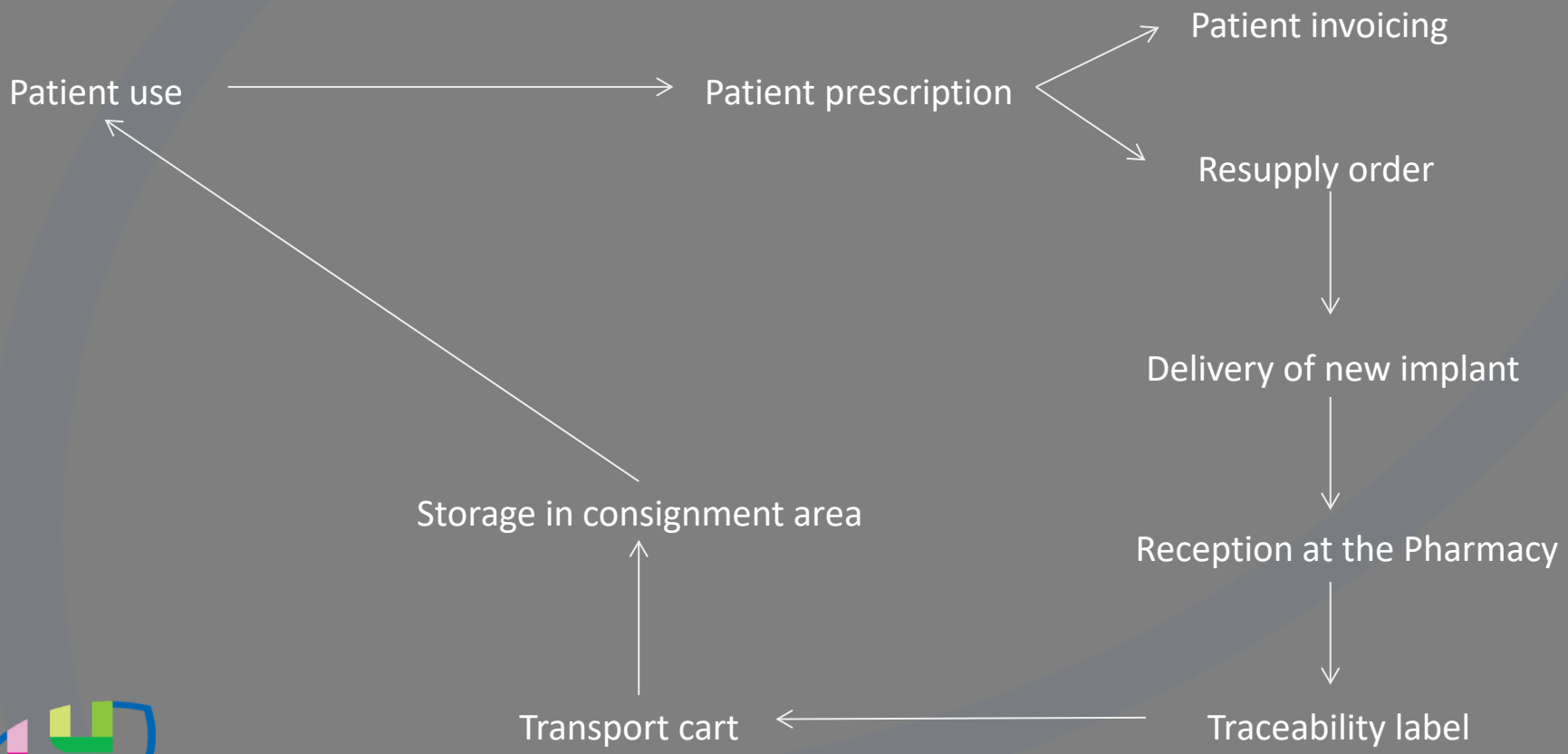


Internal traceability tag

Internal traceability tag : parameters

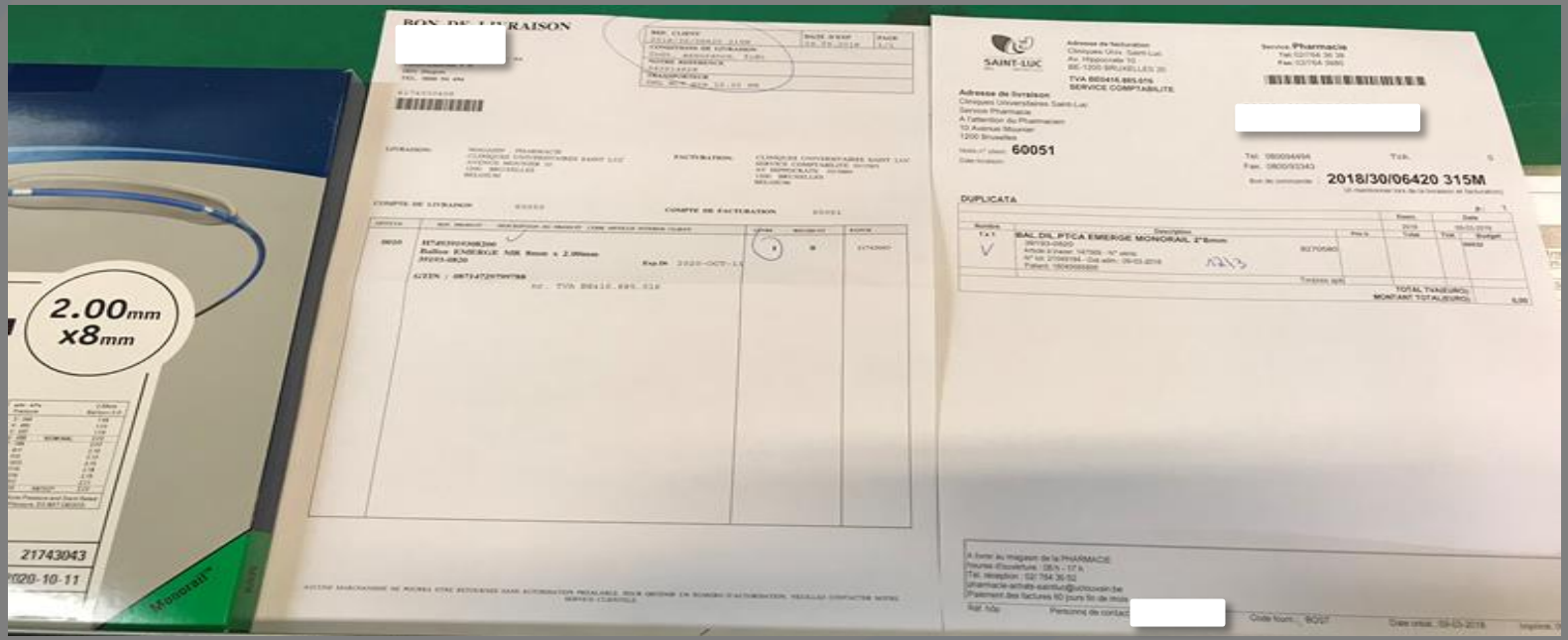
- Polyethylene
- Semi-permanent adhesive
- Dimensions : 10,7 cm x 3,6 cm in size
- Thermotransfer printing
- Impervious to liquids in the operating room
- Detachable (remove from packaging)
- Adhereable on paper prescriptions

Current hospital work flow for implants

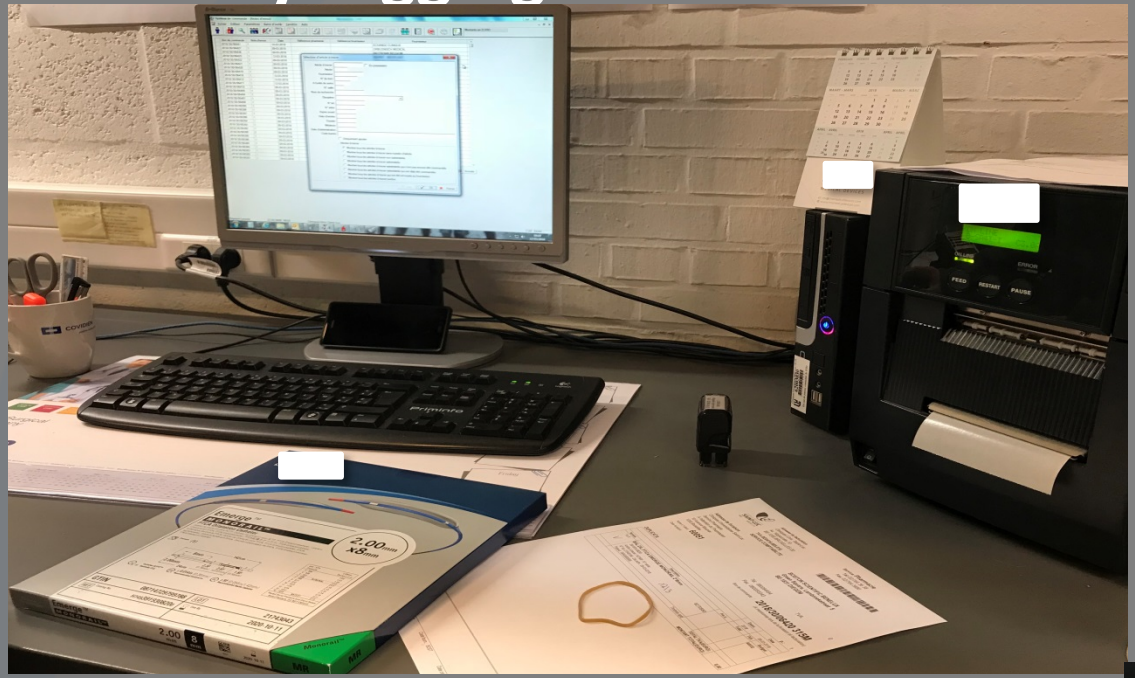


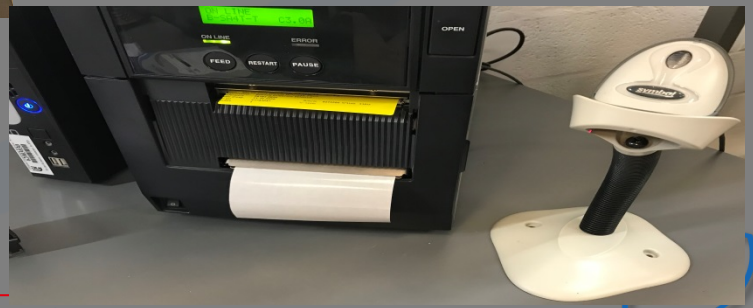
Pharmacy reception

Reception quality control procedures : quantity and quality validation



Pharmacy tagging

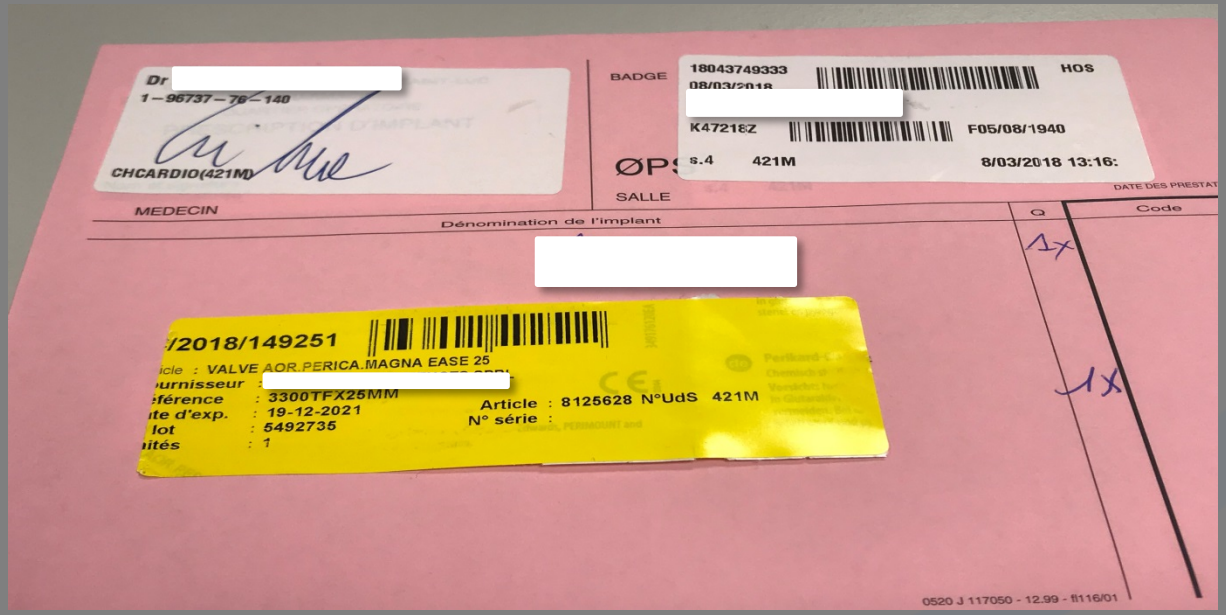




Transport carts

Operating ward and medico-technical services

Patient use


Dr
1 – 96737 – 76 – 140
CHCARDIO(421M)
BADGE
18043749333
HOS
K47218Z
F05/08/1940
s.4
421M
8/03/2018 13:16:
SALLE
MEDECIN
Dénomination de l'implant
Q
Code
1x
1x
/2018/149251
VALVE AOR.PERICA.MAGNA EASE 25
3300TFX25MM
19-12-2021
5492735
1
Article : 8125628 N°UdS 421M
N° série :
0520 J 117050 - 12.99 - fl116/01

Resupply order

Cliniques Universitaires SAINT-LUC UCL BRUXELLES

Adresse de facturation
Cliniques Univ. Saint-Luc
Av. Hippocrate 10
BE-1200 BRUXELLES 20

TVA BE0416.885.016
SERVICE COMPTABILITE

Service: Pharmacie
Tél: 02/764 36 38
Fax: 02/764 3680

Adresse de livraison
Cliniques Universitaires Saint-Luc
Service Pharmacie
A l'attention du Pharmacien
10 Avenue Mounier
1200 Bruxelles

Notre n° client:
Date livraison:

Tél: 0800/39032
Fax: 02/481 30 56

TVA: 0

Bon de commande : **2018/30/06311 QOP**
(A mentionner lors de la livraison et facturation)

DUPLICATA

p.: 1

Nombre	Description		Prix U.	Exerc. 2018 Total	Date 08-03-2018 TVA	Budget
1 x 1	**VALVE AOR.PERICA.MAGNA EASE 25** 3300TFX25MM Article à tracer: 149251 - N° série: N° lot: 5492735 - Dat.adm.: 08-03-2018 Patient: 18043749333	8125628				60070
	Timbres apb					
				TOTAL TVA(EURO):		
				MONTANT TOTAL(EURO):		0,00

A livrer au magasin de la PHARMACIE
heures d'ouverture : 08 h - 17 h
Tél. réception : 02/ 764 36 52
pharmacie-achats-saintluc@uclouvain.be

Implant delivery

Consignment convention

Modèle de convention pour la mise en consignation de dispositifs médicaux (implants, consommables et/ou instruments
Août 2009

CONTRAT DE CONSIGNATION

Entre:

- -

- -

- -

Représenté(e) par: M./Mme: . . . . . .

Fonction: . . . . . .

désigné(e) ci-après "l'entreprise"

et

.....

(adresse)

Représenté(e) par: M./Mme .....
Directeur général
et
Pharmacien .....
Pharmacien Chef de service

désigné(e) ci-après "l'hôpital", il est convenu ce qui suit:

Article 1: Objet de la convention:

La présente convention fixe les conditions générales et modalités concernant la mise en consignation par l'entreprise, à l'hôpital, des biens énumérés dans la liste reprise à l'annexe 1. La liste du stock de départ reprend tous les produits pris en consignation avec leur numéro de référence, leur prix et leur quantité.

Article 2: Principe de la consignation:

Le stock en consignation est placé à l'hôpital par l'entreprise sans facturation.

Les biens mis en consignation restent, à tout moment et en toute circonstance, la propriété de l'entreprise. L'hôpital est co-responsable du suivi des produits pris en

New traceability projects

- July 2018 : **LOQO project** in operating ward
  1. Centralized storage area for medical devices and implants
  2. Picking street for logistical preparation of surgeries
  3. New management software in operating ward

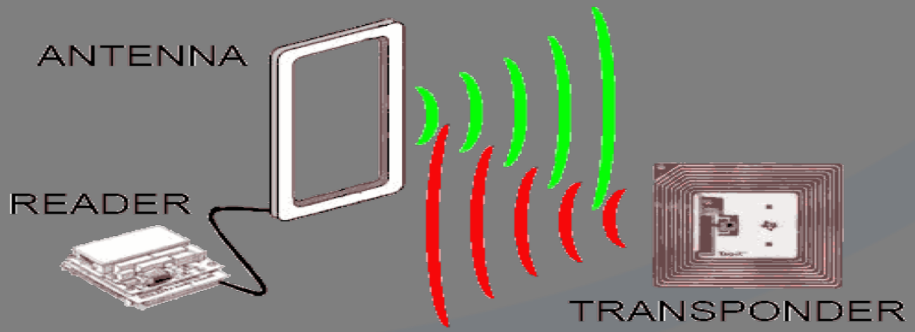
- 2018-2019 : **RFID project** to improve traceability of implants

RFID Technology

RFID = Radio Frequency Identification

2 essential components and 1 basic principle :

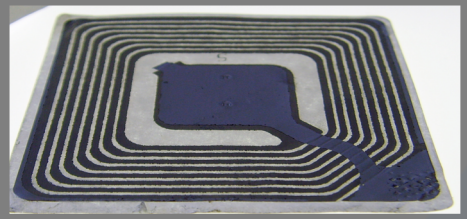
- The RFID Tag = the **transponder**
- The RFID interrogator = the **reader**

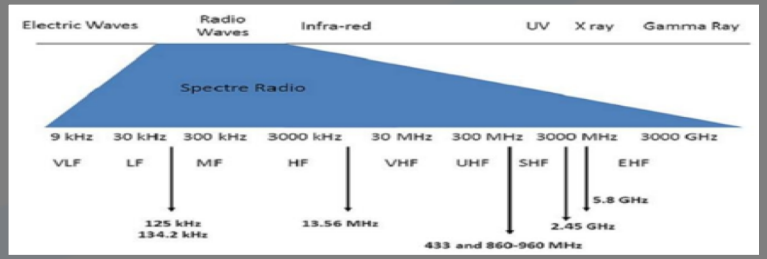


RFID Technology

The RFID Tag

- TAG = antenna + chip + encapsulation
- Single use or reusable
- Fixed or modifiable information storage
- 3 types :
  - Passive RFID Tags
  - Semi-active RFID Tags
  - Active RFID Tags





RFID Technology

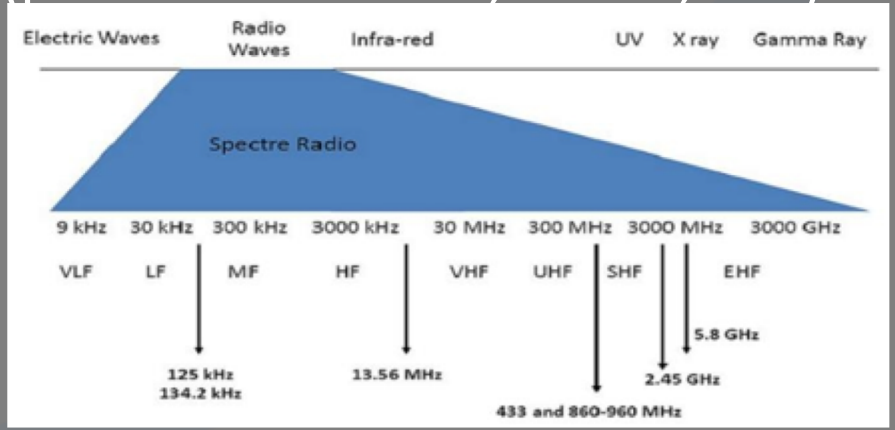
Communication frequency

The frequency determines :

- The distance of emission
- The speed of emission
- Adaptability to the environment (presence of metal, waves, etc.)

Three main ranges :

- LF : 125 – 135 KHz
- HF : 13,56 MHz
- UHF : 433 MHz, 860-960 MHz
- SHF : 2,45 GHz

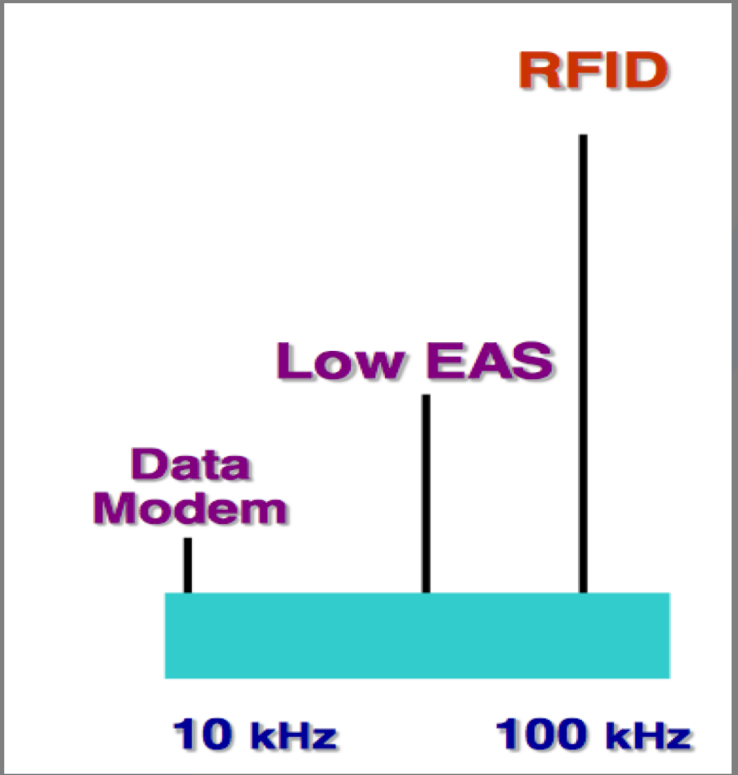


RFID Technology

Communication frequency

Choice of 125Khz LF band :

- Reliable for the identification of liquid products and materials such as aluminum
- Used worldwide in diamond traceability



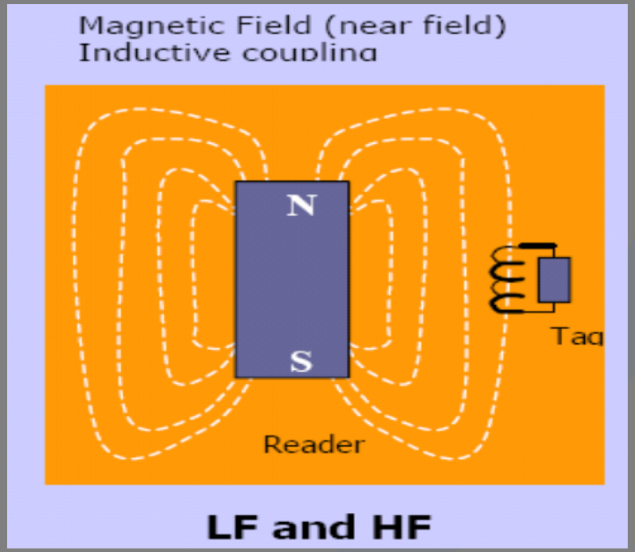
RFID Technology

Communication method

Two approaches :

- **Electrical coupling** (far field)
  - UHF or SHF
  - Antennas = dipoles or patches

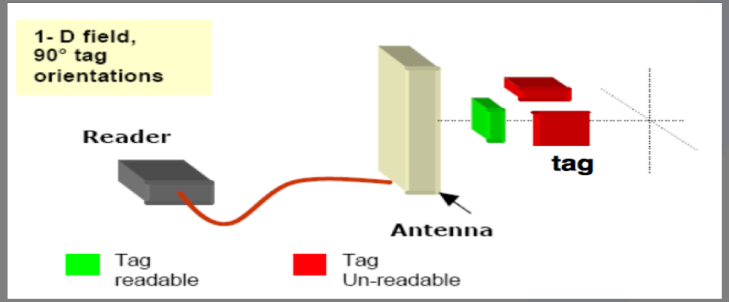
- **Magnetic coupling** (near field)
  - Method used in this project
  - LF or HF
  - Antennas = inductive loops



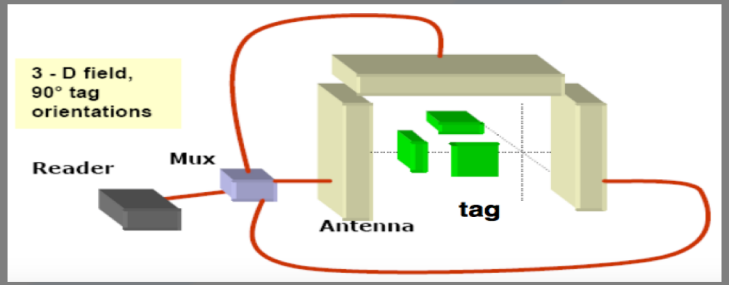
RFID Technology

1D reading / 3D reading

- **1D** : reading perpendicular to tag
  - Simple
  - Fast reading



- **3D** : three dimensional reading
  - Increased complexity but necessary
  - 3D tag larger than 1D tag
  - Influence on speed of reading



RFID Project

Objectives

- Improve the quality of implant traceability process
- Secure the traceability of implant use in patients
- Improve the reliability of the supply chain
- Optimize stock management (consignment control, batch reminders, return to supplier, stock accessibility to doctors and suppliers, ...)
- Facilitate access to electronic registration of implants
- Comply with new legislation
- Reduce the administrative costs of entire supply chain

Project implementation

First step: choose a supplier

Anticipated work flow :

Project implementation

Pharmacy reception

Reception → Storage → Preparation → Use → Validation

Physical reception of implantable medical device

Pharmacy software

Creation of unique internal code

Tag printing

Tag placing

- Very close to current process
- Visual control possible with information printing on tag

RFID traceability tag

Project implementation

Implant storage

Reception → **Storage** → Preparation → Use → Validation

- Centralization of tagged implants in 'RFID' cabinets:
  - Secure and confined storage
  - Automatic permanent inventory
  - Remote management of consigned items possible

Project implementation

Implant preparation and delivery

Reception → Storage → **Preparation** → Use → Validation

- User identification
- Patient identification
- Manual retrieval of necessary implants
- Automatic allocation of implant during patient surgery

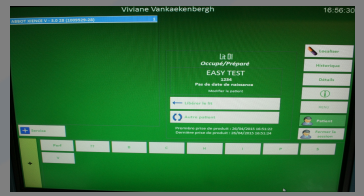
Project implementation

Implant use

Reception → Storage → Preparation → **Use** → Validation

- Confirmation of implant arrival in operating room by tag or barcode reading

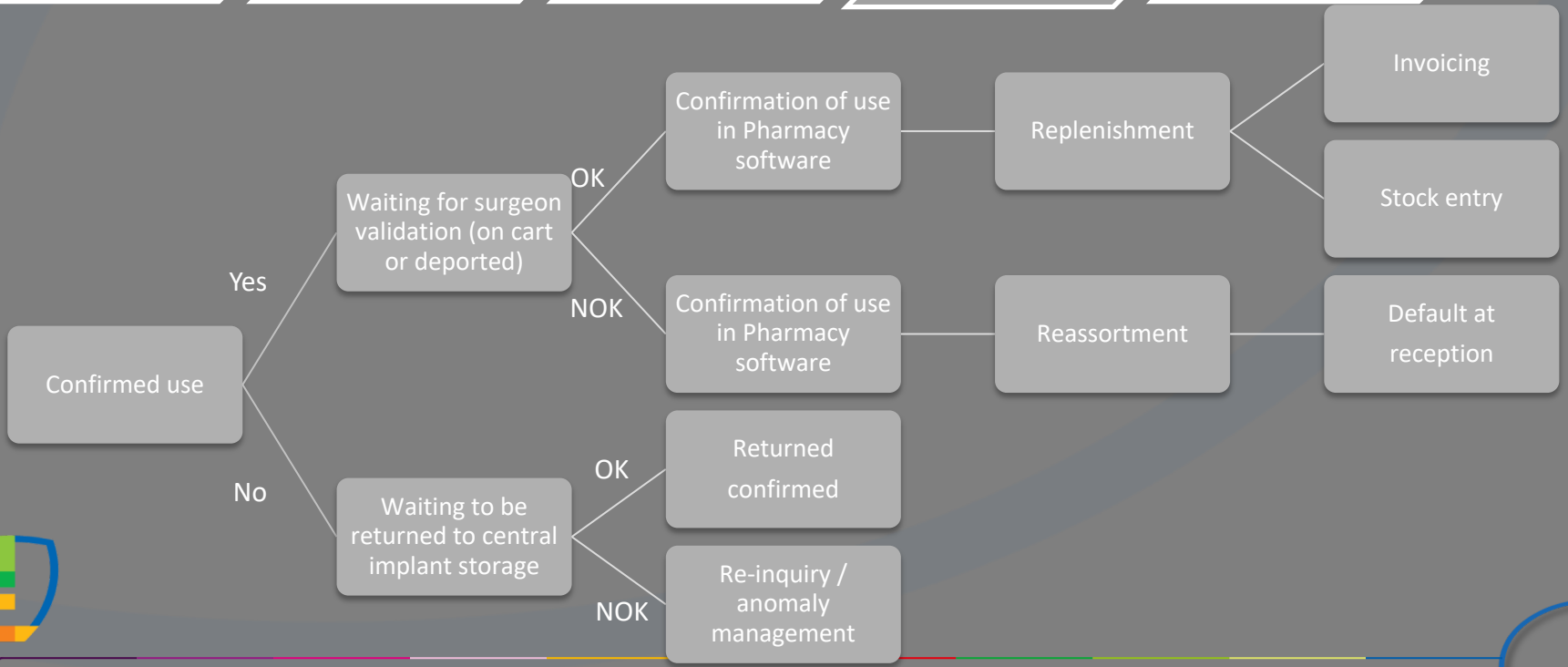
- During or before finalization of surgery, confirmation of which implants have been used



Project implementation

Validation of used implants

Reception → Storage → Preparation → Use → **Validation**



UDI

- Remove barcodes
- Facilitate the integration of data
- RFID relabeling
- Localisation

RFID Project

Expected benefits

- Unit-based traceability through entire cycle with a minimum of user intervention
- Validation of traceability circuit
- Integration with existing tools: Pharmacy software, operating room management tool, medication carts ...
- Acceleration of replenishment process
- Remote inventory consultation for Pharmacy
- Remote consultation of consignments by suppliers
- Simplification of invoicing flow

Self assessment questions

1. Current implant packaging barcodes use uniform traceability data format ?
- False
- True

2. The communication frequency used in RFID technology for implants is :
- Low frequencies
- Ultra high frequencies

3. Which type of RFID tag reading is best suited for daily practice in a surgical ward ?
- 1D reading
- 3D reading

Take home messages

1. The lack of standardization in current medical device packaging does not permit the use of industry-based barcodes within the hospital.

2. The traceability of implants within the hospital speeds up the treatment of materiovigilance information thanks to:
   - Registration of batch numbers
   - Assignment of specific batch number to patient after use

3. RFID technology strengthens the traceability of the system by :
   - The clear identification of the different stages within the internal cycle for an implant
   - The possibility of physically locating implants in centralized cabinets

Thank you for your attention