Status Report Work Team
‘Instruments & Implants Marking’

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The Team

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Hospitals? we talk about a ‘core process’ !!!
**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?**

<table>
<thead>
<tr>
<th>reusable / single use products (instruments)</th>
<th>mass / physician specific products</th>
</tr>
</thead>
<tbody>
<tr>
<td>made of steel, plastics, ...</td>
<td>large / very small / all forms</td>
</tr>
<tr>
<td>one-piece / multi-part products</td>
<td>active / passive</td>
</tr>
<tr>
<td>container systems 'parents-child-relation'</td>
<td>motor systems</td>
</tr>
<tr>
<td>repair processes</td>
<td>spare parts (instruments)</td>
</tr>
<tr>
<td>hips, knees, plates, stents, screws, ...</td>
<td>cardiac pacemakers, heart valves, ...</td>
</tr>
<tr>
<td>life cycle management (&gt;10 years)</td>
<td></td>
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</tbody>
</table>

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

Manufacturer

- Ordering
- Delivery
- Goods receipt
- Consignment
- Stock managem.
- Asset managem.
- ...

Hospital purchase / logistics

- Loaner Sets

- Repair

- Micro Logistics
  - marking of prod. itself

- Macro Logistics
  - marking of packagings

Preparation

- Cleaning
- Dis-/assembling
- Maintenance
- Substitution
- Set configuration
- completeness check

Sterilization

- Creation of 'Steri Batches' (e.g. labels)
- Documentation
- special Software

OP theatre

- Application
- Docum. per patient (steri batch, e.g. labels)

single use WASTE

GS1 HUG
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)
Track&Trace: SET vs. INSTRUMENT level

1 scan per SET
- easy to find

many scans per SET
- (up to 90, in average 50)
- multiple effort
- user-friendly?
- hospitals/users view?
Track&Trace: SET vs. INSTRUMENT level

- positioning of scanner difficult
- it takes time
- ...

where is the code?
Implants Material Flow

- Manufacturer
  - sterile + non-sterile
  - Hospital Storage (close to OP)
    - non-sterile (unpacked)
    - sterile (packed + bar coded)
    - MICRO – Log.
      - trays of small items (e.g. screws)
    - Ordered
      - scanner based 'SEDICO'
      - Delivery
      - Goods receipt
      - Consignment
      - Stock management
      - ...
  - OP theatre
    - Application
      - Documentation per patient → peel-off labels
    - Patient
      - Creation of 'Steri Batches'
      - Documentation
      - special Software
      - Refill trays (e.g. screws)
      - ...

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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)
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?, …)
- …
Thank you for your attention!

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