Summary of safety and clinical performance (SSCP)

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Revision 2

02-10-2024

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.

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 to use OPRA™. The team discusses 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.

Device description

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 a 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.

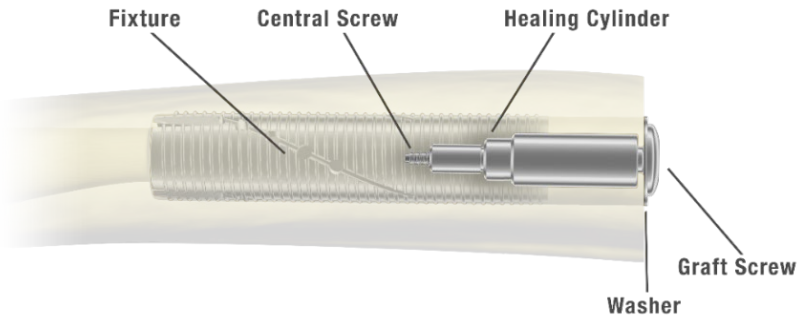

Figure 1. OPRA™ Implant System parts in the bone after the First Surgery (Stage 1).

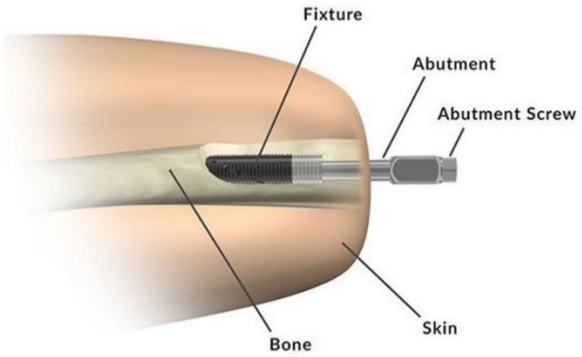

Figure 2. OPRA™ Implant System parts in the bone after Second Surgery (Stage 2).

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

<table>
<tr><td rowspan="5">Older versions. Description of differences.</td><td>Year</td><td>Devices</td><td>Nature of change</td></tr>
<tr><td>1999</td><td>OPRA™ Implant parts for use with leg</td><td>No change, first launch</td></tr>
<tr><td>2001</td><td>Rotasafe, product for leg</td><td>No change, first launch</td></tr>
<tr><td>2013</td><td>Axor, product for leg – successor to Rotasafe</td><td>No change, first launch</td></tr>
<tr><td>2014</td><td>OPRA Implantable parts for use with leg and digits
OPRA parts for humerus</td><td>Extended application</td></tr>
<tr><td rowspan="5">Description of accessories to use with OPRA™</td><td colspan="3">The accessories below are not supplied with OPRA™.</td></tr>
<tr><td colspan="2">Accessory</td><td>Description</td></tr>
<tr><td colspan="2">OPRA Connector</td><td>The Connector is used during training with a short training prosthesis.</td></tr>
<tr><td colspan="2">OPRA Humerus Training kit</td><td>The Humerus training kit is used during rehab.</td></tr>
<tr><td colspan="2">OPRA Abutment Support E</td><td>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>
</table>

	OPRA Abutment Support F/G	The Abutment Support covers the Abutment after Stage 2 surgery. It helps to keep a low pressure on the soft tissues during healing.
	OPRA Soft Tissue Support Pylon II	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.
	OPRA Soft Tissue Support Plate Small	The Soft Tissue Support Plate is put on top of the Pylon. It gives support for soft tissue.
	OPRA Soft Tissue Support Plate Large	The Soft Tissue Support Plate is put on top of the Pylon. It gives support for soft tissue.
Other products to use with OPRA™	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.	

Material structure

Implant material: Titanium Alloy Grade 5.

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

Risks and warnings

Contact your healthcare professional if you believe that you are 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 the product exceeds the risk.
The risks that remain are listed below.

- Low level 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
  - 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 join 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.

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 finding osseointegration.
Osseointegration bonds titanium implants to bone.
OPRA™ is made using lots of research and experience. More than 500 surgeries have been done.

Clinical evidence for CE-marking

The company has done clinical studies to assess the safety and performance of the system. The OPRA study was a study on the OPRA™ Implant System. This started in 1999 and ended in 2007. 51 patients took part. The patients received an OPRA™ implant. The patients were rehabilitated and then followed for 2 years. The study measured how well OPRA works and if there were any side effects or problems with the device. OPRA™ was used according to instructions.

This and other 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:

Description of activity	Objective	Rationale	Timelines / completion date
Review of scientific literature and other sources of clinical data	Collect any new information on device safety and performance	Establish safety and performance of	Yearly

Description of activity	Objective	Rationale	Timelines / completion date
		OPRA™ Implant System Review of state-of-the-art and advances in medical practice, surgical options and prosthetic limb technology	
Gather information on serious side effects from all markets where OPRA Implant System is sold	Analyse adverse incidents from case report	Establish safety of OPRA™ Implant System	On-going, following receipt of an adverse incident report
Collect data in a registry from patients implanted with OPRA Implant System on transfemoral level	Long term follow up of transfemoral patients. Follow-up time 5 years. (	Confirm safety and performance of OPRA™ Implant System	On-going until study completion
Collect data in a registry from patients implanted with OPRA Implant System on transhumeral level	Long-term follow-up of transhumeral patients Follow-up time of from 6 months to >20 years	Collect and evaluate clinical data on safety and performance for OPRA Implant System at Transhumeral amputation level, and within the scope of normal use.	Completion estimated in 2025
Survey to 10 prosthetists (N.B. previous experience with Axor is required) who provide patients with the new Axor II Guide.	Collect information on how the patients and prosthetists perceive the addition of the Guide in terms of ease of donning, ability to achieve correct alignment, and if they	New Guide added to the Axor II component of the OPRA Implant System to help with positioning	Completion estimated in 2025

Description of activity	Objective	Rationale	Timelines / completion date
	find the new version better or worse than the old one.	during donning. Does not affect safety or performance	
Preparation of Post Market Clinical Follow-Up report	Analysis and presentation of collected data	Conclusion from post-market activities Analyse findings and update technical documentation including risks Determine any preventive and/or corrective measures	Yearly

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

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.

Revision History

Rev	Change Description	Issuer	Date	Revision validated by the Notified body
00	Initial version including BSI's comments on drafts	JK	04-01-2023	× 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)	JK	16-01-2023	× 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	Clarification to the description of accessories. Feedback from BSI regarding PMCF activities incorporated, date format and page numbering added.	KG	02-10-2024	× 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)