Approach to Traceability of Endoscopic Devices

Olympus Medical Systems Corp.
Naomi Sekino
Endoscopy & Laparoscopic Surgery

Endoscopic Treatment

Less Invasive Surgery Utilizing a small incision
Flexible Endoscope for Gastroenterology

Video scope

Video system

Electro surgery unit

EndoTherapy Accessories

Endoscope reprocessing device
Surgical Endoscopy Equipment

- Laparoscopic Surgery
- Urology Instrumentation
- Electro surgery unit
- Video scope
- Ultrasonic Surgical System
System Integration of Endoscopy

Improve the workflow for endoscopic treatment & surgery

Endoscopic Lab

Operating Room

Endoscope Network System

One touch control for equipment
Issues & problems: control of medical instruments

- **Article control**
  - Prevention of missing or lost instruments
  - Identifying loan instruments

- **Control of infection history**
  - Identifying infection route at the occurrence of secondary infection
  - Sterilization and history control of instruments used for a Creutzfeldt-Jakob disease patient

- **Regular maintenance check**
  - Implementing regular check-ups of instruments according to the use

- **Economical efficiency**
  - Providing required minimum goods, in a timely manner
Surgical instruments cycle in a hospital

Storage → OR → Cleaning/Disinfection → Sterilization → Instruments check → Dry
Problems for medical instruments

- Which instrument?
- Where is the Lab or OR?
- Who is the Doctor?
- Who’s the patient?
- When is the surgery?
- What type of surgery?
- How long is the surgery?

Risk of human error

Manual checking of instruments by hand

Missing 6W1H
Importance of Traceability for Endoscopic Instruments

- Attach data carriers for ID control to endoscopic instruments to connect the “Items” and “Data”
- Centralized control of use history
Approach for traceability of endoscopes

Global Standard

GS1 Healthcare Regulation (Japanese MHLW, FDA)

Application Study

In collaboration with Osaka University

Technology

Laser Marking
Labeling
RF-ID
In collaboration with Osaka University

- Verification of usefulness for traceability utilized direct marking or RF-ID on surgical endoscopes and instruments

Number of beds = 1,076
Number of operations/year ≈ 7,984

Dr. Nakada, Director of the Surgery Center
TUR-P  Transurethral Resection of Prostate
Experiments utilizing resectoscope system

Application of resectoscope system for TUR to trial study
Why was the resectoscope for Traceability?

- The instruments contain many parts in various shapes and sizes

⇒ Preparation and maintenance is quite troublesome

Approximately 30 parts per container

↑ Autoclavable items

Camera Head

EOG or Plasma sterilization
Coding on package

- GS1-128
- Supply chain management
- Assignment for direct part marking
Direct marking adopted for pilot study

- **Prerequisite conditions**
  - Standard code recommended by GS1
  - Durable against cleaning, disinfection and sterilization
  - Size which can be marked on endoscopic instruments

- **Adopted conditions**
  - Data carrier: Data matrix or QRcode
  - Data contents: 25 digits (GTIN + S/N), 16 digits (S/N in hospital)
  - Minimum size: 1.44×1.44mm (25 digits)
Instruments check

Data capturing after cleaning & disinfection

Code Reader

PC Data base
Direct marking on the metal parts

**Flat stainless**
- 1.44mm x 1.44mm, 25Byte

**Curve stainless**
- 1.2mm x 2.6mm, 16Byte

Φ4.5(mm)
Results ~ Clinical trial ~

Previous type Impossible to read 5 per 16 (Durability avg. 4 case)

Improved type Impossible to read 0 per 5 (Durability avg. 12 case)

<table>
<thead>
<tr>
<th></th>
<th>Previous marking</th>
<th></th>
<th>Improved marking</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>After 4 cases</td>
<td>Before use</td>
<td>After 12 cases</td>
<td></td>
</tr>
<tr>
<td>Loop 30°</td>
<td><img src="image1" alt="Image" /></td>
<td><img src="image2" alt="Image" /></td>
<td><img src="image3" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Loop 12°</td>
<td><img src="image4" alt="Image" /></td>
<td><img src="image5" alt="Image" /></td>
<td><img src="image6" alt="Image" /></td>
<td></td>
</tr>
</tbody>
</table>
Applied study utilizing RF-ID

ID information
Serial No.

RF-ID
Scope ID tag

Olympus system server
PDA with scanner

Surgical scope

Software
Objects for traceability
A. Surgical Endoscopes 24pcs
B. Work Stations/ 9sets. Equipments containing 87 separate parts
C. LCD Monitor/ 6sets
System Chart

10 B A S E category 5  Special Network for OR

**CE room**
- 10BASEhub
- Drawing data by USB memory
- Server PC
- Access point
- Wireless LAN
- PDA 1 - 3
- PDA 2 - 2 (for check)

**Cleaning room**
- Access point
- Wireless LAN
- PDA 2 - 1
- Label printer
- PDA 2 - 1

**Clean hall**
- Access point
- Wireless LAN
- Access point

PDA2: Bar code + RFID scanning model
PDA1: Barcode + 2D code code scanning model
Individual recognition by RF-ID & 2D code

RFID tag
Size $\varnothing 36\text{mm} \times 7\text{mm}$
Weight : 9g

Identification No.: Adoption of GS1 code
(01)04953170201165(21)XXXXXXXX(241)6001

- GTIN No.
- S/N
- S/N used by hospital
PDA Scanning

- Start from 20\textsuperscript{th} August 2007
- Scanning system is favorably reviewed by staff.
Result (HD EndoEye Video scope)

- **Rigid Video scope**
  - A50011A: O.D. φ10mm, 0°, 2 pcs.
  - A50013A: O.D. φ10mm, 30°, 8 pcs.
  - A50021A: O.D. φ5.4mm, 0°, 2 pcs.
  - A50023A: O.D. φ5.4mm, 30°, 2 pcs.

- **Bending Videoscope (Flexible)**
  - LTF Type VH: O.D. φ10mm, 8 pcs.
  - LTF Type VP: O.D. φ5.4mm, 2 pcs.

Period: 2007/8/20 ~ 2008/7/
Total numbers of surgery performed:
- Laparoscopic or endoscopic surgery: 7800 cases
- 1300 cases
A record of an scope

Rigid scope 10mm30°
IDNo.2006

<table>
<thead>
<tr>
<th>Date</th>
<th>OR No.</th>
<th>Course</th>
<th>Method</th>
<th>Doctor</th>
<th>Start</th>
<th>End</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007/8/21</td>
<td>7082138</td>
<td>Thoraco</td>
<td>Thoracoscopic ***</td>
<td>Dr.S</td>
<td>9:40</td>
<td>13:15</td>
<td>215</td>
</tr>
<tr>
<td>2007/8/27</td>
<td>7082714</td>
<td>GS</td>
<td>Laparoscopic ***</td>
<td>Dr.Y</td>
<td>9:40</td>
<td>17:25</td>
<td>465</td>
</tr>
<tr>
<td>2007/9/5</td>
<td>7090520</td>
<td>GS</td>
<td>Laparoscopic ***</td>
<td>Dr.N</td>
<td>13:40</td>
<td>17:50</td>
<td>250</td>
</tr>
<tr>
<td>2007/9/12</td>
<td>7091211</td>
<td>GS</td>
<td>Laparoscopic ***</td>
<td>Dr.S</td>
<td>14:40</td>
<td>18:30</td>
<td>230</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Usage frequency by type

(2007/8/20 ~ 2008/7/18)

Kinds of endoscope

Usa ge number

- Rigid 10mm 0°
- Rigid 10mm 30°
- Rigid 5mm 0°
- Rigid 5mm 30°
- Flexible 10mm
- Flexible 5mm
Usage frequencies by individuals

- Rigid 10mm 0°
- Rigid 10mm 30°
- Rigid 5mm 0°
- Rigid 5mm 30°
- Flexible 10mm
- Flexible 5mm

Graph showing usage frequencies and repair details for different endoscope IDs and types.
Usage frequency by departments

- Rigid 10mm 0°
- Rigid 10mm 30°
- Rigid 5mm 0°
- Rigid 5mm 30°
- Flexible 10mm
- Flexible 5mm
Conclusion

- We can build a traceability system that shows when, where and to whom the surgical instruments are used.
- This system will allow Osaka University Hospital to visualize their use of devices and instruments based on the history of use and lead to improvement of efficiency and patient safety.