# documentation REDEFINED
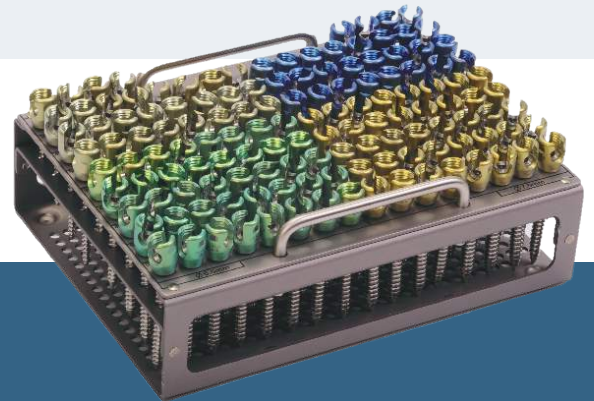
# TRACKING MEDICAL IMPLANTS

Over the last decade, global tracking of medical implants has been the subject of immense regulatory efforts. The passing of the FDA's UDI Final Rule in September 2013 stimulated an unprecedented level of collaboration amongst healthcare industry stakeholders. Suppliers and providers are working together to design and deploy solutions for UDI tracking and documentation throughout the supply chain. These joint efforts have led to several innovative solutions for medical device UDI tracking, but challenges still exist for conveying UDI to the point of use for products such as orthopedic implant sets used in various types of spine, trauma, craniomaxillofacial, or extremity surgeries.

Implant sets are particularly challenging because i) the implants are separated from their original, UDI compliant packaging before being assembled into sets, ii) the sets may be composed of hundreds of individual implants that are designed to be reprocessed and sterilized between each use, iii) multiple sets may be utilized for one procedure, iv) the sets may be hospital owned or manufacturer owned, and v) **there are currently no AIDC technologies designed for use in the sterile field.** Because of these challenges and more, the FDA extended the UDI compliance deadline, to September 2016, for single use implants that are designed to be cleaned and sterilized between each use.

## How can you be assured that **ALL** medical implants have been identified and documented?

# THE SOLUTION

TRACTUS is a comprehensive, fully integrated hardware and software solution that provides rapid and accurate medical implant UDI capture and documentation **in the sterile field** of the operating room. TRACTUS is a "turn-key" solution that addresses and meets the unique complexities and challenges in conveying medical implant UDI for products such as orthopedic implant sets used in various types of spine, trauma, craniomaxillofacial, or extremity surgeries at the point of use. The TRACTUS hardware has been designed to sit atop a Mayo stand and consists of a battery powered high-speed data scanner that wirelessly links to a small laptop device containing the TRACTUS software. Upon capturing the medical implant's UDI information, the TRACTUS scanner then parses the information and wirelessly communicates with the user-friendly TRACTUS software to identify and document the implant. Using a simple drag-and-drop functionality the software operator may assign the final placement of the implanted product on an anatomical model.

matrix iT
MEDICAL TRACKING SYSTEMS, INC.

# Tractus
THE solution for UDI documentation

**SCAN**    **THEN**    **ASSIGN**

TRACTUS is a comprehensive, fully integrated hardware and software solution that provides rapid and accurate medical implant UDI capture and documentation **in the sterile field** of the operating room. The user-friendly TRACTUS software allows for real-time documentation of final implant placement and ensures that implant UDI documention is *100% accurate* before being documented in the hospitals' information systems.

# THE TRACTUS SOLUTION

- The only sterile field UDI documentation solution (reads as small as 1mm$^2$ 2D data matrix)

- Unmatched point of use clinical documentation (during implantation)

- Intuitive software allows for positional documentation and visualization of implants.

- Tracks utilized and discarded implants (full accountability)

- Immediately identify counterfeit implants not registered in GUDID database

- Completely integrated facility EMR interface

- Fully customizable – may be used as a stand-alone solution or integrated with current inventory management or UDI tracking systems.

- Benchmark testing yielded 100% accurate throughput of scanned information

- Eliminates inaccurate recordkeeping, billing, and identifies actual implanted products.

- Builds database for recall identification and post market surveillance of implants.

- Comprehensive reporting and analytics capabilities

# ABOUT MATRIX IT

Matrix IT Medical Tracking Systems, Inc., is a healthcare information technology company leading the industry in providing real-time medical implant UDI verification, documentation, and tracking solution **in the sterile field** of the operating room. Matrix IT's medical implant UDI documentation system, TRACTUS, verifies, captures, and documents medical implant UDI information at the point of use. TRACTUS securely shares this information with the hospital's electronic medical record (EMR), supply chain, and other information management systems.

Unlike other documentation systems which track medical implant UDI information at different points throughout the healthcare supply chain, TRACTUS is the only solution that has been designed for use **in the sterile field**, at the point of use.

For more information about TRACTUS, please visit our website, call us at **(262) 299-6007**, or email us at info@matrixmedical.co

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