UNIQUE DEVICE IDENTIFIER (UDI)

FOR NON-STERILE AND REUSABLE DEVICES

Overview

The Food and Drug Administration (FDA) requires a unique device identifier (UDI) to ensure medical devices have traceability to the manufacturer. The goal is to identify all medical devices and maintain the traceability through all steps of the supply chain down to distribution and use. Device identifiers (device model) and production identifiers (lot or batches) are the inputs in creating a UDI.

For more information and for the full text of the rule, visit the FDA's web site: *This is a shortened link* - **https://bit.ly/3zNutte**

UDI is comprised of the Device Identifier (DI) and may include a Production Identifier (PI):

Understanding a HIBCC formatted UDI

Captiva Spine manages unique device identifier requirements following Health Industry Business Communications Council (HIBCC). HIBCC is a data standards organization that regulates many standards across industries, such as UPCs in grocery stores or ISBNs on books. The FDA accredited HIBCC is an issuing agency to assign unique device identifiers (UDIs) for medical devices. The standards organizations provide UDI formats and establishes requirements for how the barcodes containing those UDIs appear on packaging.

For more information on HIBBC, visit the following web site: *This is a shortened link* - **https://bit.ly/3cXnghn**

CAPTIVA SPINE AND UDI

Do Captiva Spine products meet UDI requirements?

Captiva Spine implemented operational requirements to meet UDI requirements successfully.

Sterile devices contain UDI marking on the labeling throughout the packaging.

Non-sterile and reusable devices have direct UDI marking on the device when space is available and UDI on the package label.

Where can I find UDI for Captiva Spine products?

To find UDI on our product label for packaged non-sterile devices, packaged reusable devices, and packaged sterile devices look below the scannable 1D barcode (1) or adjacent to the scannable 2D barcode (2).

In addition to product labeling, UDI is marked directly on our non-sterile and reusable devices (3).

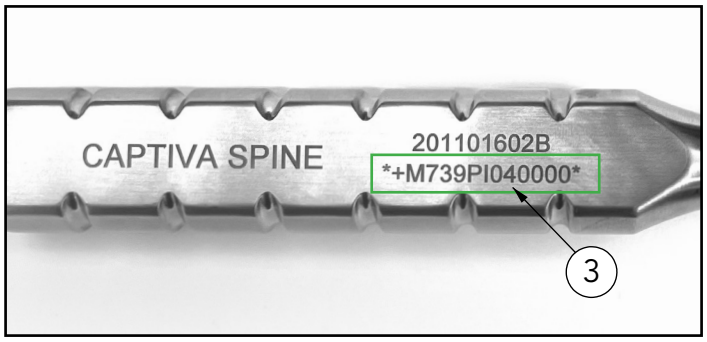
If you discover a distributed non-sterile or reusable device without UDI marking or the packaging with label, you can reference the part number within the United States FDA GUDID database.

See page 3 for instructions.

Examples of a UDI marking on sterile implant package, instrument label, and physical device.

Sterile Device Package

Reusable Device Label



Direct Marking - Reusable Device

How do I locate UDI for non-sterile or reusable devices through GUDID (Global Unique Device Identification Database)?

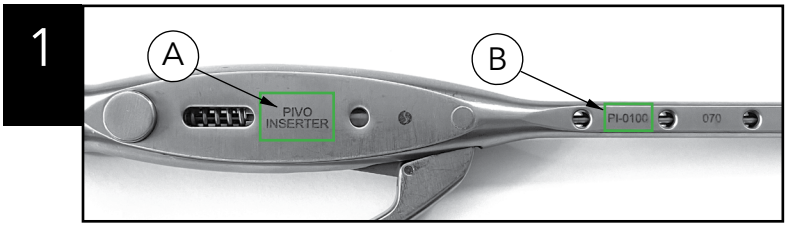
Non-sterile and reusable devices have markings for identification (part number, description, etc.). UDI can be obtained from these markings by following the steps outlined below.

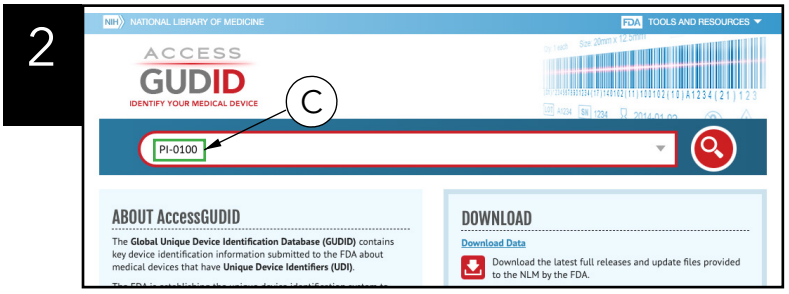
1. Locate the description (A) and/or part number (B) marked on the non-sterile or reusable device.

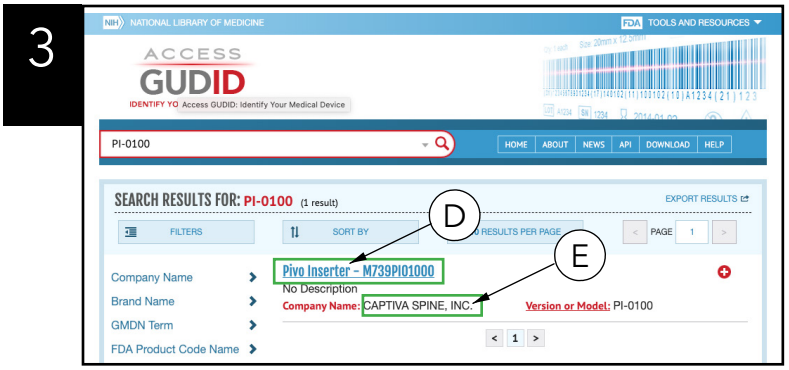
2. Visit the "***Access GUDID***" website: *This is a shortened link* - **https://bit.ly/3SgliHS** and enter the part number in the search bar (C) and hit enter.

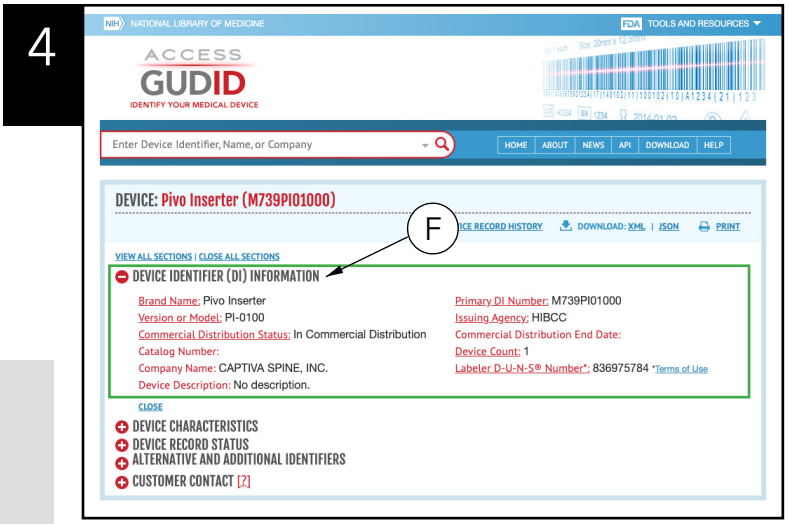
3. Review the search results. Confirm the part description matches (D) and the company name indicated is Captiva Spine (E) and then click on the part description for the device specifications (D).

4. UDI (Primary DI Number) and additional device information is displayed on the default view (F). Further device information may be obtained by clicking on the plus (+) symbols to expand the fields.









Email questions to **service@captivaspine.com** or speak with a Customer Service Agent direct at **561-277-9480 ext: 700.**

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