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Status Report Work Team
‘Instruments & Implants Marking’

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Volker Zeinar

The global language of business

www.gs1.org

The Team

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GS1 MO's

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Hospitals ?

we talk about a ‚core process' !!!

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Objective and Scope

Objective :

‚Analysis of the necessity of marking instruments and implants.‘

taking into account !

technical feasibility
on manufacturer side

practical application
in hospitals

Scope :

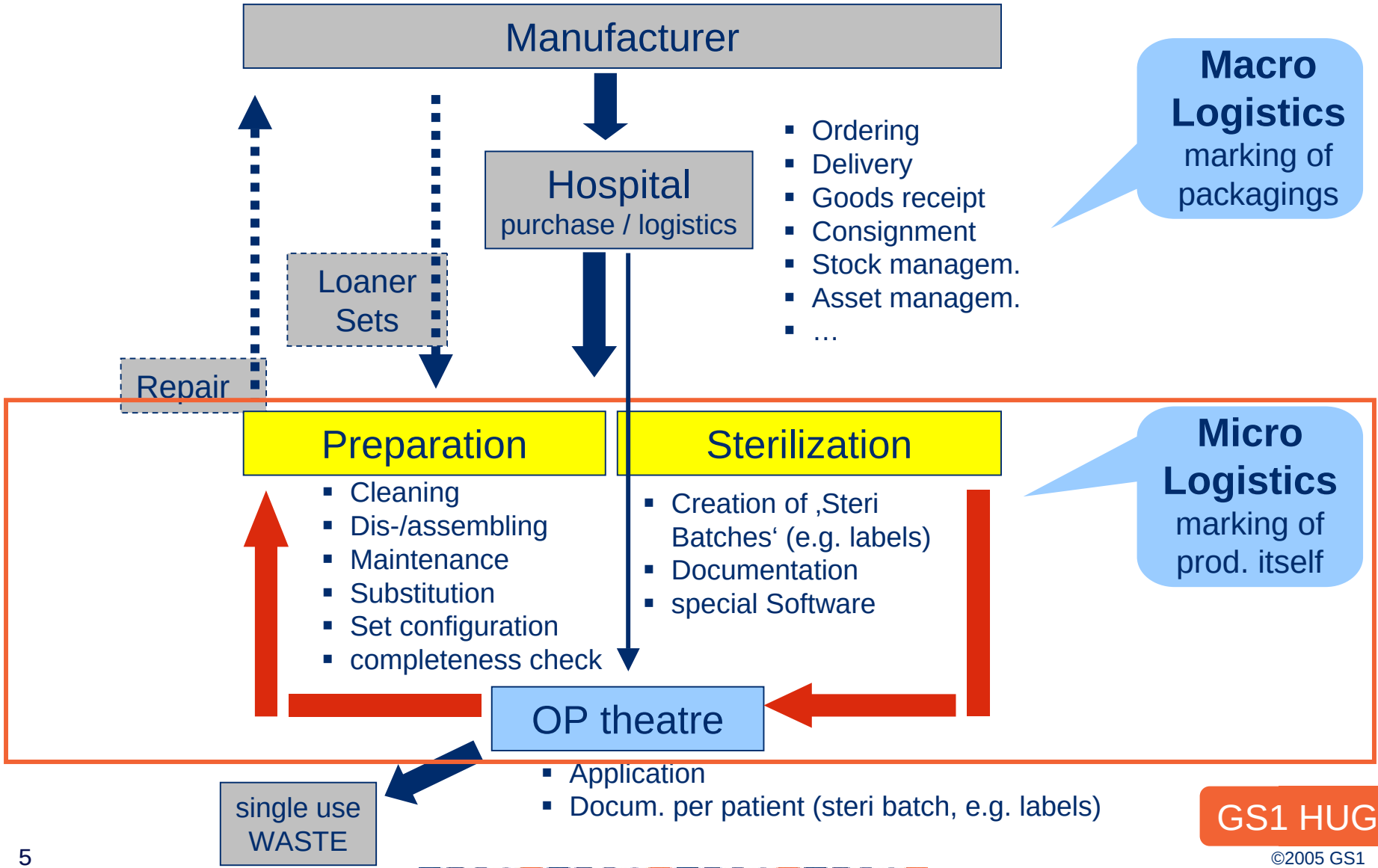
- ❑ Level of track & trace (e.g. set level or single instrument level) ?
- ❑ Marking of packaging and/or direct marking ?
- ❑ Data content + data carrier ?
- ❑ Regulatory compliance !

Where do we talk about ?

reusable / single use products (instruments)		mass / physician specific products	
made of steel, plastics, …	large / very small / all forms	sterile / non-sterile	
one-piece / multi-part products	active / passive	motor systems	spare parts (instruments)
container systems ‚parents-child-relation'	hips, knees, plates, stents, screws, cardiac pacemakers, heart valves,…		
repair processes	life cycle management (>10 years)		

- huge variety of products !
- all these characteristics have influence to marking solutions and track & trace processes !

Instruments Cycle



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Track&Trace : SET vs. INSTRUMENT level

SET

machine-readable marking
- linear BC / datamatrix / RfiD
- space is no issue
- marking process uncritical

Bill of Materials (BOM)
- list of instrument types
- quantity per instrument type

Scanning (in sterilization environment)
- one scan per SET
- BC easy to find (marking always in the same place possible)

INSTRUMENT

machine-readable marking
- serialisation
- datamatrix / RfiD
- space is often an issue
- surface partly unsuitable for datamatrix (rough, round, plastics,…)

Scanning (in sterilization environment)
- one scan per INSTRUMENT
- code very small (difficult to find)

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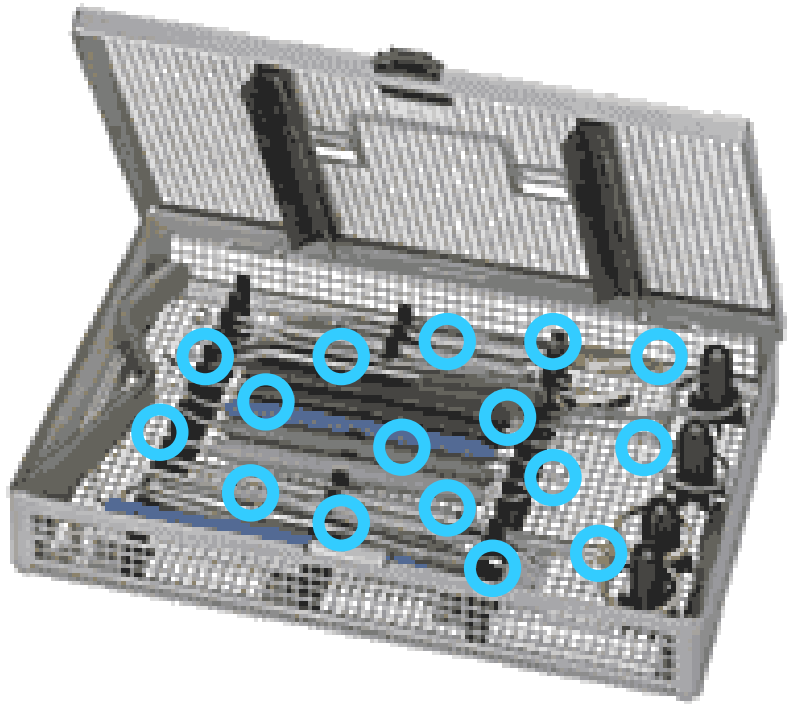
Track&Trace : SET vs. INSTRUMENT level

1 scan per SET
→ easy to find



many scan‘s per SET
(up to 90, in average 50)

- ❑ multiple effort
- ❑ user-friendly ?
- ❑ hospitals/users view ?

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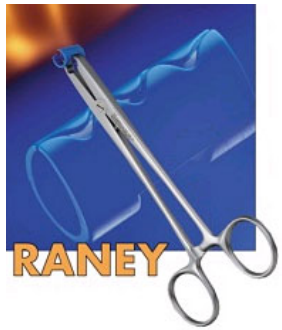
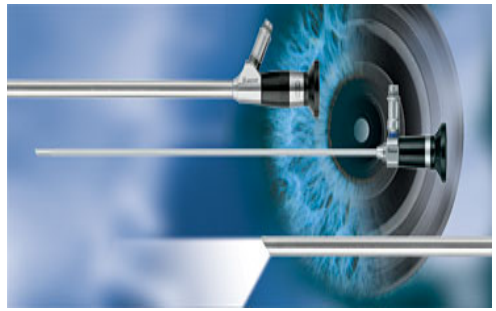
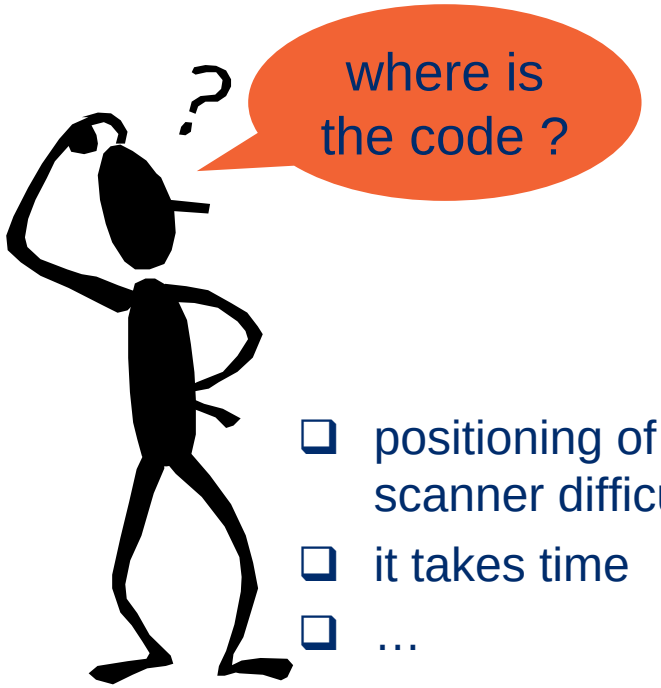
Track&Trace : SET vs. INSTRUMENT level







- positioning of scanner difficult
- it takes time
- …

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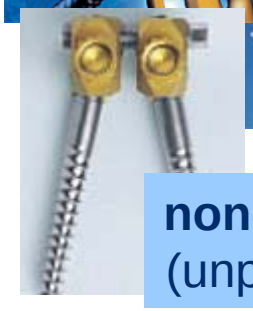
Implants Material Flow

Manufacturer

sterile + non-sterile

- Ordering
  → scanner based ‚SEDICO'
- Delivery
- Goods receipt
- Consignment
- Stock management
- …



non-sterile (unpacked)

Hospital Storage (close to OP)

sterile (packed + bar coded)

MICRO – Log.

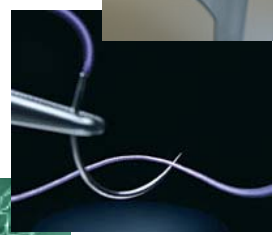
trays of small items (e.g. screws)

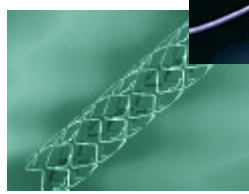
Sterilization

OP theatre

- Creation of ‚Steri Batches'
- Documentation
- special Software
- Refill trays (e.g. screws)
- …

- Application
- Documentation per patient
  → **peel-off labels**





Patient

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Issues

- **Direct marking + space**
  - instruments and implants
  - smallest DataMatrix to large for many products
  - expiration of DataMatrix (cleaning methods)
  - RFID tags – a suitable alternative ? for which products ?
- **Serialization of multi-part instruments ?**
- **Data content**
  - different recommendations GS1 MO's : ***‚(01)GTIN(21)Serial no.'*** versus ***‚(8004)GIAI'***
  - manufacturer / hospital specific coding
- **Why track & trace on instrument level and for which instruments ?**
  - today : high value, maintenance intensive, property issues, …
- **Track & trace of very small implants ?**
  - not single packed (screws, nails, …), re-sterilization several times, …
- **Prerequisites on hospital side for track & trace ?**
  - e.g. set optimization, IT, process organisation, …

The acceptance of a solution
depends on their convenience in daily business !
(impact on processes in preparation / sterilization / OP theatre)

Next Steps

Questions to discuss and decide during WT sessions :

- **What should be the scope of the WT in detail ?**
- **Priorities ?** e.g.
  - Prio 1 = Implants : entire supply chain
  - Prio 2 = Instruments : MACRO – Logistics
  - Prio 3 = Instruments : MICRO – Logistics
- **Timetable ?**
- **Methods of working together ?**
  - Conference calls, F2F meetings, visit hospitals, …
- **Decision/confirmation work team leader**

Start work !!!

- Review and complete instruments cycle + implants material flow
- Collect legal / customer requirements (track & trace / documentation)
- Product classification (significant impact on patient safety ?, level of risk ?, …)
- …

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Thank you for your attention !

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