FO 42503 Summary of Safety and Clinical Performance

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1	25/03/2026	Initial version	☐ Yes Validation language: EN ☒ No

As a Class III implantable devices, the Summary of Safety and Clinical Performances is reviewed annually together with the Clinical Evaluation and the PMCF reports.

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Abbreviations

ACIF – Anterior Cervical Interbody Fusion
DDD – Degenerative Disc Disease
TSC – Titanium Sputter Coat

Summary of safety and clinical performance for users and healthcare professionals

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 Orthobion ACIF cages. The SSCP is reviewed annually together with the Clinical Evaluation and the PMCF reports.

The SSCP is not intended to replace the instructions for use as the main document to ensure the safe use of the Orthobion ACIF cages, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1 Device identification and general information

1.1 Device trade name(s)

Cervical interbody fusion cage:

- TSC ACIF Domed
- TSC ACIF Lordotic

1.2 Manufacturer's name and address

Name – Orthobion GmbH
Address – Gottlieb-Daimler-Str.5, 78467 Konstanz, Germany

1.3 Manufacturer's single registration number (SRN)

DE-MF-000005797

1.4 Basic UDI-DI

Product name	Basic UDI-DI
TSC ACIF Domed	4050762OrthSpacerGroup45
TSC ACIF Lordotic	

1.5 Medical device nomenclature description / text

Product name	EMDN code	EMDN Category description
TSC ACIF Domed	P09070101	Spinal cages
TSC ACIF Lordotic		

1.6 Class of device

The Orthobion ACIF cages are Class III medical devices per Rule 8 of Annex VIII of Regulation (EU) 2017/745.

1.7 Year when the first certificate (CE) was issued covering the device

25 September 2012

1.8 Authorised representative if applicable; name and the SRN

Not Applicable

1.9 Notified Body

TÜV NORD CERT GmbH
Genovevastraße 5, 51065 Köln,Germany
CE0044

2 Intended use of the device

2.1 Intended purpose

The Orthobion ACIF spacer group is intended for surgical treatment of the cervical spine. The Orthobion cervical cages are intended for use patients with degenerative disc diseases (DDD) or levels C2-C5 instabilities.

DDD is defined by:

- Radiculopathy and/or
- Myelopathy and/or
- Disc herniation and/or
- Osteophytes
- Root or spinal cord compression

2.2 Indication(s) and target population(s)

The Orthobion cervical is intended for use, in skeletally mature patients, with DDD or levels C2-C5 instabilities. These cages are not intended for use, in either paediatric cases, or where the patient still has general skeletal growth and skeletal system is not fully grown

2.3 Contraindications and/or limitations

The following contraindications have been identified for the ACIF cages:

- The Orthobion cervical interbody cage is contra-indicated for any lumbar/posterior surgical transplantation.
- Any case not described in the above described indications for ACIF
- Congenital abnormalities
- Presence of spinal tumours
- Elevation of sedimentation rate unexplained by other diseases
- Elevation of white blood cell count
- Patients with inadequate tissue coverage over the operative site
- Patients having inadequate bone stock, bone quality, or anatomical definition.
- Patients unwilling to follow postoperative instructions.
- Fever or leukocytosis
- Local, Spinal Infections at index level
- Patients suffering from mental illness
- Morbid obesity
- Pregnancy
- Cancer
- Smoking
- Alcoholism or drug addiction/abuse
- Spinal fractures
- Rapid joint disease, bone adsorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Signs of local inflammation
- Suspected or documented metal allergy or intolerance
- Paediatric patients, where the patient has limited to no skeletal growth

3 Device description

The device in question is the Orthobion ACIF Spacer Group. It is intended for surgical treatment of the cervical spine. Following Orthobion Cervical Spacer Group has been considered:

- Titanium Sputter Coated ACIF with Tantalum Marker
- Titanium Sputter Coated domed ACIF with Tantalum Marker
- Titanium Sputter Coated domed ACIF with Tantalum Marker

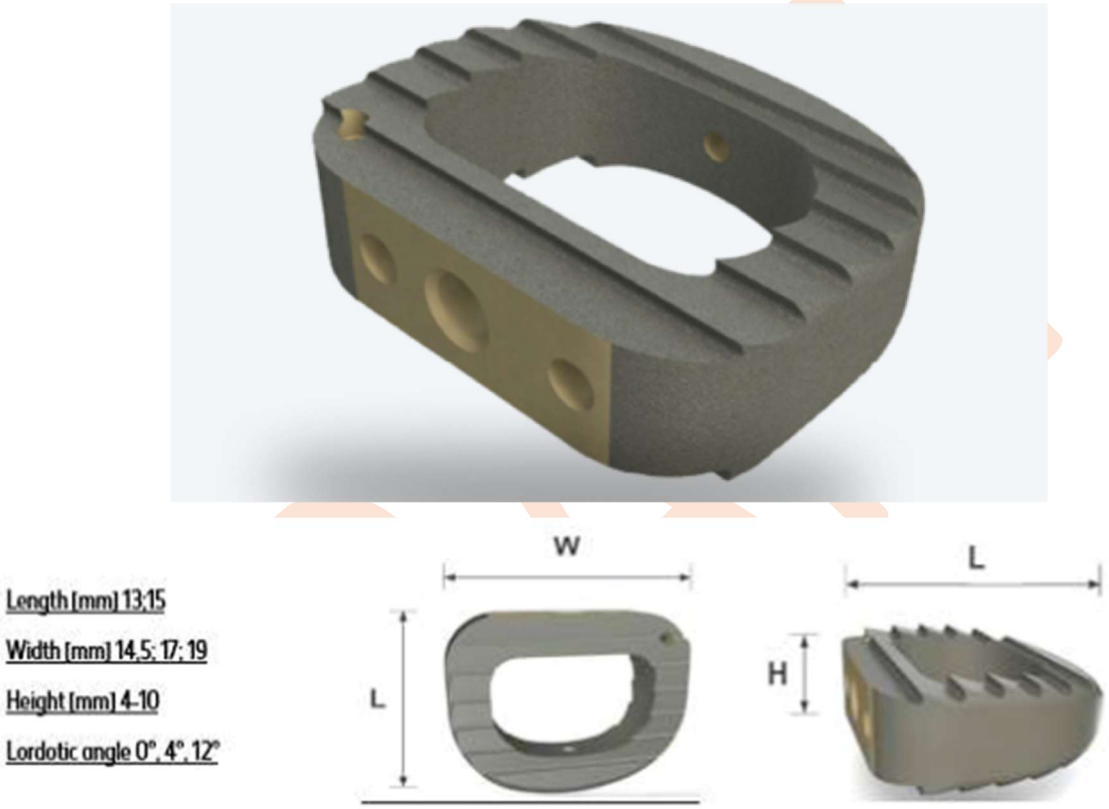
Operating principles: Cervical degenerative disc disease (CDDD) is a common and debilitating condition that can initially be managed conservatively. If non-surgical treatments fail, anterior cervical discectomy and fusion

(ACDF) is a well-established surgical option. ACDF involves removing the affected disc and facilitating intervertebral fusion using the interbody cage with or without an anterior plate construct (APC).

Key functional elements: The Orthobion cervical interbody cage consists of a Titanium Sputter Coated PEEK cage – with tantalum marker or titanium marker. The Orthobion ACIF cages are gamma sterilized and packed in in two blisters to obtain a safe sterilization. They are single use.

Mode of action: The objective is to restore the normal height of intervertebral space and cervical lordosis through the implantation of cervical interbody fusion cage. The Orthobion ACIF cages are designed to assist in providing an adequate biomechanical environment for fusion and can be used with an autogenous source bone graft, iliac crest, or other chosen material at the preference of the physician.

Figure 1 Schematic representation of Orthobion ACIF



3.1 Previous generation(s) or variants

Not applicable

3.2 Accessories intended to be used in combination with the device

Dedicated surgical instruments are provided to handle the cage and help surgeon in placing the cage. Trial cages are also provided to help surgeon in the selection of the appropriate cage design.

ACIF
Direct connection: 99.009 Inserter ACIF 99.026 ACIF Inserter Thread
99.011 Trial Cage Inserter 99.170 – 99.185 Trial Cages

3.3 Devices and products intended to be used in combination with the device

Not applicable

4 Risks and warnings

Orthobion GmbH performed comprehensive risk assessments in conformance with EN ISO 14971. The Failure Mode and Effect Analysis (FMEA) was applied for the identification of potential failure modes, effects of failures, the potential causes or mechanisms of failure as well as applicable mitigation actions for risk reduction. Product, user, clinical related risks were taken into consideration when using Orthobion ACIF cages for their intended use. Non-clinical data is addressed were related to potential toxicity.

4.1 Residual risks and undesirable effects

Literature search has been performed for the device under evaluation and comparable substantially similar devices. All risks were analysed and evaluated to ensure that risk mitigation measures of Orthobion are defined and considered. The risks are minimized to acceptable level. Residual risk is deemed as acceptable. No earlier unknown complications or side effects that have been not yet treated with risk mitigation measures of Orthobion have been identified in publications relating to generic device group/ benchmark devices in the currently updating cycle.

Product-related residual risk	Risk mitigation measure by Orthobion
cage migration	IFU POSSIBLE SIDE EFFECTS: postoperative migration of the implant; Teeth on top and bottom minimize the wandering or wobbling of the cage. CE compliant stabilization system is required. For better preparation of disc we have developed the blunt shavers and trial cages
cage breakage	Risk was checked by mechanical testing
subsidence	Teeth on top and bottom minimize the wandering or wobbling of the cage. CE compliant stabilization system is required. For better preparation of disc the “blund” shavers and trial cages have been developed.
pseudarthrosis	Teeth on top and bottom minimize the wandering or wobbling of the cage

Side-effects		Information provided by Orthobion (possible adverse events)
Damage to surrounding tissues or bones	adjacent segment failure	Adjacent segment disease
	cervical spondylotic stenosis	Nerve damage due to surgical trauma
	cervical myelopathy and cervical radiculopathy	-Nerve damage due to surgical trauma -Pain, discomfort, or abnormal sensations due to the presence of the device
	kyphosis	Decrease in bone density, due to stress shielding
Dysphagia		Permanent dysphagia
Recurrent laryngeal nerve, paresthesias, difficulties with speech		Neurological, vascular or visceral injury
Radiating pain		Pain, discomfort, or abnormal sensations due to the presence of the device

Based on the critical appraisal of the results of the risk assessment, it is concluded that the Orthobion ACIF cages do not impart any unacceptable risks associated with its clinical intended use.

4.2 Warnings and precautions

Detailed list of warnings and precautions is provided in the Instructions for Use.

- Before use please consult Orthobion surgical technique.
- Instruments: To implant an Orthobion cage, special instruments are needed. 99.011 Trial cage inserter, 99.170- 99.185 Trial cages, 99.009 Inserter ACIF and 99.026 ACIF Inserter thread. For further information please consult the surgical technique.
- Implant selection: The Orthobion cervical interbody cage is available in wide variety of sizes to ensure appropriate sizing of the implanted components. The potential for success of the fusion is increased by way of selecting the correct size of the implant. Under sizing, or oversizing the implant can lead to premature failure of the component.
- Delayed union or non-union: If a delayed union or non-union occurs, then implant may fail due to component fatigue. Patients shall be fully informed of the risk of implant failure.

- Patient selection: Appropriate patient selection is critical to the success of the surgical outcome. Only patients who satisfy the criteria set forth under INDICATIONS section of the IFU [3] and who do not have any of the conditions set forth under the CONTRAINDICATIONS section of the IFU [3] shall be considered for the interbody fusion surgery using the Orthobion cervical interbody cage. The benefits of the spinal infusions have not been adequately established in patients with stable spines.
- Furthermore, patients who smoke have been shown to have an increased incidence of pseudo-arthrosis.
- Single use only: These devices are provided as single use implants, only, and are not to be re-used, re-sterilized, or re-implanted, regardless of any apparent un-damaged conditions.
- Handling: Implant and its components shall be handled and stored appropriately to protect them from unintentional damage. The surgeon shall avoid introducing notches or scratches into the cage surface, as they may induce premature failure of the component. Care must be taken when placing the cervical interbody cage to avoid damage.
- Patient education: Preoperative instructions to the patients are essential. The patients shall be made aware of the limitations and potential adverse effects of the surgery. The patients shall be instructed to limit the postoperative activities as this will reduce the risk of bend, break and/or loosened implant.
- The patient shall be made aware that implants may bent, break or loosen, even though restrictions in activity are fulfilled.
- MRI Compatibility:
  - The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.
  - The Orthobion ACIF spacer group has not been evaluated for safety or compatibility in the MR environment.
  - The Orthobion ACIF spacer group has not been tested for heating or migration in the MR environment.
  - Patients with previous spinal surgery at the levels) to be treated may have different clinical outcomes compared to those without a previous surgery.
  - During MRI scans no abnormalities had been observed in individual cases.

4.3 Summary of field safety corrective actions

Date	Event	Actions undertaken	Status
2021	Missing x-Ray marker	Recall of LOT 0CK. Update in process Control at milling and assembly as well as packaging.	Closed

5 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent devices

Not applicable

5.2 Summary of clinical data from conducted investigations of the device

Study ID/ Hospital/Surgeon	Surgery field/Indication	Country	Nbr patients	Evaluation	Adverse events
Dr. G. Mahieu at AZ Monica, Belgium	Anterior Cervical Disectomy and Fusion (ACDF) surgery	Belgium	63	Evaluate the performance within the intended purpose and the effect of smoking and multilevel surgery, both on radiological fusion and clinical outcome. 94 % of the patients achieved a fusion. 86% of the patients were in the Excellent/Good quoting related to Odom's criteria.	None of the patients required post-operative additional treatment. No unknown side effects or contraindications were considered in any of the patients. No adverse effects directly related to the implant have been observed. No device related revision surgeries have been performed in observation period.

TOTAL	**63**

5.3 Summary of clinical data from other sources

In accordance with PMCF plan the manufacturer collected proactively user feedback from clinicians at different hospitals and surgeons with respect to post market surveillance definition in MDR Article 2(60). The collected clinical user feedback data cover the time interval of January 2020 till September 2022 and refer to the use of ACIF cages and follow up to 1 and 2 years after surgery. The user (operating surgeons) feedback for this timeframe includes more than 1.200 cervical cages inserted in these 3 years follow-up and refers to the device related side effects, contraindications, off-label use, revision surgeries and other cage operation related information.

The questionnaires reported positive feedback with never or rarely (<10%) post operative treatment and never or rare (<5%) side-effects such as subsidence, cage migration or vertebral osteolysis. Although cervical cages have been used sometimes by contraindications such spinal tumours or fractures, morbid obesity, smoking, signs of local inflammation, no unknown side effects were observed.

5.4 Overall summary of the clinical performance and safety

Based on analysis of the identified clinical data relevant to cervical cages, it is concluded that the Orthobion ACIF cages achieve the intended performances during normal conditions of use. The clinical performance is measured and demonstrated using meaningful clinical end points such as supporting an appropriate biomechanical environment for fusion. These are consistent with the contemporary fusion techniques.

The intended performance of the Orthobion ACIF cages is supported by sufficient clinical evidence. The clinical data enables an adequate evaluation of the device performance.

Clinical performances	Reference
Support an appropriate biomechanical environment for fusion	Biomechanical environment for fusion allows properly fusion and stabilization of the patient's spine. As primary radiological outcome parameters measured in PMCF study for DUE were implant stability and fusion status, assessed by x-ray and computed tomography (CT) scans. 6 months after the surgery, 95% of the patients in Non-Smoker group (NS) and 93% in Smoker group (S) achieved definite fusion.
Restoration of the height of the intervertebral disc space and subsequent decompression of neural elements	Stabilization of spine and decompression of neural elements appeared via surgery using Orthobion ACIF cages. For evaluation of clinical outcome Odom's have been used. 86 % of the patients were in the Excellent/Good group. The design and form of Orthobion cervical interbody cages is close to the shape of the cervical disc space shape. It leads to correction of intervertebral disc height and restoring physiological lordosis. However, it was not investigated for Orthobion Cervical cages how long height restoration lasts. This will be the subject of the ongoing PMCF clinical investigation.
Enables long term radiological clinical follow-up via tantalum markers / titanium markers integrated in the cage structures.	The integrated markers (titanium or tantalum markers) allow verifying and visualization of the final position of the TSC Cage with per operative image intensifier. The marker compatibility with X -Ray or MRT was confirmed by surgeon's feedback via questionnaires. An x-ray monitoring of the implants is carried out first days after surgery as initial findings. In addition, for a follow-up monitoring after approximately 8-12 weeks as an outpatient treatment for another x-ray.

Safety	Reference
Biocompatible titanium surface and PEEK optima as structural constituents	The Orthobion Cages consist of PEEK with Titanium coating. Titanium and titanium alloys exhibit a high specific strength, which makes titanium an excellent choice for biomedical applications. Furthermore, titanium is considered to be biocompatible because it has a low electrical conductivity which contributes to the electrochemical oxidation of titanium leading to the formation of a thin passive oxide layer. The oxide layer in turn leads to a high resistance to corrosion. This protective passive layer is retained at pH values of the human body due to titanium having an oxide isoelectric point of 5–6. In aqueous environments Ti and its oxides have low ion-formation tendency and low reactivity with macromolecules. Titanium alloys are used in biomedical implant devices which replace damaged hard tissue. Titanium nanocoating on PEEK cages developed by Orthobion GmbH is the clinically efficient design solution whereby the elasticity modulus of the Implant remains close to the bone thus reducing the chances of cage subsidence as well as improving the bony on growth profile owing to active titanium nano-surface. Furthermore, the nano layering of titanium on PEEK cages is relatively advantageous compared to other coating procedures which yield layers in micrometers depth. The advantage lies in the clinical application where a thick coating could lead to formation of granular debris of heterogeneous sizes which may lead to inflammation or other local adverse reaction during and after operation.
Sterility	Orthobion Cages are Gamma sterilized through a validated process.

Based on the review of the pertinent clinical data, information supplied by the manufacturer, risk documentation and taken the state of the art into consideration, it is concluded that The Orthobion ACIF cages is appropriate for its intended use and does not impart any unacceptable risk associated with its use.

Risks and undesirable side-effects in the claimed indications are low and acceptable. The Orthobion ACIF cages perform as intended. The undesirable side-effects thus constitute acceptable risks when weighed against the performances intended.

The databases BfArM (DE), ANSM (FR), MHRA (UK), DAEN (AU), and MAUDE were searched for the timeframe 01.01.2023 till 31.12.2025 with focus on medical device alerts, recommendations and recalls related to the Orthobion Cervical interbody fusion spacer group and generic device group (benchmark devices).

There are no reported incidents for Orthobion ACIF cages from safety data bases for the searching time period.

5.5 Ongoing or planned post-market clinical follow-up

A PMCF study has been initiated. Authorization from the Ethics Committee has been granted. Results are expected to be published in 2027. Study aims to confirm clinical safety and performance of the device on the long-term (3-10 years follow-up), confirm the product's security data, identify previously unknown side-effects and monitoring the identified side-effects and contraindications, confirm the level of acceptability of the identified risks and detect new potential risks, identify possible systematic misuse or off-label use of the device, with a view to verify that the intended purpose is correct.

6 Possible diagnostic or therapeutic alternatives

Cervical degenerative disc disease (CDDD) is a common and debilitating condition that can initially be managed conservatively. If non-surgical treatments fail, anterior cervical discectomy and fusion (ACDF) is a well-established surgical option. ACDF involves removing the affected disc and facilitating intervertebral fusion through various methods, such as using an interbody cage with or without an anterior plate construct (APC). Locking stand-alone cages (LSC) offer stabilization without a plate construct by integrating screw systems. Studies have shown that the prevalence of spinal degenerative disease increases with age, with a significant rise in disc degeneration both with and without myelopathy.

The North American Spine Society (NASS) recommends surgical intervention for rapid relief of symptoms in cervical radiculopathy caused by degenerative disorders. Both anterior cervical discectomy (ACD) and ACDF are considered effective and comparable treatment options, with the addition of an interbody graft in ACDF

suggested to improve sagittal alignment. Research comparing LSC and APC in ACDF has found no significant differences in clinical outcomes, fusion rates, or hospital stays, though LSC is associated with shorter operation time, less blood loss, lower dysphagia incidence, and reduced adjacent-level ossification (ALO) rates.

Regarding cage materials, tantalum fusion devices have been shown to offer shorter operative times and fewer complications compared to autologous iliac crest bone grafts, though fusion rates and clinical outcomes remain similar. Studies have evaluated various surgical techniques such as ACDF, cervical disc replacement (CDR), and minimally invasive posterior cervical foraminotomy (MI-PCF). CDR demonstrated the lowest rate of secondary surgical procedures, while MI-PCF had the lowest rate of adverse events, with all three techniques proving effective in managing cervical radicular symptoms.

ACDF surgery can lead to complications, including subsidence of the intervertebral device and adjacent segment degeneration/disease. While rare, Horner syndrome can occur, causing cosmetic and functional impairments due to sympathetic fibre damage. Overall, the adverse event rate for ACDF is reported to be 57%, with serious events accounting for 38% and device/surgery-related complications at 13.3%. The estimated complication rate for symptomatic adjacent segment disease (ASD) is around 16%, varying between single and multilevel ACDF procedures.

7 Suggested profile and training for users

The Orthobion ACIF cages are for professional use only.

The product and its accessories are operated and used only by personnel with the required training, knowledge or experience related to spine surgery.

8 Reference to any harmonised standards and CS applied

General	EN ISO13485:2016 Medical devices — Quality management systems —Requirements for regulatory purposes EN ISO14971:2019 Medical devices — Application of risk management to medical devices MDR 2017/745, as amended
Guidelines	MDCG 2019-9 Rev.1 - Summary of safety and clinical performance A guide for manufacturers and notified bodies
Chemical, physical and biological properties	EN ISO 10993 Series Biological Evaluation of Medical Devices
Sterilization	EN ISO 11137-1:2006 Sterilization of health care products — Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices EN ISO 11137-2:2013 Sterilization of health care products — Radiation - Part 2: Establishing the sterilization dose
Packaging	EN ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
Information supplied by Manufacturer	EN ISO 20417:2021 Information supplied by the manufacturer EN ISO 15223-1:2021 Medical devices – Symbol to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
Usability	EN 62366-1:2015 Medical devices. Application of usability engineering to medical devices.
Clinical	EN ISO 14155:2020 Clinical investigation of medical devices for human subjects-good clinical practice

Mechanical properties	EN ISO 7438:2021 Metallic materials - Bend test EN ISO 14630:2025 Non-active surgical implants - General requirements ASTM F1147:2017 Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings ASTM F2267:2024 Standard Test Method for Measuring Load-Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression ASTM F2077:2024 Standard Test Methods for Intervertebral Body Fusion Devices ASTM F1044:2025 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings ASTM F1160:2025 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings ASTM F1978:2022 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser

Summary of safety and clinical performance for patients

This Summary of Safety and Clinical Performance (SSCP) gives the public an updated overview of how safe and effective the Orthobion ACIF cages are. It is not meant to replace the main instructions for using the cages safely, nor to give medical advice or treatment suggestions to users or patients.

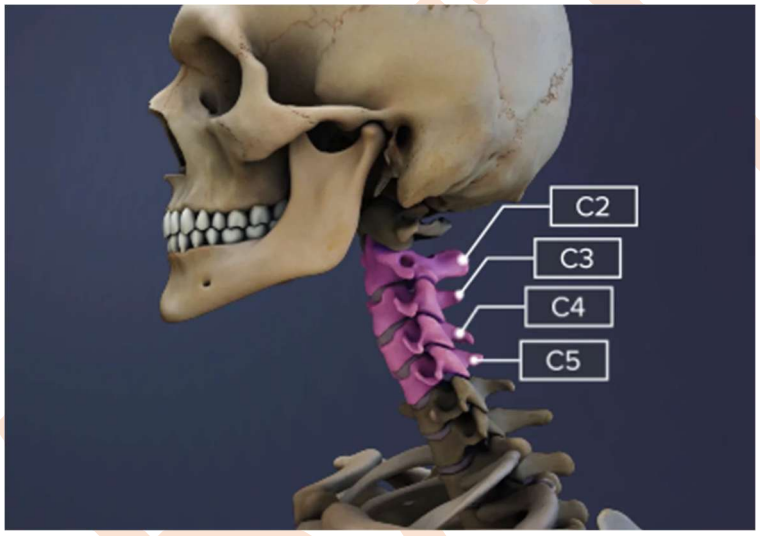
The following information is intended for patients.

9 Intended use of the device

9.1 Intended purpose

The Orthobion ACIF spacer group is used in surgeries to treat problems in the neck part of the spine. These cervical cages are meant for patients with degenerative disc diseases (DDD) or instabilities in the C2-C5 (Figure 2) levels of the spine.

Figure 2 Vertebrae and joints from C2 through C5



DDD includes conditions such as:

- Nerve pain (Radiculopathy)
- Spinal cord issues (Myelopathy)
- Bulging discs (Disc herniation)
- Bone spurs (Osteophytes)
- Compression of the spinal cord or nerve roots

9.2 Who can use the Orthobion ACIF spacer group?

This device is meant for adults whose bones have fully grown. It should not be used in paediatric cases, or in patients whose bones are still growing.

9.3 Who should NOT use Orthobion ACIF spacer group?

This device is not suitable for patients with:

- Tumours in the spine
- Severe bone weakness (osteoporosis)
- Active infections
- Poor bone quality
- Certain medical conditions (e.g., cancer, severe obesity, or mental illness)
- Allergies to the materials used in the implant

10 How does the device work?

Cervical degenerative disc disease (CDDD) is a painful condition that can sometimes be treated without surgery. If these treatments fail, a surgery called Anterior Cervical Discectomy and Fusion (ACDF) can be performed. This surgery involves removing the damaged disc and replacing it with an interbody fusion cage to maintain spinal stability and encourage fusion between the vertebrae.

The device helps restore proper spacing and alignment of the neck vertebrae. It supports bone fusion by providing a stable environment for healing. Doctors can use different bone graft materials, such as the patient's own bone (from the iliac crest) or other suitable options.

The main objective of the Orthobion ACIF cage is to restore the normal height of the intervertebral space and maintain the natural curvature of the cervical spine (cervical lordosis). The device creates a stable biomechanical environment that promotes bone fusion.

The ACIF cages can be used with different types of bone graft materials, including:

- Autograft: the patient's own bone (usually harvested from the iliac crest)
- Allograft: bone graft from a donor
- Bone graft substitutes that provide structural support while encouraging cell attachment and growth.

Figure 3 Schematic representation of Orthobion ACIF

The cage is placed between the bones in your neck to provide support. Over time, the bones grow and fuse together. The cage may be coated with titanium to help bone growth. The device is not reusable; it is designed for one-time use only.

11 Possible risks and side effects

While this device is generally safe, some risks exist. These may include:

- Implant migration: The device may shift from its original position.
- Implant breakage: The device may crack or break over time.
- Pain or discomfort: Some patients experience pain or unusual sensations near the implant.
- Difficulty swallowing (dysphagia): This may occur after surgery but usually improves over time.
- Nerve damage: Rare but possible, leading to numbness or weakness.
- Failure of the bones to fuse properly (pseudarthrosis): This may require additional surgery.

11.1 Warnings and precautions

Before using this device, please follow these precautions:

- Consult your surgeon: Your doctor will use a special surgical technique to implant the device safely.
- Bone healing risks: In some cases, bones may take longer to fuse or may not fuse at all. If this happens, the implant may fail and require additional treatment.
- Patient selection: Not all patients are suitable for this implant. Your doctor will determine if this device is right for you based on your medical condition.

- Smoking risks: Smoking can increase the risk of poor bone healing (pseudo-arthrosis), which may affect the success of the implant.
- Single-use only: This implant is designed for one-time use. It must not be reused, resterilised, or reimplanted.
- Proper handling: The implant must be handled carefully to prevent damage. Even small scratches on the device can affect its performance.
- Patient education: It is important to understand the risks and limitations of the surgery. Patients should follow post-surgery instructions to reduce the risk of implant movement, breakage, or loosening.
- MRI and imaging considerations: The implant may affect CT or MRI scan results.
    - It has not been tested for safety in MRI environments.
    - Patients who have had prior spinal surgery may experience different outcomes compared to those without previous procedures.
    - In past cases, no MRI-related issues have been observed.

12 Clinical Evaluation Summary

Many studies have looked at different types of spinal implants used in neck surgery (ACDF). These studies show that cervical implants work well to support spinal fusion and improve patient outcomes. This research helps doctors choose the best implant for each patient, balancing the risks and benefits to achieve the best possible results.

12.1 Overall summary of the clinical performance and safety

The Orthobion ACIF cages have been tested in clinical studies and have shown to be effective in supporting spinal fusion and stabilizing the neck. The results confirm that:

- Successful bone fusion: The majority of patients (over 93%) experienced successful bone fusion within six months after surgery.
- Improved spine stability: The implant helps restore proper spacing between the bones in the neck, reducing nerve pressure and improving alignment.
- Clear imaging for follow-up: Special markers in the implant allow doctors to monitor healing with X-rays or MRIs over time.

12.2 Safety and materials

- Biocompatible materials: The implant is made of safe materials like PEEK and titanium, which are strong, lightweight, and well-tolerated by the body.
- Titanium coating benefits: The thin titanium layer improves bone growth.
- Sterile and safe: The implants are sterilized using a strict process to ensure patient safety.
- Low risk of complications: No major safety concerns or recalls were reported for this implant in recent medical databases.

Overall, the Orthobion ACIF cages are designed to provide long-term stability and support for patients needing spinal fusion, with minimal risks when used correctly. Always consult your doctor for personalized advice.

12.3 Post-Market Clinical Follow-Up

The PMCF plan is part of the overall safety monitoring of the Orthobion ACIF cages. It aims to:

- Confirm the device's safety and performance over its lifetime.
- Check the device's security data.
- Identify any new side effects and monitor known side effects.
- Confirm that the risks are acceptable.
- Detect any new potential risks.
- Identify any misuse or off-label use of the device.
- Verify that the device is being used correctly.

From January 2020 to September 2022, feedback was collected from doctors and surgeons who used the ACIF cages. This feedback covered more than 1.200 cervical cages used in surgeries during this period. The feedback included information on side effects, contraindications, off-label use, revision surgeries, and other related information.

The questionnaires reported positive feedback with never or rarely (<10%) post operative treatment and never or rare (<5%) side-effects such as subsidence, cage migration or vertebral osteolysis. Although cervical cages have been used sometimes by contraindications such spinal tumours or fractures, morbid obesity, smoking, signs of local inflammation, no unknown side effects were observed.