Integrum

Summary of Safety and Clinical Performance (SSCP)

OPRA Implant System

For lay persons

Document revision: 03
Date issued: 2025-May-06

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. ***The information presented below is intended for patients or lay persons.*** *A more extensive summary of the device safety and clinical performance is presented in the Safety and Clinical performance (SSCP) for healthcare professionals.*

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical conditions or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instruction for Use to provide information on the safe use of the device.

1. Device identification and general information

Device trade name(s)	OPRA™ Implant System
Manufacturer's name and address	Integrum AB Gemenskapens gata 9 SE-431 53 Mölndal, Sweden
Manufacturer's single registration number (SRN)	SE-MF-000026900
Basic UDI-DI	73401521oprasystemRW
Medical device name	OPRA Implant EMDN code: P9099
Class of device	IIb (MDR 2017/745 Annex VII – Rule 8)
Year when the device was first CE marked	1999
Authorized representative if applicable; name and SRN	N/A
Validating notified body name (notified body validating SSCP) and notified body's single identification number	BSI Group The Netherlands B.V. NB 2797

Intended use of the device

- Intended purpose
- Indications and intended patient groups
- Contraindications

Intended purpose

The OPRA™ Implant System is implanted directly in the bone. Prostheses can then be attached to the system. OPRA™ is for patients with amputations due to trauma or cancer. Patients who have or might have problems with socket prostheses should use it. OPRA™ should be used by adults whose bones have stopped growing.

Indications and intended patient groups

- Patients with amputations due to trauma or cancer.
- Adult patients whose bones have stopped growing.
- Patients who have problems with socket prostheses, such as:
  - Skin infections and skin problems from the socket

  - Pain
  - A short stump where a socket cannot be used
  - Swelling in the stump
  - Scars on the stump
  - Large skin transplant areas on the stump
  - Sweating under the socket
  - Difficulties to move
- The OPRA™ Implant System for fingers is an alternative to standard finger/thumb prostheses.
- A medical team assesses each patient before suggesting using OPRA™. The team discusses the benefits and risks of the treatment. In the team there is always a surgeon, a prosthetist and a physiotherapist.

Contraindications

- The patient is still growing.
- The patient has an unusual bone anatomy, such as:
- Inborn defects that might affect treatment with OPRA™.
- Deformities, fractures, infections etc.
- The patient has poor bone quality.
- The patient has other problems that might affect treatment, such as:
  - Severe blood circulation problems
  - Diabetes mellitus with complications
  - Skin problems on the stump
  - Nerve problems and severe phantom pain
  - Active infection or inactive bacteria
  - Metabolic bone disease
  - Metastases in the stump
- The patient is pregnant.
- The patient has difficulty to comply with the treatment.
- The patient weighs more than 100 kg / 220 lbs. including the prosthesis. This is only for leg amputations.

2. Device description

The OPRA™ Implant System has a bone anchoring part (Fixture) and a part that goes through the skin (Abutment). The Abutment Screw secures the Abutment to the Fixture.

The Fixture is put in the bone in the first surgery (Stage 1). A healing period follows this. The healing period lasts three to six months. The time can vary with bone quality and amputation level. During this time, the bone grows into the Fixture to fix it to the bone.

The Abutment is fixed to the Fixture in a second surgery (Stage 2). The Abutment Screw locks the Abutment to the Fixture. Figure 1 and Figure 2 show the OPRA™ Implant parts.

Part of the Abutment is outside the skin to connect with the prosthesis.

Figure 3 shows the system on two people.

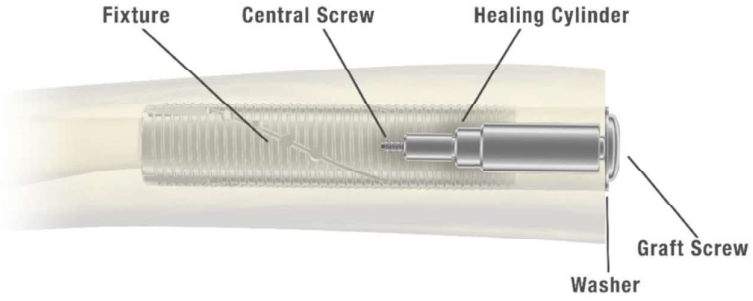


Figure 1. OPRA™ Implant System parts in the bone after the First Surgery (Stage 1).

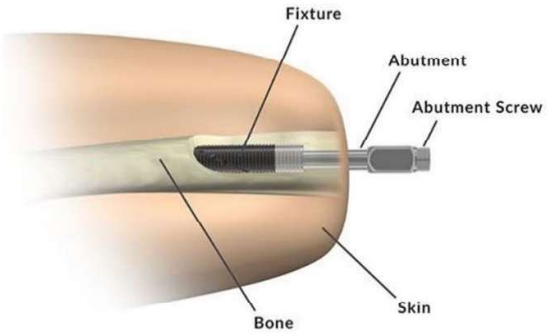


Figure 2. OPRA™ Implant System parts in the bone after Second Surgery (Stage 2).



Figure 3. Left: Shows prosthetic system (Axor II) on a leg. Right: Shows prosthetic system on an arm.

Older versions. Description of differences.	Year	Devices	Nature of change
	1999	OPRA™ Implant parts for use with leg	No change, first launch
	2001	Rotasafe, product for leg	No change, first launch

<table>
<tr><td></td><td>2013</td><td colspan="2">Axor, product for leg – successor to Rotasafe</td><td>No change, first launch</td></tr>
<tr><td></td><td>2014</td><td colspan="2">OPRA Implantable parts for use with leg and digits
OPRA parts for humerus</td><td>Extended application</td></tr>
<tr><td rowspan="8">Description of accessories to use with OPRA™</td><td colspan="4">The accessories below are not supplied with OPRA™</td></tr>
<tr><td colspan="2">Accessory</td><td colspan="2">Description</td></tr>
<tr><td colspan="2">OPRA Connector</td><td colspan="2">The Connector is used during training with a short training prosthesis.</td></tr>
<tr><td colspan="2">OPRA Humerus Training kit</td><td colspan="2">The Humerus training kit is used during rehab.</td></tr>
<tr><td colspan="2">OPRA Abutment Support E</td><td colspan="2">The Abutment Support covers the Abutment after Stage 2 surgery. It helps to keep a low pressure on the soft tissues during healing.</td></tr>
<tr><td colspan="2">OPRA Abutment Support F/G</td><td colspan="2">The Abutment Support covers the Abutment after Stage 2 surgery. It helps to keep a low pressure on the soft tissues during healing.</td></tr>
<tr><td colspan="2">OPRA Soft Tissue Support Pylon II</td><td colspan="2">The Pylon is put around the outside part of the Abutment. Together with the Plate it gives support for the soft tissue. It is used with Axor™ II or OPRA™ Connector.</td></tr>
<tr><td colspan="2">OPRA Soft Tissue Support Plate Small</td><td colspan="2">The Soft Tissue Support Plate is put on top of the Pylon. It gives support for soft tissue.</td></tr>
<tr><td colspan="2">OPRA Soft Tissue Support Plate Large</td><td colspan="2">The Soft Tissue Support Plate is put on top of the Pylon. It gives support for soft tissue.</td></tr>
<tr><td>Other products to use with OPRA™</td><td colspan="4">OPRA™ Implant System is used with external prosthesis
For femur use with:
• non-microprocessor controlled prosthetic knees and
• microprocessor controlled prosthetic knees that are not powered
For fingers: used with custom made cosmetic covers
For Humerus: used with upper arm prostheses.</td></tr>
</table>

Material structure

Implant material: Titanium Alloy Grade 5.

6% Aluminum, 4% Vanadium, 0.25% (maximum) Iron, 0.2% (maximum) Oxygen and 89.55% Titanium.

3. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks.

This document is not intended to replace a consultation with your healthcare professional if needed.

How potential risk have been controlled or managed

In Instructions For Use and Patient Information, there is information on:

- how to use the OPRA™ Implant System
- how to remove or reduce risk of problems

Remaining risks and undesirable effects

OPRA™ risks have been reduced as far as possible. The benefit of using the product exceeds the risk.
The risks that remain are listed below.

- Low level superficial infection
- Deep infection
- Fixture removal
- Mechanical problems, such as:
  - screw loosening
  - damage and bending of the Abutment and/or Abutment Screw.
- Axor II problems such as wear and attachment issues

How to remove or reduce risks:

For leg amputations

- Low level infection – careful regular cleaning, antibiotics.
- Deep infection – antibiotics.
- Mechanical problems with Abutment/Abutment Screw.
  - Bending or fracture – replace Abutment and/or Abutment Screw.
  - Wear – replace Abutment with a larger Abutment.
- Pain, due to:
  - Infection – careful regular cleaning, antibiotic treatment.
  - Loading – temporary reduce loading, pause training.
  - Severe and lasting pain – removal of Abutment. If pain continues – removal of Fixture.
- Loose or fractured Fixture – X-ray and, removal of Fixture.
- Removed Fixture – replacement with new Fixture after healing. A socket prosthesis can be used if no Fixture replacement.

For arm and finger/thumb amputation level

- Low level infection – careful regular cleaning, antibiotics.
- Deep infection – antibiotics.
- Mechanical problems due to:
  - Loose Abutment Screw – Retightening of Abutment Screw.
  - Bending or fracture of Abutment and/or Abutment Screw – replace Abutment or Abutment Screw.
  - Wear – Exchange of Abutment to a larger Abutment.

- Severe and lasting pain – removal of Abutment. If pain continues – removal of Fixture.
- Skeletal fracture – treatment according to routines for skeletal fractures.
- Loose or fractured Fixture – X-ray followed by removal of the Fixture. A new Fixture can be placed after the site has healed completely. A socket prosthesis can be used if no replacement is performed.
- Suspected overload – Stop using external prosthesis. Do not load the implant until pain free.

Warnings and precautions

Warnings

- The OPRA™ components are for one person use only
- Smoking is bad for bone osseointegration
- Healing problems can occur in obese patients
- Patients with the OPRA™ should have antibiotics before surgery
- Rule out ongoing infections. This is especially important for patients with prior infections
- Joint problems (also joints of the opposite side) may affect treatment results
- The following drugs may cause Fixture loosening:
  - Steroids for systemic use
  - Chemotherapy agents
- Do not use the following drugs during the first year of treatment:
  - NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) and ASA (Acetylic Salicylic Acid) two weeks before surgery and for long-term use after surgery
  - Bisphosphonates
  - Other drugs that might affect bone remodeling.

MRI Safety Information

- MRI scans are safe if:
  - Static Magnetic field is 1.5 or 3.0 T
  - Maximum spatial field gradient is 4500 gauss/cm (45 T/m)
- It is likely that the MR protocols show smaller artifacts
- This applies for all levels (leg, arm, and finger)
- For fingers: If possible, place the hand with the implant outside the RF sending coil, or if not, use padding to increase the distance to the bore wall (RF body coil)

Precautions

- If bone quality is poor go slowly with rehab
- Select prosthesis components to reduce the risk of overloading the implant system.
- Inspect parts for cracks and signs of wear. Signs of wear include dark colouring of secretion or tissue.
- The healthcare professional should tell the patient to:
  - Properly attach the prosthesis
  - Never use any tools on the device. This can damage the device.
  - Protect the Abutment from heat or cold. Wrap a wet towel around the Abutment to protect it from heat in the sauna.
  - Take care to not injure themselves or others with the Abutment.
- It is recommended to change the Abutment if:
  - There is movement in the joint between the Fixture and Abutment.

  - Dark-coloured secretion occurs
  - Abutment bends or other mechanical problems are suspected.
- For leg amputations, extra safety measures apply:
  - The Abutment Screw should only be retightened by health care professionals.
  - The Axor™ II device releases if overloaded. For more information, see the OPRA™ Axor™ II Instructions For Use.
  - OPRA™ is for activities of daily living such as: sitting, standing, and walking. The patient should avoid activities such as climbing, running, and jumping. Big forces can damage the system.
  - The patient should protect the Abutment during sleep. The prosthetist can provide a cover.
  - The patient should always use a cane or crutches for longer walks. The patient should never lift or carry heavy items.
  - When riding a bike, the patient's knee might lock in the straight position. This can seriously damage the Fixture. Always position the bike seat low enough the artificial knee does not fully straighten. Never stand up while cycling.
- For arm and finger amputations, some extra precautions apply:
  - Rehab pace should be adapted to each patient.
  - Bone quality is important to judge healing conditions.
  - Stop loading OPRA™ if pain or other discomfort occurs.

4. Summary of clinical evaluation and post-market clinical follow-up

Clinical background of the device

In the 1960s P-I Brånemark found that bones can bond with titanium. In 1977 he named this process osseointegration.

Osseointegration was initially used for dental implants, and it is since many decades a well-established treatment option for missing teeth.

The OPRA™ Implant System uses the same technology as the dental implants. It has been in use since 1990 and has been proven in multiple clinical studies in both upper and lower limbs. Around 1100 Fixtures have been implanted to date.

See also section 3; device description.

There have been several design changes over the years but the modular structure has been maintained.

Year	Device(s)	Nature of change
1999	OPRA implantable components (for transfemoral applications; Fixture Abutment, Abutment Screw, Healing Cylinder)	Launch to the market
2001	Rotasafe, Prosthetic component for transfemoral applications	No change, initial launch to the market
2013	Axor, prosthetic component for transfemoral application, - successor of Rotasafe	No change, initial launch to market
2014	OPRA Implantable components for transhumeral and digits indications	Extended application
2024	AXOR II Guide component	Design Change

Clinical evidence for CE-marking

Below, you find clinical study results on safety and performance of the system.

There are no study reports in Eudamed.

The OPRA study was published in 2014. This study started in 1999 and ended in 2007. 51 patients took part. The patients received an OPRA™ implant. They were then followed for 2 years. The study measured how well OPRA performs and if there were any side effects or problems with the device. The patients increased their use of the prosthesis, improved their mobility, and they had fewer problems. Quality of life and physical function improved.

4 implants were removed, 1 due to deep infection.

This and other studies show that patients who cannot use their socket prostheses can use the OPRA™ Implant System. OPRA™ Implant System improves function, quality of life, and helps patients return to activities of daily life. See list of main published studies below (newest publication first).

	Author of study, year	**Study information**	**Results**
1	BK Potter *et al.,* 2025	41 femur amputee patients treated with OPRA and followed for 2 years after surgery. The patients reported on outcomes. Complications were registered.	Increase in use of prosthesis. Mobility improved. Physical function improved. Superficial infections were common, they could be treated with antibiotics only. Deep infections were uncommon.
2	Forsberg J *et al.,* 2025	12 patients with upper arm amputations treated with OPRA™ Implant System and followed for 2 years after stage 2 surgery. The patients reported on outcomes. Complications were registered.	Prosthetic use increased, and the function of the arm in daily life improved. No infections were recorded.
3	Thouvenin *et al.,* 2023	14 femur patients 3 tibia patients Follow up 1-15 years	Increase in use of prosthesis. Mobility improved. Problems were reduced. 2 Fixture were removed. 2 patients had deep infections
4	Ranaldi *et al.,* 2023	3 groups: 9 able-bodied participants, 8 patients with socket prostheses. 9 patients with osseointegrated prostheses Walking abilities were evaluated	Osseointegrated and socket prostheses restored gait parameters to a similar degree.
5	Hagberg *et al.,* 2022	10 years follow up of the OPRA study patients 51 patients, 55 implants.	Increased use of prosthesis, improved mobility, reduced problems. Improved Quality of life. 8 implants were removed, 3 deep infections, 1 bone fracture
6	Hagberg *et al.,* 2021	62 answerers in a cross-sectional survey	81% find the implanted components reliable 77 % think the OPRA™ Implant System is safe
7	Hagberg *et al.,* 2020	Follow-up of OPRA transfemoral patients up to 15 years after stage 2 surgery. 111 patients.	Significantly more prosthetic use, better mobility, fewer problems and an improved overall situation. 89 % of the implants were still in place after 7 years and 72 % after 15 years. 11 removed implants, 1 fixture fracture, 6 deep infections. 55% of patients had Abutment and Abutment Screw changes over time, and the need for change was related to physical activity.
8	Li *et al.,* 2019	Follow up of 13 thumb OPRA patients.	Grip strength was 70% compared to the normal hand. Hand function was 94% of the function in the normal hand. Patients could put thumb and finger together and feel tactile sensation. 5 patients had superficial infections.1 deep infection

9	Matthews *et al.*, 2019	United Kingdom study in 18 transfemoral patients. At least 9 years follow-up	5 implants removed, all due to infection. 2 additional deep infections and 11 superficial infections, successfully treated with antibiotics.
10	Stenlund *et al.*	11 upper arm amputees. Load levels during specific movements	Load levels vary significantly in daily life activities
11	Hagberg *et al.*, 2018	Describes rehabilitation experience in 12 OPRA treated patients	At baseline: 8 patients mainly used wheelchairs. 12 had problems with sitting comfort At 5 years follow up: 5 mainly used wheelchairs 3 walked unsupported without crutches 7 had no problems with sitting comfort.
12	Brånemark *et al.*, 2018	Swedish experience with transfemoral OPRA. 51 patients, 55 amputations. 5 years follow up.	Implants still in place after 5 years was 92%. 34 patients had superficial infections. 11 patients had deep infections. 15 patients had mechanical complications. 4 fixtures were removed (i.e., one deep infection and three loosening). Significant improvements including more use of the prosthesis, better mobility, fewer issues, and improved physical health-related quality of life compared with baseline.
13	Brånemark *et al.*, 2014	The OPRA study: 51 patients, 55 implants 2 year follow up.	Increased prosthetic use, improved mobility, reduced problems. Improved Health related quality of life. Improved physical function. 4 fixtures were removed, 1 due to deep infection.
14	Tsikandylakis *et al.*, 2014	18 upper arm amputees 5 years follow up	83 fixtures still in place at 2 years, 80% at 5 years. 5 patients had superficial infections 1 dep infection.
15	Hagberg, 2014	39 patients transfemoral 2 years follow up	Two years after OPRA implantation, important improvements in prosthetic function and physical quality of life. No change in walking aids used or phantom limb pain.
16	Jönsson *et al.*, 2011	37 patients treated in upper extremities. 16 transhumeral, 10 transradial, 10 thumbs 1 partial hand.	Function and quality of life improved since osseointegration treatment.
17	Lundberg *et al.*, 2011	13 patients. The study aim was to improve understanding experience of living with an osseointegrated prosthesis.	All patients described living with an osseointegrated prosthesis as a revolutionary change. Improvement went beyond the functional improvement as such.
18	Tranberg *et al.*, 2011	Assess the first 19 patients in the OPRA study after 2 years follow up.	Hip extension improved on the amputated side.
19	Hagberg *et al.*, 2008	Assess changes in general condition and health-related quality of life 2 years after OPRA surgery.	Both Quality of life and function improved significantly.
20	Hagberg *et al.*, 2005	Assess hip joint motion and uncomfortable sitting compared to individuals using a socket prosthesis.	Hip motion is better with osseointegrated implants as well as sitting comfort.
21	Jacobs *et al.*, 2000	Gain more insight into osseoperception (the ability to perceive tactile sensation via the implant). 32 patients, 16 upper limb and 16 lower limb amputees Somatosensory feedback from the amputated side was measured.	Bone anchored prostheses had significantly lower thresholds for vibratory stimulation than socket prostheses.

The studies show that patients who cannot use their socket prostheses can use OPRA successfully. There are improvements in function, quality of life, and return to activity.

Safety

The company follows how well the OPRA works. This is done using:

- data from clinical studies
- scientific writing
- reports on side effects and other problems
- Post Market Clinical follow up activities/studies (activities that are performed after the launch of the device to the market(s)

Description of Post Market Clinical Follow Up activity	Objective	Timelines / completion date
Scientific Literature Review: Analyze clinical data from various sources	Collect any new information on device safety and performance	Annual
Adverse Events Reports: Collect serious adverse event reports from all markets	Analyse adverse events from case report	On-going, following receipt of an adverse incident report
Registry Studies: Gather data from ongoing transfemoral registry studies in the USA	Confirm safety and performance of OPRA® Implant System	On-going until study completion
Long-term Follow-up: Conduct post-market follow-up of transhumeral patients for 6 months to over 20 years	Collect and evaluate clinical data on safety and performance	Completion estimated in 2025
Prosthetist Survey: Survey 10 prosthetists with experience using Axor, focusing on the new Axor II Guide	**Feedback on Guide**: Collect opinions from patients and prosthetists about the new Guide **Focus Areas**: Ease of donning, correct alignment, and comparison with the old version	Completion estimated in 2025
Regular PMS Follow-up: Monitor sales and complaints for implantable components, healing components and plus-size abutments, noting low sales and few complaints for these components, data on at least 100 devices /data collected for 3 years is needed.	**Safety and Performance**: Gather new information and compare with previous versions Traceability is available per component. compare with previous version.	Annually, until data on at least 100 devices /data collected during 3 years
PMCF Report: Preparation of PMCF report	Conclusion from post-market activities Analyze findings. Update technical documentation including hazard analysis Determine any preventive and/or corrective measures	Yearly

Scientific Work is always done to make sure risks are as low as possible

Benefit-Risk assessment

Data from OPRA clinical studies show benefits:

- Improved hip joint movement
- Increased prosthetic use, function, and mobility
- Better quality of life
- Fewer soft tissue problems
- No fitting issues due to stump volume changes
- Easy attachment/removal of the prosthesis

Most common risks:

- Superficial infections (manageable with antibiotics)
- Rare deep infections (manageable with antibiotics and debridement)
- Mechanical issues (mainly abutment/screw changes, outpatient procedure)

Conclusion: The benefits of the OPRA™ Implant System outweigh the risks, improving comfort, function, and quality of life. Risks can be managed with proper care and rehabilitation

5. Diagnostic or therapeutic alternatives

When thinking about other treatments, you should contact your health care professional who can review your individual situation.

General description of therapeutic alternatives

There are two options:

- Socket prostheses
- Other bone anchored systems

Socket prostheses hold the stump and allow attachment of a prosthesis. This is the most common type of prosthesis. The most common problem with socket prostheses is poor attachment. Skin and soft tissue problems are also common.

There are three other types of bone anchored systems. Most systems use 2-stage surgery. The bone-anchored part is implanted in the first surgery and the skin penetrating part is implanted in a second surgery. One system (OPL) is often implanted in a single surgery. Infections are the most common side effects.

Bone anchored systems, like OPRA™ have benefits over socket prostheses. They work better, so Quality of Life is better.

6. Revision History

Rev	Change Description	Date	Revision validated by the Notified body
00	Initial version including BSI's comments on drafts	01 April 2023	× Yes Validation language: English ☐ No (only applicable to class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which SSCP not yet validated by notified body)
01	Update of the company address (page 1 and 42)	16 Jan 2023	× Yes Validation language: English ☐ No (only applicable to class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which SSCP not yet validated by notified body)
02	Update with clarification to the description of accessories	19 Aug 2024	× Yes Validation language: English ☐ No (only applicable to class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which SSCP not yet validated by notified body)
03	Update lay person's section with OPRA™ Implant System publications, section 5, benefit -risk assessment and PMCF activities	30 April 2025	× Yes Validation language: English ☐ No (only applicable to class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which SSCP not yet validated by notified body)