



Executive Summary

Unique Device Identification for Australian Healthcare

The Therapeutic Goods Administration (TGA) has implemented a Unique Device Identification (UDI) system in Australia to enhance patient safety through improved traceability of medical devices.

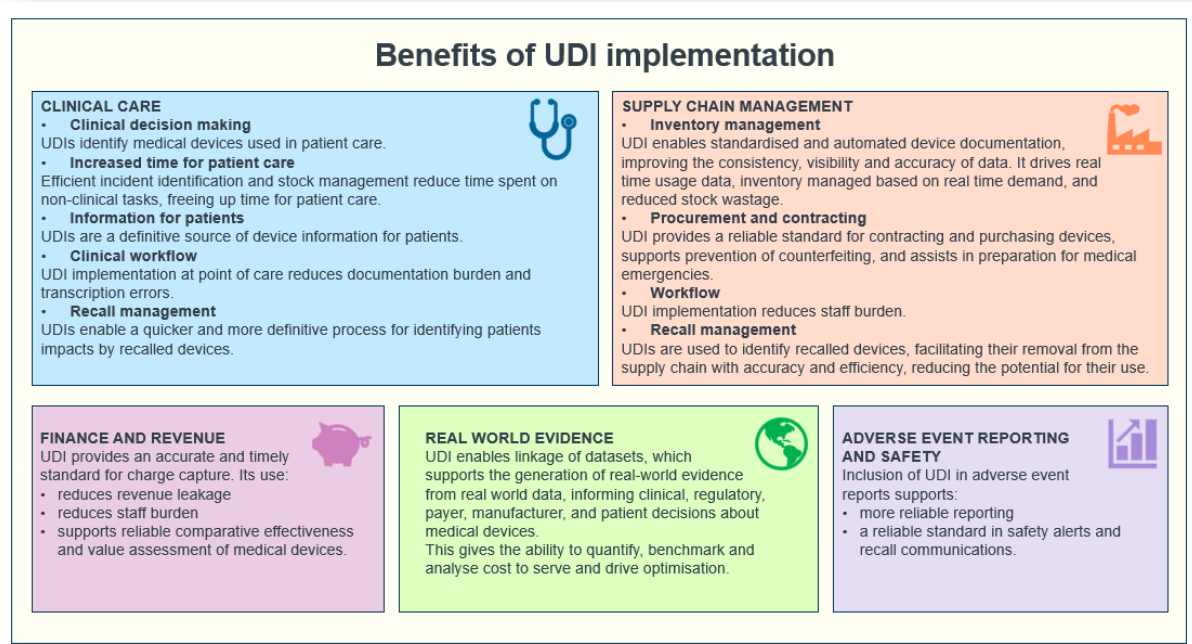
Australia's UDI implementation aligns with how medical device regulators across the globe have adopted UDI to help identify and act more quickly when issues are found.

Medical device manufacturers and sponsors supplying medical devices in Australia must place this Unique Device Identifier (UDI) in the barcodes on their device labels as well as all applicable higher levels of packaging. The sponsor must also submit data about the device to a central database managed by the TGA.

The UDI is a globally unique code that identifies the manufacturer and model/version as well as production information such as the batch, lot or serial number, expiry date and manufacture date. It will be a cornerstone to improving the safety of medical implants.

The UDI can support healthcare providers identify, manage, and monitor medical devices within their processes and systems and assist in recording and identifying specific devices implanted in patients.

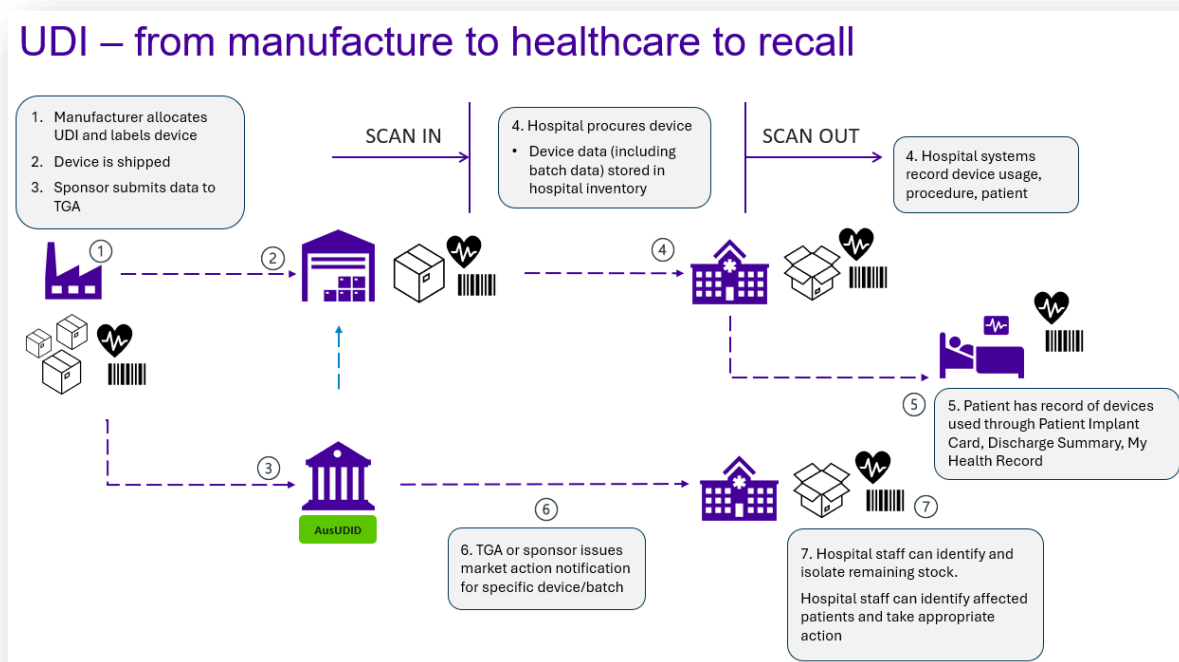
Figure 1: Benefits of UDI implementation



Introduction of the UDI requirements is phased, starting with high-risk implantable devices from 1 July 2026 and then progressively rolled out to other device classes. Information about UDIs will also be included in recall action notices and Patient Implant Cards (PICs).

To achieve the benefits of UDI, the UDI must flow through all stages of the healthcare system and be captured in processes and systems that handle product or patient data.

Figure 2: UDI from manufacture to healthcare to recall



Hospitals and healthcare organisations use of UDI in processes and systems, including in adverse event reporting will be included in the 3rd edition of the National Safety and Quality Health Service (NSQHS) Standards planned for release in 2028-29.

EXECUTIVE CALL TO ACTION

To ensure you are ready for UDI:

- contact the TGA at UDI@health.gov.au
- visit the [UDI: Information for healthcare providers](#) on the TGA's UDI Hub.