



The Global Language of Business



Technologies for Marking Surgical Instruments

Guidance Document





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About the Healthcare User Group

The Healthcare User Group (HUG) is made up of invited senior representatives from healthcare trade associations, providers, suppliers, solution and service companies and other related organisations. The objectives of the group are:

- To actively support and accelerate the adoption of GS1 standards throughout healthcare, by sharing learnings and best-practice solutions from local implementations
- To help healthcare providers comply with Unique Device Identification (UDI) and Falsified Medicines Directive (FMD) regulations
- To identify and review opportunities that enhance efficiency and patient safety
- To provide feedback and advice on GS1 UK's healthcare plans and activity
- To act as the UK point of contact for the GS1 Global Healthcare Group, and to provide feedback to the GS1 Global Standards Management Process



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1 Introduction

Healthcare providers throughout the world have been implementing Automatic Identification and Data Capture (AIDC) systems to ensure traceability of their surgical instruments, improve patient safety and improve asset management. The purpose of this document is to show the various AIDC technologies that can be used to identify individual surgical instruments that are used in a clinical environment, and need to be cleaned and sterilised in a decontamination facility. This document only looks at AIDC technologies that are capable of using GS1 standards correctly and adhere to the relevant ISO/IEC standards and GS1 General Specifications Version 17.

NB: This document is not an exhaustive overview of the technology available, nor is it intended as an endorsement of any specific technology. It is suggested that each technology is evaluated before adoption or implementation and appropriate risk assessment is carried out. Case Study information is provided for reference purposes only and not to endorse the technology detailed in it.

The types and capabilities of technologies are changing all the time so choosing which technology to use needs to take into account the following criteria:

- Risk of impacting the patient
- Possible damage to instruments
- Possible impact on surgeon handling
- Reliability of scanning
- Susceptibility of damage to the marking technology
- Degradation of mark over period of time
- Cost and process of marking including any impact on instrument availability

The two marking methods we're covering here for identifying surgical instruments are:

- Direct Part Marking (DPM) using a two dimensional GS1 DataMatrix barcode
- Radio Frequency Identification (RFID) technology

2 Direct Part Marking (DPM)

Direct Part Marking (DPM) is a technology used to produce two different surface conditions on an item. It refers to the process of marking a GS1 barcode directly onto an item, rather than using a label or another indirect marking process. The only barcode approved for use with DPM is the GS1 DataMatrix.

There are a variety of methods for applying DPM, as shown in **Table A** below. GS1 Standards define key aspects of DPM including substrate requirements, symbol dimensions, symbol quality, and symbol placement.

Table A

DPM MARKING METHODS	
<p>INTRUSIVE MARKING</p> <p><i>methods that remove or alter the material of the host (i.e., Subtractive Methods)</i></p>	<p>Abrasive blast Dot peen Electro-chemical marking, coloring, or etching Engraving/milling Fabric embroidery/weaving Direct laser marking Laser shot peening Laser Inducted Surface Improvement (LISI) Gas Assisted Laser Etch (GALE) Laser Induced Vapor Deposition (LIVD)</p>
<p>NON-INTRUSIVE MARKING</p> <p><i>methods that do not affect the host material, and usually involve the addition of material (i.e., Additive Methods)</i></p>	<p>Cast, forge, mold Inkjet Laser bonding Liquid metal jet Silk screen Stencil</p>

Before marking any surgical instrument, it's important to analyse the selected method of marking in relation to several considerations:

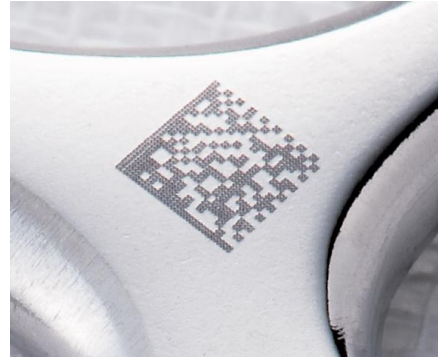
- Finishes that cause an excess of shadowing or glare
- Surfaces that do not provide sufficient contrast - less than 20 percent difference in surface reflectance
- Safety critical parts that cannot be marked with intrusive methods
- Marking method must comply with the users' requirements
- Location of the symbol should not be:
 - In direct air/water (streams, etc.)
 - On sealing surfaces
 - On surfaces subject to wear or exposure to heavy contact

For more information on the relevant guidance from GS1 please refer to **Section 2.1.4 Direct Part Marking** and the **Symbol Specification Table 7 - 5.5.2.7.7-1 for DPM** of the 2017 version of the GS1 General Specifications (V17). They can be downloaded here:

www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

2.1 Impact Marking – formerly called Dot Peening

The technology is used to directly mark the material and is particularly suitable for titanium, stainless steel and other hard metals. It can be used for all the information to be marked on the item (text, date, logo, etc.), as well as the GS1 DataMatrix symbol. A small head with a diamond-tipped stylus is computer controlled to make a defined series of identical punch marks in the surface of the substrate. The depth of marking can be carefully controlled to ensure all indents are identical, making this technique particularly suited for printing GS1 DataMatrix directly on items made of metal or other material with very hard flat surfaces.



A case study for the implementation of impact marking at “University Hospitals of Morecambe Bay (UHMB) NHS Foundation Trust” can be found here: <https://www.gs1uk.org/our-industries/healthcare/demonstrating-success-in-healthcare/improving-patient-safety-through-surgical-instrument-tracking>

2.2 Laser etching

Laser etching, or laser engraving, uses precisely controlled lasers to engrave or mark a barcode on a product. A computer controlling a series of mirrors and lenses focuses the laser to burn or etch the barcode. The process allows a product to be directly and permanently marked but is only suitable for ‘laserable’ materials. The power of the laser needs to be set based on the volume printing required as well as the speed of printing. The power must be adapted to substrates and commonly ranges from 10 to 100 watts.



2.3 Electro-chemical etching (ECE)

Electro-chemical etching is the process where a mark is produced from oxidation of metal from the surface being marked through a stencil impression. This is achieved by sandwiching a stencil between the surface being marked and an electrolyte soaked pad, and passing a low voltage current between the two leaving a dark contrasting finish.



2.4 Ink-jet marking

Ink-jet printers precisely propel ink drops onto the part surface, after which the fluid that makes up the ink dot evaporates. This leaves a coloured die on the surface of the part creating the pattern of modules that make up the mark. The application of ink-jet marking may require preparation of the part surface, as it is the chemical interaction of the ink to the surface of the part that determines the level of mark permanence and contrast. Ink-jet marking provides fast marking of moving parts, and offers very good contrast.



2.5 Info Dots

An Info Dot sometimes referred to as a Key Dot is a small, laser-etched, 2D GS1 DataMatrix barcode label that can be applied directly to an instrument's surface. These can be pre-ordered with the appropriate information encoded in the barcode.



3 Radio Frequency Identification (RFID) technology

RFID technology, as detailed by Wikipedia: "Radio-frequency identification (RFID) uses electromagnetic fields to automatically identify and track tags attached to objects. The tags contain electronically stored information. Passive tags collect energy from a nearby RFID reader's interrogating radio waves. Active tags have a local power source such as a battery and may operate at hundreds of meters from the RFID reader. Unlike a barcode, the tag need not be within the line of sight of the reader, so it may be embedded in the tracked object. RFID is one method for Automatic Identification and Data Capture (AIDC)."

GS1 RFID and barcoding are technologies that happily co-exist - RFID technology allows you to count a whole tray of instruments in one go rather than individually scanning each instrument that has been marked with a GS1 DataMatrix barcode. A comparison of RFID vs barcoding can be seen on **Table B** below.

Table B

Barcodes	RFID
Requires line of sight to be read	Can be read without line of sight
Can only be read individually	Multiple tags can be read simultaneously
Cannot be read if damaged or dirty	Can cope with harsh or dirty environments
Requires manual tracking and therefore susceptible to human error	Can be automatically tracked removing human intervention

Below are some examples of RFID technology when it's applied to surgical instruments:



More information on RFID and GS1 standards can be found here: <http://www.gs1.org/epc-rfid>