

## Determining UDI Information from Product Labeling without UDI Barcode

Dear End User:

In line with FDA's requirements for including Unique Device Identification (UDI) information on medical device labeling and products, DJO Surgical has been meeting this requirement since Q4 2015. This compliance includes barcode labeling and submitting required information to FDA's GUDID system.

However, there may be some products currently in distribution that were put into the market prior to the initiation of the UDI process. In line with FDA's communication, UDI-A170001, the following information provides an overview on how to determine the UDI information from the labeling that does not have the barcode.

The DJO Surgical UDI information includes the following elements:

- Product Brand
- Device part number
- Description
- Device lot number
- Expiration Date
- Single Use

As noted on the following page, this same information can be determined from the product package.

If you have any questions, or require additional instructions, please contact Teffany Hutto, Manager, Regulatory Affairs at 512-834-6255 or at [teffany.hutto@djoglobal.com](mailto:teffany.hutto@djoglobal.com)

### Outer Box Labeling

**Product**

TAPERFILL™ HIP SYSTEM

Femoral Hip



Sz 10  
P2 Porous Coated  
STANDARD OFFSET

**Description**

MATERIAL: Ti6Al4V/Ti

In The US, This Device For Cementless Use Only

REF 425-96-010    LOT XXXXXXXXXXXX    QTY 01  
 STERILE R  
 2023-03-21

**Device Part Number**

**Lot Number**

**Expiration Date**

REF 425-96-010    LOT XXXXXXXXXXXX    QTY 01  
 Hüftschaft  
 Tige fémorale  
 Componente femoral  
 Stelo Femorale

EC REP MDSS GmbH  
 Schiffgraben 41  
 30175 Hannover, Germany  
 Sz 10  
 P2 Porous Coated  
 STANDARD OFFSET  
 CE 0086    ⚠    ☔    ⌚ 2023-03-21  
 STERILE R

**Single Use Only**