



Identification of Surgical Instruments with RFID

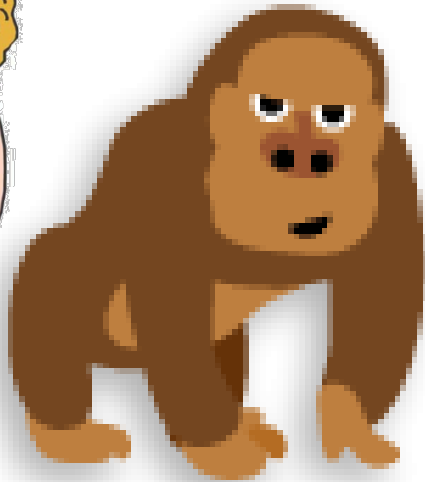
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I wanna be a
first climber!
Can't wait!



TOKYO SKY TREE

Spring ,2012
Completion

634m



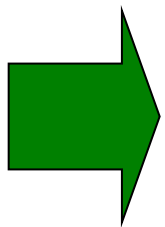


Patient Safety & Quality Management - An urgent problem for Healthcare -

Estimate of the death toll caused by medical errors

- ✓ 98,000 / year in US by IOM report
- ✓ 23,000 / year In Japan by a report sponsored by MoH

- Collection of accurate and quantitative data (data management)
- Automated system for physicians, nurses, medical workers, and patients
- Building Evidence for medical safety





Problem of management on surgical instruments

Medical errors at clinical sites  Social problem

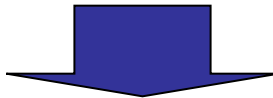
✓ Rate of incidents that surgical instruments or sponge are left inside human bodies : **1 / 10000**

✓ ^{operation} Frequency of errors in setting containers :

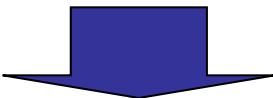
2 %

How frequently is the instrument used?

Is quality assured? To whom is it used?



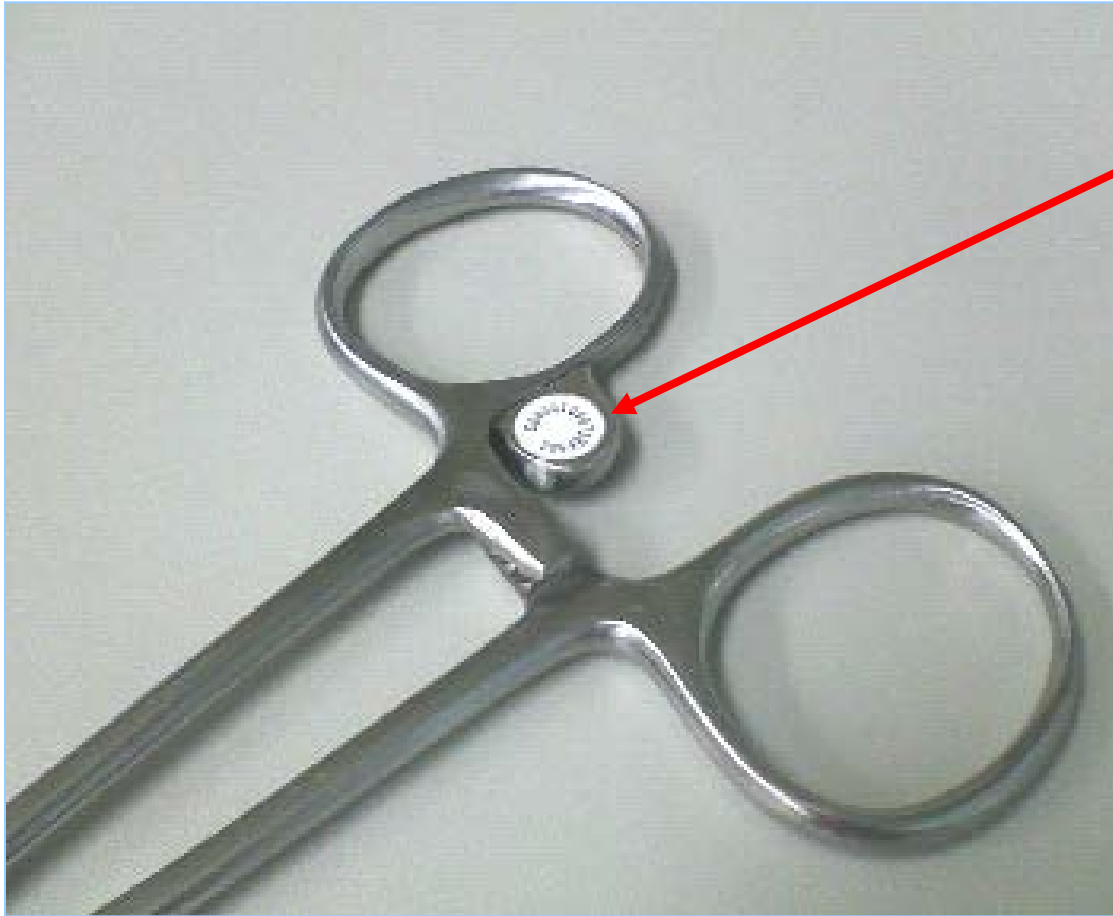
Management of those items by RFID



Computerized data management of surgical instruments (**user friendly, burden free**)



Ceramic RFID tag for surgical instruments



Carved seal ID

- Frequency
13.56MHz
- Diameter 6
mm , thickness
2mm

①Applicable to metals , ②Low dilatibility → low trouble rate , ③Rigid →low damage



Results of basic tests on RFID Tag

1. sterilization test (cycle test) → 50 tags
30 min, pressure 1.5 kgf/cm² , 50 cycles
→ **trouble rate 0 %**

2. High temperature challenging test → 20 tags
200 °C, heating time 300 hours
→ **trouble rate: 0 %**

3. Water and ultrasonic test → 80 tags
28 kHz, 150 W, 30 min, 30 cycles
→ **trouble rate: 0 %**

4. High pressure test → 10 tags
average pressure value 126.2kgf, 150 cycles
→ **trouble rate: 0 %**

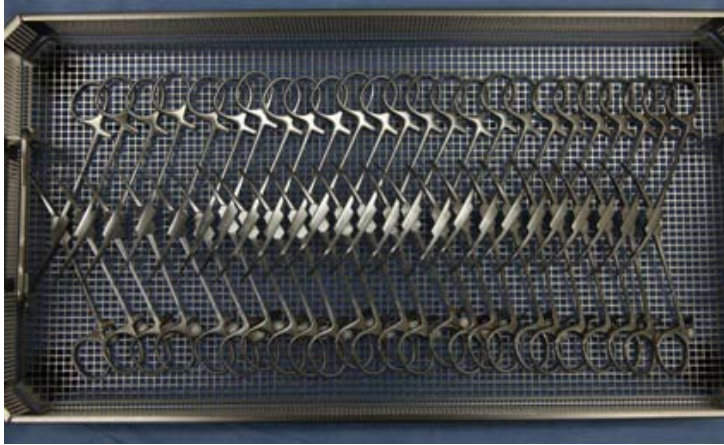


Durability & Contamination Tests at medical institute

- **Durability test by washer-disinfector**
→ 77 surgical instruments, 31 cycles
- **Durability test by autoclave**
→ 68 surgical instruments, 15 cycles
- **Contamination test by ATP method**
→ 35 surgical instruments (A pair of scissors, 7 Mosquito Clamps, 27 Kocher Clamps) : After contaminated by sheep blood, cleaned by a washer-disinfector
→ **Comparing Tag attachment section and Box-rock section**



Durability/Contamination Tests



Instruments in a washing basket



Setting in sterilization container



Washer disinfector

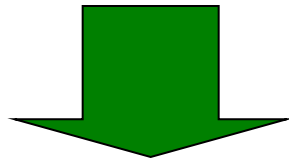


Autoclave



Results of the tests

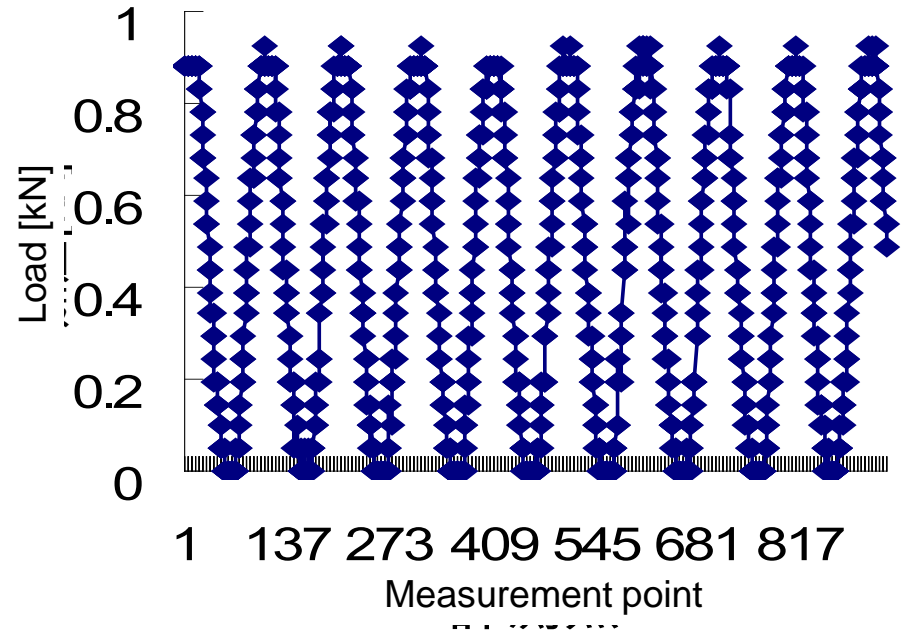
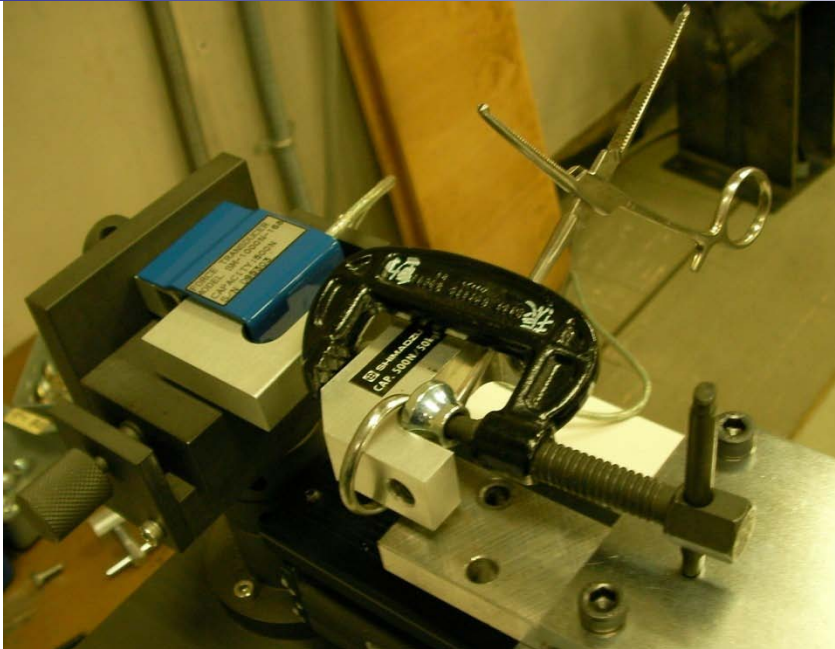
- Durability test
Malfunction, No communication : 0
- Contamination Test
→ A T P Method : Luminescence test
Tag attachment section : 38.7 ± 6.1 [RLU]
Box-rock section : 39.8 ± 6.0 [RLU]



- ✓ Meet the standard of “less than 100RLU” by Japanese Association for Operative Medicine
- ✓ No breakage or separation of RFID tag



Load Test of RFID Tag



Test material : 6 surgical instruments

Load : 0.9kN(9kgf), 10000 Cycles

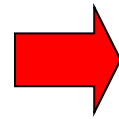
→breakage, drop out, no communication : 0



Tag Reader/Writer



The movement of the instruments can be monitored by Reader/Writer under spread board for surgical instruments.



No need of intentional motion for reading



Tag Reader/Writer



Operation Room



The reader/writer is equipped under the spread board for surgical instruments



Data to be written in RFID

- In accordance with Steel Instrument 2D Symbol Marking Guideline & GS1 Spec.
(EPCglobal in the future)
- Data Structure : to be based on ISO/IEC15418

(AI) GTIN-14 (AI) Serial No. (8 digit)
01 0 45 1234567 123 0 21 12345678

Global standard a master data

➔ Common serial number of surgical instrument

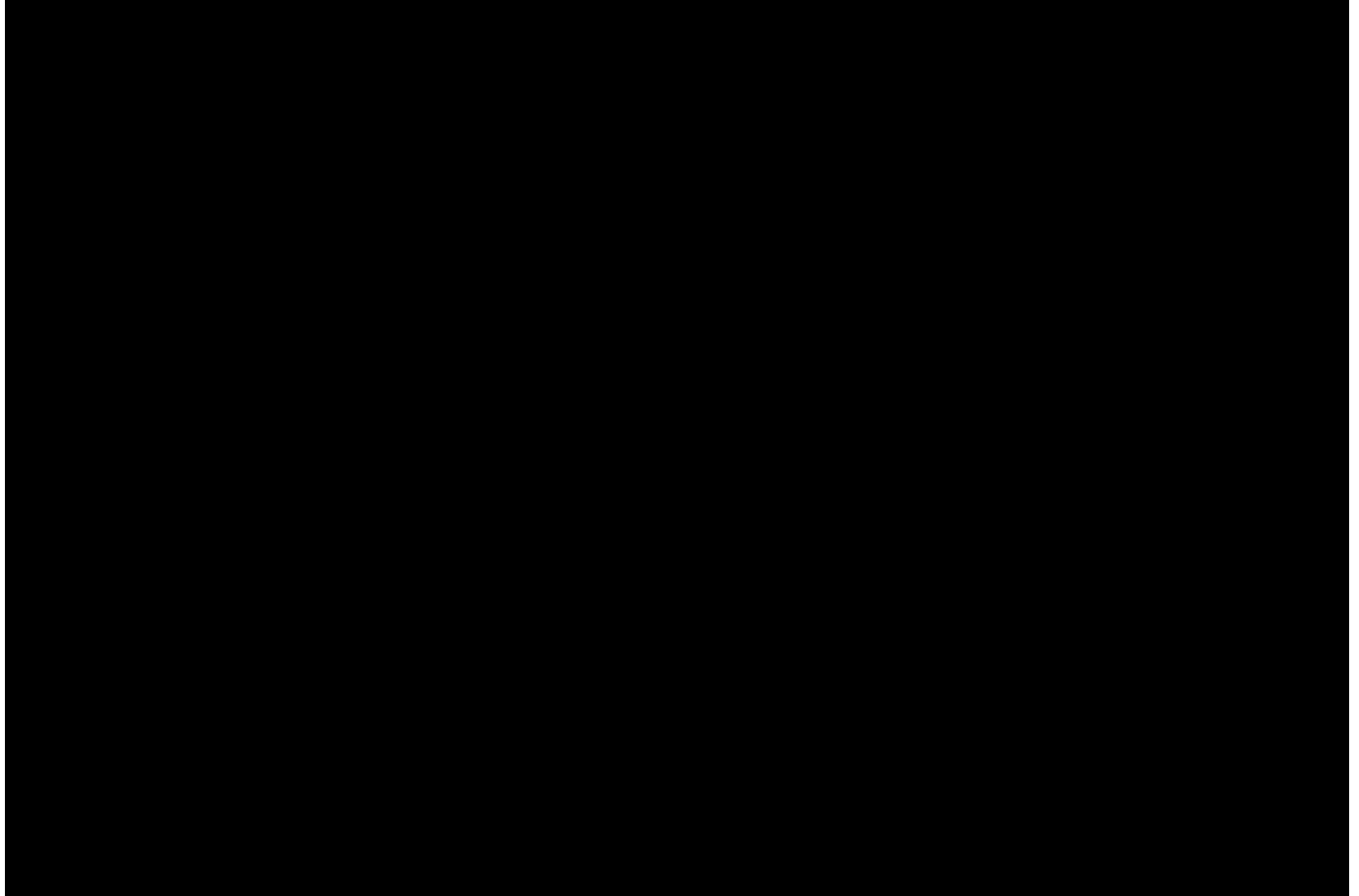


Actual use for human surgery





Actual use for human surgery





Summary

- Developed RFID Tag for surgical instruments
→ Checked the basic performance of the tag attached to surgical instrument
- Developed a reader/writer for operation room and central supply.
- Developed a basis of software for collecting data

Effects of surgical instrument with RFID

Surgical instruments manufacturer



Traceability, assist of individual management

Central supply room

Maintenance, washing and sterilization



Setting container

Increasing set of container, burden free

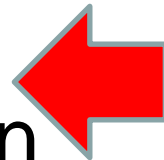
Build evidence on surgical instruments



For medical staff and patient safety



Checking, number of times, keeping quality of surgery, depreciation



Counting instruments before, during, after operation

A system can check automatically, management of asset in hospital

burden free on instruments count, increase quality of operation

Operating room



“Insanity:
Continuing to do the
same thing and expecting
different results.”

- Albert Einstein

Contact us.
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