

IMPLANT CARD INSTRUCTIONS FOR USE

OPRA™ Implant System for Direct Skeletal Anchorage of Amputation Protheses



INSTRUCTION FOR COMPLETION











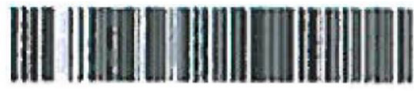
To be filled by the healthcare institution/provider

1. Name of the patient/ patient ID.
2. Name and address of the healthcare institution/provider.
3. Date of implantation.
4. Detach and place sticker on Implant Card. It is important that sticker outline is aligned with marked area on the Implant Card.
 - 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. Serial Number.
 - 4.5. Name and address of the manufacturer of the medical device.

The diagram shows an Integrum Implant Card with the following fields and sections:

- 1:** Patient name field, next to a person icon and a question mark.
- 2:** Healthcare institution name and address field, next to a person icon with a plus sign.
- 3:** Date of implantation field, next to a calendar icon.
- MD:** Manufacturer Designation field.
- UDI:** Unique Device Identification field.
- SN:** Serial Number field.
- 4:** A large rectangular area on the right side of the card, representing the sticker placement area.
- 4.1:** Device name field, containing "OPRA™ Implant System".
- 4.2:** Device type field, containing "REF 1800 Fixture BioHelix 17,5x80 -12".
- 4.3:** UDI field, containing a barcode and the number "07340152100207".
- 4.3.1:** UDI-DI field, pointing to the top part of the UDI barcode.
- 4.4:** Serial Number field, containing "I 1234".
- 4.5:** Manufacturer name and address field, containing "Integrum AB", "Krokslätts Fabriker 50", "431 37 Mölndal, SWEDEN", and "www.integrum.se".

At the bottom left of the card, there is a laptop icon and the URL: <https://integrum.se/patient-info/>.

	Patient Name or patient ID
	Name and Address of the implanting healthcare institution/provider
	Date of Implantation
	Device Name
	Manufacturer
	Information website for patients
	Serial number
	Reference number
	Unique device identification number UDI - DI: Device Identification number UDI - PI: Device production identification number <div style="text-align: center;">  UDI-DI  UDI-PI </div>

INTEGRUM AB

Kroksläotts Fabriker 50
SE-431 37 Mölndal, Schweden
PHONE: +46 (0)31-760 10 60
E-MAIL: info@integrum.se
WEBSITE: www.integrum.se

INTEGRUM INC

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

