GS1 UK | Healthcare User Group

Surgical instrument traceability guidance

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About the Healthcare User Group (HUG)

The HUG is made up of invited senior representatives from healthcare trade associations, providers, suppliers, solution and service companies, and other related organisations. Its purpose is to promote the adoption of GS1 standards throughout UK health systems, its suppliers and partners, in line with necessary regulatory requirements.

The objectives of the group are to:

- Drive adoption of standards across the NHS, starting with acute trusts in England, and extending to health systems in Northern Ireland, Wales and Scotland
- Support implementation of standards to identify every person, product and place
- Create a sharing and learning environment
- Offer support and advice to regional groups implementing our standards
- Be responsive to the evolving healthcare environment
- Provide feedback and advice on GS1 UK's healthcare plans and activity
- Work with regulatory and other bodies, to support national and international standards activity
- Act as the UK point of contact for the GS1 Global Healthcare Group and to provide healthcare related feedback into the Global Standards Management Process (GSMP)

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1. Introduction

1.1 Foreword

GS1 is a not-for-profit, member-owned association, operating in more than 150 countries. The GS1 vision is to enable organisations to speak the same language when it comes to identifying things, including people, products and places, capturing information at the point of interaction, sharing data throughout a trust's systems and processes from supplier to point of care/point of use.

GS1 defines standards for healthcare in concert with the global healthcare industry. This includes globally unique numbers, which are used in the identification of patients and caregivers, products, locations, and assets, anywhere within the global healthcare supply chain.

These standards enable, among other things, the accurate scanning of medicines at the pharmacy, the recording of medical instruments used in a surgical procedure, and the location of equipment in a hospital that supports patient safety.

GS1 understands the importance of having efficient and smooth-running supply chains for healthcare. Barcodes and identification technologies in hospitals are very important with huge patient-safety benefits drawn from positively identifying patients, their interaction with caregivers, and the items used in their treatment.

Standards have been deployed successfully within healthcare around the globe to drive improvements in patient care and safety, while at the same time reducing costs through improved efficiencies.

The main benefit of implementing GS1 standards is improved patient safety, achieved through:

- Recording of information scanned at the point of use
- Improved traceability
- Enabling checks on usage
- Fewer Never Events and critical errors
- Reduced administration errors
- More efficient processes
- Better medicines management
- Simplification and enhanced accuracy of order processing and receipting

GS1 standards are endorsed by the Department of Health and Social Care (DHSC), NHS Digital, NHS England, and the Medicines and Healthcare products Regulatory Agency (MHRA).

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1.2 Background

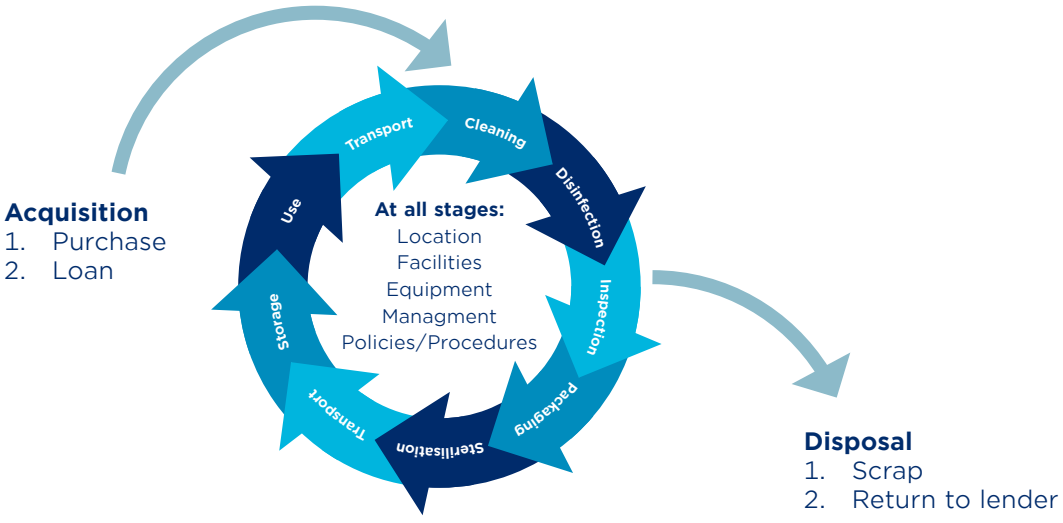
Due to regulatory requirements – the publication of the both the Independent Medicines and Medical Devices Safety (IMMDS) Review (the Cumberlege Review) and the Medicines and Medical Devices Act 2021 – and the impact of Brexit, there is an increasing requirement to standardise and automate the traceability of instruments, trays, and other products that are required to be sterilised.

The aim of this document is to show how GS1 standards can be used to improve traceability and increase the reliability of data for managing surgical instruments. As a result, trusts will benefit from tangible financial and time savings. Most importantly, more accurate and efficient recall processes will directly improve patient safety.

The Scan4Safety Evidence Report details financial benefits achieved from using GS1 standards to manage surgical instruments and other medical products:

- Leeds Teaching Hospitals NHS Trust estimates it will save £84,411.07 each year on product recalls thanks to the introduction of point-of-care scanning
- Through scanning, Leeds Teaching Hospitals saved £83,548.41 from October 2016 to March 2017, by standardising and rationalising the items in the surgical trays used for the five most common procedures
- Since introducing Scan4Safety, University Hospitals of Derby and Burton NHS Foundation Trust has worked with its supplier and now uses pre-sterilised screws. These are scanned before use, meaning complete traceability of the items and no need to sterilise the tray again. Each item costs about 50p more, but £36 is saved on sterilisation costs

This document explains which GS1 Identification Keys and GS1 data carriers are to be used across the instrument lifecycle (see diagram below), and shows examples of the information that should be stored in master data and other systems (e.g. sterilisation management systems).



Only once data can be automatically captured, stored, and shared across the instrument lifecycle, can true traceability be achieved.

There are numerous regulations and recommendations that detail traceability requirements for surgical instruments, several of which specify the use of GS1 standards (see “other documents” in References).

1.3 Current situation in the UK

- The DHSC and MHRA guidance is for hospitals to track instruments to at least tray level
- Different hospitals have different tracking practices ranging from manual systems to automated systems
- Some track instruments at tray or group level while others track them at individual instrument level
- Several hospitals have implemented automatic identification and data capture (AIDC)-supported systems, with some marking individual instruments
- Few systems used for medical-device management rely on each individual item being identified and marked in a way that would allow information on that instrument to be captured as it is passed through the different processes
- Quite often, markings are done with proprietary numbers and barcodes
- Increasing numbers of manufacturers mark instruments with a globally unique identifier to meet Unique Device Identification (UDI) regulations, which are likely to be the GS1 Global Trade Item Number (GTIN), (see “other documents” in References)

1.4 Target audience

This document is a reference guide to implementing full traceability of surgical instruments in hospitals. It is intended for any hospital, including those that have centralised sterilisation service departments, hospitals that provide sterilisation services for other hospitals, and any other service providers who want to implement GS1 standards to improve the traceability of surgical instruments and facilitate interoperability across different parties and systems.

It is important to recognise that the GS1 standards detailed in this document will enable traceability across the associated healthcare landscape, beyond the more narrowly defined “dirty and clean” process. As such, any function involved in the procurement, storing, maintenance, clinical use, and recall of surgical instruments, can benefit from their accurate identification using GS1 standards.

This document is also intended for solution providers. In line with current drives to improve the consistency, flexibility, and interoperability of technology across health and social care, all systems developed in house, commissioned, procured, or adopted should be “GS1 compliant” (as applicable). The GS1 UK compliance specification for the NHS provides guidance for buyers and commissioners on what that really means, and how to ensure that new systems are GS1 compliant.

New and existing systems will need to utilise the appropriate GS1 Identification Key as either a primary or secondary identifier for the required data elements based on the functionality and purpose of the system being considered.

A key benefit of adopting GS1 standards is the ability to represent the different identification keys in standardised barcodes and radio-frequency identification (RFID) tags. Therefore, any systems implemented also need to be able to encode and/or decode compliant GS1 data carriers.

If providers are unable to provide GS1 compliant systems in line with the recommendations in this document, then full interoperability and traceability will be impossible.

2. Approach

2.1 Principles of the GS1 System

GS1 Identification Keys give companies efficient ways to access information about items across their systems and throughout their supply chains.

They provide organisations with a way to assign standard identifiers to products, documents, physical locations and more. As GS1 Identification Keys are globally unique, they can be shared between organisations, enabling interoperability, and increasing supply-chain visibility for trading partners.

These guidelines describe which of these identifiers should be used on which objects to enable data capture during procurement, the sterilisation process and in theatre.

For certain scenarios there will be more than one option presented with a supporting rationale. The course of action taken by an implementor could be affected by their starting position, technology and systems used, and their current processes.

2.2 Instrument and kit identification

For the traceability of surgical instruments and other items that need to be sterilised, organisations typically have a choice between two GS1 identifiers that can be utilised across the process:

- Products: Global Trade Item Number (GTIN)
- Assets: Global Individual Asset Identifier (GIAI)

The GS1 General Specifications (section 2.1.8 Medical devices) details that medical devices should be identified by GTINs, whether it is the manufacturer or hospital marking the items, though the GIAI is also compliant.

These guidelines will explore the options in more detail and there is a table (Appendix B) which details the features and considerations for the implementation of each identifier.

2.3 Location identification

Global Location Numbers (GLNs), when used by trusts and their suppliers, enable the unambiguous identification of physical and operational locations across the healthcare system.

This means information can be collected and stored where an event occurs – whether this event involves the dispensing of patient care, the sterilisation of instruments or the ordering and delivery of goods.

These guidelines advocate the use of GLNs for surgical-instrument management and will provide examples of how they could be allocated.

2.4 Patient identification

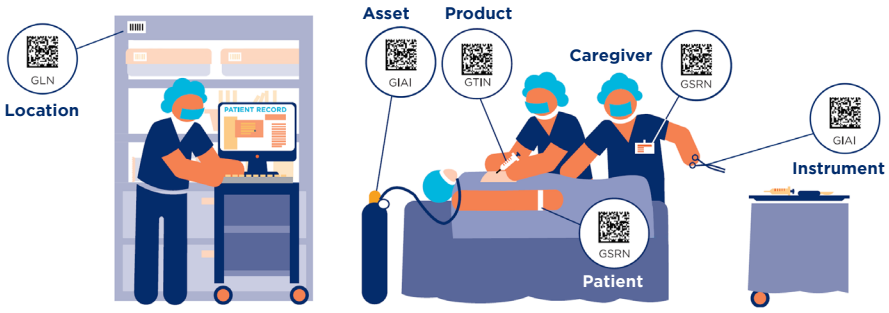
The globally unique identification of the patient enables accurate and consistent information to be captured and stored in the patient record at all relevant points along the patient pathway.

The NHS Digital standard DCB1077, supports the accurate, timely and safer identification of NHS patients, by defining how to encode the NHS approved patient identifiers into a GS1 DataMatrix for patient identity bands. This utilises the Global Service Relation Number (GSRN) – a globally unique code for the identification of a care giver or care receiver.

The barcode can be scanned at relevant points along the patient pathway, from admission through to discharge, recording events including patient observations, assessments, and medicines administration.

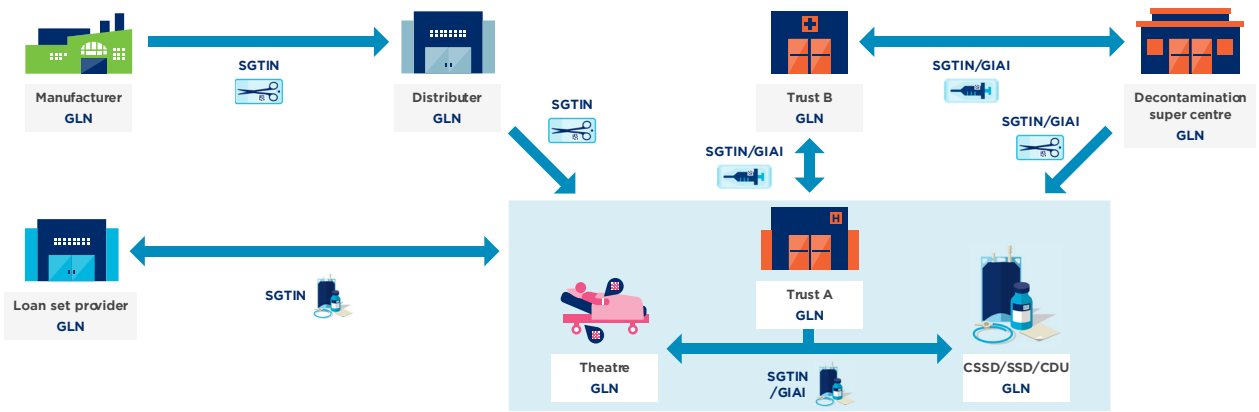
Scanning a patient wristband eliminates the need for hand-written records, enabling accurate and real-time capture of information to minimise risk to the patient. This should include the association of GS1 identifiers relating to instruments and kits used in a theatre procedure that can be updated and stored within the patient's medical records.

GS1 Traceability Standard



2.5 A common language

Using GS1's standardised, unique identification keys, interoperability can be facilitated across the healthcare supply chain. By utilising a common language of identification keys and data carriers, parties will be able to move physical products and share information about them without conflicting demands or manual intervention.



GS1 standards should be used to identify surgical instruments and capture information about them, using data carriers for the following processes (non-exhaustive):

Supplier

Process	GS1 identifier
Meeting UDI requirements	GTIN
Identifying company and devices for MHRA Field Safety Notices (FSNs)	GTIN and GLN
Purchase to pay with customers	GTIN and GLN
Managing catalogues	GTIN
Inventory management	GTIN and GLN

Procurement

Process	GS1 identifier
Ordering products	GTIN and GLN
Identifying items that have been recalled	GTIN
Identifying locations of recalled items	GTIN and GLN
Inventory management	GTIN and GLN

Central Sterile Services Department (CSSD)/Central Decontamination Unit (CDU)

Process	GS1 identifier
Receiving unsterile loan tray sets	GTIN/GIAI and GLN
Items being sent for repair	GTIN/GIAI
Receiving unsterile surgical kits on loan from another trust	GTIN/GIAI and GLN
Identifying items that are quarantined awaiting test results from a patient, approval for repair, replacement or decommission	GTIN/GIAI
New inventory surgical kits and items awaiting quality approval process, which may include checking appropriate decontamination instructions for use (IFU), etc	GTIN/GIAI
Processes including washroom and cleanroom activities, instrument assembly and packing (IAP) and sterilisation	GTIN/GIAI and GLN

2.6 Gradual introduction of traceability

Whilst the section above illustrates how GS1 standards can be fully adopted across the instrument management process, it is recognised that each trust or Health Board will have different requirements for the traceability of its instruments. Organisations will need to assess if complete traceability to the individual instrument is necessary.

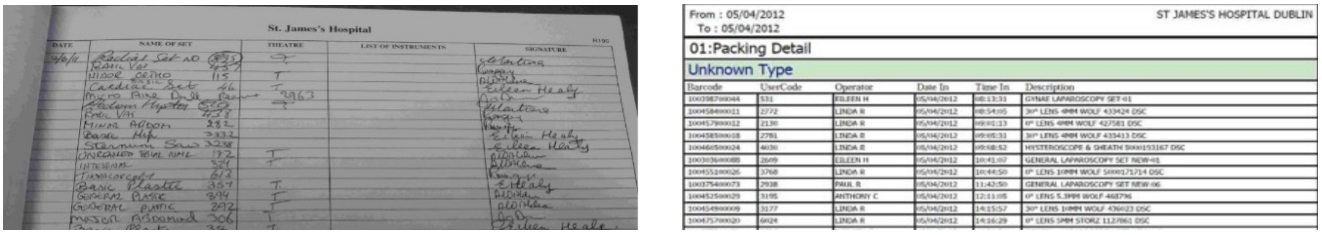
Process and traceability requirements may include:

- Traceability of instruments up to the respective patient
- Traceability to the setup process and/or sterilisation process
- Instrument management (inventory, lifecycle management)
- Sterilisation services for other hospitals
- Third-party service providers and loan kits

It is recognised that some organisations may only be able to move to a full traceability system using GS1 standards via a phased approach.

While any sort of traceability system is better than none, limitations on implementing a partial or non-GS1 process are detailed below:

- Increased human error and processing time wherever manual data entry or stickers are used
- Loss of interoperability across systems and parties wherever proprietary identifiers and barcodes are used
- Loss of traceability to trays and patients if individual instruments are not marked



Paper versus electronic processing

3. Instruments

3.1 Instrument identification

GS1 is a UDI issuing agency/entity for many global regulations, including the US, EU, China, South Korea and Saudi Arabia, meaning that manufacturers supplying regulated medical devices to these markets can use GS1 standards to implement UDI requirements.

This means that manufacturers can identify their instruments and medical devices with a GTIN. Because it enables the identification of product types, the GTIN can be used throughout inventory-management and supply-chain processes, including product recalls. By using a Serialised GTIN (SGTIN) to identify individual instruments, an extra level of granularity and traceability is achieved.

However, it is recognised that a significant number of manufacturers are yet to implement UDI. In cases where the manufacturer has not marked an instrument and a trust wishes to, they should use their own SGTIN (GS1 General Specifications, section 2.1.8 Medical devices). Supplementary items should also be identified and marked with SGTINs. See the NHS Digital document, ISB 0108: AIDC: Automatic Identification and Data Capture which details instrument marking methods.

Keydots encoding GTIN and Serial number (01)05022304000031(21)ABC123

Alternatively, GIAIs can be used to identify instruments if the trust considers them to be “assets” rather than “products” and there is no requirement to identify them by type (e.g. for ordering by clinicians). The GIAI can then be used to manage the instrument throughout its lifecycle. However, it is important to note that GIAIs are used to identify the “instance” of an instrument rather than the “class”, so an additional identifier would be required to identify it by type.

3.2 Implementation considerations for instrument identification

- If an instrument has been marked with a manufacturer SGTIN, this should continue to be used by the trust (and cross-referenced to their own identifiers, if required)
- Manufacturer GTINs (if available) should be recorded in an appropriate database and mapped against trust-allocated identifiers (if allotted), in case of recalls
- The format of the serial number is at the discretion of the party responsible, but it will need to adhere to the structure requirements specified in the GS1 General Specifications and Tag Data Standard (TDS)
- A serial number needs to be unique to each GTIN
- In GS1 standards, serial numbers are always to be understood as attributes of a GTIN. Only the combination of both guarantees uniqueness, so a serial number must never be read and processed without the GTIN
- Unlike GTINs, GIAIs cannot be associated with Application Identifiers (AI), such as dates or the batch in GS1 barcodes
- An instrument should only ever be marked with a single GS1 identifier (GTIN or GIAI)

3.3 Examples of associated data for instruments

The table below illustrates the type of data that would be held in different systems across a trust, for which the specified GS1 identifier would be used to reference.

The systems expected to hold this data would include:

- Inventory-management systems
- Sterilisation-management systems
- Theatre-management systems
- Electronic patient record (EPR)

The use of GS1 Identification Keys makes it possible to exchange and evaluate data between disparate systems.

Master data per type of instrument	Data per instance of instrument
GTIN	**SGTIN or GIAI**
Name	Link to procedure kit to which the instrument belongs (SGTIN)
Type of instrument	GLN of maintenance supplier
Size	Date of purchase
Weight	Date of last maintenance
Maintenance cycle	Date of last maintenance
GLN supplier	Next maintenance date
Etc.	Count of maintenance
	Etc.

3.4 Data carriers for instruments

- Instruments should be marked with a GS1 DataMatrix and/or encoded in EPC/RFID tag
- See appendices F and G for more detail

4. Containers

4.1 Container identification

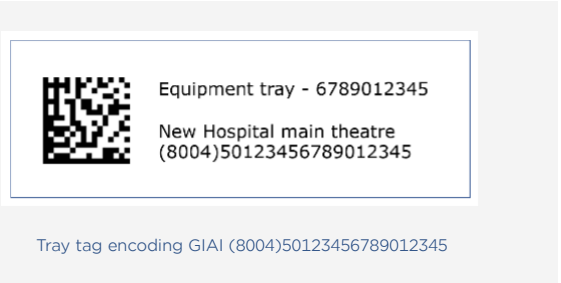
In these guidelines, “container” will be used as a catch-all term for the empty tray, basket or box in which instruments can be held.

The sterilisation process and the link between the procedure kit and the patient can be controlled without identifying containers. However, it is possible that the containers may become relevant and need to be distinguished from one another.

To meet regulatory requirements (such as US FDA UDI, and EU MDR), manufacturers are increasingly likely to have identified types of containers with GTINs and individual containers with SGTINs.

These containers can also be considered assets and can additionally be identified with a trust GIAI, if required. Where available, a supplier GTIN should be mapped against any trust-allocated identifier for the same item in a database, in case of recalls.

If a container has not already been marked by the manufacturer, a trust can mark it with a GIAI.



Tray tag encoding GIAI (8004)50123456789012345

4.2 Implementation considerations for containers

- If trusts do want to individually identify and mark containers as assets, it is important that they are not confused with any additional numbers and barcodes identifying the procedure kit.

  For example, a container could theoretically have two barcodes present:

  - One identifying the complete procedure kit which contains instruments (SGTIN or GIAI)
  - One identifying the container (GIAI)

- To reduce the chance of misidentification, there are three options:

  1. **Preferred**: the procedure kit is identified with a SGTIN on the tracker label rather than on the container itself, and the container is marked with a GIAI identifying it as an asset. The procedure kit SGTIN identifies all its components, including the container.
  2. **Typical of some legacy implementations**: there is a GIAI on the container but this identifies the procedure tray (i.e. the container plus instruments), rather than the container as an asset in its own right.
  3. **Least desirable**: the barcode that identifies the individual container is placed inside the container itself, and the barcode which identifies the instance of the procedure kit is placed on the outside of the container (e.g. on a tag). This method could lead to confusion and misidentification.

4.3 Examples of associated data for containers

Master data per type of container	Data per instance of container
GTIN	GIAI
Brand name	GLN of maintenance supplier
Type of container	Date of purchase
Size	Date of last maintenance
Weight	Next maintenance date
Maintenance cycle	Count of maintenance
GLN of supplier	Etc.
Etc.	

4.4 Data carriers for containers

- Either the GS1-128 or GS1 DataMatrix can be used
- See appendices F and G for more detail

5. Procedure kit

5.1 Procedure-kit identification

The equipped procedure kit can consist of several parts, each of which can be independently identified:

- Procedure kit containing:
  - One or more instruments
  - A container

Procedure kit, consisting of surgical instruments in containers

The combination of the container and associated instruments can be considered a product. Using GTINs to identify different types of procedure kit will enable improved supply-chain and inventory processes, and facilitate information sharing between different parties and systems.

Whoever assembles the kit is responsible for allocating the GTIN, for example, the trust, manufacturer, or loan-kit provider. The GTIN identifies the type of kit and is mapped to its components (e.g. types of instruments contained) as master data. The GTIN enables that type of kit to be ordered (either by procurement or in theatre) and enables better visibility of stock.

Procedure kit	GTIN
Left-hip replacement	05012345000008
Right-hip replacement	05012345000015

While the GTIN identifies the type of kit – through the addition of a serial number, it is possible to identify an instance of a kit. Through this SGTIN, it will then be possible to manage individual kits through the decontamination process, linking kits to their specific components, and associating kits used in theatre to the patient.

Procedure kit	GTIN	Serial number
Left-hip replacement	05012345000008	1
Left-hip replacement	05012345000008	2
Right-hip replacement	05012345000015	1
Right-hip replacement	05012345000015	2

Legacy GS1 implementations

Some trusts that have already implemented GS1 standards for surgical-instrument traceability have identified and marked individual procedure kits as assets with GIAIs. This enables the management of the kits through their lifecycle. However, as GIAIs cannot be associated with the Application Identifiers (AI) required for the tracker labels (batch and date), the GIAIs would need to be mapped against SGTINs in a one-to-one relationship in an appropriate database.

Whilst this "double identification" may not be considered ideal, it is a compliant workaround when kits need to be identified both as assets and as orderable items alongside additional sterilisation information.

Procedure kit	GIAI	GTIN	Serial number
Left-hip replacement	5012345000ABC	05012345000008	1
Left-hip replacement	5012345000DEF	05012345000008	2
Right-hip replacement	5012345000GHI	05012345000015	1
Right-hip replacement	5012345000JKL	05012345000015	2

Manufacturer-assembled procedure kits

Due to UDI regulations, manufacturers responsible for the supply of reusable, finished kits (e.g. Stryker, Smith & Nephew, Medtronic) are increasingly likely to have identified and marked their products with GTINs and production information, such as date, batch, and serial numbers.

It is recommended that trusts map their own GTINs against the manufacturer's GTINs in the appropriate databases. It is the trust's GTIN that will then be encoded on the tracker label alongside the associated sterilisation data.

Manufacturer kit identifiers should be mapped to trust GTINs which can be encoded on tracking labels

The recommended option for procedure kit identification and marking:

- The procedure kit is identified with an SGTIN. Following sterilisation, it is wrapped and the SGTIN is encoded on the tracker label.
- The container within is identified and marked with a GIAI (e.g. on an asset tag).
- Each instrument within the container is identified and marked with either an SGTIN or GIAI.
- The SGTIN which identifies the procedure kit can be used to retrieve information about all its components (container and instruments).

5.2 Implementation considerations for procedure kit identification

- In GS1 standards, a GIAI cannot be associated with date or batch information, so if a trust has allocated GIAIs to individual procedure kits, these identifiers would need be mapped to SGTINs to produce GS1-compliant tracker labels
- If a trust has not already allocated GIAIs to individual procedure kits, it is recommended that the type and instances of kits are identified by GTINs and SGTINs
- The format of the serial number is at the discretion of the party responsible, but it will need to adhere to the data structure requirements specified in the GS1 General Specifications and Tag Data Standard (TDS)
- A serial number needs to be unique to each GTIN
- In GS1 standards, serial numbers are always to be understood as attributes of a GTIN. Only the combination of both guarantees uniqueness, so a serial number must never be read and processed without the GTIN
- If a component is uniquely identified and is replaced like-for-like (e.g. due to it going missing or developing a fault), this would not require a new identifier to be allocated to the kit – instead, the new details will be recorded in the kit's associated master data in the appropriate database
- If a component type is changed to another component type (e.g. from forceps 9.5" to forceps 10"), this would not require a new identifier to be allocated to the kit – instead, the new details will be recorded in the kit's associated master data in the appropriate database.
- Of course, if a significant component is changed and the trust needed to distinguish between the old and new versions of the procedure kit using the identification number and barcode, a new GTIN could be allocated at the trust's discretion.

5.3 Examples of associated data for procedure kits

Master data per type of procedure kit	Data per instance of procedure kit
GTIN	**GIAI**
Brand name	GLN of maintenance supplier
Type of container	Date of purchase
Size	Date of last maintenance
Weight	Next maintenance date
Maintenance cycle	Count of maintenance
GLN of supplier	Etc.
Etc.	

5.6 Data carriers for procedure kits

- Either the GS1-128 or GS1 DataMatrix can be used
- If there is not sufficient space for a GS1-128 barcode, a GS1 DataMatrix should be used
- See Appendix F for more details

6. Loan kits

A loan kit consists of one or more consumables (e.g. implants) and reusable instruments on or within one or many trays which may be configured specifically to the requirements of the healthcare provider and individual surgical procedure.

Using GS1 standards across the loan-set management process will ensure that products are in the right place at the right time and in the right conditions.

Although there may not be one solution to cover all use cases, it is recommended that the loan-set provider should allocate:

- A GTIN to the procedure kit: this will enable the kit to be ordered by the healthcare provider using the GTIN. The GTIN may or may not be marked via a data carrier
- A GTIN to each type of tray within the kit: this enables the loan of the tray to be priced and invoiced and identifies the types of instruments within the tray
- An SGTIN (or a GIAI when not source-marked by the manufacturer and an “asset”) to uniquely identify each instance of a tray. The identifier should be encoded within an applicable GS1 data carrier and marked on the tray (via a label or directly)
- Ideally each item in the tray should be identified and marked with a GTIN plus serial number (or a GIAI if applicable). As a minimum each item in the tray should be identified by a GTIN
- Appendix H provides an overview of the loan-set process overlaid with the GS1 identifiers which will facilitate full traceability.

7. Tracker/production labels

7.1 Tracker-label format

The use of GTINs on the tracker label enables the operating theatre to order sterilised instruments in sets, or individually, from an in-house or outsourced provider. The GTIN will be used to identify a set that can be ordered by a clinician. In this instance, the GTIN identifies the service of making this set of instruments available for use in a particular operation. Each set or instrument that can be ordered individually has a different GTIN. For example, a small hip replacement set has a different GTIN to a large hip replacement set.

Tracker labels on sterilised and wrapped procedure trays

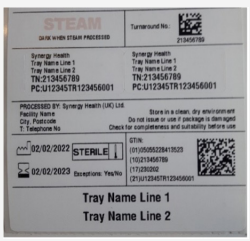
Each tracker label needs a set of mandatory data to achieve the desired outcome of identification. This can be supplemented with an optional location identifier to optimise processes.

- The **GTIN** identifies the type of set/instrument (mandatory)
- The **serial number** identifies that instance of the set/instrument. The serial number will be used to distinguish one set/instrument from another of the same type (mandatory)
- The **expiry date** enables the hospital or service provider to identify if the sterilisation has expired and to manage stock rotation. Alternatively, **expiry date and time** can be used (mandatory)
- The **batch number** is used to identify the sterilisation process cycle (mandatory)
- The **GLN of the production or service location** would enable details of the last processing site to be captured automatically through the barcode rather than via manual data entry (optional)

GS1 standards specify Application Identifiers (AI) which are used to ensure that a GTIN is always processed as a GTIN when it is scanned or read from a data carrier such as a barcode or RFID tag. AIs are two, three or four-digit numbers, and they denote the format and meaning of the data that follows them.

The table below lists the AIs that relate to the tracker label:

AI	Title	Format	Mandatory/optional
01	GTIN	14-digits	Mandatory
17	Expiry date	YYMMDD	Mandatory if 7003 is not being used
416	GLN of the production or service location	13-digit	Optional
10	Batch	Up to 20 alphanumeric characters	Mandatory
21	Serial number	Up to 20 alphanumeric characters	Mandatory
7003	Expiration date and time	YYMMDDHHMM	Mandatory if 17 is not being used



Tracker label showing mandatory AIs encoded in GS1 DataMatrix barcode

7.2 Implementation considerations for tracker labels

- Batch (10) would be used to encode what is sometimes called the “turnaround number”, and its format is at the discretion of the trust/service provider
- The serial number (21), together with the GTIN, will identify the record that provides all the identifiers of all the items that comprise each individual set and any other information that relates to the cleaning, packing and sterilising process
- In the GS1 System, the serial number is always to be understood as an attribute of a GTIN: only the combination of GTIN and serial number guarantees uniqueness. A serial number must never be read and processed without a GTIN
- Serial number (21) could be used to hold the GIAI of the container (or kit) contained within the packaging, if the implementation requires. If this is done, the complete data string should be included

  E.g.
  - GIAI of container is (8004)50123456789012345
  - Serial number on tracker label is (21)8004123456789012345

- For an optimal barcode symbol, fixed-length Application Identifiers (GTIN, dates, GLNs) should appear in the data element string before variable-length Application Identifiers (batch, serial numbers)

7.3 Data carriers for tracker labels

- Either the GS1-128 or GS1 DataMatrix can be used
- If there is not sufficient space for a GS1-128 barcode, a GS1 DataMatrix should be used
- GS1-128 barcodes have a 48-character limit – if data required for the tracker label exceeds this, then a GS1 DataMatrix should be used
- See Appendix F for more details

8. Locations

With kits and instruments being constantly on the move between departments, the growing number of outsourced service providers, and the sharing of equipment across trusts, the ability to accurately identify the parties and locations involved is more important than ever.

That is why these guidelines recommend the use of GLNs by those involved in the movement of instruments and sets to facilitate and automate traceability.

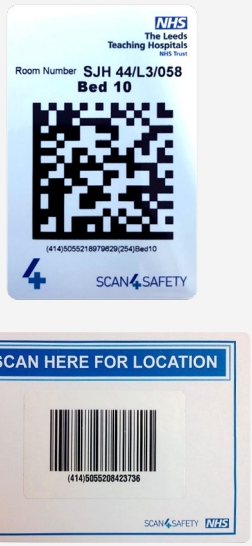
GLNs can be allocated by manufacturers, suppliers, service providers and trusts to identify:

- Organisations
- Departments
- Rooms and cupboards
- Delivery points
- Processing sites
- Systems

8.1 Examples of location use

GLNs can be stored and shared across different systems and locations as well as encoded into barcodes where the process requires. Because they are standardised and unique, they enable interoperability across the healthcare setting:

- A trust's GLN and supplier's GLN are accessible in GS1 UK's LocationManager, and are used to order and invoice instruments in the purchase-to-pay process
- A trust records the GLN of an instrument's manufacturer in their inventory-management system to facilitate the traceability process (MHRA FSNs include the manufacturer GLN)
- GLNs are allocated to a trust's theatre and SSD departments so an instrument's whereabouts can be tracked to its current location
- A trust records the GLN of another trust to which it has loaned equipment, so inventory can be accurately monitored
- A loan-set supplier scans the barcoded GLN of the delivery location
- An outsourced decontamination provider can be identified as the last processors of a kit through the inclusion of its GLN on the tracker label



Example of physical location GLN labels used in Scan4Safety sites

8.2 Examples of associated data for locations

Master data per location
GLN
Party/location name
Supplier code
Address
Contact details
Opening hours
Etc.

9. References

GS1 documents

1. EPC Tag Data Standard (TDS)
https://www.gs1.org/standards/epc-rfid/tds

2. GS1 DataMatrix Guideline
https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf

3. GS1 General Specifications
https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications

4. GS1 RFID/Barcode Interoperability Guideline
https://www.gs1.org/docs/barcodes/RFID_Barcode_Interoperability_Guidelines.pdf

5. GS1 UK Compliance Specification for NHS systems
https://www.gs1uk.org/our-industries/healthcare/gs1-standards-for-suppliers/compliance-specification

6. GS1 UK LocationManager
https://www.gs1uk.org/our-industries/healthcare/location-management/locationmanager

Other documents

7. NHS Digital information standard: ISB 0108: AIDC: Automatic Identification and Data Capture
https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/isb-0108-aidc-automatic-identification-and-data-capture

8. The Independent Medicines and Medical Devices Safety Review (Cumberlege Report) – First Do No Harm
https://www.immdsreview.org.uk/Report.html

9. Decontamination of surgical instruments (HTM 01-01)
https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care

10. Department of Health's NHS eProcurement Strategy for information on the need to adopt GS1 standards
https://www.gov.uk/government/publications/nhs-e-procurement-strategyEPC Tag Data Standard (TDS)

11. European Commission EU Medical Device Regulation
https://ec.europa.eu/growth/sectors/medical-devices_en

12. Global Harmonization Task Force – Definition of the Terms "Medical Device" and "In Vitro Diagnostic" (IVD) Medical Device
http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf

13. IMDRF Guidelines
http://www.imdrf.org/

14. ISO 13485:2016 Medical devices – Quality Management systems – Requirements for regulatory purposes
http://www.iso.org/iso/catalogue_detail?csnumber=59752

15. Loan Set Management Principles between Suppliers/Manufacturers, Theatres & Sterile Service Departments
https://www.afpp.org.uk/filegrab/1Guidanceontheprocessfortheprocurementofloansets.pdf?ref=1167

16. Management and decontamination of flexible endoscopes (HTM 01-06)
https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopesMedical Devices and In Vitro Diagnostic (IVD) Devices

17. MHRA – Guidance on legislation "Borderlines with medical devices"
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284505/Borderlines_with_medical_devices.pdf

18. NHS Never Events Report April – Dec 2020
https://www.england.nhs.uk/wp-content/uploads/2021/02/Provisional-publication-NE-1-April-31-December-2020.pdf

19. NICE (National Institute for Health and Care Excellence) Interventional Procedure Guidance IPG 666
https://www.nice.org.uk/guidance/ipg666

20. Scan4Safety benefits report
https://healthcare.gs1uk.org/scan4safety/

21. US FDA Convenience kits
https://www.fda.gov/media/95120/download

22. US Food and Drug Administration (FDA) UDI Regulation
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

23. Medicines and Medical Devices Act 2021
https://bills.parliament.uk/bills/2700

10. Appendices

Appendix A: Quick reference guide

Item	Supplier/service provider	Healthcare provider	Data carrier	Document reference
Instrument	(01) Supplier GTIN/ SGTIN	(01) Trust GTIN/SGTIN or (8004) Trust GIAI	GS1 DataMatrix EPC RFID	Section 3
Container	(01) Supplier GTIN/ SGTIN	(01) Trust GTIN/SGTIN or (8004) Trust GIAI	GS1 DataMatrix GS1-128 EPC RFID	Section 4
Procedure kit	(01) Supplier GTIN/ SGTIN	(01) Trust GTIN/SGTIN or (8004) Trust GIAI	GS1 DataMatrix GS1-128 EPC RFID	Section 5
Production label	**Mandatory:** (01) GTIN (10) Batch (17) Expiry date or (7003) Expiry date and time (21) Serial number **Optional:** (416) GLN of the production or service location	**Mandatory:** (01) GTIN (10) Batch (17) Expiry date or (7003) Expiry date and time (21) Serial number **Optional:** (416) GLN of the production or service location	GS1 DataMatrix GS1-128	Section 6
Location	Legal entity GLNs, Physical location GLNs, Function GLNs	Legal entity GLNs, Physical location GLNs, Function GLNs	GS1 DataMatrix GS1-128 EPC RFID	Section 7

Appendix B: Comparison of GTIN and GIAI

		Global Individual Asset Identifier (GIAI)	Global Trade Item Number (GTIN)
Features	Used to identify	Individual assets	Types of items/services
	Description	The GIAI is a GS1 Key for asset identification. Companies can apply a GIAI on any asset to uniquely identify and manage that asset. This could be a computer, desk, vehicle, piece of transport equipment, or spare part, as just a few examples. Companies assigning the GIAI can be either the asset owner or a leasing or rental company.	The GTIN can be used to identify types of products at any packaging level (e.g. consumer unit, inner pack, case, pallet). Groups of trade items with similar production and usage characteristics – such as production batches – can be further identified with the help of the batch/lot number, expiry date, and similar data elements. Individual trade items can be uniquely identified using a GTIN plus serial number.
	Application identifier (AI)	(8004)	(01)
	Format	<30 alphanumeric characters	8, 12, 13, 14 digits plus optional additional <20 alphanumeric character serial number
	Capacity from 8-digit prefix (type of item)	N/A	10,000 GTIN-13s 80,000 GTIN-14s
	Capacity from 8-digit prefix (individual item)	Billions	Billions
	Barcodes	GS1 DataMatrix GS1-128	GS1 DataMatrix GS1-128
	RFID (UHF, 96-bit tags)	Numeric only with no leading 0 for the asset number	Numeric only with no leading 0 for the serial number
Considerations		GIAIs already being used by several trusts	SGTINs not currently being allocated by trusts
		GIAIs being used by some loan set providers	SGTINs increasingly being used by manufacturers (UDI)
		Less easy to use GIAIs for ordering and inventory management	GTINs can be used to identify type of item, allowing for ordering and inventory management through the identifier.
		No capacity issues	Trust requires prefix length appropriate for total number of supplemental and tray types

*Please note that the Application Identifiers are not part of the GIAI or GTIN, they are used when encoding these identifiers in barcodes so that they can be correctly processed when the barcode is scanned.

Appendix C: Creating Global Trade Item Numbers (GTINs)

Creating GTINs

Each organisation that wishes to use GTINs to identify its products or services will obtain a GS1 Company Prefix number by becoming a member of a GS1 Member Organisation. In the UK, this is GS1 UK. GTINs are created by allocating different item-reference digits to identify each product line, as shown below, and then calculating the last check digit.

GS1 Global Company Prefix	Item reference element	Check digit	Format
5012345	67890	0	n13*
50551234	7890	3	n13*
506009876	123	3	n13*

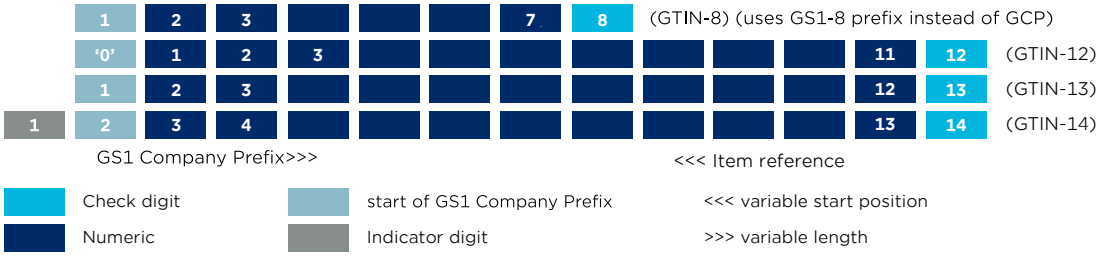
*GTINs may be eight, twelve, thirteen or fourteen-digit numbers. The table above shows how 13-digit GTINs are created. All GTINs are unique, and they may be treated as fixed-length 14-digit numbers in any database record if this is required. In effect, any GTIN of less than 14 digits may be prefixed with leading zeros.

GTINs have this administrative structure to ensure that all product lines and services are identified uniquely, but the complete number has no meaning. The GTIN is not intended to ever be divided into its component parts. Although the GS1 Company Prefix number can only be used by one organisation and is unique, it is not regarded as a company identifier.

The item-reference elements should be allocated sequentially, with the complete GTIN used as an identifier or key in an internal database that may also record an in-house code or classification for this item. The GTIN contains no information about the item being identified – it is a non-significant identifier.

GTIN data structures

The table below shows the position of each individual digit in each data structure for a GTIN.



0 represents a filler digit for those data structures that are not 14-digits long.

GTIN-13

GTIN-13s are formed by adding an item reference after the GS1 Company Prefix, and then calculating a check digit and placing it at the end.

GTIN-14

GTIN-14s are formed by adding an indicator digit to a GTIN-13 and recalculating the check digit.

The indicator digit can take any value from one to eight, and simply creates a different item number for a different packaging configuration. (The number nine is only ever used when identifying outer cases of variable measure product, which is usually weight).

Serial numbers

The Serialised Global Trade Item Number (SGTIN) is an add-on to a GTIN that allows different instances of the same product to be identified individually.

SGTINs require the use of AIs (Application Identifiers). These are used for systems to understand which information elements are contained in the barcode. The AI (01) is used to identify a GTIN, while (21) is used for the serial number. The AI (21) allows you to have a serial number of up to 20 alphanumeric characters.

In a barcode, you can utilise the full 20 alphanumeric characters. If you are using an RFID tag, you may be limited to numeric only, and have further restrictions on the structure and length of the number. See the GS1 Tag Data Guidelines for more information.

Examples of the same SGTIN in both GS1-128 and GS1 DataMatrix barcodes below:

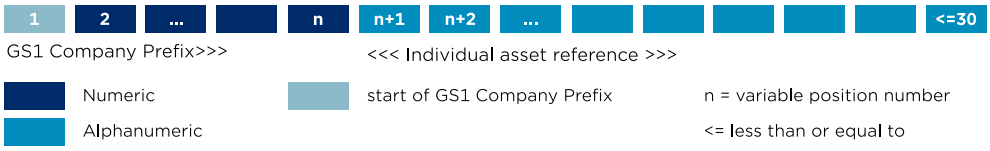
(01)05012345000008(21)123

(01)05012345000008(21)123

Appendix D: Creating Global Individual Asset Identifiers (GIAIs)

Creating GIAIs

The GIAI is simply a unique reference that is used to identify individual assets. It incorporates a GS1 Company Prefix number to guarantee this uniqueness. Please note that there is no check digit for the GIAI.



Appendix E: Creating Global Location Numbers (GLNs)

Creating GLNs

The GLN is a 13-digit number used to uniquely identify any legal entity, functional entity, or physical location. The table below shows its components.

For ease of administration, it is recommended that the location reference be allocated sequentially and not contain “classifying” elements.

Appendix F: Barcodes

Barcode individual items

One way of automatically tracking and tracing each individual instrument is using barcodes, where each instrument has its own unique barcode applied.

There are several benefits of using such a system:

- Each instrument has a unique number which allows its history to be recorded and retrieved as required
- Barcoding each instrument allows the data to be captured more quickly as the barcode is simply scanned whenever it passes a point where the instrument needs to be identified
- As the barcode is machine readable, there are fewer errors when reading the code as compared to manual transcription
- Permanent ways of marking the barcode on the instrument mean that once this is done, it stays with the instrument throughout its life
- With the introduction of super centres where instruments from different hospitals are processed together, hospitals can be sure that the instruments that go out for processing are the same as those that come back from the super centres

GS1-128

The GS1-128 barcode, together with the AI standards, enable companies to provide additional information about a product along with the GTIN for the product itself. GS1-128 is a subset of one-dimensional, linear Code 128 barcode.

Below is an example of a GS1-128 encoded with a GTIN, expiry date and batch number. The different types of data are specified by AIs, which normally appear in brackets in the human-readable characters (the brackets are not encoded in the barcodes).

GS1 DataMatrix

GS1 DataMatrix is a two-dimensional, machine-readable code, which can encode the same information as any other GS1 linear codes but in a fraction of the space. The code also has the advantage of built-in error correction so that could still be read with only 75 per cent of the code remaining.

It can be used where the marking area will preclude the use of ink, thus requiring the symbol to be applied by means of direct-part marking. GS1 DataMatrix cannot be read by laser scanners, and all hospitals are advised to procure suitable camera-based barcode scanners to ensure all barcode types can be scanned.

(01)05012345764213
(17)151122
(10)ABCDE12345

For further information on the implementation and use of the GS1 DataMatrix barcode, refer to the GS1 DataMatrix Guideline.

Barcode-enabled system issues

- The barcode needs to be permanent and should not interfere with the decontamination process which means that the method used for marking the instrument is important
- Most manufacturers are currently not barcoding instruments. Any hospital thinking of using such a system should make decisions on when the barcoding is done.
- If a hospital does not require suppliers to barcode the instruments, then the barcoding can be done at the hospital before their first use. However, this adds a lot of cost for the hospital and even if the hospital decides to do the barcoding at the beginning, the long-term aim should be to encourage the manufacturers/suppliers to do the barcoding at source.
- Existing instruments will need to be marked
- Initially, the hospital will have to do some marking whether it is just for the existing instruments, or for both the existing and new instruments if the manufacturer is not doing the marking on new instruments.

Instrument identification

A barcode or an RFID tag is applied directly on the surgical instrument. The barcode to be used on surgical instruments is the two-dimensional GS1 DataMatrix symbol. There are different methods of marking instruments, common methods include dot peening, laser etching, electro-chemical etching, and ink jet marking.

Some solution providers offer marking services for hospitals. The main advantage of this kind of service is that the hospital does not need to invest in marking equipment and find qualified people who understand the marking technology and data requirements. More information on the technologies available to identify surgical instruments can be found in the GS1 UK document, Technologies for Marking Surgical Instruments.

Marking surgical instruments

Instruments should ideally be marked at source for a number of reasons. Firstly, the marking of instruments can be done as part of the production process. Secondly, marking of instruments by parties other than the manufacturer may affect the product's warranty.

The manufacturers can use different marking methods but all systems will have to use GS1 coding standards. The introduction of this by all manufacturers will mean that as old instruments are replaced, all instruments within the NHS will be identified with a GS1 number.

Marking existing instruments

Some hospitals in the UK have already decided to mark their existing instruments. The main solution providers who provide marking products and services are part of the GS1 System, and their solutions are GS1 compatible. The cost for marking will vary depending on the technique and technology used.

It should be noted that by marking the instruments, the organisation carrying out the marking could be interfering with the integrity of the instrument, and, therefore, the liability for the instrument passes to them from the manufacturer.

All hospitals in England wishing to mark their instruments are already members of GS1 as part of the latest five-year contract agreement between NHS Digital and GS1 UK dated 11 April 2019. The GS1

Appendix G: Radio-frequency identification (RFID)

Aside from barcodes, an additional method of identifying each individual instrument is through radio-frequency identification (RFID) tags.

GS1's EPC (Electronic Product Code) Tag Data Standard specifies the data format of the EPC and provides encodings for numbering schemes – including the GS1 Keys – within an EPC. This means either the GTIN or GIAI can be encoded in an EPC.

When unique EPCs are encoded onto individual RFID tags, radio waves can be used to capture the unique identifiers at extremely high rates and at distances of more than 10m without line-of-sight contact. These characteristics of RFID can be leveraged to boost supply-chain visibility and increase inventory accuracy.

Surgical instruments can be fitted with a GS1-compliant passive RFID tag that responds to signals received from a nearby RFID reader's interrogating radio waves.

Ideally, the tag must remain affixed for the entire lifecycle of the instrument it has been paired with, so it is important to ensure that the correct tag type is chosen and that it can withstand the relevant chemicals, cleaning techniques, and high temperatures that it will encounter within the decontamination process.

To protect the tag from being damaged, many tag suppliers encapsulate it within an external casing, and they offer training to ensure that the tags are applied safely, securely, and correctly on the instruments.

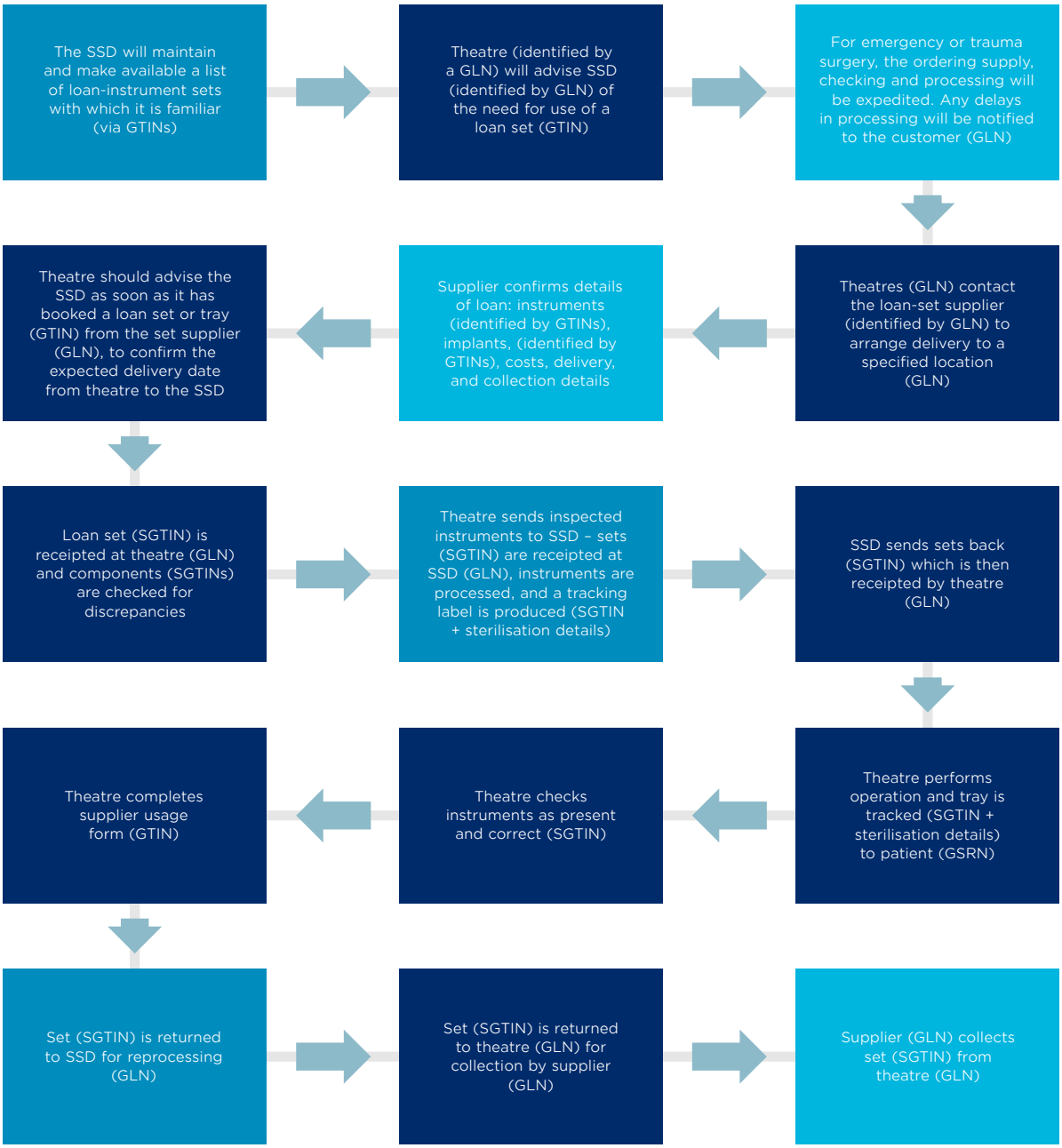
The benefits that EPC RFID technology provides are as follows:

- Unlike barcodes, an RFID reader can read multiple tags, and identify multiple surgical instruments simultaneously
- RFID tags can be read even when out of sight of an RFID reader (e.g. in a drawer)
- RFID tags can cope with harsh or dirty environments
- Ultra-high frequency (UHF) passive tags are often used within asset-tracking applications, whereby the reading distance from the tag can even extend up to 12 metres, depending on the limitations of the reader

Further information on EPC/RFID can be found on the GS1.org website.

Appendix H: Loan-set management principle using GS1 standards

The diagram below is based on the document Loan Set Management Principles between Suppliers/ Manufacturers, Theatres & Sterile Service Departments.



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