

## Safer Surgery Saves Lives

### GS1 Identification and Barcode Standards deployed throughout the HSE's Central Decontamination Units (CDUs)

There is well documented evidence highlighting the importance of effective decontamination processes to prevent the spread of infections. Numerous international and regulatory bodies recognise this. The Medical Devices Directive (93/42/EEC) specifies the minimum standards in relation to decontamination of medical devices. Hospital acquired infections are a concern for all hospitals. Surgical Site Infections (SSIs) can have an impact on both patient safety (e.g., development of a serious illness) and hospital costs (e.g., additional cost of treatment for the patient).

The importance of a robust track-and-trace system that complies with national, regional and international best practices for medical instruments is recognised as an integral part of all Central Decontamination Units (CDUs). Under the current economic and budgetary pressures that face most health services in European member states, including Ireland, there is often a need to share important hospital resources such as medical instruments between hospitals and, additionally, there is a significant market for manufacturers to loan instrument sets to hospitals.

Sharing Reusable Medical Instrument Sets has obvious benefits, but can challenge proprietary track and trace systems. Having multiple proprietary systems can result in the chain of traceability breaking when an item leaves a hospital because there is no guarantee that the identification of that item is unique. The Health Service Executive (HSE) in Ireland in recognising this challenge has implemented a solution using GS1 Standards initially in eight hospitals, with a roll out to all remaining hospitals to follow.

### Using GS1 Standards of Identification

A GS1 Global Individual Asset Identifier (GIAI) is assigned to the instrument trays owned by the hospital. As the tray moves through the decontamination process, its unique identity is enhanced by adding batch codes, expiry dates and Global Location Numbers (GLNs) where applicable. Each step of the process is time and date stamped and recorded. Technicians working in the CDU scan their ID badges to complete the "who, what, where and when" of the traceability system.

Because GS1 standards-based identification numbers have been used to mark loaned tray sets, the chain of traceability is also maintained when an instrument tray is loaned between hospitals. When a hospital borrows an instrument set, they simply scan the GS1 barcode which acts as the key to access the loan set provider's database. The details associated with each particular "loaned" instrument set can then be downloaded to the local system to maintain traceability data and to ensure accurate data on the contents of the loan set. Prior to the adoption of GS1 Standards this was a paper-based, error prone and labour intensive process.

The HSE have published three documents that now explicitly recommend the use of GS1 Standards to help them realise their exacting standards:

- HSE Standards and Recommended Practices for Central Decontamination Units;
- Decontamination of RIMD Standards and Recommended Practices for Endoscope Reprocessing;
- HSE Standards and Recommended Practices for Dental CDUs.

These documents describe a set of standards which define the structures and processes needed to identify, assess and manage specified risks in relation to the decontamination process.

## Benefits and Outcomes

The objectives of the project (to reduce manual labour, increase efficiency and create assurances that an effective decontamination process has occurred) have all been achieved through the track-and-trace solution. For both patients and the internal customers of the CDU, the implementation of GS1 Standards has exceeded expectations and many unanticipated benefits have also been realised.

Indeed, one of the biggest benefits identified is the ability to loan instruments seamlessly between the eight hospitals currently participating in the initiative.

Ultimately full benefit from this initiative will be realised when the manufacturers apply the GS1 Identifier at the point of manufacture. In this regard, Synthes is the first manufacturer to mark their loaned tray sets at source to guarantee traceability from manufacturing site right through to the patient record.

## Benefits Delivered

- Patient safety
- Quality assurance
- Instrument tracking in CDU and theatre, both within and between hospitals
- Reduced inventories
- Ability to locate instruments anywhere, at any time, quickly
- Reduced administrative work
- Improved workflow
- Ease of reporting both during and post event
- More efficient and traceable loan set management.

## The Future

The success of implementing GS1 Standards for tracing instrument trays between and within Irish hospitals has highlighted that a combination of effective processes, the application of GS1 Standards and use of integrated scanning technologies has measurable benefits for all Healthcare stakeholders. The instrument track-and-trace solution, incorporating GS1 Standards is currently being rolled out to all HSE hospitals. Further phases of the project will involve single instrument marking, helping to ensure a level of traceability and reporting that would not have been previously possible with a manual or proprietary system of identification.

# CASE STUDY

## St. James's Hospital

### Surgical Instrument Traceability

St. James's Hospital is a leading major acute and academic teaching hospital, dealing with over 14,000 surgically invasive procedures per year. St James's is among the many healthcare organisations in Ireland that utilise GS1 Standards for the patient safety and supply chain efficiency benefits they deliver.

With 30,000 surgical trays, including over 300 shared loan sets, being reprocessed by St James's Central Decontamination Unit every year, an interoperable, standards-based, instrument set tracking system that enables data sharing is a must. A GS1 Global Individual

Asset Identifier (GIAI) is assigned by St James's to instrument trays, and when combined with GS1 Global Location Numbers (GLNs), batch and expiry data, the system maintains traceability and quality assurance, even when the tray is loaned outside of the hospital. The system has delivered on the efficiencies sought in terms of reduced manual labour; increased efficiency; and quality assurance. St James's was the first hospital to roll out the traceability solution under the HSE's National Sterile Instrument Tracking Programme.



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