

Embedding RFID Tags within the Molded Components of Medical Devices

Complying with the FDA's Unique Device Identifier Rule While Differentiating Your Products



Robust, Built-In Protection of Medical RFID Tags

Compliance with the machine-readable requirement of the U.S. FDA's Unique Device Identifier (UDI) Final Rule can be achieved using Parker's proven, patented, techniques for embedding RFID tags into molded components during their fabrication.

Using embedded RFID tags for auto identification and data capture (AIDC) offers numerous additional opportunities for product enhancement and/or differentiation, including high level anti-counterfeiting characteristics, damage/tamper resistance and automatic parameter settings.



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Product Features:

- Molded-in RFID tags have no labels, adhesives or plugs to fail
- Embedded tags are totally encapsulated in, and fully protected by, the device's own material
- Completely tamper-resistant identification
- Extremely counterfeit resistant
- Covert in opaque materials
- Embedded tags match the device's resistance to autoclave and gamma sterilization cycles
- No contaminant-harboring seams or manufacturing marks
- Equipment can automatically recognize components with embedded tags
- On-board tracking of device life cycles
- Available now for embedding into your Class I, II or III devices

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Preventable Medical Errors Prompt U.S. FDA's UDI Rule

Preventable medical errors cause as many as 98,000 deaths each year.¹ The U.S. Food and Drug Administration's Unique Device Identifier (UDI) system aims to reduce medical device errors through:

- 1) More rapid and precise identification of devices and their accompanying information/characteristics (e.g., expiration dates).
- 2) Improved tracking of medical device use across all systems.
- 3) Reduced counterfeiting and diversion of medical devices.
- 4) Improved reporting of adverse events.
- 5) Better management of medical device recalls.
- 6) The development of a Global Unique Device Identification Database (GUDID).²

UDI Requirements for Medical Device Manufacturers

All UDIs are issued by an FDA-accredited issuing agency, with each UDI having a unique numeric or alphanumeric code consisting of two parts.

The **device identifier (DI)** is the fixed portion of a UDI that identifies:

- 1) The labeler
- 2) The manufacturer's name, address and contact information
- 3) The specific version or model of a device
- 4) Product characteristics: for example, whether the product is single-use, sterile, latex-containing, etc.
- 5) Clinic size and/or storage conditions

The **production identifier (PI)** identifies characteristics of *each unique (specific) device*:

- 1) Its manufacturing lot or batch number
- 2) The device's serial number
- 3) Its expiration date
- 4) Date of manufacture
- 5) ID code for human tissue-based products regulated as a device.³

UDIs are not only required on the medical device but also its packaging, which can include device box, carton, case, etc.

UDI readability: Each Unique Device Identifier must be human- and machine-readable.



FDA Final UDI Rule is Now in Effect

Table 1: Key Compliance Dates for UDI Final Rule⁴

Device Classification	Class III		Class II		Class I	
	Labels/ Packaging	Permanent Markings on Device Itself (Reusable Devices)	Labels/ Packaging	Permanent Markings on Device Itself (Reusable Devices)	Labels/ Packaging	Permanent Markings on Device Itself (Reusable Devices)
9/2014	•					
9/2015		•*	•*	•*		
9/2016		•	•			
9/2018				•	•	
9/2020						•**

* Implantable, life-supporting or life-sustaining devices

** Class I devices and all devices not classified as I, II or III

Automatic exceptions include the following:

- 1) Finished devices manufactured/ labeled prior to compliance date. However, this exception automatically expires three years after compliance date.
- 2) Class I devices exempt from Good Manufacturing Practice (GMP) requirements⁵, e.g., a manual toothbrush.
- 3) "...individual single-use devices that are distributed together in a particular package and are intended to be stored in that package and then removed from those packages for use do not need to have the UDI on the individual device itself. Rather, the UDI can go on the next higher level of packaging. And this applies for all classes of single-use devices."⁶ This exception is not available for any implantable device."⁷

- 4) Investigational devices or devices not intended for any clinical use, i.e., research, teaching or chemical analysis.
- 5) Custom devices.
- 6) Exported devices. Note, however, that **The International Medical Device Regulators Forum (IMDRF) UDI Working Group** (nations outside the U.S.) is working on a comparable UDI system.⁸

Exceptions to the UDI Rule (§ 801.30)

Manufacturers must prove that a UDI for their device is technically unfeasible or possibly unsafe, or that they can better address the objectives of the UDI rule through alternative means. The FDA must approve the requested UDI exception or extension and may rescind it at any point.

Automatic Identification and Data Capture Technologies for Medical Devices and Instruments

The FDA UDI Final Rule states: "Automatic identification and data capture (AIDC) technology means any technology that conveys the UDI or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process."³

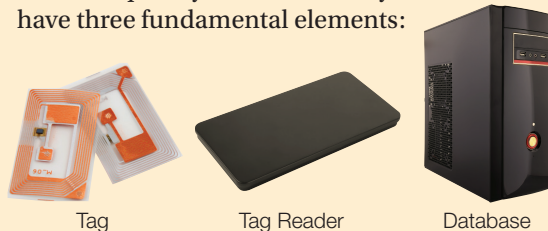


Barcode Labels vs. RFID Tags for Medical Devices

- 1) RFID systems can have their reading distances “tuned” over a broad range through tag selection, tag antenna size and configuration, choice of tag reader/reader power, and Parker Chomerics RF shielding technologies.
- 2) Barcode readers must have direct line of sight; RFID readers do not.
- 3) Barcodes require either a specific orientation to their reader or a larger reader that is omni-directional; RFID tags can be read in virtually any orientation.
- 4) Barcode readers read one label at a time; RFID readers can read hundreds or thousands of tags at once.
- 5) RFID tags can contain much more information than is practical on most barcodes.
- 6) RFID tags can be written-to (and locked and/or encrypted) at their point of use. For example, the number of autoclave cycles a device has endured could be recorded on both its tag and in a database: data collection and its use become real-time.

A Primer on RFID Tags

Radio frequency identification systems have three fundamental elements:



A RFID tag is a combination of a RFID chip and an antenna. Tags are available in low, high and ultra-high frequencies:

- LF is 120 to 135kHz; e.g., implanted RFID tags in animals
- HF is 13.56MHz; also known as near field communication (NFC), with a range of about three inches
- UHF is 900MHz; e.g., RFID tags for retail clothing, inventories, etc.

RFID tags can be either “active,” meaning they are powered by an on-board battery, or, more commonly, “passive,” meaning they are energized by the tag reader.



Tags can be smaller than a grain of rice to a few inches in length. In general, RFID tag size is proportional to its data capacity while read range is a function of antenna size and power.

The Unique Advantages of Built-In RFID Tags for Plastic Medical Devices

The most robust way to incorporate RFID is to **embed the tags directly within the device's material during molding**:

1) No adhesives to fail: Built-in RFID tags cannot peel off like adhered inlay tags (AKA “smart labels”).

2) No plugs to fail: One conventional method to protect RFID tags is to place them into a cavity on the product and secure them using a bonded plug, epoxy, permanent liquid adhesive or, in some cases, a film adhesive. While this method of incorporating tags provides better protection than adhering inlays to a surface, it may not be possible in all applications, and it requires a sometimes costly secondary operation. Worse, plugs or adhesives can fail. The more robust embedding method is to mold the RFID tags into the device's material, eliminating all dependence on plugs or adhesives.

3) Optimal tag placement and protection: One scratch on a surface inlay can damage the antenna and render the tag inoperable. Molded-in tags, by comparison, are completely encapsulated within the medical device's physical dimensions and fully protected by the device's own material.

4) Streamlined device designs: Built-in RFID tags have no contaminant-harboring seams or manufacturing marks.

5) Completely tamper resistant: Molded-in tags are completely tamper resistant as long as the medical device itself is not compromised.

6) Covert in opaque objects: Built-in RFID tags “disappear” in opaque polymers, adding to their tamper resistance (and another deterrent to device counterfeiting).



7) Autoclave and gamma radiation resistant: In addition to RFID tags for single-use devices, embedded RFID tags can be specified that withstand a prescribed number of autoclave or gamma sterilization cycles — as long as the material is resistant, the tags will be resistant.

8) Potential for on-board tracking of device life cycles: Healthcare workers could be automatically alerted when to use new (fresh) products after a prescribed number of uses or autoclave cycles, or when a device is past its expiration date.

9) Protect intellectual property: Producing counterfeit medical devices with built-in RFID tags would be extraordinarily difficult. Counterfeiters do not have access to your database, the source for identifying genuine tags. So employing even moderate security measures would substantially deter counterfeiters and unauthorized third-party manufacturers from producing compatible devices.

10) Specify system settings automatically: Equipment can automatically recognize components with fully embedded (and protected) RFID tags, allowing the machines to configure themselves for a specified process or procedure, allowing for faster, safer and more effective use.

Patented Technology for Embedded RFID Tags

Parker Hannifin first embedded RFID tags into its products to stem the counterfeiting of its mission-critical elastomeric O-rings.

Parker has now extended this technology into a variety of shapes and materials, covering many of the elastomers and thermoplastics commonly used in medical devices, including but not limited to:

Thermoset Elastomers

Butyl Rubber
EPDM
FFKM
FKM
Polyisoprene
Silicone

Thermoplastics and Thermoplastic Elastomers (TPEs)

ABS
Polycarbonate
Polyethylene
Polypropylene
PVC
TPEs and TPUs (Thermoplastic Elastomers and Urethanes)



Using proprietary, patented and patent-pending techniques, Parker can embed a variety of RFID tags into a wide range of medical device component configurations.

Parker has been particularly successful integrating RFID tags within thin walls or space-limited molded polymer components, requiring only very small offsets from the part's outer surfaces.



FAQs about Parker's Embedded RFID UDI

Q: Can the tags withstand gamma radiation sterilization?

A: Yes, gamma resistant tags can be utilized for many applications.

Q: Can the built-in RFID tags withstand repeated autoclave sterilization?

A: Yes. As long as the device and the material are designed to withstand autoclave cycles, the tags will as well.

Q: How small can the tag be?

A: RFID tags can be as small as a grain of sand. However, as you increase the tag's data capacity and its read range, the tag, in general, increases in size.

Q: What are the data capacities of RFID tags?

A: As noted, the larger the tag, the greater the potential for increased information capacity. Parker can evaluate your storage needs against your device's footprint and other requirements and provide advice on what is possible. Most applications will not require excessively large tags to accommodate their data storage requirements.

Q: Can the tags be written-to?

A: Yes.

Q: Can the data on the tags be locked? Encrypted?

A: Yes and yes.

Q: What are the read ranges for polymer-embedded RFID tags?

A: RFID read distances can range from near contact to 30+ feet. RFID read range is a function of the tag's antenna size and the reader's antenna size and power. "Active" RFID tags (i.e., with a battery) can have even longer ranges, but most medical device applications likely only need smaller "passive" tags that receive energy from the reader's antenna.

Q: Does the embedded RFID tag make the medical device look different?

A: In general, no. However, it depends on the device: with opaque polymers, most patients won't know about the built-in RFID tag unless they see it read by a healthcare worker. Parker has been very successful embedding RFID tags into small components without altering the size, form factor or appearance of the part.



Why Parker?

Parker's Composite Sealing Systems Division, part of the Parker Engineered Materials Group, can help you fast track your FDA UDI compliance for molded polymer medical devices:

- Leverage Parker's patented polymer fabrication technology for embedding RFID tags directly into your devices' plastic materials.
- Quickly re-engineer existing molded polymer components to include built-in RFID UDI technology.
- Jump start new product development by working directly with Parker Medical Systems Division — from the earliest device concept to high-volume component production.
- Ensure both polymer and RFID performance as you investigate new or modified thermoset elastomers and thermoplastics for your devices.
- Improve your medical device lifecycle management: Achieve UDI compliance while offering expanded

data utilization opportunities for your planning, production and distribution, as well as for your healthcare customers' real-time tracking, locating and inventorying of your medical devices.

More Information

For additional details on Parker's capabilities to build RFID UDI compliance directly into your medical plastics, contact:

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BUL CSS 22744 rev. 2022-04



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