July 23, 2015

Japan Association of Medical Devices Industries(JAMDI)

Japanese Society of Medical Instrumentation (JSMI)

Technical Guideline on Direct Marking for Two-Dimensional Symbol on Steel Instruments (Ver.1.2)

I. Introduction

In hospitals, it is common that a hundred or more of surgical steel instruments (most of which are made of stainless steel) are arranged in a sterile container in order to sterilize and prepare them according to the surgical technique in the operation or material department by the day before the operation.

Steel instruments are managed effectively, after being purchased, with a sequential flow of regeneration activities which are processed through “instrument setup in a surgical tray” → “sterilization” → “retention” → “transfer from the storage for use” → “use in surgery” → “immediate postsurgical quantity inspection” → “cleaning” → “drying.” Respective hospitals have their own type and composition of instrument setup differently.

Since the “instrument setup in a surgical tray” for steel instruments requires to correctly prepare and arrange the steel instruments in a sterile container in accordance with the specified setting adequate for the surgical technique, it is true that incorporation of any similarly-shaped instrument into the tray or any mistake in counting the number is frequently brought about by even an experienced nurse.

Confirmation of “sterilization” is made accordingly by inserting the sterilization indicator with which sterilization status is confirmed at the time of sealing a sterile container, and sterilization status is inspected after the sterilization. Furthermore, “immediate postsurgical quantity inspection,” in order to confirm the number of steel instruments in a set, a nurse compares the number of steel instruments with the number indicated in the setup menu, as well as it is reconfirmed by taking an image with the portable X-ray equipment that no instrument is retained in the body.

Subsequently in the final process of “cleaning” of steel instruments, in which the prevention of infection and rust formation in indispensable, it has become common that blood and/or protein adhered to steel instruments is removed using a washer disinfector after the operation or another.

For the pointed out problems on handing steel instruments, Notification of the Ministry of Health, Labour and Welfare “Self-Inspection of Orthopedic Surgical Apparatus and Instrument”[1), “Practical Guideline for Operative Medicine”[2) by the Japanese Association for Operative Medicine, and “Guideline for Sterility Assurance in Healthcare Setting 2005”[3) by the Japanese Society of Medical Instrumentation (JSMI) have been established, however in some medical institutions cleaning and sterilization management is not conducted as specified in these guidelines due to complicated procedures or difference in understanding of the safety management.

Thus, since the alibi management for steel instruments depends on visual inspection of large volume of steel instruments in each place of regeneration activities, under the existing circumstances, the safety management of steel instruments cannot be operated adequately only by the current personnel, taking infection prevention and any instrument retained in the body into consideration.

What is requested in the medical front line, as a new innovation to solve these issues, is technology for marking the two-dimensional symbol on the steel instrument body in order to check whether any mistake is made in instrument setup for steel instruments or not and to be able to trace when an instrument was used to which patient.[4)]

The Japan Association of Medical Equipment Industries (JAMEI) (the present "Japan Association of Medical Devices Industries (JAMDI)") establish the "Standard Guideline for Two-dimensional Symbol Marking on Steel Instruments" in 2006 and set out the policy that the two-dimensional symbol consisting of GTIN (Global Trade Item Number) and serialized number should be indicated on the surgical steel instrument body, for the sake of assuring safe use and traceability of surgical steel instruments.[5)]

It is concerned, however, that only this guideline cannot deal with surface wear or rust formation associated with long-term use of steel instruments in addition to the fact that the accuracy of readout methods depends substantially on respective marking methods, and the guideline does not describe the detailed means of direct marking available and effective for change over the years.

On the other hand, since 2011, discussions have been made around the world on traceability of medical devices, including the Final Guidance on Global UDI System for Devices[6)] by the Global Harmonization Task Force (GHTF) and the legislation of the Unique Device Identification (UDI) System[7)] by the Food and Drug Administration (FDA), and opinions and views that Direct Marking is essential to trace reused products are also represented.

This guideline clarified the method of direct marking for the device body to be recommended as steel instruments in a manufacturer as well as "Technical Guideline on Direct Marking for two-dimensional symbol on Steel Instruments" as the technical specifications to be consulted at the time of marking in user's own way at the medical facility and when purchasing steel instruments, based on the study results verified through the demonstration experiment on the direct marking for two-dimensional symbols on steel instrument body in cooperation with the JAMDI and the JSMI.

II. Conditions Necessary for Direct Marking for Two-dimensional symbols on Steel Instruments

The reason why to place direct marking on the steel instrument body is to avoid risks of labels falling off due to sterilization and cleaning or labels retained in the patient's body as foreign matters for the method to apply labels (including stickers) in the surface of a steel instrument, with the purpose of enabling individual ID (identification) recognition and assuring long-term effects of heat resistance and corrosion resistance required for sterilization and cleaning by directly marking of two-dimensional symbol on the steel instrument body.

According to the intended use and use environment of steel instruments, labeling of two-dimensional symbols on the steel instruments requires essential conditions including:

- No toxicity in coloring or coating agent used in the marking process.
- No falling off of marking or no rust formation under the circumstances where autoclave sterilization is repeated.
- With GTIN and serial number necessary for the individual identification control for coding system.

When direct marking for two-dimensional symbols is placed on steel instruments with the existing marking technology, the points to be recommended for the following conditions should be shown in this guideline.

1) Quality of the materials of steel instruments (such as stainless steel, titanium, ceramics, and brass)
2) Surface finishing of steel instruments (such as mirror, hairline, and satin-like surface)
3) Shapes of steel instruments (plane surface, curved surface, and rod shape)
4) Marking methods for two-dimensional symbols (such as dot pin marking, and laser marking) and evaluation of them
5) Quality assurance for reading markings (AIM DPM Evaluation)
6) Marking locations of two-dimensional symbols (locations specified according to types of steel instruments)
7) Manufacturer’s responsibility for marking to assure medical safety and traceability

III. Material Quality Suitable for Marking and Marking Methods

1. Various Marking Methods

ISO/IEC TR24720 “Information technology -- Automatic identification and data capture techniques -- Guidelines for direct part marking (DPM)” specifies 18 kinds of marking methods, such as electrolytic etching method, laser method, and dot pin method for metal or nonmetal materials suitable for marking (including industrial materials) as shown in Table 1.[8)]

As steel instruments used for surgical procedure are necessary to undergo cleaning and sterilization processes, they are required to be superior in heat resistance, corrosion resistance, and abrasion resistance and thus generally made of materials including stainless steel (carbon steel), titanium, ceramics, and brass.

On the limited surface of those steel instruments, made of those materials, 3 to 5 mm square and 26 bytes of two-dimensional symbol marking should be placed and the marking is required to be accurate to the structure of n × n dots in 1 cell, not 1 dot in 1 cell, which constitutes a two-dimensional symbol, for the sake of clear reading with a reader.

Actually, a marking method which has endurance for practical use as labeling on the body of a surgical steel instrument is the laser method or the dot pin method.

Table 1. Selection of Marking Methods

	Metal								Nonmetal								
Material quality suitable for marking / Marking methods	Aluminum	Anodized aluminum	Beryllium	Carbon steel	Copper	Brass	Magnesium	Titanium	Ceramics	Glass	Cloth	Coated material	Plastic	Rubber	Teflon	Wood	Epoxy glass
Abrasive blast	●	●		●	●	●	●	●	●			●	●		●		
Adhesive coating	●	●	●	●	●	●	●	●	●	●	1	●	●	●		●	
Casting, forging, molding	●	●	●	●	●	●	●	●	●				●	●			
Dot pin	●			1	●	●		●				1	1				
Electrolytic coloring	●	●	●	●	●	●	●	●									
Electrolytic etching	●	●	●	●	●	●	●	●									
Embroidery											●						

Engraving / milling	●	●		●	●	●						1	●			●	
Ink-jet	●	●	●	●	●	●	●	●	●	●	1	●	●	●			●
Laser bonding	●		●	●		●	●	●	●	●			●				
Laser: short wavelength	●	1	●	●	●		●	●	●	●		1	●	●	●	●	●
Laser: visible light wavelength	1	1		●	1	●						1	●				●
Laser: long wavelength		1							●	●		1				●	●
LENS	●	1	●	●	●	●	●	●									
LISI	●	2		●	●		2	2									
Silk screen	●	●	●	●	●	●	●	●	●	●		●	●	●		●	●
Stencil	●	●	●	●	●	●	●	●	●	●		●	●	●		●	
Thin film deposition	●	●	●	●	●	●	●	●	●	●			●	●			

Note) ●: Marking processes acceptable for the respective materials, if the position of marking is consistent with the marking parameters.
1: Necessary to in addition obtain technical opinion from the design supervisor and equipment/material supplier.
2: Marking method being developed for the material.
Blank: = Marking method not recommendable for the material.

2. Types of Lasers and Oscillation Methods

Laser is often called by the name of substance used as a laser medium.
Types of lasers used in various fields are shown in Table 2.[9)]

Table 2. Type of Laser and Oscillation Wavelength

Type		Wavelength [μm]	Oscillating System	Output	Efficiency [%]	Applied field
Solid-state laser	Rubby	0.694	P		≤ 1	Machining
	Glass	1.06	P	10 TW	≤ 4	Machining, nuclear fusion
	YAG	1.06	P CW	P: 10 kW CW: 400 W Q switch: 10 MW	≤ 3	Machining, welding
Diode laser	GaAs InGaAsP	1.0	P CW	P: 10 W CW: 100 mW	≤ 100	Communication, measurement, data processing
Liquid laser	Dye laser	0.3 to 0.9	P CW	P: 10 W CW: 1 W	≤ 0.3	Spectroscopy, research
Gas laser	He-Ne	0.633	CW	10 mW	≤ 1	Measurement, display, etc.
	Ar	0.514 0.488	CW	10 W	≤ 0.1	Machining, measurement
	Excimer	0.19 to 0.32	P	100 W	≤ 15	Chemistry, medicine, processing, others
	CO_2	10.6	P CW	P: 10 MW CW: 20 kW	≤ 20	Machining, welding, heat treatment

The oscillation methods are however classified broadly by temporal change in laser output, and P represents Pulse laser and CW represents Continuous Wave laser.

As the CW laser is the method to oscillate constant output continuously with capability of irradiating high energy in a short time, it is used for black marking and metal cutting. On the other hand, the pulse laser is the method to oscillate pulsed output repeatedly with constant frequency and energy and heat are not accumulated in the irradiated surface, and thus the method is useful to create a white marking with materials less denatured and superior in corrosion resistance.

3. Types of Dot Pin Markings

The dot pin method, with longer history than the laser method, is the technique developed 30 years ago which is used for marking on material surface by incising with a conical cemented carbide head. Although this method has been used until now to engrave a marking in the cell size of 1 dot per 1 cell larger than the laser method for the purpose of traceability management of automobile and aircraft components/parts, etc., there was problems in reading accuracy and impression size (Table 3).

Recently, however, precision marking technique has been developed for the dot pin method to enable printing with n × n dots in 1 cell and to enable densification in reading accuracy and impression size (Table 4).

It was verified in the demonstration experiment that the dot pin method is excellent at corrosion resistance compared with the laser method, with high adaptability to marking on steel instruments.

Table 3. State of Dot Pin Marking with the Former Machine

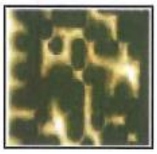
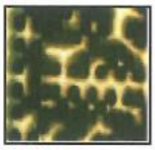
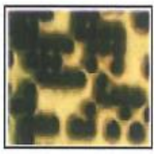
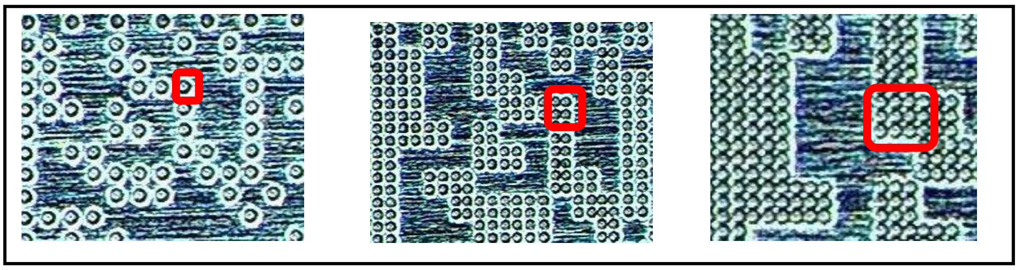
Marking size	2.8 × 5.0 mm	2.5 mm square	3 mm square	4 mm square
Surface: Mirror plane × 50				
Readability	○	×	○	○

Table 4. Variations of Dot Pin Marking



(a) Case of 1 dot in 1 cell (b) Case of 2 × 2 dots in 1 cell (c) Case of 3 × 3 dots in 1 cell

IV. Surface Finishing and Marking Qualification for Steel Instruments

Surfaces of steel instruments are categorized broadly into mirror finish, hairline finish, and satin finish by finishing methods. For all kinds of surface finishing, there is no difficulty in technology for two-dimensional symbol marking, but a large difference arises in readability of two-dimensional symbols.

1. Characteristics of Mirror Finish

Mirror finish is the method to polish up the surface of a steel instrument smoothly like a mirror (Figure 1, the left). The characteristics of the mirror finish are the capability not only to maintain the most stable quality of steel instruments but also to easily read the two-dimensional symbol marked in white. However, since the surface is mirror plane, there is a nonnegligible defect of reflection which affects on the surgeon’s eyes when laser or light source is used in brain surgery or ophthalmologic surgery.

2. Characteristics of Satin Finish

Satin finish includes wire brush method, sandblast method, and dispersion plating method, and is the finishing method to make the surface of a steel instrument texture coarse texture like pear-skin surface for frosting (Figure 1, the center).

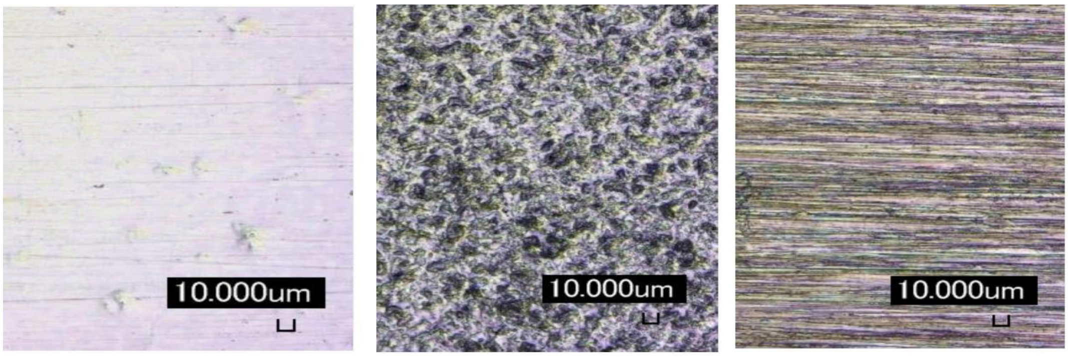
The characteristics of satin finish have advantage to reduce effect on the surgeon’s eyes as a steel instrument diffuses the light source and disadvantages that the coarse surface makes blood and protein apt to remain and rusts easily. On the top of it, the average surface roughness of satin finish is 3 to 5 μm, and it has been demonstrated in the demonstration research that two-dimensional symbols become unreadable if the dot shape of the two-dimensional symbol resembles the surface roughness closely.[10), 11)]

3. Characteristics of Hairline Finish

Hairline finish is the finishing method to make approx. 2 μm width of fine scratches in a single direction on the steel instrument, by scratching the surface with an abrasive (Figure 1, the right). The frosting effect can be expected as the feature of the hairline finish. Contrarily, it was represented based on the demonstration research that the surface rust easily compared with the mirror finish, and that it is difficult to read from a certain direction is difficult when reading two-dimensional symbols.[10)]

4. Marking Qualification of Surface Finishing with Reading Two-dimensional Symbols Considered

As mentioned above, the surfaces of steel instruments are categorized broadly into the 3 categories, or mirror finish, hairline finish, and satin finish. When taking into consideration reading the markings, the optimal selection is the mirror finish. On the contrary, for marking two-dimensional symbols on steel instruments finished with the satin or hairline method, it is recommended that marking should be performed by polishing up the marking area into the mirror plane preliminarily in terms of improvement of reading rate.



(a) Mirror finish **(b) Satin finish** **(c) Hairline finish**

Figure 1. Macrograph of Test Pieces Used for Measuring Coarseness of Surface Finishing of Steel Instruments

V. Various Markings and their Adequacy

Although marking methods vary widely as shown in Table 1, lasers available for direct markings for medical instruments are restricted to YAG laser (wavelength: 1.06 μm) and CO_2 laser (wavelength: 10.6 μm). Since the YAG laser has shorter wavelength than the CO_2 laser, or 1/10 of wavelength of CO_2 laser, it is adequate for processing to steel instruments, while the CO_2 laser is appropriate for direct marking on materials including resin or glass.

As for materials of steel instruments, stainless steels vary with types including SUS410 and SUS420, and in addition there are types of surface finishings such as mirror, satin, and hairline finishes; thus it is necessary to configure laser output or exposure time in order to consider that those values appropriate for respective marking settings are not always same according to respective combinations.

Based on the quality assurance for materials of steel instruments or the improved marking accuracy for two-dimensional symbols, white marking with the laser method or the dot pin method is recommended.

This technical guideline describes the explanation on these 2 types of methods by comparison between characteristics of them.

1. Types and Principle of Marking Devices

Laser marking device is used for the method to perform marking by emitting laser beam on the surface of a steel instrument, and making use of generated heat to melt (scrape) or discolorate (oxidize) the surface of an object (Figure 2). In addition, the marking color can be set to white and black depending on output or exposure time.

On the contrary, the dot pin marking device is also called as impact method, with which a stylus made of cemented carbide is nailed to form a concave portion and then to place marking of two-dimensional symbol on the surface of the steel instruments (Figure 3).

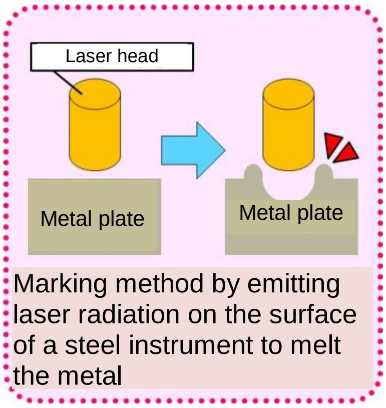


Figure 2. Marking Mechanism of Laser Method

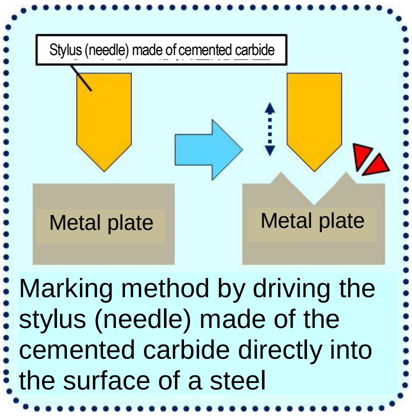
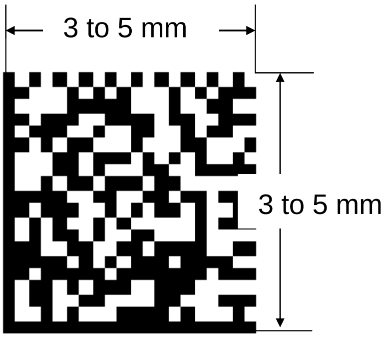


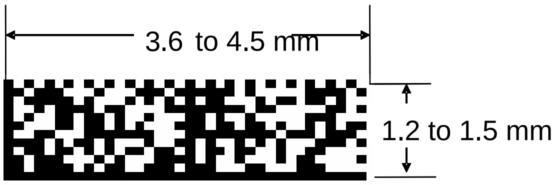
Figure 3. Marking Mechanism of Dot Pin Method

2. Dot Patterns Consisting of the Cells of Two-dimensional Symbols

"Standard Guideline for Two-dimensional Symbol Marking on Steel Instruments" recommends the method to create the direct marking on the surface of the steel instrument body using the laser equipment with the two-dimensional symbols in 3 to 5 mm square of GS1 DataMatrix consisting of a total of 26 digits: AI (01), 2 digits + GTIN, 14 digits; AI (21), 2 digits + serial number, 8 digits, in accordance with the GS1-128 code system (Figure 4, Figure 5).



(1) When 3 mm or more square of marking area is assured on the steel instrument



(2) When approx. 3 mm square of marking area cannot be assured on the steel instrument due to its rod shape

Figure 4. Size Specifications for Two-dimensional Symbol for a Steel Instrument

Herein, considering the case that a two-dimensional symbol consisting of 26 bytes (numeral), 18 × 18 cells in a 3 mm square is created, 1 cell size becomes a 0.166 mm square. In addition, there are the dot patterns of 1 cell includes 1 dot in 1 cell, n × n dots in 1 cell, and spiral shape, however the marking with n × n dots is recommendable taking into account the corrosion resistance (Figure 5). As for the method to create the two-dimensional symbols using laser marking device, the attention should be paid for dot pattern because there exists the prior patent.

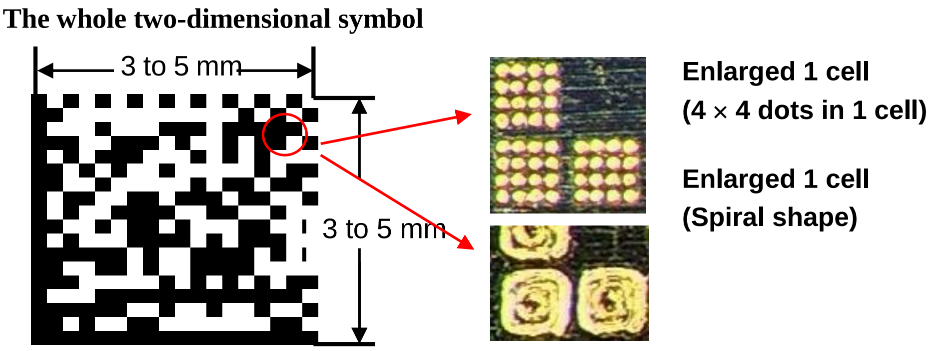


Figure 5. Example of Marking Pattern of Cell

3. Types of Data Carriers

For data carrier, GS1 DataMatrix which is specified in the GS1 General Specifications out of the two-dimensional symbols by ISO Standards is recommendable.

When printing GS1 DataMatrix, FNC1 must be configured at the head of the data column as shown below.

Data column **FNC1 01 04912345678904 21 050039999**

Head definition AI GTIN 14 digits AI Serial Number

4. Comparison of Depth and Width of a Dot in Marking

Steel instruments are used for a long period under the repeated severe regeneration activities, including instrument setup, cleaning, sterilization, and deployment. Therefore, scratches, rust, and wear against the area of two-dimensional symbols marked on steel instruments is necessary to be considered adequately.

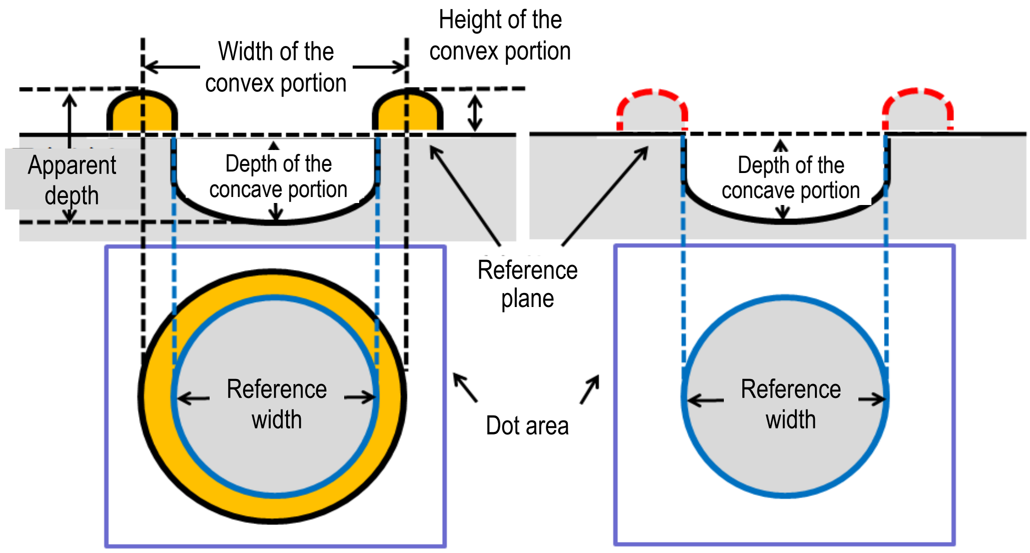
It was found in demonstration experiment that on the surface of steel instruments having been used for long terms occur countless scratches, most of which are generated in the central area where steel instruments contact each other during the instrument setup with scratch depth of approx. 5 μm in average and width of 10 μm or less.[12)]

Now, Figure 6 shows the conceptual illustration of 1 dot, indicating that in both of laser marking and dot pin marking systems convex portions are generated. Combination of the height of the convex portion (the upper part of the reference plane) and the depth of the concave portion (the lower part of the reference plane) represents the whole depth (apparent depth), whereas it should be taken into consideration that the height of the convex portion influences reading of markings due to wear in the convex portion caused by long-term use.[12)]

In particular, the convex portion generated by the laser marking method shows a crater-like shape due to melting and denaturation of stainless steel through laser irradiation. Meanwhile in the dot pin marking method, the convex portion is generated by bulging around the dot due to engraving stainless steel, however it has been shown that the convex portion bulges less compared to the laser marking method (Figure 7).

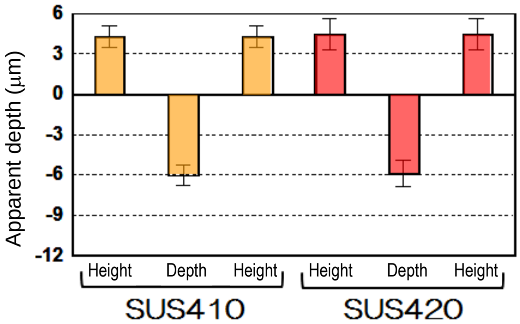
From this, when any convex portion is rubbed and worn to fall off due to long-term use of steel instruments, it is estimated in laser marking method that the height of the convex portion is reduced and reading of two-dimensional symbols may become unstable depending on the surface condition of steel instruments with satin finishing, etc.[14)]

Based on the above, it is considered adequate that the depth of two-dimensional symbol marking should be approx. 10 µm.[13)]

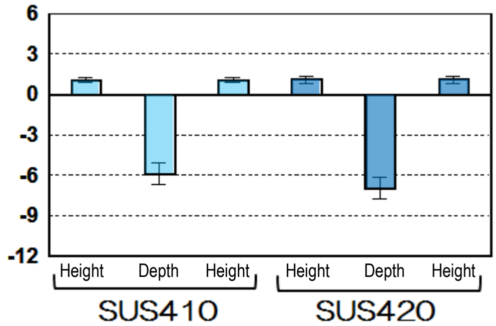


a) Dot shape with an instrument not used　　b) Dot shape with an instrument worn

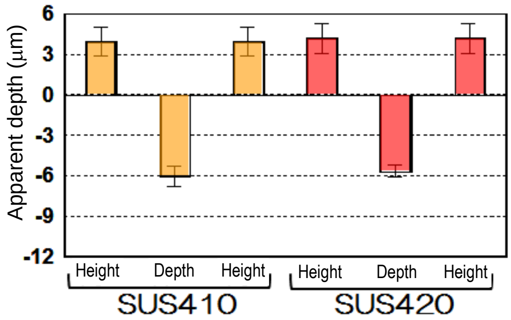
Figure 6. Cross Section and Upper View of the Dot Formed by Marking



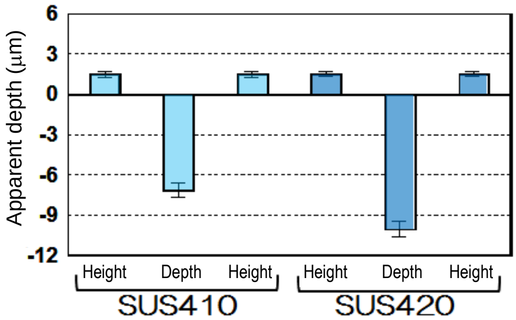
a) White laser marking (3 mm square, 3 × 3 dots)



b) Dot pin marking (3 mm square, 3 × 3 dots)



c) White laser marking (5 mm square, 4 × 4 dots)



d) Dot pin marking (5 mm square, 4 × 4 dots)

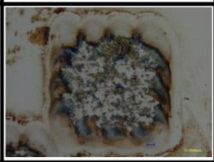
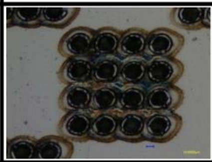
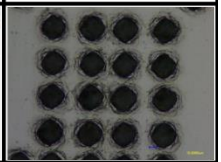
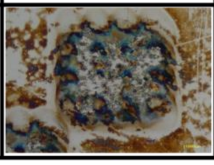
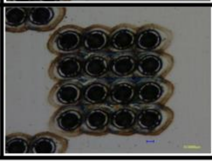
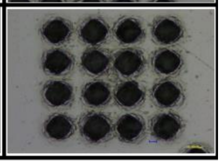
Figure 7. Comparison of Dot Shape between White Laser Marking and Dot Pin Marking

5. Comparison of Corrosion Resistance and Readability among Various Markings

What is important in evaluation of two-dimensional symbol markings on steel instruments is, needless to say, the marking accuracy at the time of creating marking, as well as deterioration of the marking accuracy associated with rust formation through cleaning and sterilization and/or surface worn during instrument setup.

It is thus necessary to use the laser method and the dot pin method, being well versed in the proper use of them. In establishing this guideline, comparison of corrosion resistance was made after marking on stainless steel (SUS410, SUS420) with the two methods, the white marking and the black marking, with salt spray testing according to JIS Z 2371 (Table 5).

Table 5. Comparison of Corrosion Resistance among Various Marking Methods

	Black laser marking (4.2 mm square, 4 × 4)	White laser marking (3 mm square, 4 × 4)	Dot pin marking (3 mm square, 4 × 4)
SUS410			
SUS420			

Although, in black marking using the laser method, material degeneration occurs in the marking portion due to irradiation of high power laser on the surface of a steel instrument and thus markings become black to make visual observation of markings easier, this also makes identification with a reader worse and rust is more apt to be formed than white marking.[14), 15)]

Meanwhile, in white marking using the laser method, as short-term irradiation of low power laser on the surface of a steel instrument makes material degeneration in the marking portion reduced, markings become white to be inappropriate for visual observation of markings, with less rust formation and better automatic identification with a reader.

It was contrarily clarified that for marking with the dot pin marking method, no rust is observed and the marking has excellent corrosion resistance.

With the result, the white marking is superior to the black marking for corrosion resistance against rust formation and thus the white marking is recommended for use of laser method.

6. Restrictions in Case of Curved Marking Surface

The surface of steel instruments is not always plane surface but semisylindrical or rod-shaped, an occasion that there is no other area than the curved surface for marking may occur.

When marking on the cylindrical curved surface, the limits listed below for the diameter of a cylinder differ depending on marking devices as indicated in Figure 8. The restrictions on the precision dot pin marking are listed below.

1) Area available for engraving (A)
2) Engraving depth possible to be carved (X)
3) Area reached by the engraving needle (B)
4) Depth reached by the engraving needle (Y)

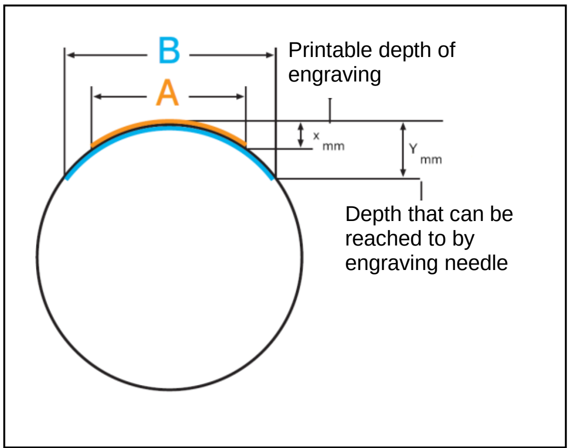


Figure 8. Area Available for Marking on the Curved Surface

It is also necessary to be considered

sufficiently that, for marking on the curved surface of a two-dimensional symbol, the range available for engraving and the depth of engraving differ depending on marking sizes.

VI. Marking Quality

In the source marking of the two-dimensional symbol code on a steel instrument to be launched on the market, disorder is brought about in the market if markings are not readable at the time of shipment.

It is recommended therefore to verify that, at the time of shipment, not only marking is readable with some of readers, but also the accuracy of marking itself is definitely assured.

Especially for two-dimensional symbol reader, a reader which has been developed so as to be able to read any two-dimensional symbol even under the adverse circumstances such as ambient light coming in or reflecting metal surface needs to be used.

Regarding direct marking for two-dimensional symbols, there is “Direct Parts Mark (DPM) Quality Guideline” (AIM DPM-1-2006) issued by the Automatic Identification Manufactures (AIM), and approved by the American National Standards Institute (ANSI) (Table 6).[16)] This quality standards also requires verification in accordance with ISO/IEC15415 (Information technology--Automatic identification and data capture techniques--Bar Code symbol print quality test specification--Two-dimensional symbols), and then the both standards should be referred to together.[17)]

AIM DPM Quality Guideline defines the measurement of quality items indicated in Table 6 in order to assess the quality of direct part markings, in which values are set for respective items and the lowest values among them are located as comprehensive quality for respective items.

The respective measurement items are indicated using the numbers from “4” to “0” with “4” the maximum, plus indicated with equivalent alphabets A, B, C, D, and F.

Instruments should be shipped when products are ranked as quality C or more after being verified with the method.

Table 6. AIM-DPM Evaluation Items

Comprehensive quality	Contrast	Minimum reflectance	Non Uniformity	Unused EC
Measurement of quality grades of the whole 2D (two-dimensional) symbols. *The lowest values for respective testing items were adopted.	Measurement of reflectance of bright and dark cells inside of a 2D symbol.	Comparison is made between the values measured at the time of calibration and the values of bright cells. Measurements not more than 5% are regarded as failed.	Measurement of symmetry to the X/Y axes for each cell within the 2D symbol.	Calculation of cord words after correction of errors due to 2D symbol damage.
Fixed pattern damage	**2D modulation**	**Grid Non Uniformity**	**Reference Decoding**	
Testing whether damages of finder pattern, quiet zone, and clock pattern within a symbol have influence on reading performance.	Measurement of readability of a symbol. Measuring the degree of separation of dark and bright cells in the whole range of the symbol using a global threshold.	Measurement of deployment error in individual cells to symbol grid.	Testing whether a symbol can be decoded. If it cannot be decoded, additional information will not be returned.	

(Source: AIM DPM-1-2006)

Table 7 is a reference example of AIM Evaluation, and the evaluation methods for respective item values are composed based on highly advanced theories and reference to technical books may be recommended for interpretations.

Table 7. Reference Example of Evaluation Based on AIM-DPM Evaluation Criteria

TP No.	Captured image	Comprehensive quality	Contrast	Minimum reflectance	Non Uniformity	Unused EC	Fixed pattern damage	2D modulation	Grid Non Uniformity	Results Decode
22 mm square n=1 600		3.000 B	0.844 A	A	0.002 A	1.000 A	3.000 B	4.000 A	0.111 A	1.000 A
2 mm square n=2 250		2.000 C	0.775 A	A	0.002 A	0.850 A	3.000 B	2.000 C	0.068 A	1.000 A
3 mm square n=2 400		4.000 A	0.846 A	A	0.015 A	1.000 A	4.000 A	4.000 A	0.074 A	1.000 A

(Source: Technical documents from DPM Committee, JAMDI)

VII. Attentions for Marking Technique

Marking for two-dimensional symbols of the GTIN (Global Trade Item Number) and the serial number in accordance with GS1-128 Code System on steel instruments is essential to assure medical safety and traceability, and a task that manufacturers should deal with positively.

From the aforementioned discussions, marking should be performed to enable long-term reading as well as to assure excellent visibility in the marking position, taking into account that:

1) The dot pin marking has high marking qualification, while the white marking using the laser method should be examined taking into consideration the limitations marking on the curved surface.
2) Using 3 to 5 mm square of GS1 DataMatrix, n $\times$ n dots in 1 cell is recommended as a dot pattern.
3) For marking on thin rod-shaped steel instruments, “Rectangular” Specification in which DataMatrixes are arranged laterally should be used.
4) For steel instruments which bear logo marks, markings should be placed near the log marks.
5) Marking location should be standardized according to intended use and shape of steel instruments.
6) The same markings are created in 2 positions (the both surfaces) of a steel instrument.
7) On the flat surfaces of steel instruments, marking is performed with the depth of approx. 10 μm.
8) For steel instruments with hinges, marking is performed near the hinges.
9) When a marking becomes unreadable, the marking is grinded and then another marking is created again on top.

VIII. Manufacturing Responsibility and User Responsibility Associated with Marking

Since the direct marking for steel instruments is necessary not only for the purpose of manufacturing management and quality control in each manufacturer, but also for application for medical safety and traceability in hospitals, markings in accordance with Standard Guideline for Two-dimensional Symbol Marking on Steel Instruments established by the JAMDI are recommendable.

The legal liability associated with markings in Japan is described below.[18)]

1. Responsibility of Manufacturer

(1) Method to display a two-dimensional symbol on the steel instrument body with laser marking

- It is unlikely that the display of two-dimensional symbols using the laser marking has influence on performance and safety, and thus without legal label, marking cannot be regarded as manufacturing activity.
- However, a manufacturer is not required to acquire approval or certificate but has the following responsibilities on marking in distribution stage.
- If a manufacturer performs marking by itself or by outsourcing before the instruments are shipped, the responsibility lies with the manufacturer.
- If by request from a certain hospital, a distributor performs marking by itself or by outsourcing for the instruments under the relevant sales contract before shipment, the responsibility lies with the distributor.

(2) Method to display a two-dimensional symbol after the steel instrument body is color coated for improving accuracy of reading the two-dimensional symbol

- As coating on a steel instrument is regarded as manufacturing activity, coating is not allowed to a distributor in the distribution stage.

- However, when a manufacturer markets a medical device which is produced by coating the existing products, marketing notification or change notification is not newly required.

(3) Method to attach an IC tag to the steel instrument body by processing such as welding or brazing

- As attachment of an IC tag to a steel instrument is regarded as manufacturing activity, that is not allowed to a distributor in the distribution stage.
- However, when a manufacturer markets a medical device which is produced by attaching IC tags to the existing products, no application of marketing notification or change notification is newly required for individual items if appearance form is changed but the change gives no influence on quality, effectiveness and safety.

2. Responsibility of Medical Institution

(1) Method to display a two-dimensional symbol on the steel instrument body with laser marking

(2) Method to display a two-dimensional symbol after the steel instrument body is color coated for improving accuracy of reading the two-dimensional symbol

(3) Method to attach an IC tag to the steel instrument body by processing such as welding or brazing

All of the above-mentioned is allowed on the assumption that the instruments should be used within the hospital, if the proprietary rights of those instruments are possessed by the hospital. However, the activities are modification in the medical institution concerned and are all the medical institution's own responsibility.

Table 8. Comparison of Superiority or Inferiority among Various Marking Methods[19),20)]

	Laser Marking	Dot Pin Marking	Color Coating	IC Tag Attached
Handling by Manufacturer	◎	◎	○	△
Handling by Distributor	△	△	×	×
Handling by Medical institute	○	○	○	○
Reading Stability	○	◎	○	◎
Rust Formation	△	◎	○	△
Promotion of Normalization	◎	◎	△	△
Quality Assurance of Steel Instruments	○	○	△	△
Repair by Manufacturer at the time of Modification	○	○	△	×

Note) ◎: Preferable, ○: Possible, △: Partly problematic, ×: Inappropriate

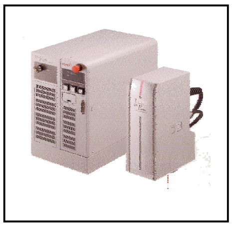
IX. Companies That Provided Cooperation to Prepare This Guideline and their Devices

・Laser marking device

[1] SUNX Co., Ltd.: LP-V FAYB Laser Marker

[2] Miyachi Technos Corp.: ML-7111A LD-pumped YVO4

[3] Omron Corporation: MX-SL579A 5W Fine Single Mode Laser Marker



LP-V FAYb Laser Marker

ML-7111A LD-pumped YV04

MX-SL579A 5W Fine Single Mode Laser Marker

・Dot pin marking device

[1] Roland DG Corporation: METAZA MPX-90M Small Type Precision Marking Device

[2] Vector Co., Ltd.: Marking Device VM1040

[3] Gravotech K.K.: MEDRIX ID CN312CM Microimpact Marking Device

METAZA MPX-90M Small Type Precision Marking Device

Marking Device VM1040

MEDRIX ID CN312CM Microimpact Marking Device

・Two-dimensional symbols reader

[1] Cognex Corporation: DataMan 100 (For verification)

[2] Mizuho Corporation: Surgical Eye

[3] MNEXT Co., Ltd.: HN-06-16-M

[4] Denso Wave Incorporation: QD25

[5] Omron Corporation: V400-F

Surgical Eye

HN-06-16-M

QD25

V400-F

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