Traceability of Surgical Instruments in Japan

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Tokyo Medical and Dental University and Tokyo Institute of Technology are merged to establish Institute of Science Tokyo
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2. Why we implement the traceability system

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Reprocessing of Surgical Instruments

Reusable medical devices are cleaned, disinfected, and sterilized to make them reusable in the Central Sterile Supply Department (CSSD).

Storage → Surgery → Collection Recording

Sterilization → Inspection & Assembling → Cleaning → Cleaning Preparation
Reprocessing of Surgical Instruments

Cleaning

Retention of blood, tissue and other biological debris

Risk of infection

Remove contaminants as much as possible

- For worker safety
- To facilitate the achievement of Sterility Assurance Level
- To maintain the quality of RMD

RMD: reusable medical device
Reprocessing of Surgical Instruments

Inspection and Assembling

Inspection

Assembling
Reprocessing of Surgical Instruments

Sterilization

High temperature  Low temperature
Reprocessing of Surgical Instruments

Storage and Supply

Container

Bag or Drape
Why we implement the traceability system

What is required of CSSD

- Sterility assured RMD
- Stable supply
- Efficient operation
## Why we implement the traceability system

### Standards for cleaning and sterilization

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount of residual protein</td>
<td>Sterility Assurance Level (SAL)</td>
</tr>
<tr>
<td>Less than 200μg/RMD</td>
<td>Less than $10^{-6}$</td>
</tr>
</tbody>
</table>
Why we implement the traceability system

Quality Management

Factors that can cause harm to RMD

Cleaning
- High-pressure water flow
- Hot water
- Ultrasonic wave
- Detergent

Sterilization
- High temperature
- High pressure
- Vacuum
- Sterilant (e.g., $\text{H}_2\text{O}_2$)
- etc.
Why we implement the traceability system

Process management

- Conduct a visual inspection of the RMD
- Complete the record book and sign it
- Maintain operation record sheets
- Monitor, record, and store various indicators

Management by documents

- Heavy staff workload
- Information management limitations
Why we implement the traceability system

Process management

• When?
• Who?
• Where?
• What?
• How?
Why we implement the traceability system
CSSD is like a manufacturing plant.

Quality management is important!

• Recording the data
• Reviewing the histories

Traceability system
Pharmaceutical and Medical Devices Act

To ensure the efficacy and safety of pharmaceuticals and medical devices.

PMD Act was revised in December 2019.

Summary of Amendments

Improve the system from development to post-marketing to provide pharmaceuticals and medical devices more safely, quickly, and efficiently.
Pharmaceutical and Medical Devices Act

Mandating GS1 barcode marking

- On the packaging
- Direct marking (NOT included in the law)
Pharmaceutical and Medical Devices Act

Direct marking
(NOT included in the law)

Obtaining a GS1 Company Prefix

Direct marking
With
GS1 DataMatrix Barcode
Efforts at TMDU Hospital

Trace information (use history for the patient)

Search by date, patient ID, etc.

List of surgical instruments used

Export to Excel format file
Efforts at TMDU Hospital

Standardization of operations
Efforts at TMDU Hospital

Standardization of operations
Efforts at TMDU Hospital

Standardization of operations
Efforts at TMDU Hospital

Optimization of operations

A. Considered appropriate (93.1%)

B. Considered inappropriate (56.8%)
**Efforts at TMDU Hospital**

**Optimization of operations (maintenance of RMD)**

Disposal Registration

<table>
<thead>
<tr>
<th>Serial</th>
<th>Product Name</th>
<th>Model No.</th>
<th>Date of disposal</th>
<th>Set Name</th>
<th>Date of purchase</th>
<th>Number of uses</th>
<th>Number of sterilization</th>
<th>Duration Of uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>15010002</td>
<td>Sheath 24Fr Olympus</td>
<td>'A22040A'</td>
<td>2017/12/14</td>
<td></td>
<td>2015/1/1</td>
<td>163</td>
<td>188</td>
<td>3 years</td>
</tr>
<tr>
<td>15010003</td>
<td>Reflux Sheath 26Fr Rotating Olympus</td>
<td>'A22026A'</td>
<td>2017/12/14</td>
<td></td>
<td>2015/1/1</td>
<td>161</td>
<td>182</td>
<td>3 years</td>
</tr>
<tr>
<td>17030001</td>
<td>Cutting tube 15mm</td>
<td>'26713550'</td>
<td>2017/12/12</td>
<td>Morcellator 15mm</td>
<td>2017/3/15</td>
<td>21</td>
<td>25</td>
<td>9 months</td>
</tr>
</tbody>
</table>
Efforts at TMDU Hospital

Optimization of operations (maintenance of RMD)

Duration and number of uses before RMD disposal

- Forceps
- Needl Holders
- Tweezers
- Scissors
- Others

Number of uses vs. Year chart.
Efforts at TMDU Hospital

Optimization of operations (maintenance of RMD)

How many RMDs were repaired in a year?

<table>
<thead>
<tr>
<th>Repaired</th>
<th>Number of items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>749</td>
</tr>
<tr>
<td>• Scissors</td>
<td>251</td>
</tr>
<tr>
<td>• Forceps</td>
<td>98</td>
</tr>
<tr>
<td>• Needle Holders</td>
<td>36</td>
</tr>
<tr>
<td>• Tweezers</td>
<td>68</td>
</tr>
<tr>
<td>• Cameras, Endoscopes</td>
<td>29</td>
</tr>
<tr>
<td>• Punches, Chisels, Hammers</td>
<td>127</td>
</tr>
<tr>
<td>• Other</td>
<td>140</td>
</tr>
</tbody>
</table>

What kind of problems?
- deformation, damage 44.4%
- polishing, 37.1%
- improper occlusion, 14.3%
- chip in a blade, 3.6%
- surface defect, 0.6%
Efforts at TMDU Hospital

Workload Reduction

Before

After
Efforts at TMDU Hospital

Workload Reduction

Before

Double check

Need 2 staffs

After

1 staff + PC
Efforts at TMDU Hospital

Workload Reduction

When to check on the return of surgical instruments

**Before**
1. Before closing the wound
2. Before returning to CSSD
3. After receiving RMD

**After**
1. Before closing the wound
2. Before returning to CSSD
3. After receiving RMD
Efforts at TMDU Hospital

Workload Reduction

Where is the surgical instruments?

I need a Trauma set as soon as possible!
Where can I find it?
Could you get it ready as soon as you can?

I’m not sure.
I'll find it right away!

CSSD
Surgical Center
Efforts at TMDU Hospital

Reduce staff workload

Where is the surgical instruments?

Search by keyword

Show current status

Under sterilization
Effects of Visualization

- Checking through the system (double-checking function)
- Centralization of data (information sharing between surgical center and CSSD)
- Reduction and standardization of skill gaps among staff

Reduction of human error and inadvertent errors
Effects of Visualization

• Data on the activities of individual workers can be presented in meetings with hospital personnel and contractors.
• The visibility into previously invisible work has led to the resolution of operational issues.

Raise awareness of sterilization supply workers
Effects of Visualization

Management data can be utilized to understand the usage conditions accurately.

• Visualize the CSSD to other departments in the hospital
• Eliminate waste and optimize surgical instrument operation
• Cost optimization
Conclusion

1. Proper management of medical devices is crucial for ensuring their safe use.

2. Using GS1 DataMatrix directly marked on surgical instruments enables individual management.

3. Individual management of surgical instruments contributes to patient safety and hospital management.

4. The implementation of the system is expected to reduce the staff workload.

5. Source marking facilitates a comprehensive understanding of medical devices throughout their life cycle, thereby enabling the delivery of safer, more reliable medical care.

6. Information is not confined to a single hospital or company. Data linkage will facilitate the provision of advanced, high-quality medical care.
Advancing science and human wellbeing

Institute of

SCIENCE TOKYO

Science Tokyo will be established on October 1, 2024, following the merger between TMDU and Tokyo Tech.

Science Tokyo introductory website
https://www.isct.ac.jp