



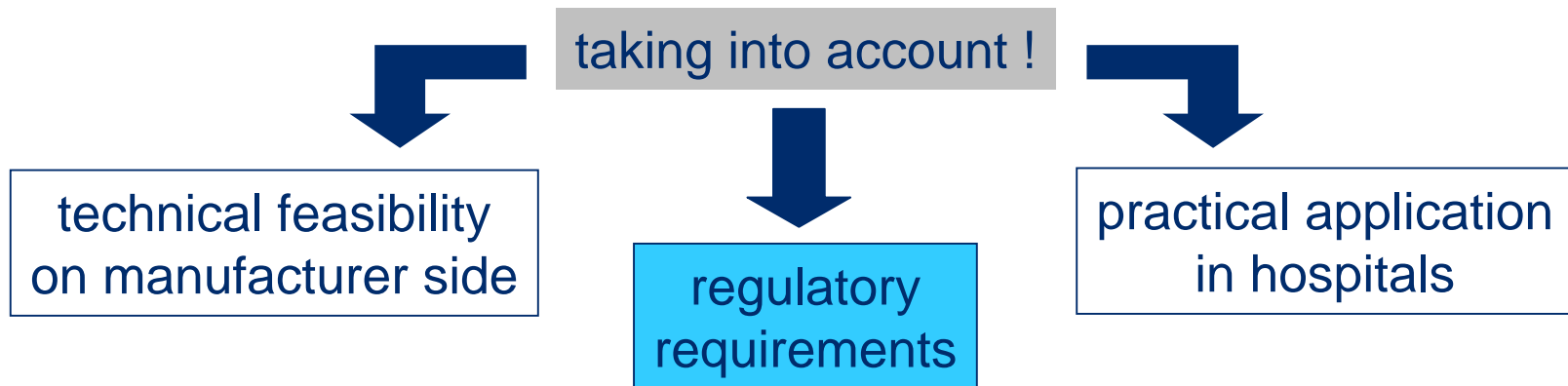
Status Report Work Team 'Instruments & Implants Marking'

Minneapolis, US - June 13th, 2006
Volker Zeinar

The global language of business

www.gs1.org

„Analysis of the necessity of marking instruments and implants.“



Core question :
What is the right level of track & trace ?



Team + Leadership

MANUFACTURER

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GS1 MO's

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Co-Chairs : Herve Ney + Volker Zeinar



Main topics and priorities

Agreements of the work team at the Kick-Off in Rome :

Concentrate on

- 1. phase → Instruments (direct marking)
- 2. phase → Implants (marking of packagings)

Step 1 : Clarify the level of track & trace

- set level vs. single item level
- evaluate the business driver
- analysis of the processes (where do we need which information ?)

Step 2 : Data content

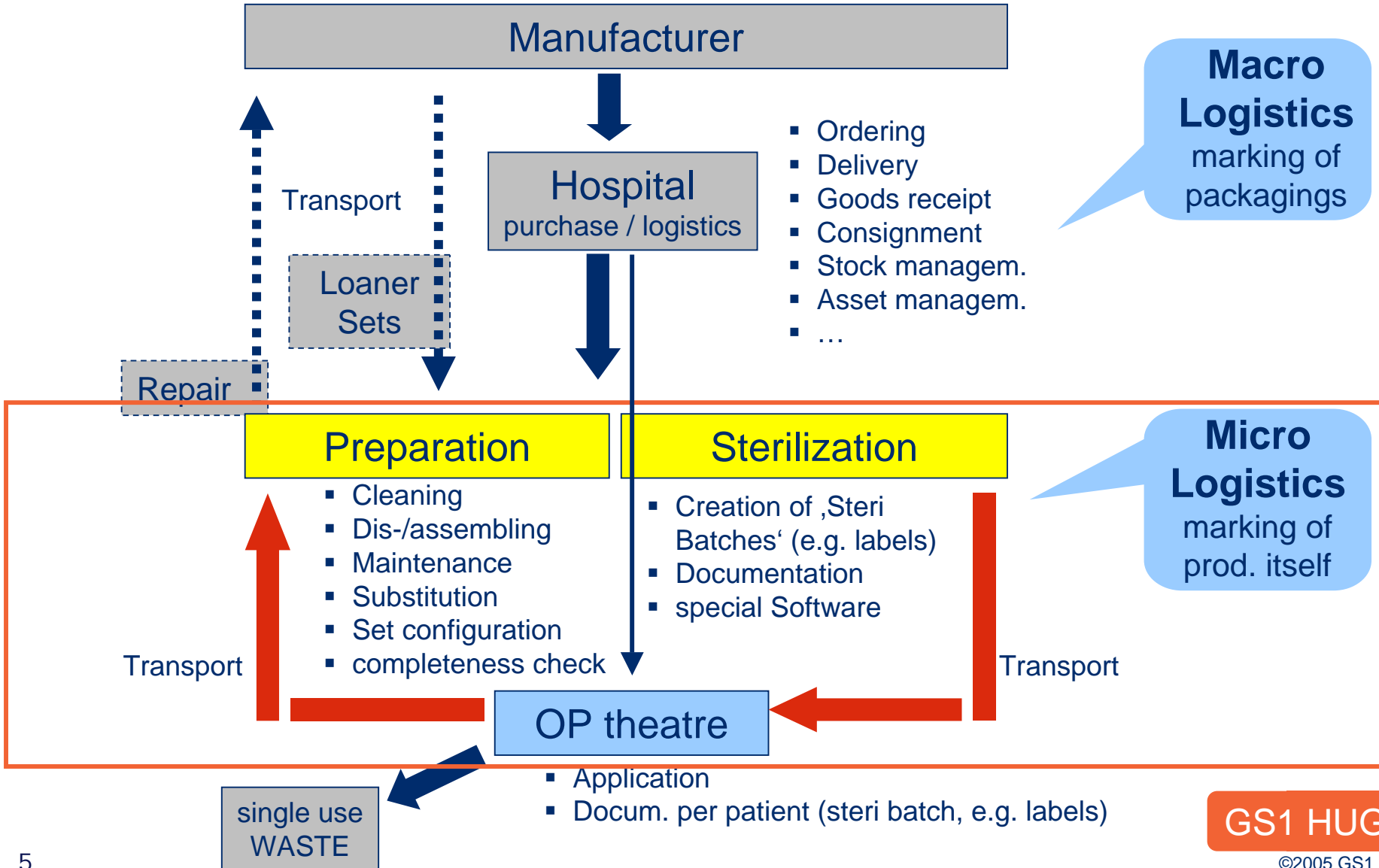
- which information are necessary ?
- evaluation of existing guidelines / recommendations

Step 3 : Data carrier and methods of marking

- DataMatrix (laser etched, Infodot), RFID, ...
- advantages, disadvantages, prerequisites, ...



Instruments Cycle





WT activities : get information

- ❑ **Conference calls**
- ❑ **Definition of the process steps within the instruments cycle**
- ❑ **Development of a questionnaire in supplement to instruments cycle**
 - at which process step ?
 - do we need which information ?
 - on which level ?
 - and for what (business case) ?
- ❑ **Using the questionnaire for personal interviews of hospitals (CSSD) or sterilization service providers**
 - 4 interviews per WT member / country
- ❑ **Up to now 27 interviews have been carried out**
 - 7 countries : US, F, CH, DE, I, A, JP
- ❑ **Software for data capturing and summary of the results**

❑ Hospital European Georges Pompidou, Paris

- 830 beds (300 cutting beds)
- 146.000 sterile sets per year
- pilot : track&trace on instrument level → based on DataMatrix (laser etched and micro percussion)

❑ Problems raised during the tests

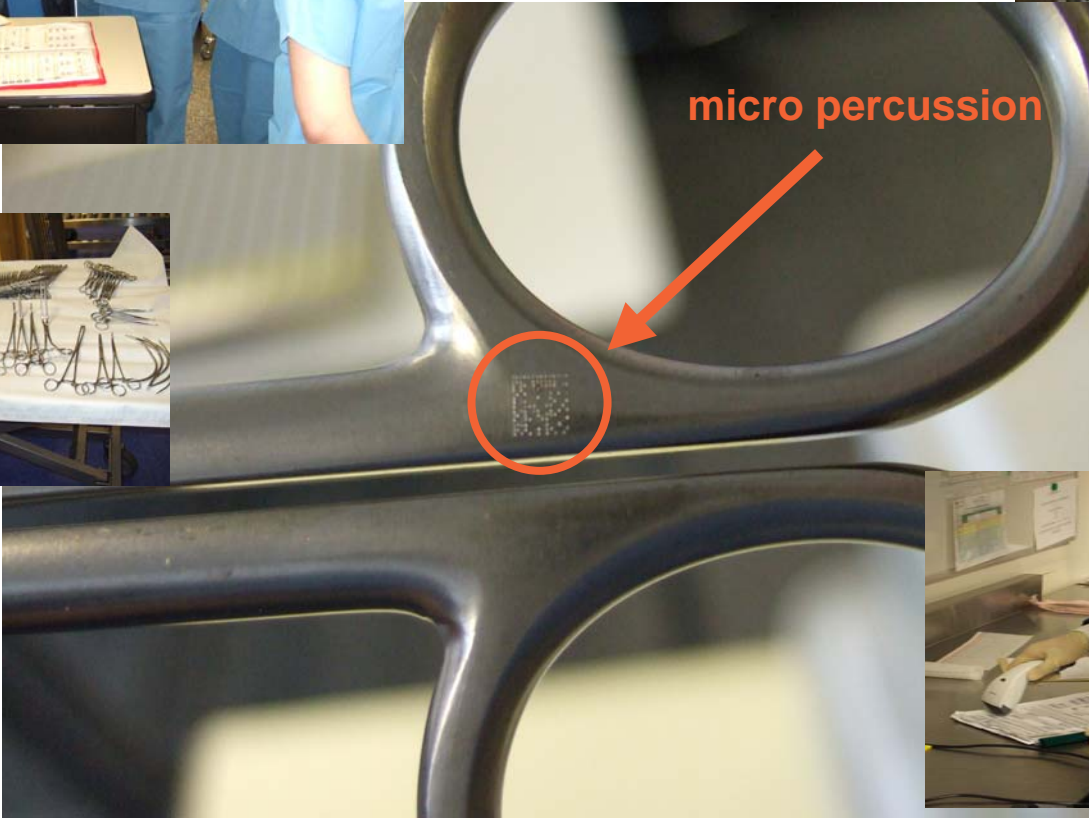
- positioning of the code (small codes difficult to find)
- quality of the laser etched code (legibility, contrast, reflection, ...)
- life time of the code (e.g. cleaning with aggressive base → problems after 3 cycles !)
- reading distance and speed
- not all instruments are suitable to carry a DataMatrix

❑ Advantages of traceability on instrument level

- sets assembling by non-qualified staff
- automated data capturing possible
- reasonable costs



Impressions HEGP





WT activities : site visits hospital CSSD

❑ Hospital Bichat, Paris

- 1.000 beds (600 surgical beds)
- 29.000 sterile sets + 210.000 wrapped packs per year
- pilot : track&trace on instrument level → based on RFID

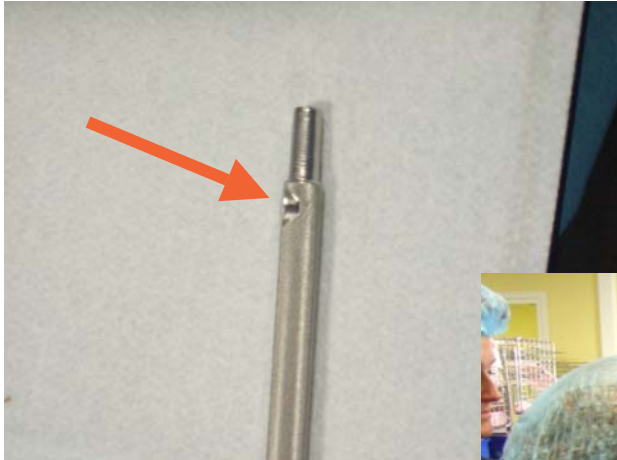
❑ Problems raised during the tests

- tag positioning (perfect for right-handed person / not acceptable for left-handed)
- welding quality (tags dropped, antenna insufficiently protected, ...)
- short read/write distance – tags sometimes difficult to find
- not all instruments are suitable to carry a tag
→ alternative DataMatrix or single-use instruments
- how to handle the existing stock ?
- attach tags afterwards → CE marking, guarantee, ... ?

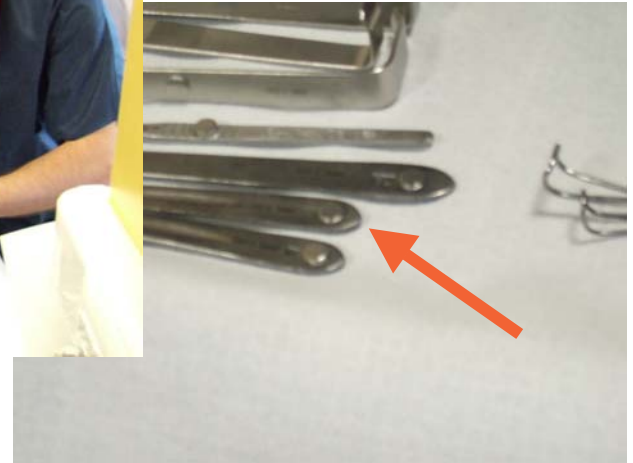
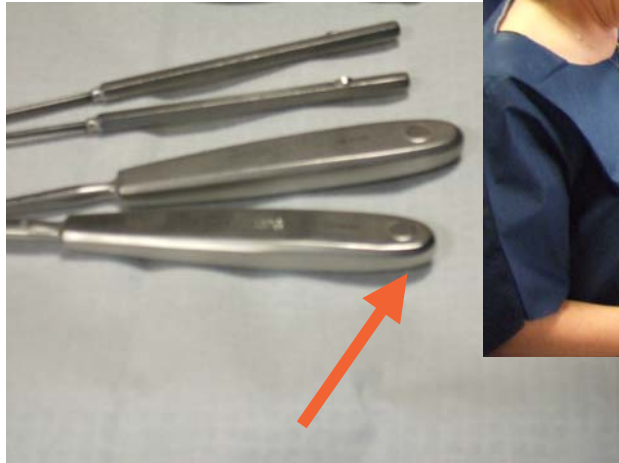
❑ Advantages of traceability on instrument level

- packaging help (staff information, not qualified staff)
- limit instruments crossing between different trays
- manage the instruments of the hospital, incl. maintenances

Impressions Bichat



imbedded
RFID tags

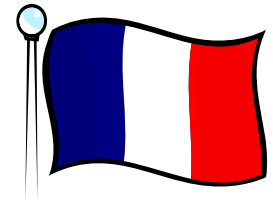


□ University Hospital Rouen, France

- participant of site visits in Paris
- experience : track&trace on instrument level → based on ,InfoDot‘
- InfoDot = sticker with DataMatrix placed on the instruments (alum. foil)
- 60.000 instruments on stock / 35.000 stickered with Infodot
- replace progressively qualified staff for assembling operations by non-skilled staff (not unusual in France : OR nurses responsible for set assembling)

□ Why did we visit French hospitals ?

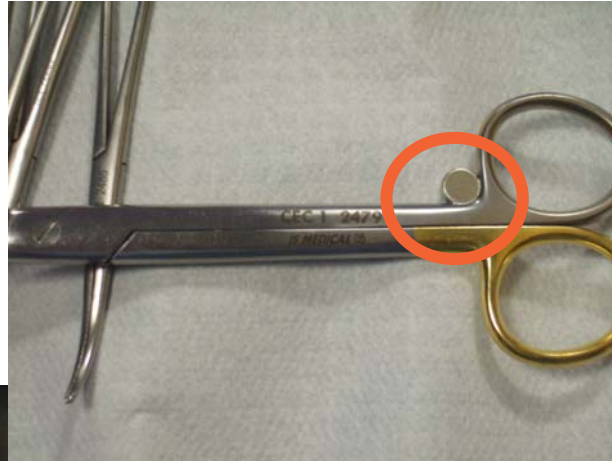
- legal regulation regarding traceability is existing
- due to Creutzfeldt-Jakob Disease (CJD) cases it must be able to identify ***,the last 5 patients with whom an instrument was used‘***
- 3 risk groups :
 - normal patients
 - risk surgeries (at the brain or eyes or bloody teeth)
 - CJD patients (not allowed to use instrum. any more)



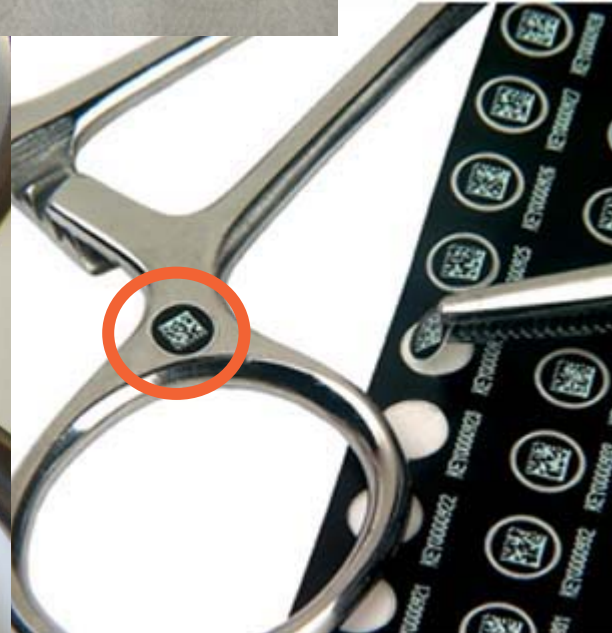


Direkt Marking Solutions

DataMatrix
micro percussion
or laser etched



RFID tag



DataMatrix
InfoDot

GS1 HUG

❑ Study of the 'The Patients Association, UK'

- title : 'Tracking Medical Devices and the Implications for Patient Safety'
- survey has been proceeded in 2004
- questionnaire (13) has been sent out by eMail, > 120 replies

❑ Executive summary of the survey

- agreement about the need to have track&trace systems in place when the new off-site '**sterile service Super Centers**' are built (97%)
- automated data capture would help **improve stock control systems** (84%)
- only a third always knows when a **device went missing** (37%)
- it's **impossible to track back** and locate a single individual instrument (39%)
- **paper based** tracking systems are still in use (33% CSSD + 66% OP)
- automated tracking systems would **improve patient safety** (79%)

„With 'sterile service Super Centers' being developed, the patient safety case becomes overwhelming.“

□ Breakout session (June 14th)

- start to review the results of the interviews
- discuss key findings + conclusions
- identify differences between US – EU – AP
- identify knowledge gaps and define ways to close the gaps

□ Site visits in the UK, probably London

- what will change after establishment of ‘sterile service Super Centers’ ?
- visits will be organized by GS1 UK
 - 1st day : visit hospitals CSSD
 - 2nd day : discussion of the results from the breakout session
(WT members which couldn't attend in Minneapolis)



Important for the progress of the work team :
**Engagement of the WT members,
 especially from manufacturer + hospital side !**



Thank you for your attention !

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