

Direct Part Marking on Each Element of Endoscope for Securing Patient Safety and Traceability



0.96 mm x 2.80 mm 26 digits



Chikayuki Ochiai M.D., D.M.Sc.

Chief Executive, NTT Medical Center Tokyo



Facts 2011

■ Licensed beds available
606 beds

■ Surgical procedure
5,424/year

■ Personnel *
total **1,234**

■ Outpatient visits
2,300/day

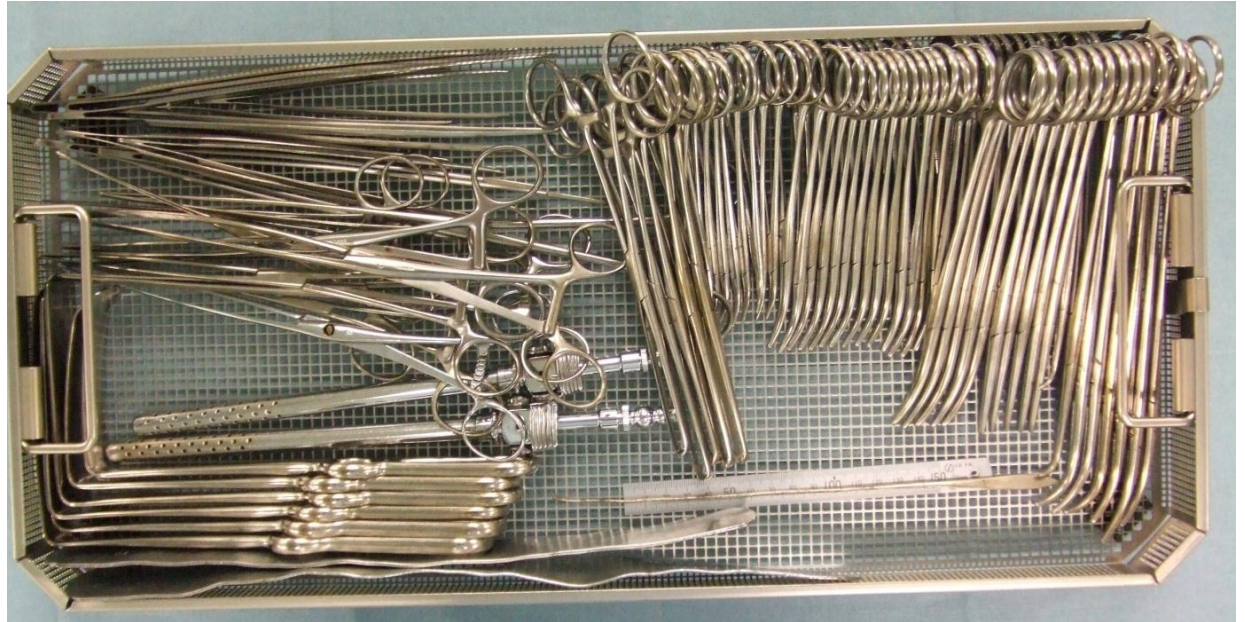
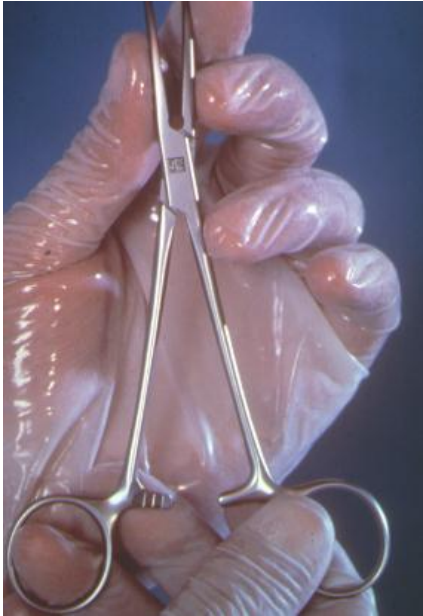
■ Hospital admissions
15,084/year

■ Average length of stay
10.5 days

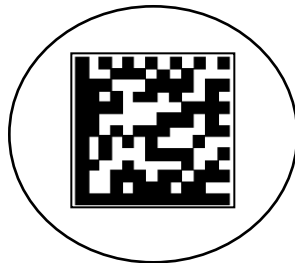




Background UDI for metal instruments



Data Matrix



3 x 3 mm ~ 5 x 5 mm





GS1 Healthcare
Reference Book
2009/2010



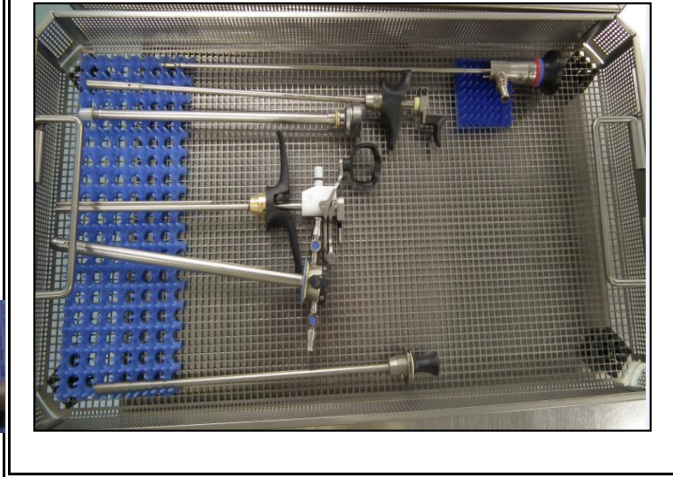
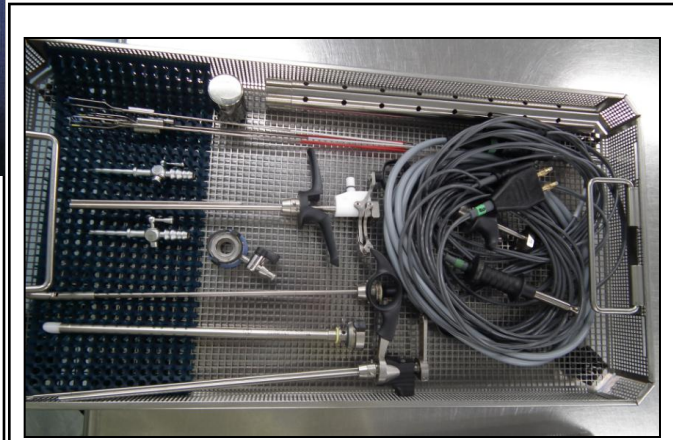


Background

Specifications of an Olympus Urological Endoscopy Set



Component name		
Scope	30°	A220001A
Irrigation sheath	26Fr Rotary type	A22026A
Continuous sheath	24Fr	A22040A
With a rotary cock attached		A22041A
Mandolin	24Fr	A22085A
TURis handle (passive)		WA22367A
Optical mandolin	24Fr	A22071A
E scalpel cord		A0393
Bipolar cord		WA00013
Light guide (with a connector)		WA03200
Irrigation adaptor		05XW
Irrigation adaptor		063W
Silicone tube		
Silicone tube		
Intermittent sheath		A22041A
Mandolin	24Fr	A22085A
Handle (passive)		WA22067A
Bridge (for 70°)		A220001A
Biopsy forceps		A220001A
Loop electrode	24Fr (30°, S)	WA22001A
Loop electrode	24Fr (30°, S)	WA22002A
Loop electrode	24Fr (30°, M)	WA22003A
Roller electrode		WA22004A
Needle electrode		WA22005A



An endoscope is composed of **24** elements



Background New Technology

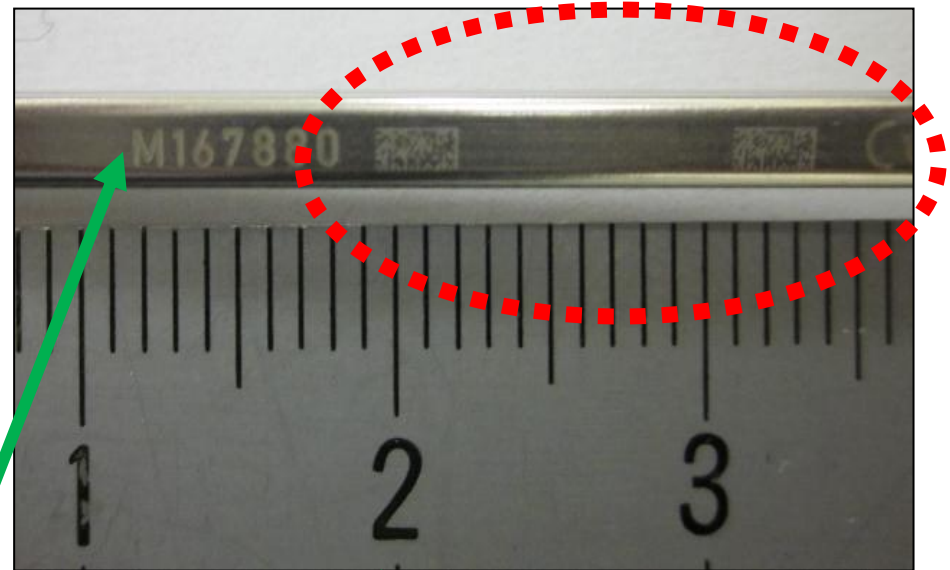
2007

3.0mm x 3.0mm



2011

0.95mm x 2.80mm



Electrode

Ruler



COMPARISON OF TWO TECHNOLOGIES

	CONVENTIONAL	NEWLY DEVELOPED
Size of GS1 Data Matrix	3.0 mm x 3.0 mm 5.0 mm x 5.0 mm	Min. 0.96 mm x 2.8 mm Max. 2.8 mm x 2.8 mm
Amount of Information	Data Capacity : 26 digits Data : Serial No.	Data Capacity : 26 digits Data : (AI) 8004 = Global Individual Asset Identifier
Objective	One UDI for One Metal Instrument	Individual UDI for Each Element of Endoscope
Applicable Material	Stainless steel	Stainless steel Titanium alloy / Resin

AI : Asset Identifier UDI : Unique Device Identifier

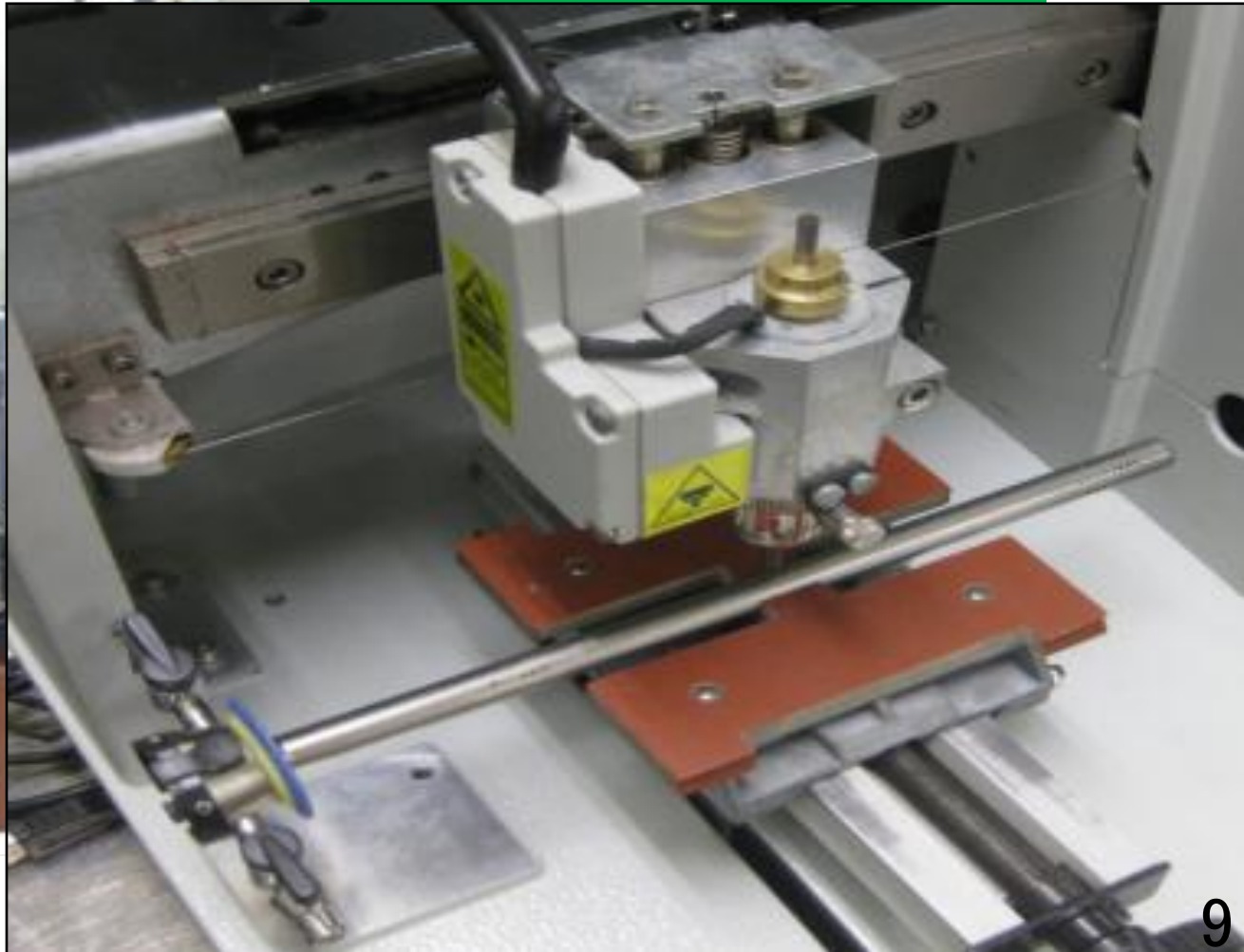


In-Hospital Marking

Laser Marker



Dot pin Marker





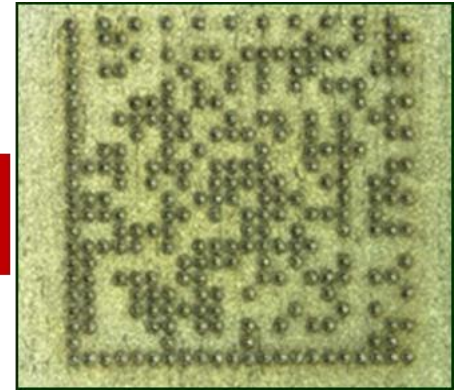
Roles of Laser & Dot Pin Markers

Laser marker

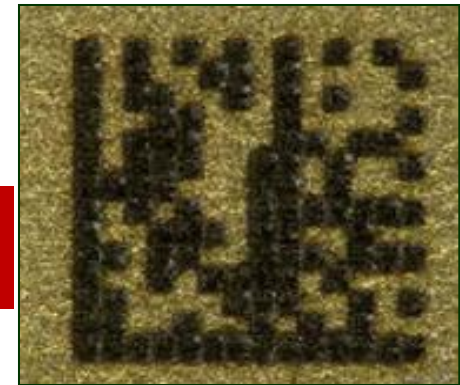


- White marking
 - mirror-like surface of relatively large instruments
 - plastic surface
- Black marking
 - surface-treated instruments

White marking



Black marking



Dot pin marker



- small instruments
- delicate components

Dot pin marking





Rules for Marking Site Selection

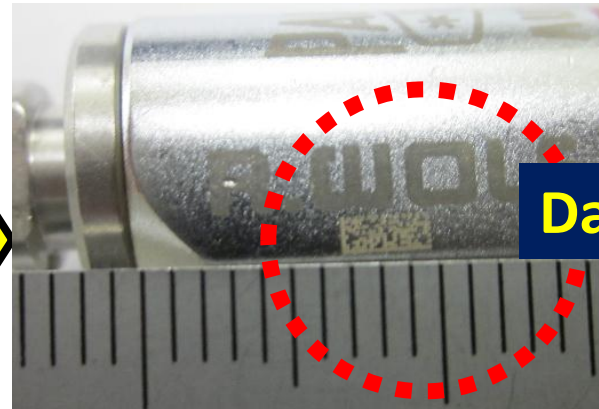
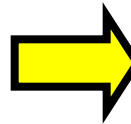
- **Marking site was determined with the direction of endoscope manufactures.**
- **Rules**
 - 1) **Sites other than areas covering lenses and cameras to avoid equipment troubles.**
 - 2) **Sites near the manufacturer's logo mark as they would be found easily.**
 - 3) **Sites with a flat or gently curved surface for easy legibility.**



Marking Samples



Sites near the logo mark
or other marks

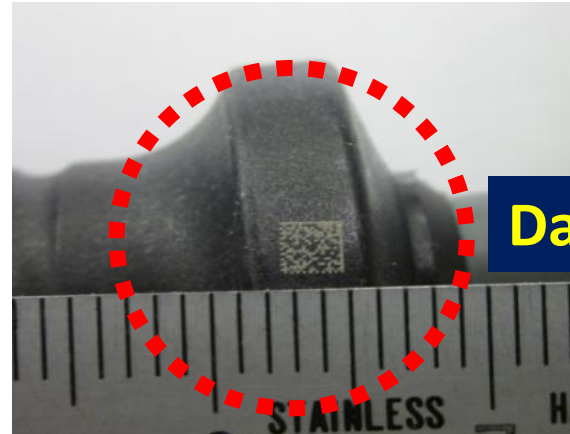
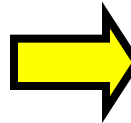
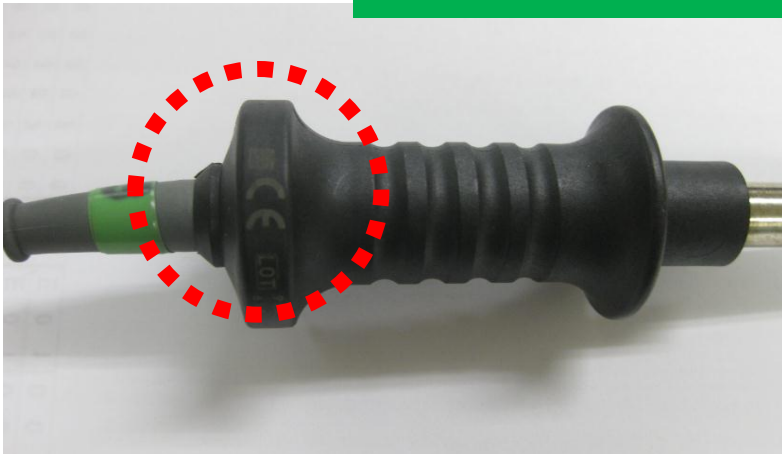


Data Matrix

1.32 mm x 2.86 mm



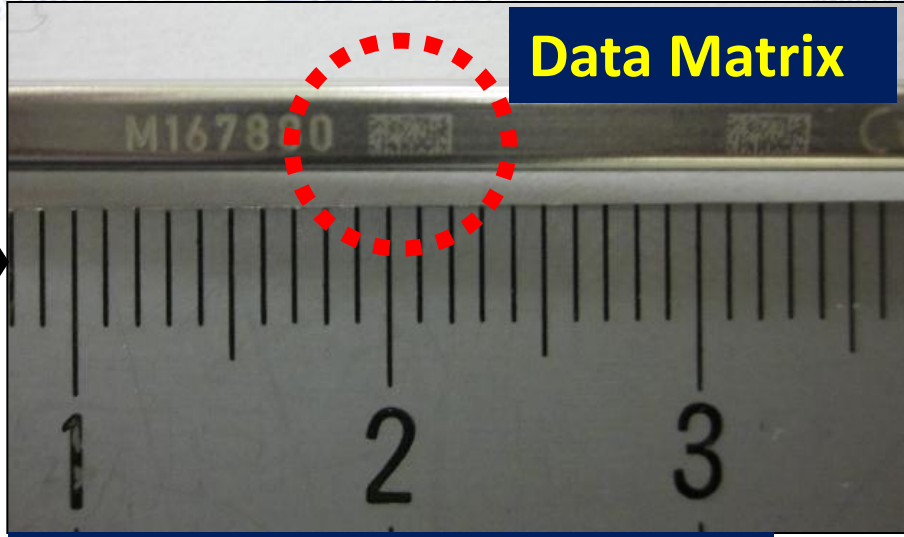
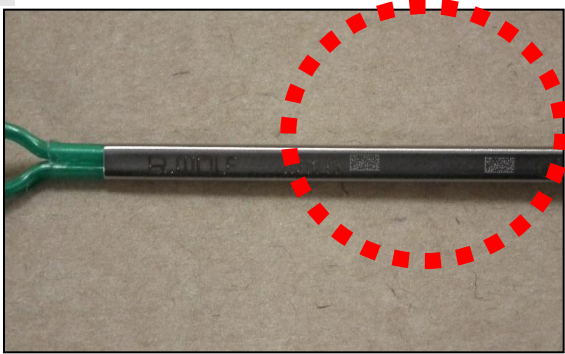
Sites near the logo mark
or other marks



Data Matrix

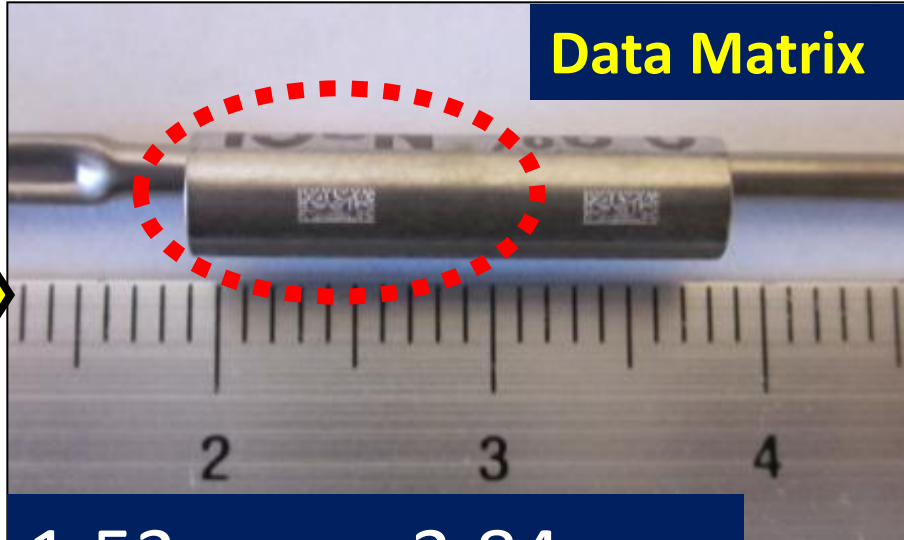
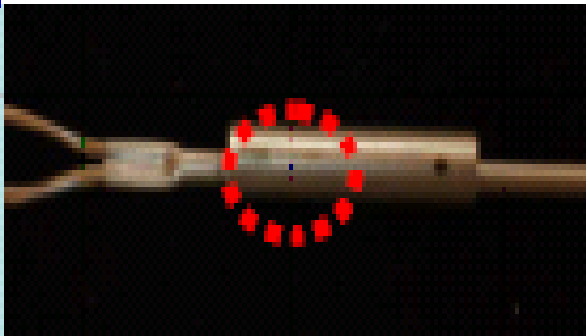
2.80 mm x 2.80 mm

Flat surface for easy reading



0.96 mm x 2.80 mm

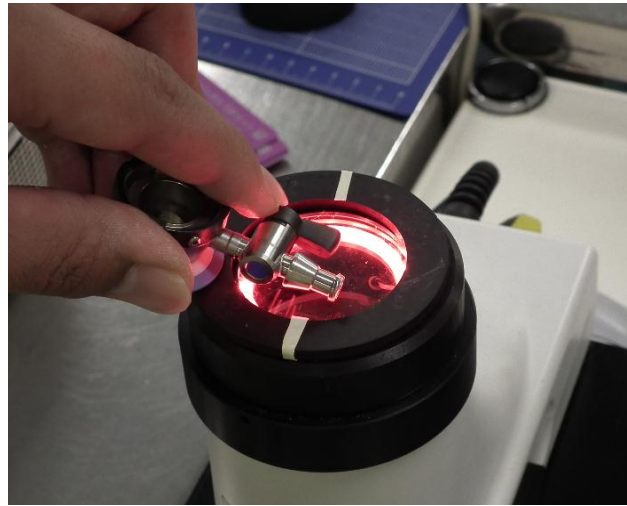
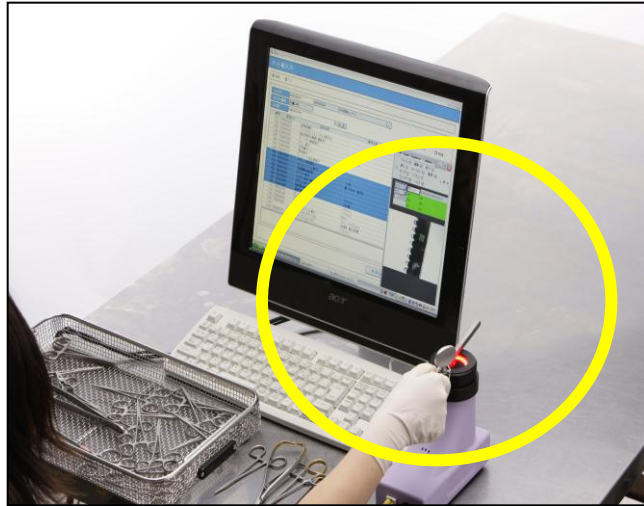
Gently curved surface for easy reading



1.53 mm x 3.84 mm



Bar Code Reader (HN-12-16M Type by MNEXT Japan)

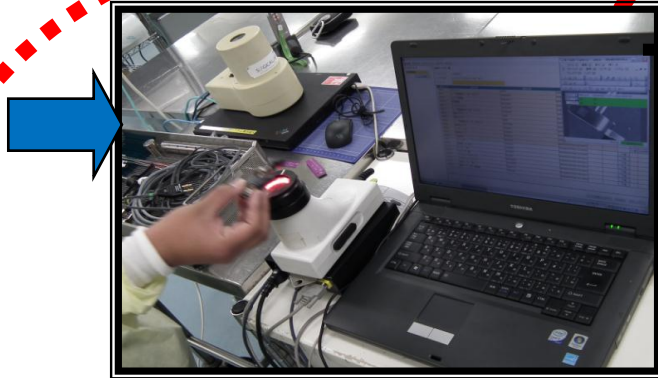


- Capable of reading
 - without adjusting the light source and its angle.
 - regardless of
 - bar code's size or surfaces' condition.
 - white marking, black marking or dot-pin marking
- Size of GS1 Data Matrix : 1 mm x 1 mm to 5 mm x 5 mm
 - **Global Individual Asset Identifier (GIAI)** Total : 26 digits



Workflow of SSU for Surgical Endoscope

Surgery

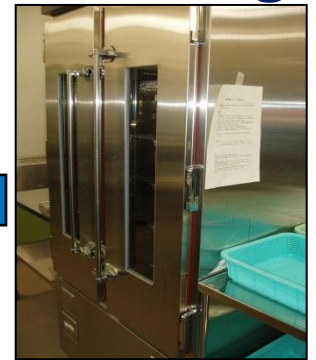


Bar Code Reading



Sort

Washing



Assembly

Assembly into new sets.

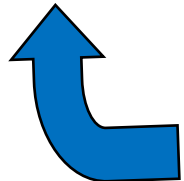
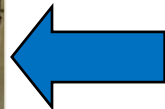
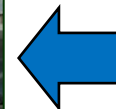
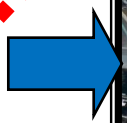
Sterilization



Storage



**Repair/
disposal**





Blue : Actually used in the operation

Ivory : Not used in the operation

List of item barcodes

Container code CU0000002

Container name Wolf resection mirror No.2, 25 units

Barcode [Redacted]

Item code	Item name	Specification name
N00036	Electrode	8424.131
N00031	Electrode	8422.131
N00030	Electrode	8420.19
N00030	Electrode	8420.19
N00031	Electrode	8422.131
N00032	Electrode	8422.151
N00034	Electrode	8423.01
N00032	Electrode	8422.151
N00038	Electrode	8424.151
N00036	Electrode	8424.131
N00034	Electrode	8423.01
N00033	Electrode	8422.351
N00033	Electrode	8422.351
N00037	Electrode	8423.023
N00040	Electric scalpel cord Do not submerge.	815.033
N00035	Electrode	
N00039	Light source cord Do not submerge	
N00035	Electrode	
N00042	Light source connector for Olympus	8088.80
N00025	Outer sheath 25.5Fr	8655.134



White: Data not yet read



World's Best Direct Part Marking on Endoscope for Securing Patient Safety and Traceability



NITE Medical Center Tokyo



Materials and Methods

- As the first trial of our system we selected 7 sets of urological endoscopes.
- On each element of 7 endoscopes we marked Data Matrix symbol of 26 digits.
 - 26 digits include GIAI (8004), GS1 Company Prefix (456238706) and Individual Asset Preference Number (13 digits).

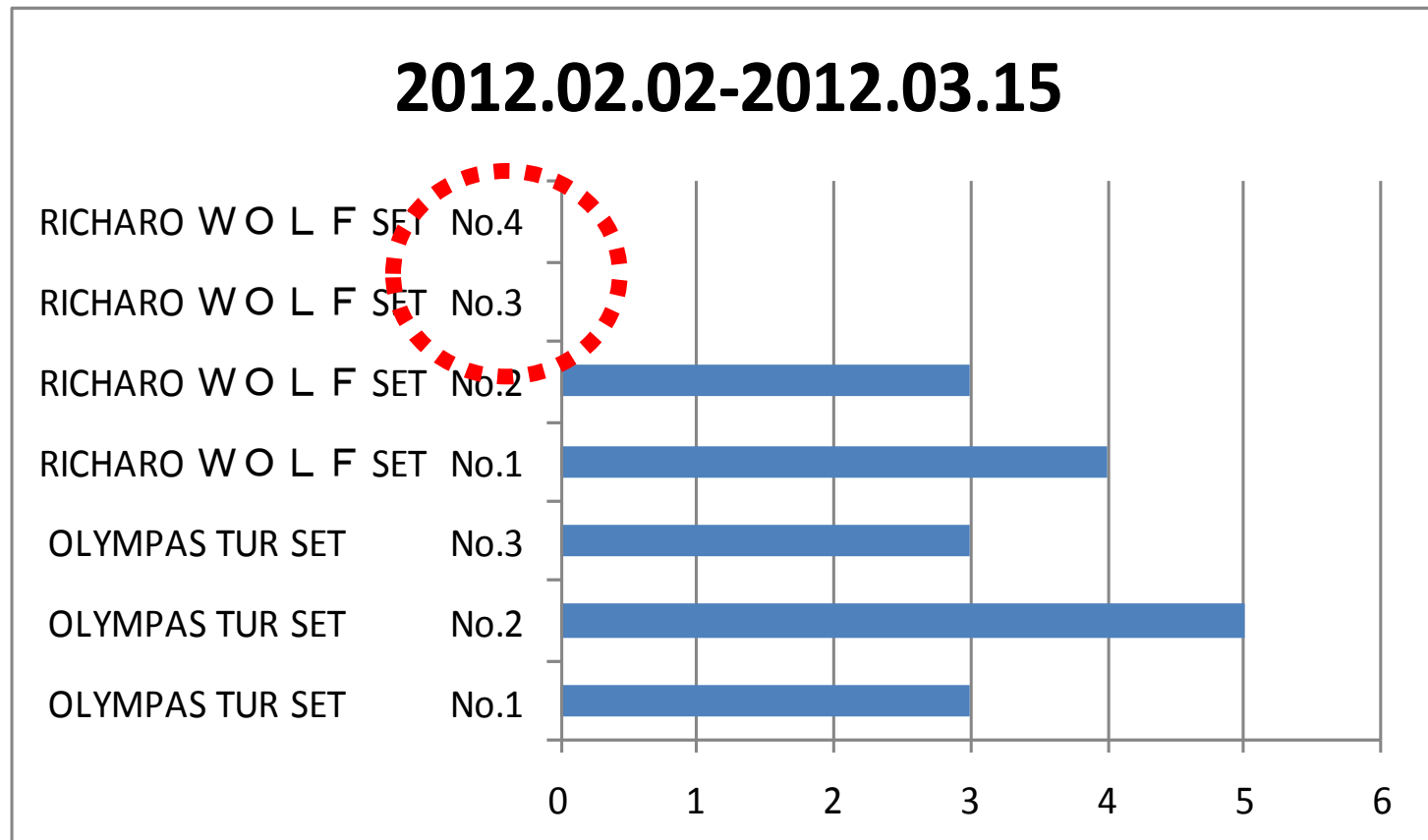


NAME		CODE
OLYMPAS TUR SET	No.1	CO0000001
OLYMPAS TUR SET	No.2	CO0000002
OLYMPAS TUR SET	No.3	CO0000003
RICHARO WOLF SET	No.1	CU0000001
RICHARO WOLF SET	No.2	CU0000002
RICHARO WOLF SET	No.3	CU0000003
RICHARO WOLF SET	No.4	CU0000004



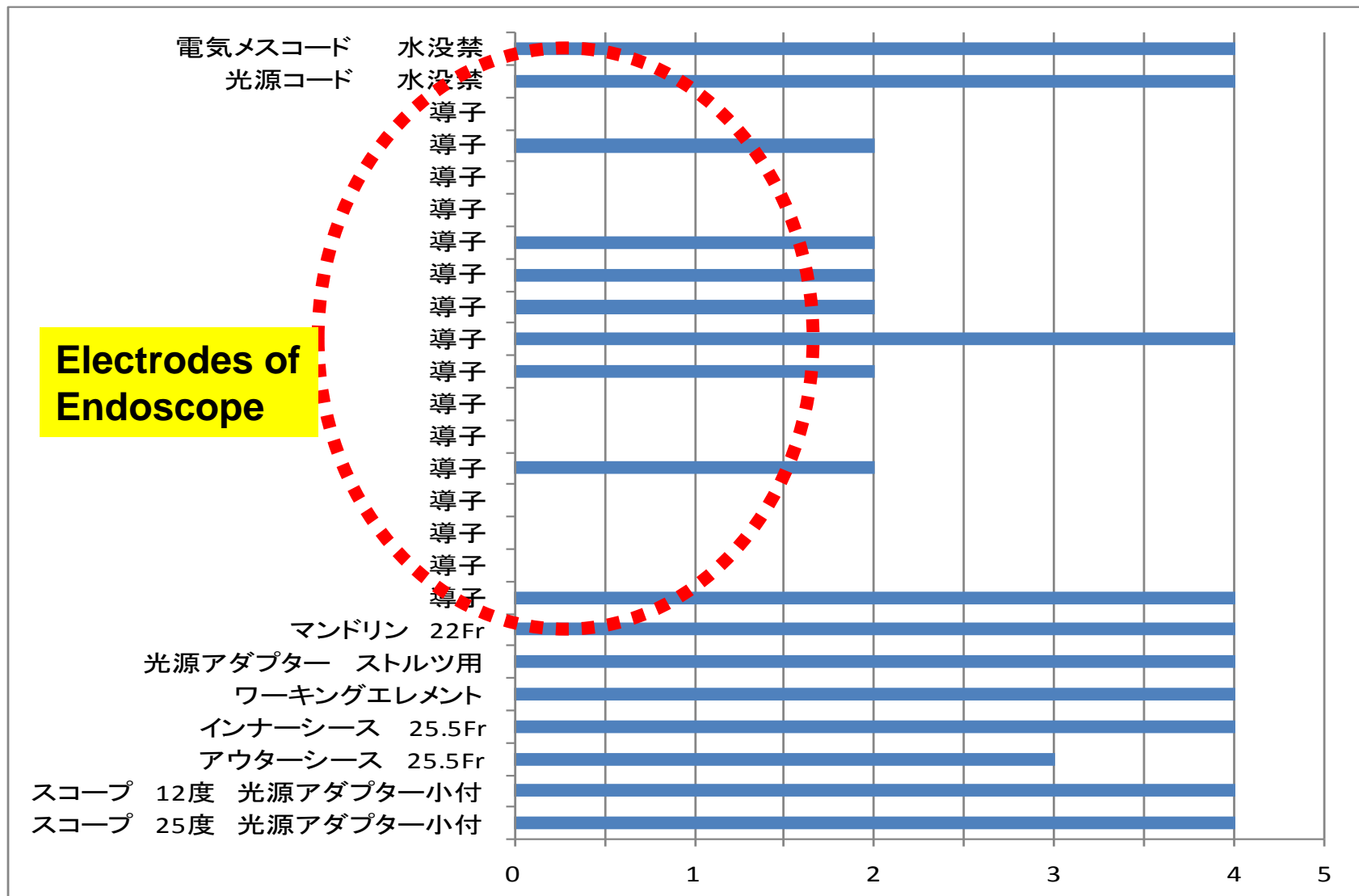
Results: Frequency of Use of Endoscopes (Feb. 2 – Mar. 9, 2012)

- There were a total of 18 surgical cases.
- Wolf's No.3 & No. 4 endoscopes have not been used.





Results: Detail of use Wolf No.1 endoscope

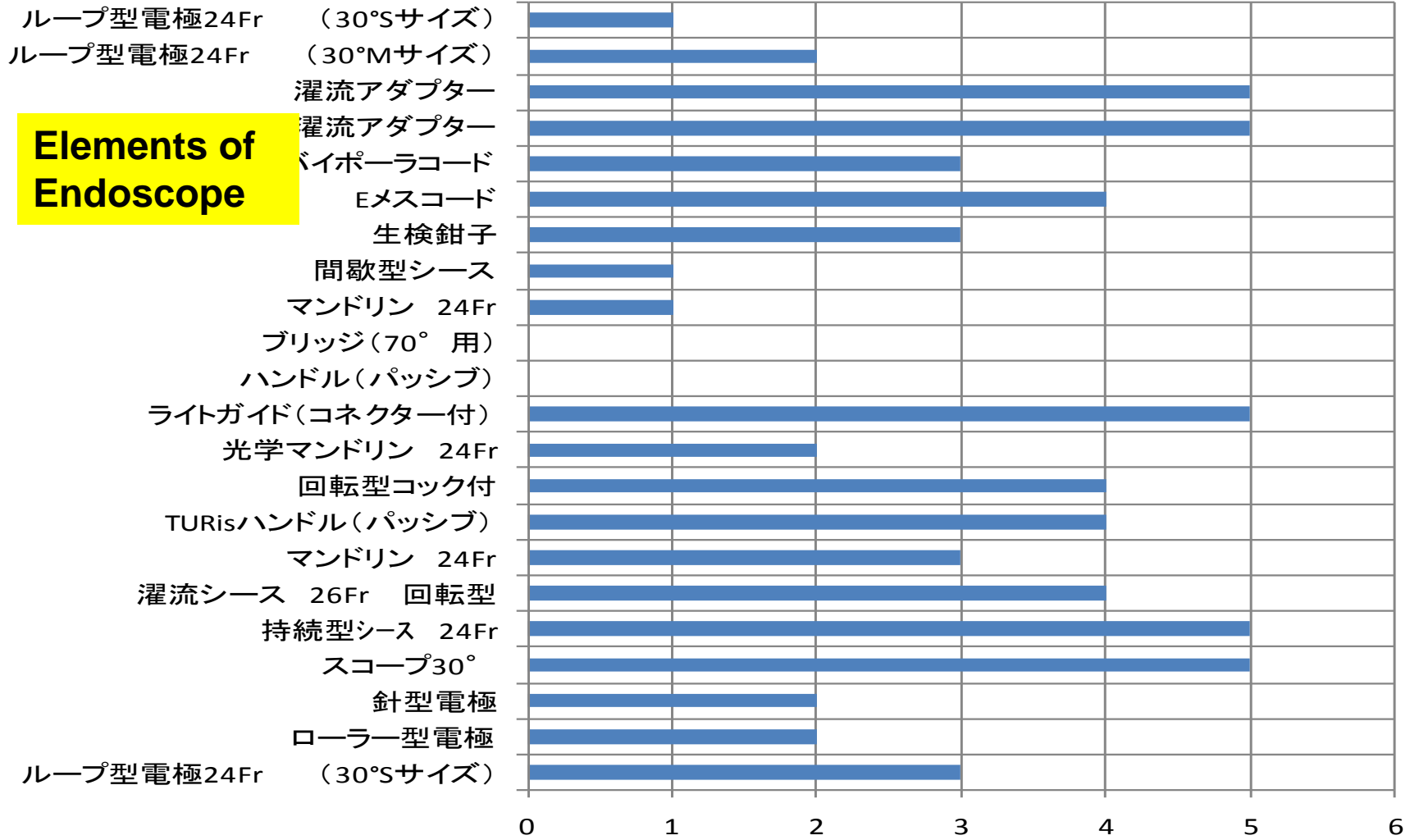




Results: Detail of use Olympus No.2 endoscope



Elements of Endoscope





Benefits / Conclusion

Results : Readability of the Data Matrix marked on the fine elements of endoscopes with using a MNEXT's technology was good even immediately after surgery.

The cumulative numbers of usages for individual scopes and their elements were well collected.

Benefits : The optimal number of uses for endoscopes and their individual elements as well as the optimal timing of their replacement might become determinable.

Conclusion : We are convinced that we will be able to produce clear rules for electrodes and other single use devices through the use of this new technology.



Chikayuki Ochiai, M.D., D.M. Sc.
Chief Executive,
NTT Medical Center Tokyo
E: ochiai@east.ntt.co.jp
T: + 81(3)3448 6600
F: +81(3)3448 6626



NTT Medical Center Tokyo