

IMPLANT CARD INSTRUCTIONS FOR USE

OPRA™ Implant System for Direct Skeletal Anchorage of Amputation Protheses

INSTRUCTION FOR COMPLETION

A. The healthcare institution or provider completes the following information:













1. Name of the patient or patient ID.
2. Name and address of the healthcare institution or provider.
3. Date of implantation.

B. Detach and place sticker on Implant Card. Align the sticker outline with the marked area on the Implant Card (4)

C. The sticker shows the following information:

- 4.1. Device name.
- 4.2. Device type (provided in the accepted language).
- 4.3. Unique device identification (UDI).
 - 4.3.1 UDI-DI: Device Identification Number.
- 4.4. LOT Number.
- 4.5. Serial Number.
- 4.6. Name and address of the manufacturer of the medical device.

The diagram shows an Integrum Implant Card and a sticker. The card has three main input fields: 1 (Name of the patient or patient ID), 2 (Name and address of the healthcare institution or provider), and 3 (Date of implantation). Below these fields, it lists the implant material: Titanium Alloy Grade 5, with 6% aluminum, 4% vanadium, 0.25% (maximum) iron, 0.2% (maximum) oxygen, and 89.55% titanium. The website www.integrum.se/sscp is also provided. The sticker, labeled '4', contains the following information: OPRA™ Implant System (4.1), REF 1800 (4.2), Fixture BioHelix 17,5x80 (4.2), UDI (4.3), and manufacturer information: Integrum AB, Gemenskapens gata 9, 431 53 Mölndal, SWEDEN, www.integrum.se (4.6). The sticker also includes a barcode for the UDI-DI (4.3.1) with the number 0730152100207, and another barcode for the UDI-PI with the number (10)P10543(21)I1234(17)250331. The LOT number is P10543 (4.4) and the SN is I1234 (4.5). The vertical text 012 123-00 is also visible on the sticker.

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|---|---|
|  | Patient name or patient ID |
|  | Name and address of the implanting healthcare institution or provider |
|  | Date of implantation |
|  | Device name |
|  | Manufacturer |
|  | Information website for patients |
|  | Serial number |
|  | LOT Number |
|  | Reference number |
|  | <div style="text-align: center;">  <p>UDI-DI</p>  <p>UDI-PI</p> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> Unique device identification number UDI-DI: Device identification number UDI-PI: Device production number </div> |

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