wfhss
World Federation for Hospital Sterilisation Sciences

Individual surgical instrument traceability: in line with the European regulation MDR 2017/745/EU

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INTRODUCTION

New European regulation text published in 2017
Incite to increase traceability
New instruments :
- UDI become mandatory before 2027

For instrument bought before
- Impossible to renew the whole stock
- Requirement standardization between old and new medical devices

REGLEMENT EU

EU MDR 2017/745

The new European regulation MDR 2017/745/EU aims to increase quality, performance, data transparency and medical devices securing
It is based in part on deeper CE marking files, notified bodies revaluation and higher traceability levels.

Article 10 : General obligations of manufactuers : “7. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.”

(41) “The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly **enhance the effectiveness of the post-market safety-related activities for devices**, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to **reduce medical errors** and to **fight against falsified devices**. Use of the UDI system should also improve **purchasing and waste disposal policies** and **stock-management** by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.”

ISO Standards

ISO 9001 : Traceability is the capacity to identify and trace the history, distribution, location and application of products, parts and materials.

ISO 13485 : The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained.

FRENCH CONTEXT

Ordre national des pharmaciens

French “Bonnes Pratiques de Pharmacie Hospitalière” (2001) :
Aims to improve quality management in sterilization units

Risk management follows the same goal

WHY T2I

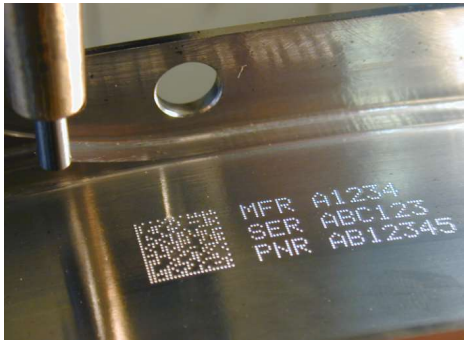
- ✓ Answer Standards and texts requirements.
- ✓ Increase health security
- ✓ Help materials vigilance
- ✓ Follow instruments lifecycle : lendings/ repairs/ upkeep/ lifetime
- ✓ Efficiency by instruments stock knowledge
- ✓ Easier skills transfer

HOW

2 ways :

- RFID chips
  - Competitive
  - Expensive

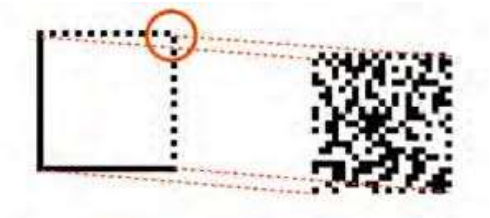
- Engraving
  - By micropercussion or laser
  - Directly on the instrument or on dots labels
  - Affordable
  - Corrosion problems



DATA MATRIX CODING

The indication "GS1 DataMatrix" allows users to have the assurance that the printed codes follow a standard data structure and therefore there is no specific development to be done in their applications to recover the data. It comes in the form of a square or rectangular symbol consisting of dots or juxtaposed squares. This representation is an ordered grid of black dots and white dots delimited by registration patterns, the horizontal and vertical axes.

Gs1 CODE
Used by suppliers, our system must be able to read and save it



EXAMPLE IN SAINT-ETIENNE

Prerequisites:

- ✓ A computer system in place
- ✓ Precise assembly lists including instrument references
- ✓ Local dedicated to this activity
- ✓ Investment budget
- ✓ The taste of adventure

Instruments stock at Saint-Etienne University Hospital

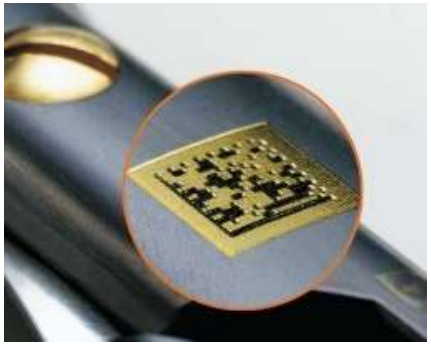
64 000 instruments

In
2170 compositions

METHODS

When available, Unique Device Identification (UDI) as data matrix given by the supplier is used.

Most suppliers deliver engraved instruments (80% of purchases)

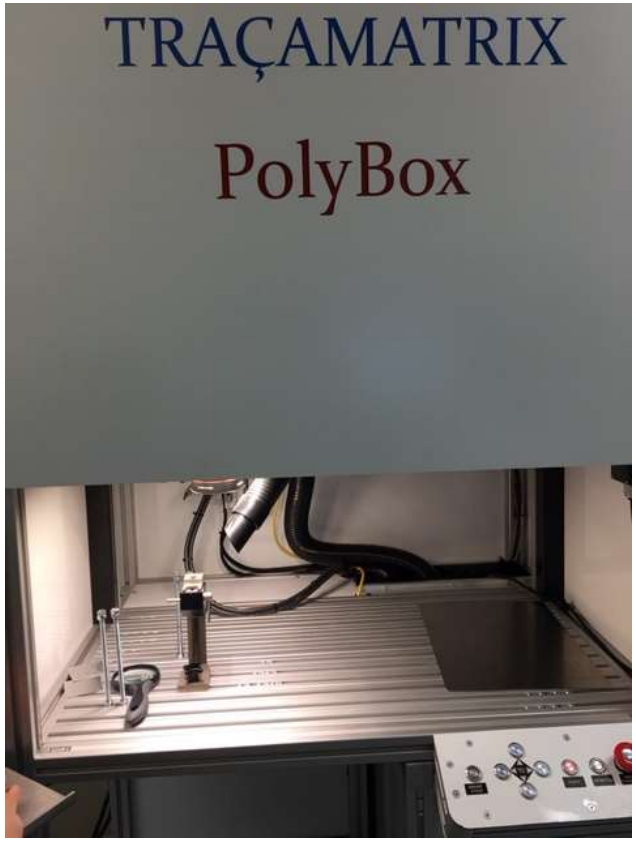


(01)3700483609062(10)520847(21)D0006

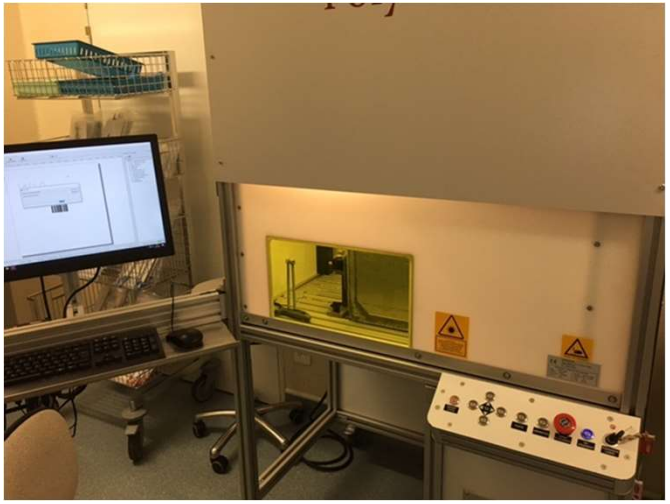
AI
(01) GS1 globally traded item number GTIN
370 = country prefix for GS1 France
(10) Batch number
(21) Serial number

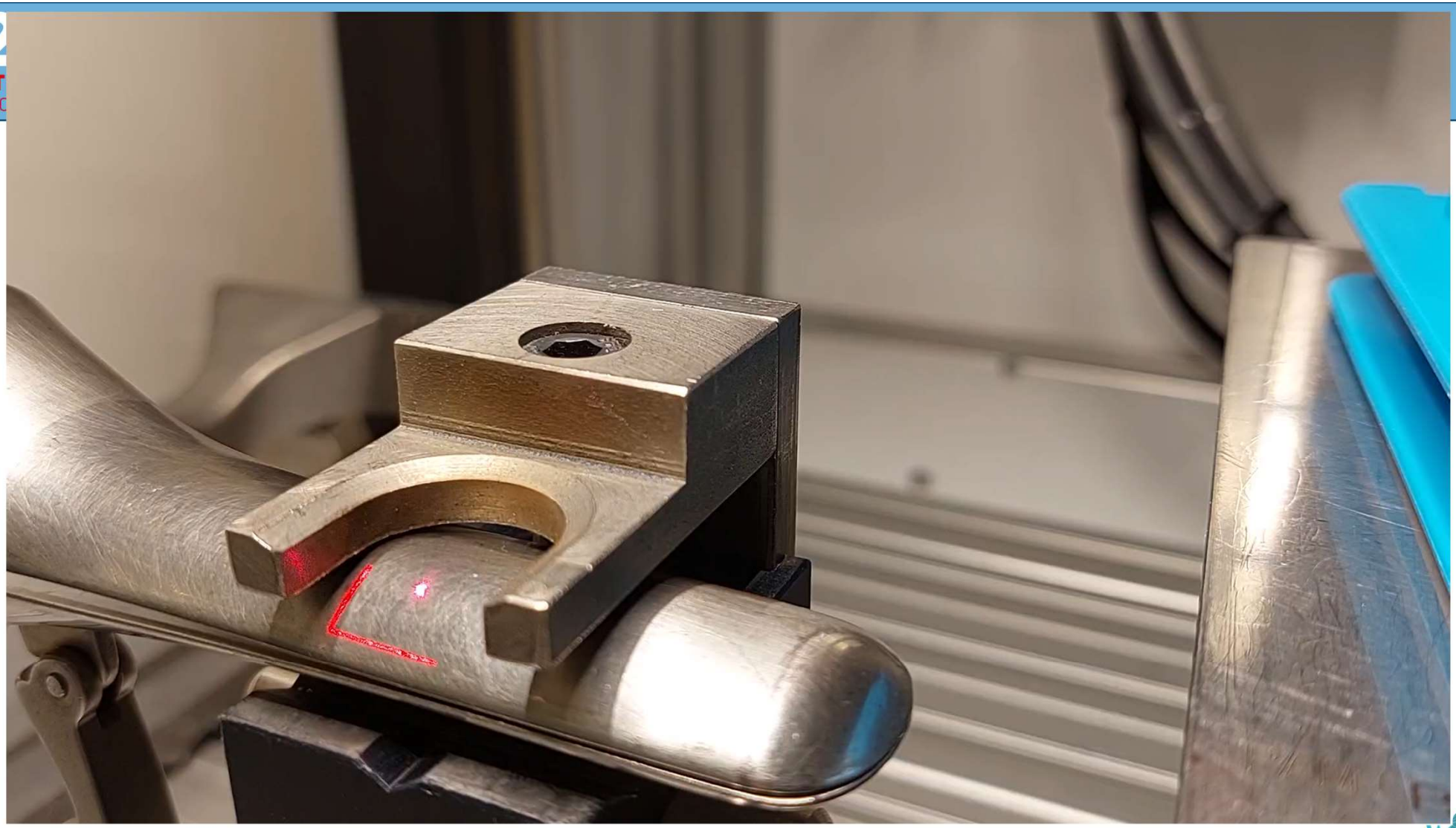
MATERIAL

If not, surgical devices are engraved in sterilization unit with Polybox® laser engraver. Marking is a unique data matrix for each surgical device. It allows an individual traceability. Marked instruments are read and identified at the stage of packaging.
Laser marker can both engrave instruments and containers.
Data matrix coding = CHUSE + 6 numbers



MATERIAL

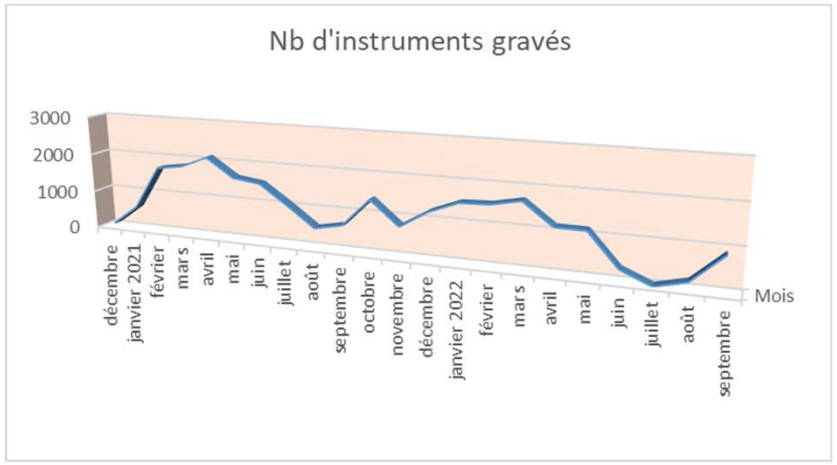




RESULTS

In 2020, instruments to be engraved were estimated at 45 000.

	Dec 2020	2021	2022
Engraved instruments	108	15600	7070
Engraved containers	32	246	109



INSTRUMENTS

INSTRUMENTS

CONTAINER

- ✓ Identification of baskets
- ✓ Maintenance organization

N°DE GRAVAGE	DATAMATRIX AESCULAP	TAILLE	REFORME	DATE DE MAINTENANCE	DATE DE MAINTENANCE
A1	10404696486012621005982	1/1		NEANT	
A3		3/4		mai-11	
A4		1/2	REFORME	juin-14	IRREPARABLE
A7	01040469648602632101908	1/2		mars-21	

ADVANTAGES

- ✓ Instruments monitoring
- ✓ Statistics about specialties
  - → Marked instruments loss was estimated at about 10%
- ✓ Easier tracking
- ✓ Shorter staff training
- ✓ Skills transfer

NEWS / REPAIR

- ✓ Instruments on order or under repair are notified in the software
- ✓ The logistics are defined
- ✓ The repair budget is justifiable
- ✓ Replacement of irreparable items is simplified

AGENT TRAINING

Engraving activity:

- 3 teams of 2 agents take turns 1 week out of 3

Assembly of surgical sets :

✓ Faster training of new agents
✓ Longer time for agent with seniority
✓ More accurate missing instrument information
✓ Sometimes difficult or impossible to read

LIMITS

- ✓ Long training program for engraver using
- ✓ Determination of the appropriate program for a support material
- ✓ Data matrix codes less and less readable over time
- ✓ Supplier's propriety ancillaries cannot be engraved.

→ Two years of work are yet necessary

DISCUSSION

Possible reading improvements:

- ✓ 1 month of testing at the beginning to find the right setting in terms of depth and intensity, maybe still to be refined?
- ✓ % hard to read marking over time: Materials, shapes, flat surfaces?
- ✓ Chemical treatments to test ?

Osteosynthesis in the process of resolution : MDR 2017/745 = All the Medical Device for Implantation be sterile in 2024

Corrosion: No major corrosion problem on the marking areas IUD

A few years of effort to engrave the existing park, then the activity becomes punctual as and when instruments already marked arrive.

CONCLUSION

- ✓ Time-consuming activity
- ✓ Needs investments and consistency
- ✓ Showing mixing of instruments between different surgery containers
- ✓ Demonstrate the loss of a lot of instruments
- ✓ Allows an exhaustive traceability, an establishment of a system for repair broken instruments and replace the permanently broken instruments
- ✓ Allows a computerize planning for containers upkeep

INSIGHTS

- ✓ Individual identification answers to 2017/745/EU
- ✓ Essential prerequisite for a future automation of packaging steps. It may be coupled, for example, to a containers following based on a radio identification system (RFID).

THANK YOU FOR YOUR ATTENTION