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Your Vision, Our Future

GS1 Healthcare conference, Tokyo
October 29 2008

Approach to Traceability of Endoscopic Devices

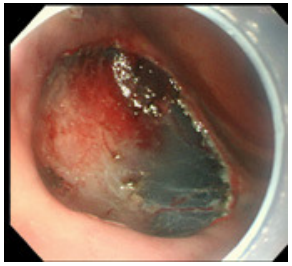
Olympus Medical Systems Corp.

Naomi Sekino

Opto Digital Technology

OLYMPUS

Endoscopy & Laparoscopic Surgery



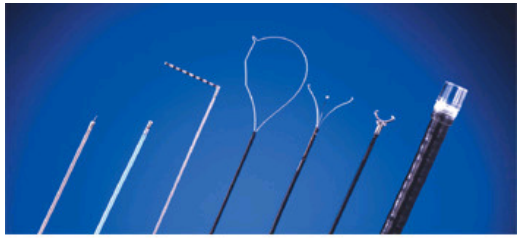
Endoscopic Treatment

Less Invasive Surgery

Utilizing a small incision

Flexible Endoscope for Gastroenterology

Video scope



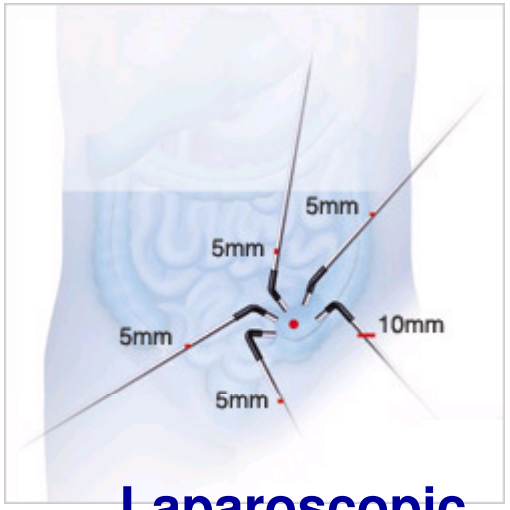
EndoTherapy Accessories

Video system

Electro surgery unit

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

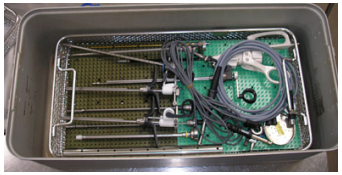
- Article control
  - Prevention of missing or lost instruments
  - Identifying loan instruments
- Control of infection history
  - Identifying infection route at the occurrence of secondary infection
  - Sterilization and history control of instruments used for a Creutzfeldt-Jakob disease patient
- 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

OR

Cleaning/Disinfection

Dry



Instruments check

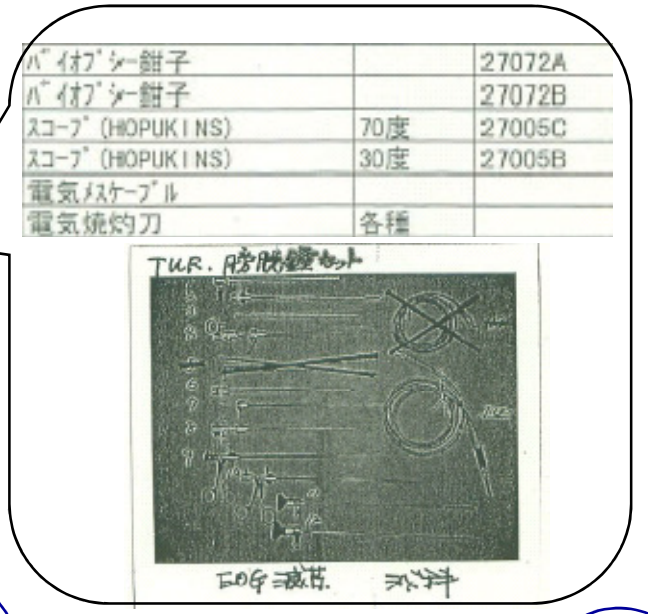
Sterilization

Storage

Problems for medical instruments

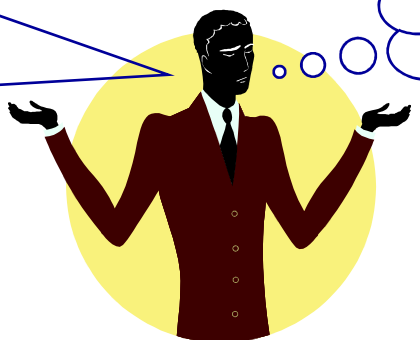
Risk of human error

Manual checking of instruments by hand



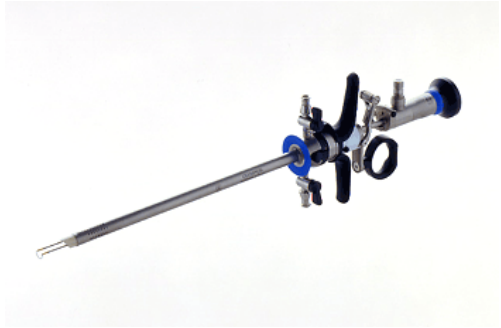
ﾊﾞｲｵﾌﾟｼｰ鉗子		27072A
ﾊﾞｲｵﾌﾟｼｰ鉗子		27072B
ｽｺｰﾌﾟ (HOPUKINS)	70度	27005C
ｽｺｰﾌﾟ (HOPUKINS)	30度	27005B
電気ﾒｽｹｰﾌﾞﾙ		
電気焼灼刀	各種	

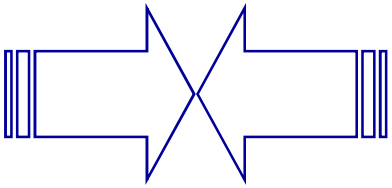
- Which instrument?
- Where is the Lab or OR?
- Who is the Doctor?
- Who’s the patient ?
- When is the surgery?
- What type of surgery?
- How long is the surgery?

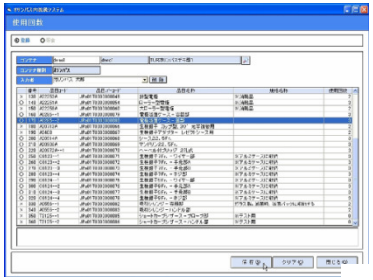


Missing 6W1H

Importance of Traceability for Endoscopic Instruments







“Items”

“Data”

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

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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

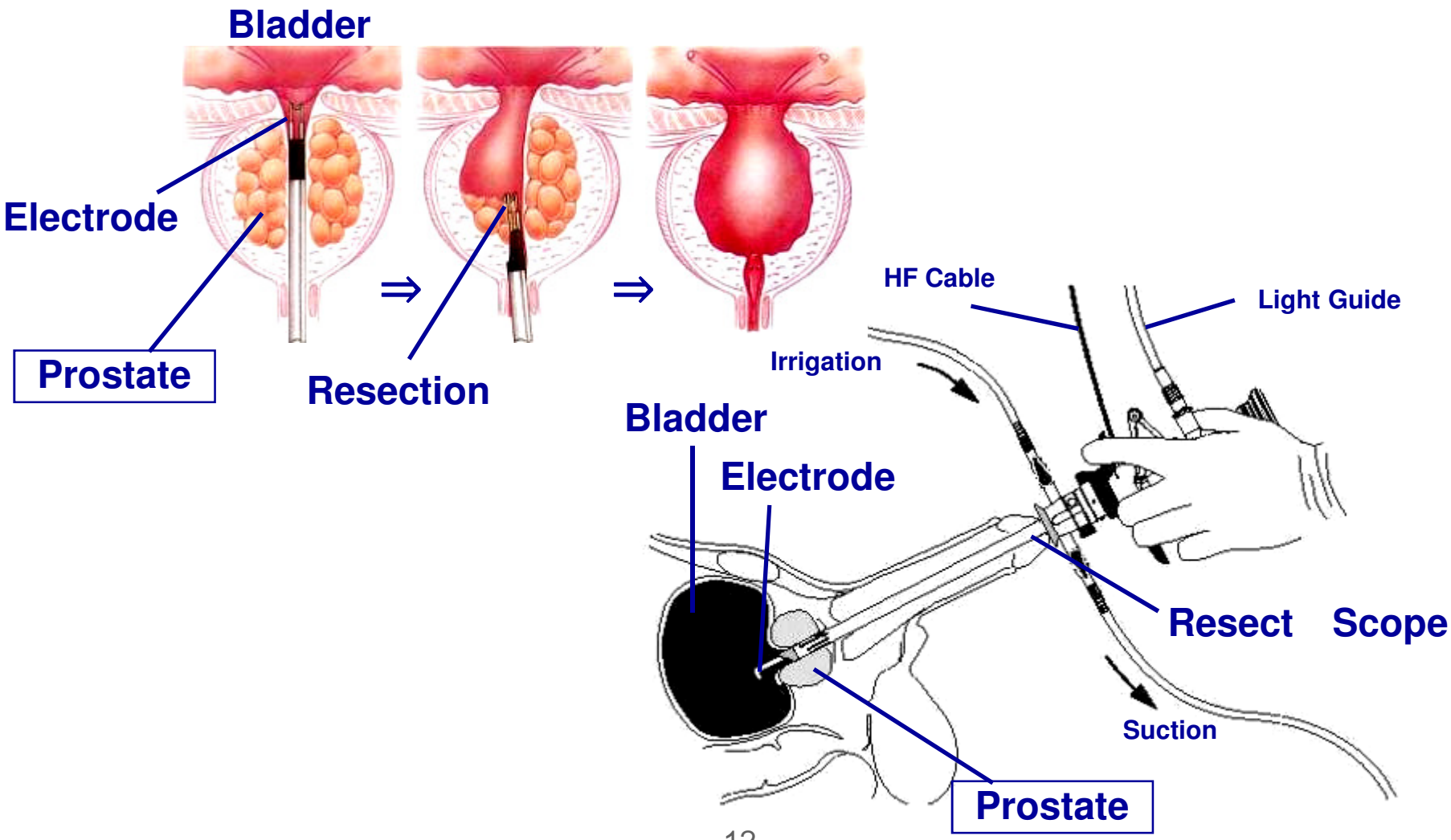
- **Verification of usefulness for traceability utilized direct marking or RF-ID on surgical endoscopes and instruments**

Number of beds = 1,076

Number of operations/year ≒ 7,984

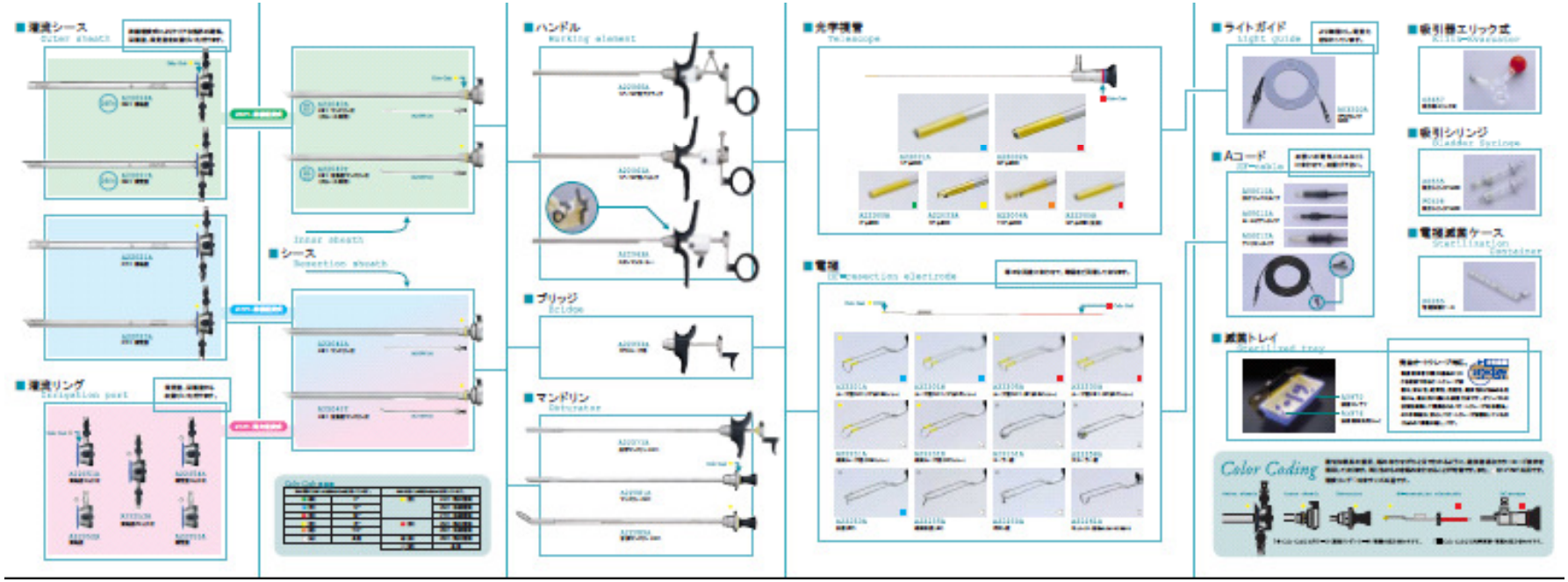
Dr.Nakada,
Director of the Surgery Center

TUR-P Transurethral Resection of Prostate



Experiments utilizing resectscope system

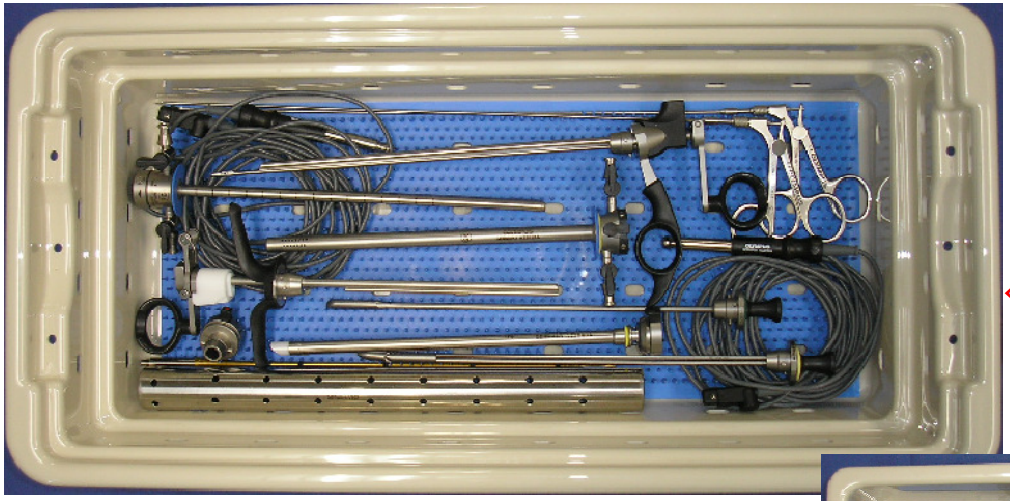
Application of resectscope system for TUR to trial study



Why was the resectscope for Traceability?

- **The instruments contain many parts in various shapes and sizes**

⇒Preparation and maintenance is quite troublesome



Approximately 30 parts per container

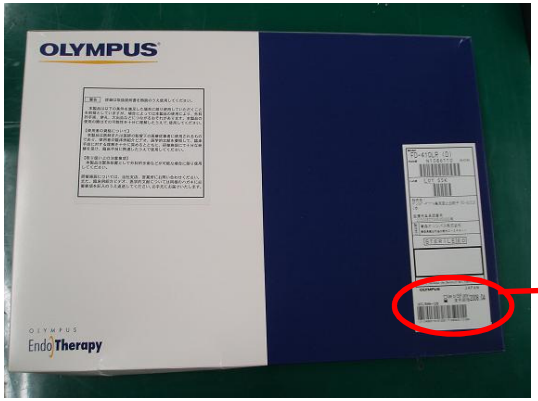
↑Autoclavable items

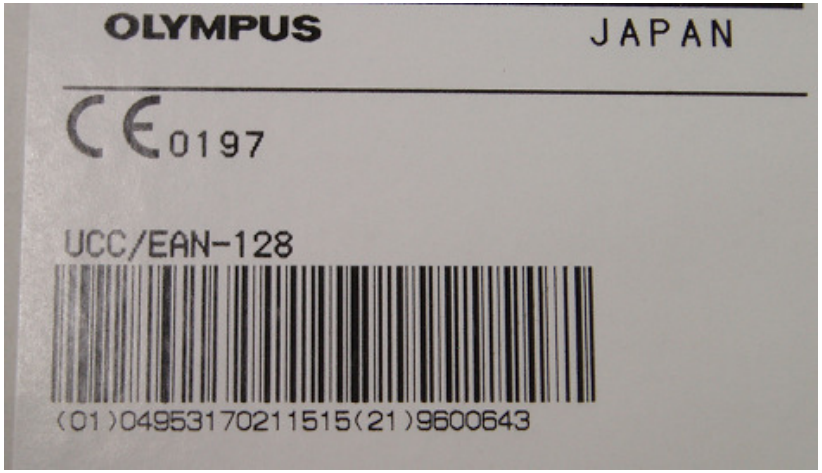
Camera Head

EOG or Plasma sterilization →

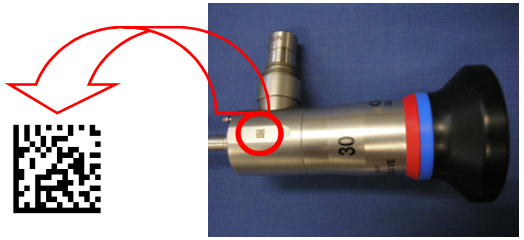
Coding on package

- GS1-128
- Supply chain management
- Assignment for direct part marking





Direct marking adopted for pilot study

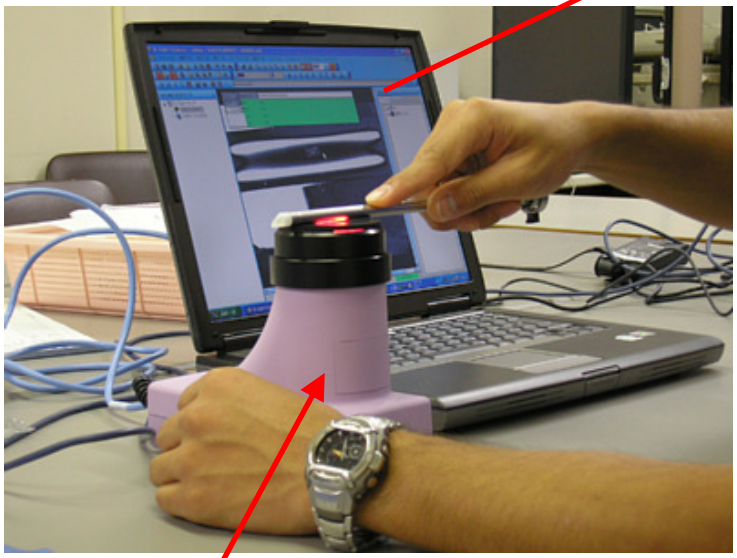


- Prerequisite conditions
  - Standard code recommended by GS1
  - Durable against cleaning, disinfection and sterilization
  - Size which can be marked on endoscopic instruments
- Adopted conditions
  - Data carrier：Data matrix or QRcode

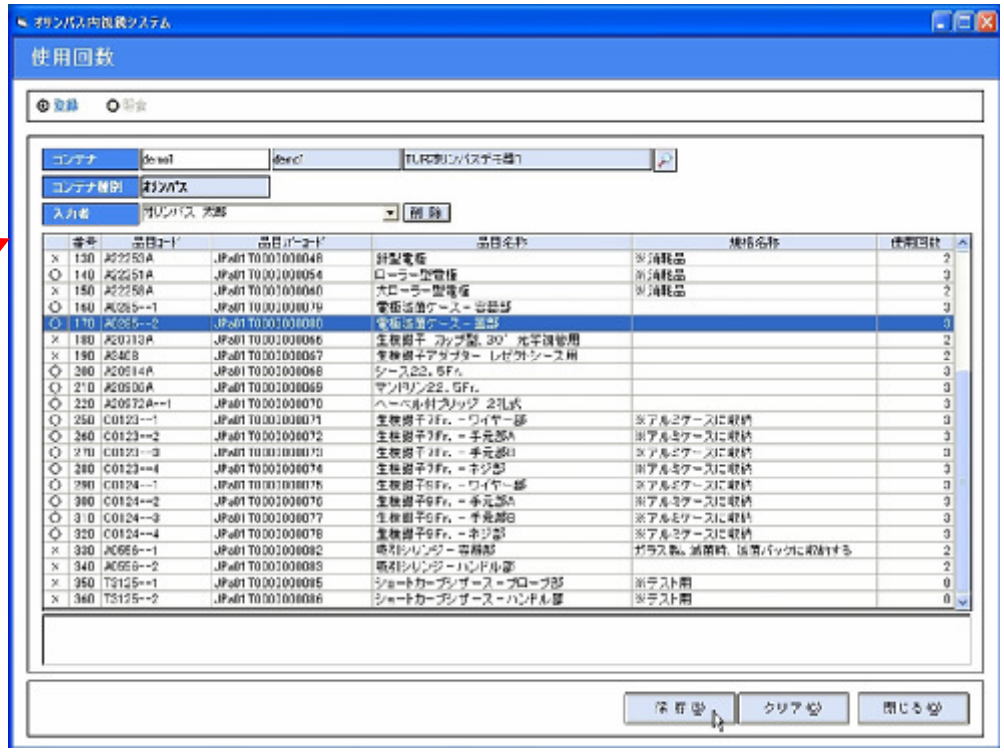
  - Data contents：25 digits（GTIN＋S/N)、16digits（S/N in hospital)
  - Minimum size：1.44×1.44mm(25digits）

Instruments check

Data capturing after cleaning & disinfection



Code Reader

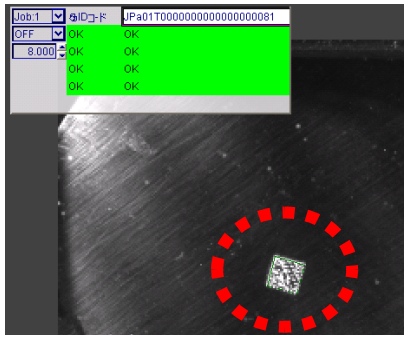


PC Data base

Direct marking on the metal parts

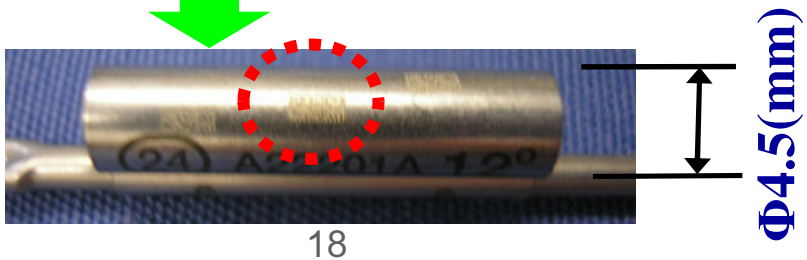
Flat stainless

1.44mm x 1.44mm□, 25Byte



Curve stainless

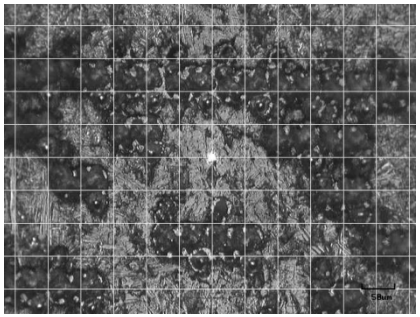
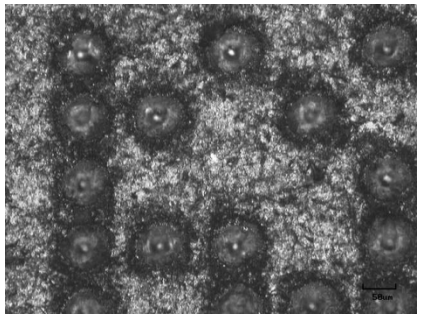
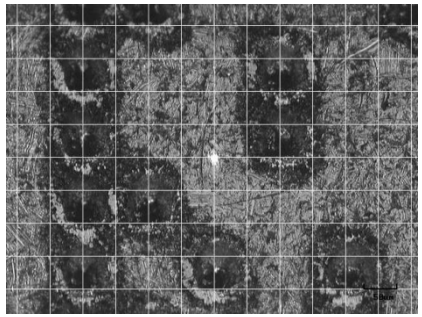
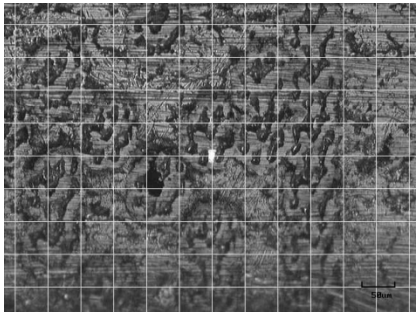
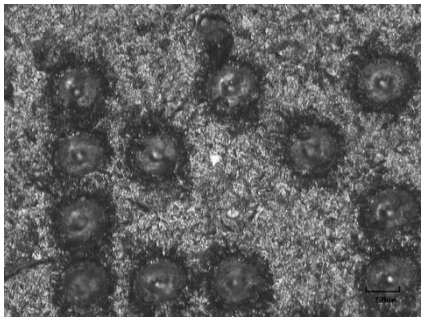
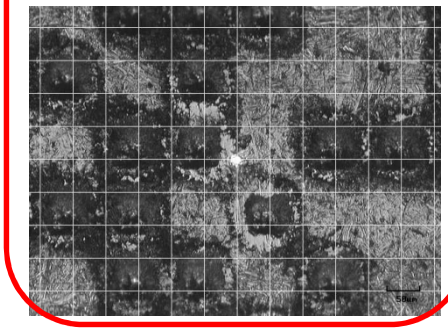
1.2mm x 2.6mm, 16Byte



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)

	Previous marking	Improved marking	
	After 4cases	Before use	After 12 cases
Loop 30°			
Loop 12°			

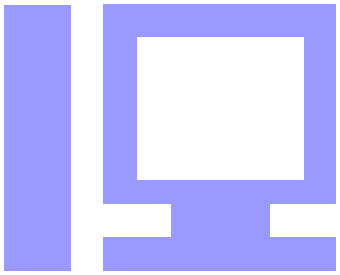
Applied study utilizing RF-ID

ID information
Serial No.

RF-ID

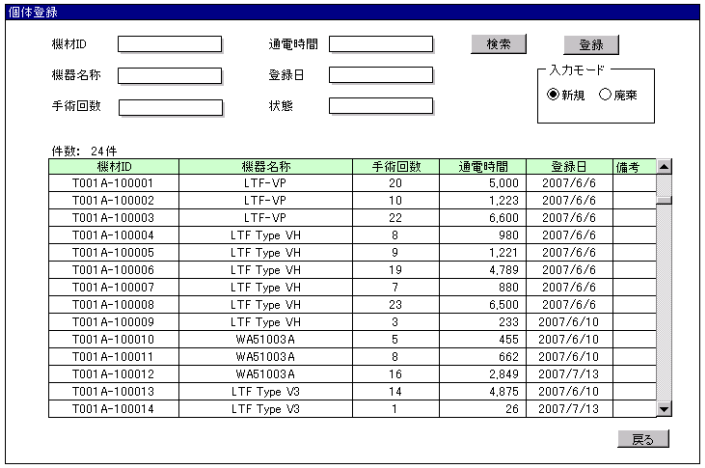
Scope ID tag

PDA
with scanner



Olympus system server

Surgical scope



個体登録

機材ID　通電時間　検索　登録
機器名称　登録日　入力モード ◉新規 ○廃棄
手術回数　状態

件数: 24件

機材ID	機器名称	手術回数	通電時間	登録日	備考
T001A-100001	LTF-VP	20	5,000	2007/6/6	
T001A-100002	LTF-VP	10	1,223	2007/6/6	
T001A-100003	LTF-VP	22	6,600	2007/6/6	
T001A-100004	LTF Type VH	8	980	2007/6/6	
T001A-100005	LTF Type VH	9	1,221	2007/6/6	
T001A-100006	LTF Type VH	19	4,789	2007/6/6	
T001A-100007	LTF Type VH	7	880	2007/6/6	
T001A-100008	LTF Type VH	23	6,500	2007/6/6	
T001A-100009	LTF Type VH	3	233	2007/6/10	
T001A-100010	WA51003A	5	455	2007/6/10	
T001A-100011	WA51003A	8	662	2007/6/10	
T001A-100012	WA51003A	16	2,849	2007/7/13	
T001A-100013	LTF Type V3	14	4,875	2007/6/10	
T001A-100014	LTF Type V3	1	26	2007/7/13	

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Software

Objects for traceability

A. Surgical Endoscopes 24pcs

B. Work Stations/ 9sets. Equipments containing 87 separate parts

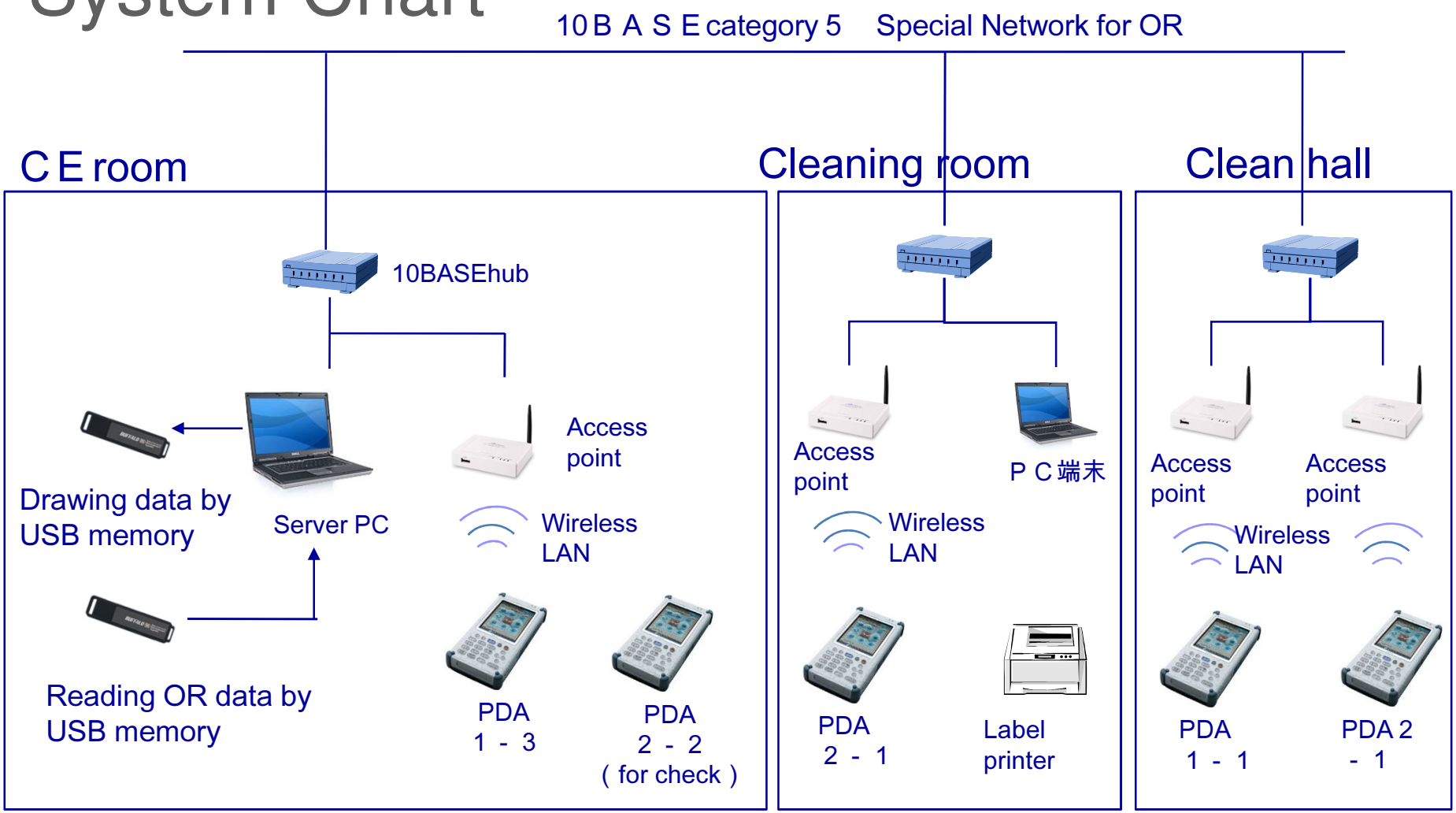
C. LCD Monitor/ 6sets

A

B

C

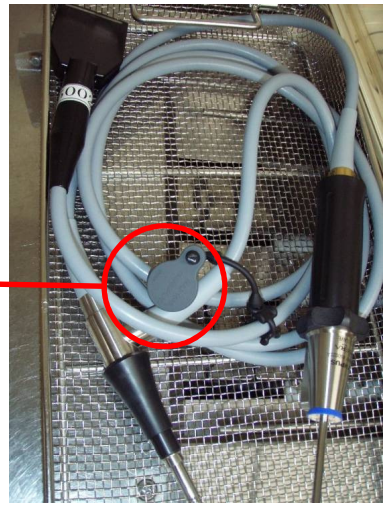
System Chart

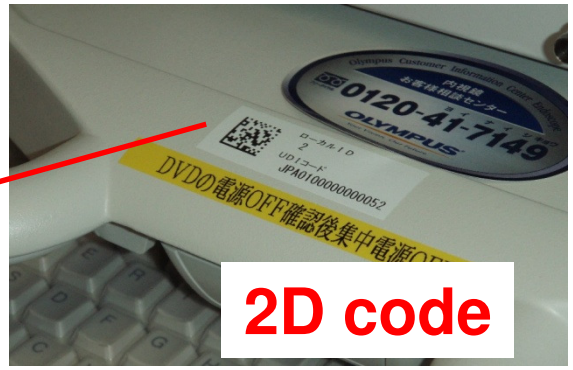


PDA2 : Bar code + RFID scanning model
PDA1 : Barcode + 2D code scanning model

Individual recognition by RF-ID & 2D code

RFID tag
Sizeφ36mm×7mm
Weight：9g



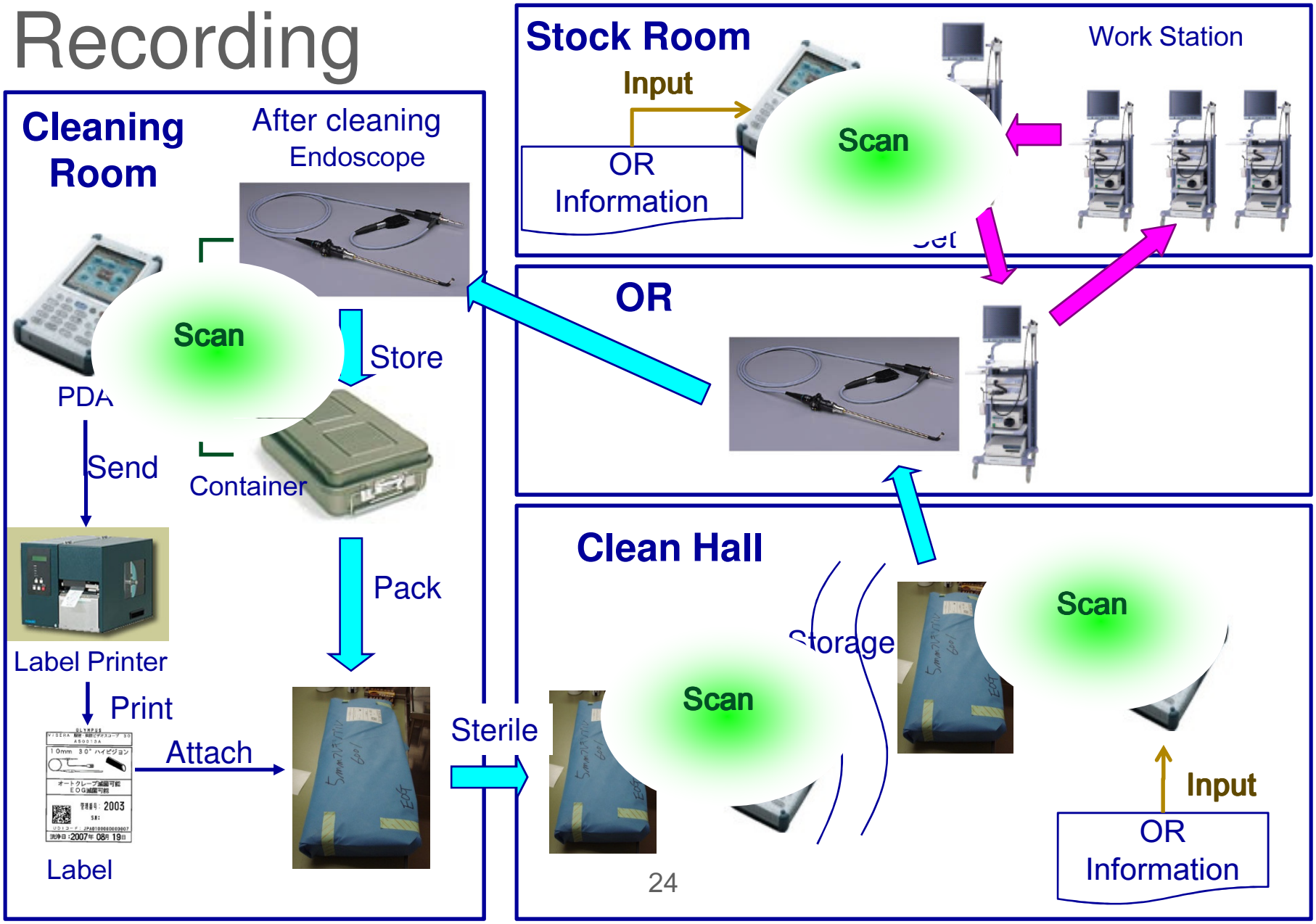


Identification No.: Adoption of GS1 code

(01)04953170201165(21)XXXXXXX(241)6001

GTIN No. | **S/N** | **S/N used by hospital**

Recording


Cleaning Room
After cleaning
Endoscope
Scan
PDA
Store
Send
Container
Pack
Label Printer
Print
Attach
Label
Sterile
Stock Room
Input
OR Information
Scan
Work Station
OR
Clean Hall
Scan
Storage
Scan
Input
OR Information

PDA Scanning

- Start from 20th August 2007
- Scanning system is favorably reviewed by staff.

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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 : 7800 cases

(laparoscopic or endoscopic surgery) : 1300 cases

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A record of an scope

Rigid scope 10mm30°
IDNo.2006

What

When | Where | Which | Who | How long

Date	OR No.	Course	Method	Doctor	Start	End	Time
2007/8/21	7082138	Thoraco	Thoracoscopic ***	Dr.S	9:40	13:15	215
2007/8/27	7082714	GS	Laparoscopic ***	Dr.Y	9:40	17:25	465
2007/9/5	7090520	GS	Laparoscopic ***	Dr.N	13:40	17:50	250
2007/9/12	7091211	GS	Laparoscopic ***	Dr.S	14:40	18:30	230
⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮

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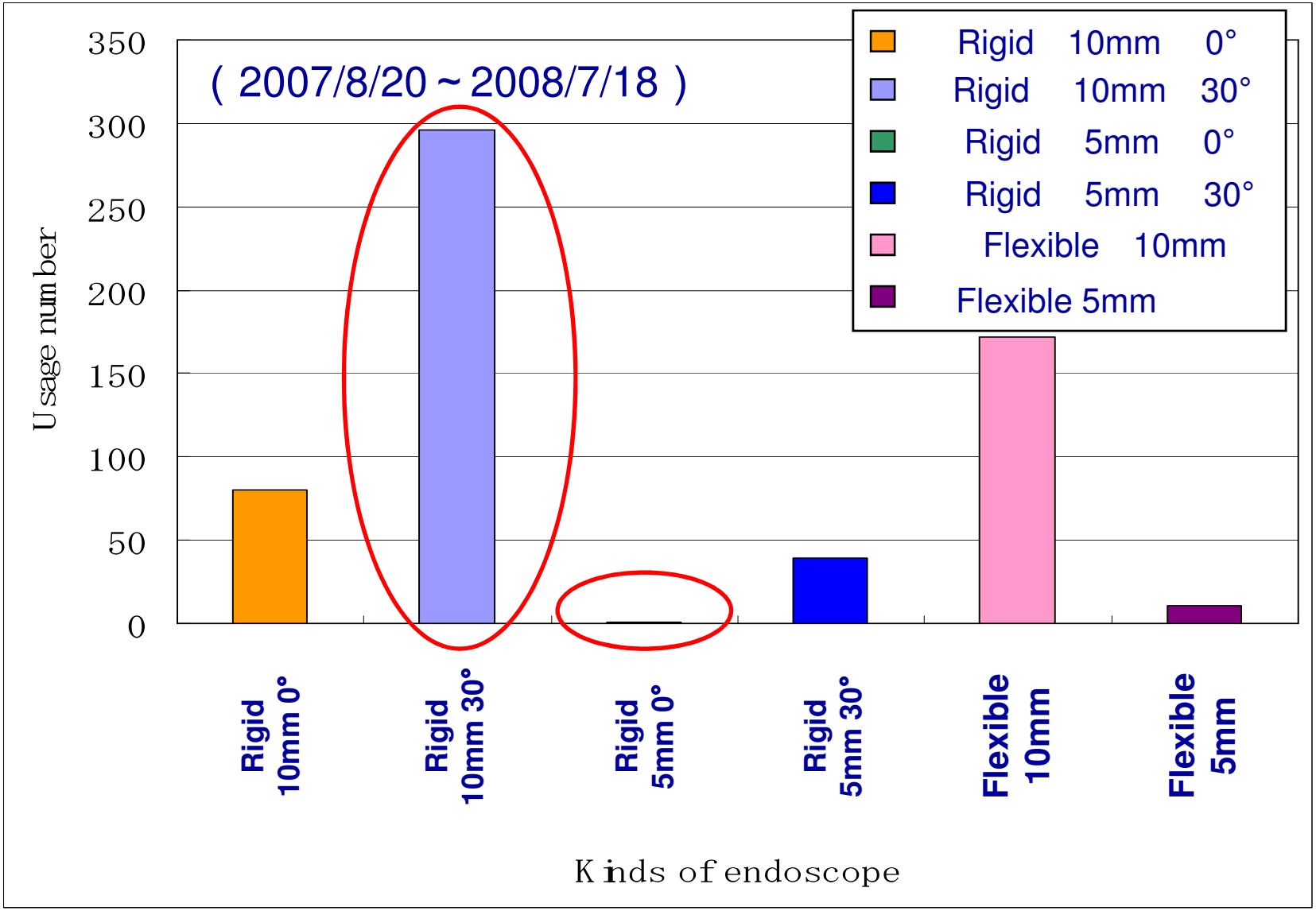
Usage frequency by type



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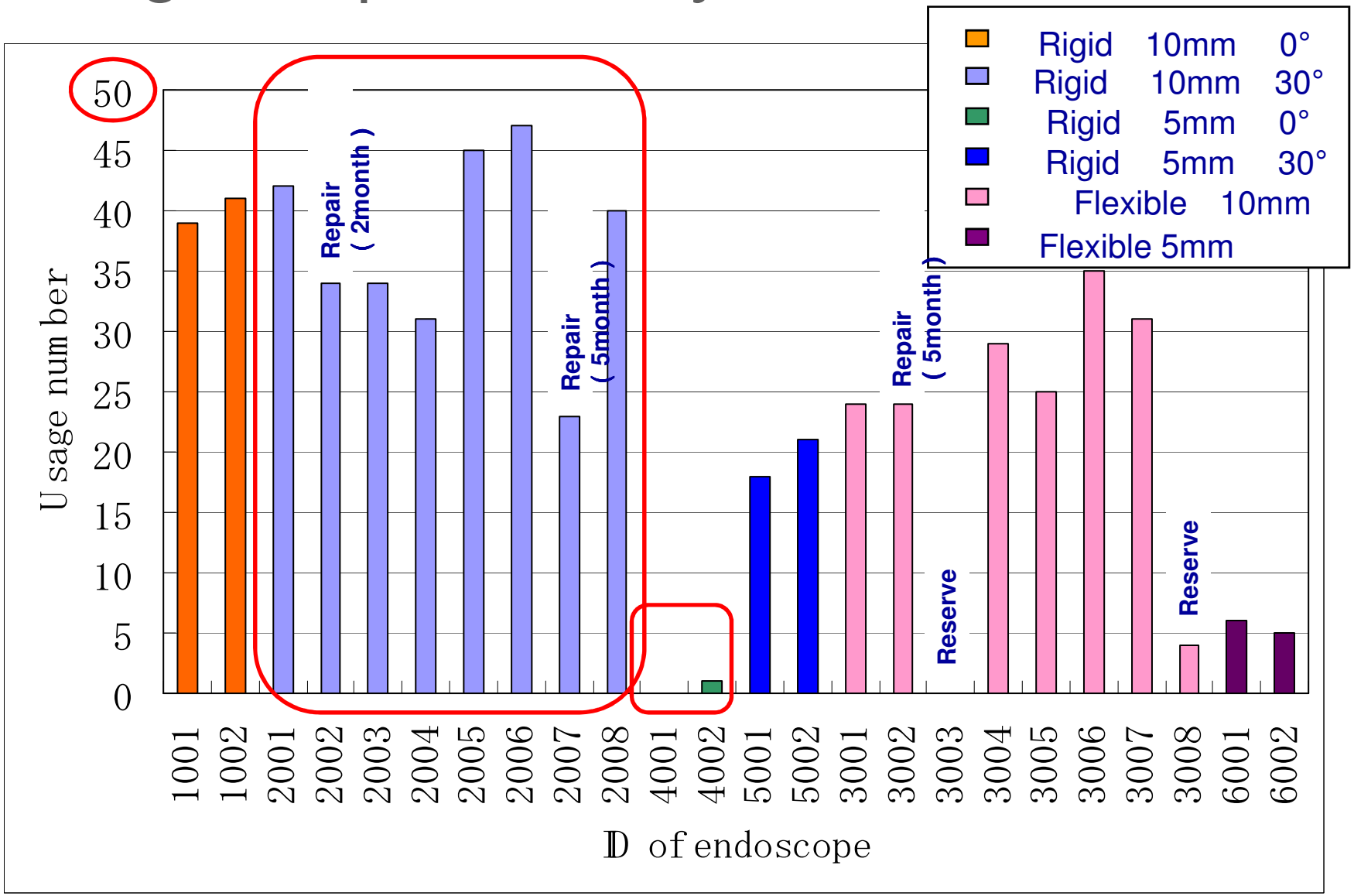
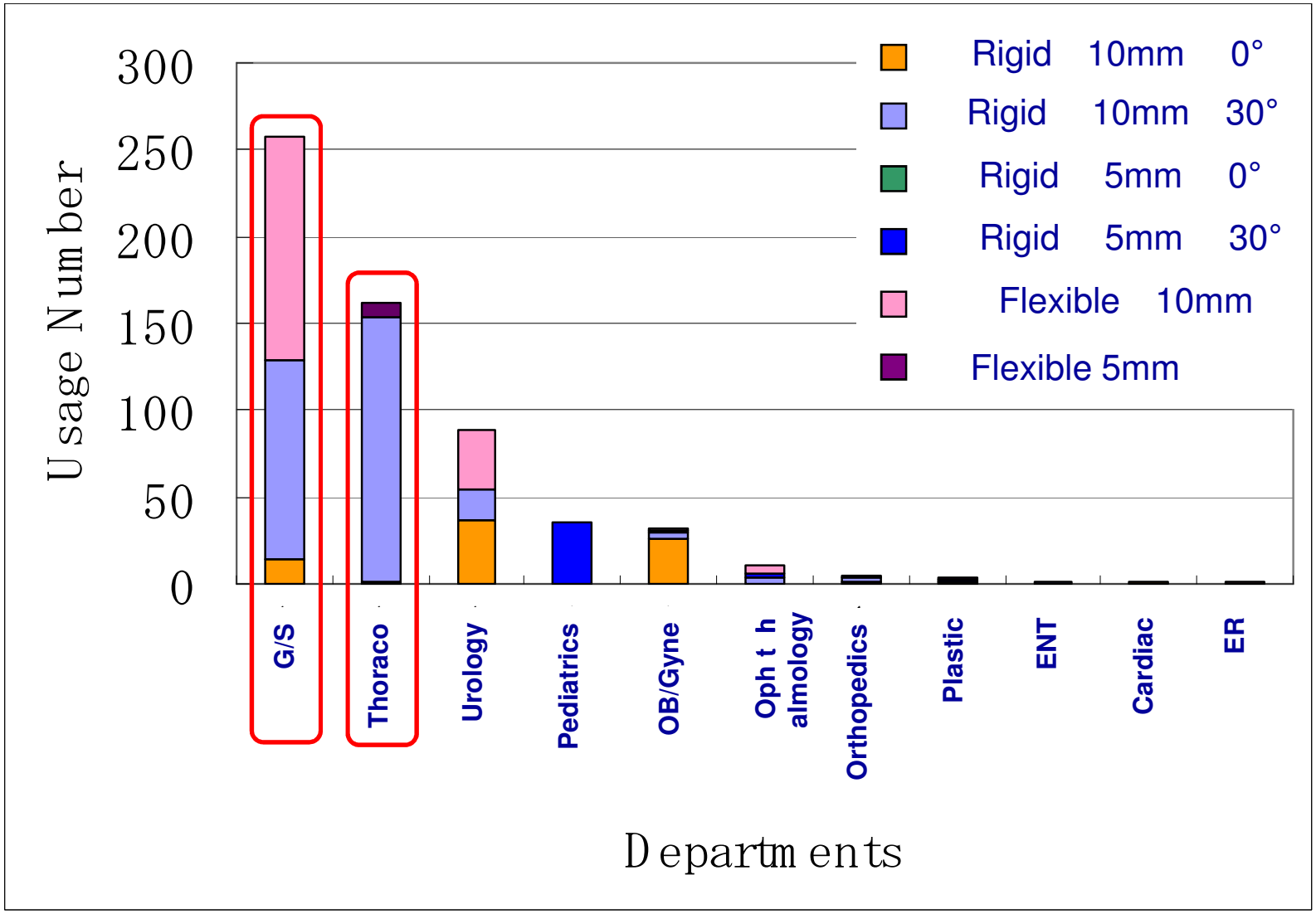
Usage frequencies by individuals



Usage frequency by departments



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.

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