

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. Patient name (with a person icon), 2. Provider name and address (with a person and plus icon), and 3. Date of implantation (with a calendar icon). Below these fields, the implant material is listed: 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: 4.1. Device name: OPRA™ Implant System; 4.2. Device type: Fixture BioHelix 17,5x80; 4.3. UDI: (10)P10543(21)1234(17)250331, with a barcode for the UDI-DI (0730152100207) labeled 4.3.1; 4.4. LOT Number: P10543; 4.5. Serial Number: 11234; 4.6. Manufacturer: Integrum AB, Gemenskapens gata 9, 431 53 Mölndal, SWEDEN, www.integrum.se. The sticker also includes a vertical barcode (011 152-XX).

	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 gray; padding: 5px; margin-top: 10px;"> Unique device identification number UDI-DI: Device identification number UDI-PI: Device production number </div>

INTEGRUM AB

Gemenskapens gata 9
SE-431 53 Mölndal, Sweden
PHONE: +46 (0)31-760 10 60
E-MAIL: info@integrum.se
WEBSITE: www.integrum.se

INTEGRUM

100 Montgomery Street, Suite 1780
USA, San Francisco, CA 94104
PHONE: +1 (800) 805-8073
E-MAIL: info-us@integrum.se
WEBSITE: www.integrum.se

