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Referenced Documents

Internal Documents:	See Chapters - -
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Change History

Revision:	Change Description:	performed by:	released by:
01	Initial creation	WKL	WKL
02	Update 2022	WKL	WKL
03	Update Chapter 7	WKL	WKL
04	Update according to new CER	WKL	WKL
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Last Change

Revision:	03
Reason:	Continuous Update
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Responsibility:	WKL	23.05.2023	WKL	23.05.2023	WKL	23.05.2023

Inhalt

1. Scope

This report follows the report structure outlined in MDCG 2019-9.

2. SSCP Identification

Device Trade Name(s)	• reCreo PLIF / TLIF Spacer with tantalum markers • reCreo PTLIF / TLIF Banana Spacer with titanium markers • TSC PLIF / TLIF titanium sputter coated with tantalum markers • TSC PTLIF / TLIF Banana titanium sputter coated with titanium markers • reCreo ACIF Spacer with tantalum markers • TSC ACIF Spacer titanium sputter coated with tantalum markers
Manufacturer name and address	Orthobion GmbH Gottlieb-Daimler-Str. 5 78467 Konstanz, Germany Email: spine@orthobion.com Website: www.orthobion.com
Manufacturer SRN	EUDAMED: DE-MF-000005797 DIMDI: DE/0000044783
Device Basic UDI-DI	4050762OrthSpacerGroup45
Medical Device nomenclature description text	UMDNS: allografts 17-165 GMDN reCreo: 60762 Polymeric spinal interbody fusion cage (en) GMDN TSC: 61230 Metal-polymer composite spinal interbody fusion cage (en)
Class of device	According to MDD Annex IX, Rule 8: Class IIb MDR rule 8; indent 9
Year of First CE Certificate covering this device	ACIF Spacer Group: 25-09-2012 PLIF Spacer Group: 06-02-2012 TLIF Spacer Group: 04-12-2013 PTLIF And TLIF Banana Spacer Group: 27-09-2017
Authorized representative incl SRN	N/A
NB Name and NB Single Identification number	TÜV NORD CERT GmbH Am TÜV 1 45307 Essen Country : Germany Phone : +49 (0) 201 825-3262 Fax : +49 (0) 201 825-3290 Email : info@tuev-nord.de Website : www.tuev-nord-cert.de Notified Body Single Identification number : 0044

3. Device Intended purpose, Indication, Contraindication and target population

3.1. Intended purpose

3.1.1. Intended Purpose of ACIF cage

The Orthobion ACIF spacer group is intended for surgical treatment of the cervical spine. The Orthobion cervical is intended for use, in skeletally mature patients, with degenerative disc diseases (DDD) or instabilities. DDD is defined by:
-Radiculopathy and/or
- Myelopathy and/or
-Disc herniation and/or
-Osteophytes
-Root or spinal cord compression

3.1.2. Intended purpose of the lumbar interbody fusion spacers

The lumbar cage is an implant intended for the surgical treatment of the lumbar spine, designed by Orthobion GmbH. The Orthobion posterior/transforaminal/posterior - transforaminal lumbar cage is intended for use, in skeletally mature patients, with the following pathologies:
Degenerative Disc Disease (DDD) at level from S1 till L2. DDD is defined by:
Discogenic back pain
Grade 1 Spondylolisthesis or retrolisthesis at the involved segments
Osteophyte formation on posterior vertebral endplates producing symptomatic nerve root or Spinal cord compression
Segmental instability

3.1.3. Other Intended Use (Optional)

N.A.

3.2. Indication / Target population

The implant is intended for use in the following patients.
The Orthobion Lumbar and cervical cages are intended for use, in skeletally mature patients. These cages are not intended for use, in either pediatric cases, or where the patient still has general skeletal growth and skeletal system is not fully grown.

3.2.1. Characterization of the Patient

The implant is intended for use in the following patients.
The Orthobion Lumbar and cervical cages are intended for use, in skeletally mature patients. These cages are not intended for use, in either pediatric cases, or where the patient still has general skeletal growth and skeletal system is not fully grown.

3.2.2. Indications for Use (cervical cages)

The Orthobion ACIF spacer groups are intended for surgical treatment of the cervical spine. Orthobion cervical interbody cages ACIF are intended for use, in skeletally matured patients, with degenerative disc diseases (DDD) or instabilities. DDD is defined by

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

3.3. Indication for Use

3.3.1. Indications for Use (lumbar cages)

The Orthobion transforaminal lumbar cage/posterior lumbar cage/posterior-transforaminal lumbar cage is intended for use, in skeletally mature patients, with the following problems:

Degenerative Disc Disease at levels from S1 till L2. DDD is defined by

- Discogenic back pain
- Grade 1 Spondylolisthesis or retrolisthesis at the involved segments
- Osteophyte formation on posterior vertebral endplates producing symptomatic nerve root or Spinal cord compression
- Segmental instability

3.3.2. Indications for Use (cervical cages)

It is intended for surgical treatment of the cervical spine Level C2 til C7. The Orthobion cervical interbody cage is intended for use, in skeletally mature patients, with degenerative disc diseases (DDD) or instabilities.
DDD defined by:
• Radiculopathy and/or
• Myelopathy and/or
• Disc herniation and/or
• Osteophytes
• Root or spinal cord compression

3.4. Contraindication

3.4.1. Contraindications for Lumbar cages

The Orthobion posterior lumbar cage is contra-indicated for Cervical spine surgery as well as the following contra-indications that include:
• Any case not described in the above indications
• Infection, local to the operative site
• Signs of local inflammation
• Fever or leukocytosis
• Morbid Obesity
• Pregnancy
• Mental Illness
• Cancer
• Smoking
• Alcoholism or drug abuse
• Any other condition which could preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
• Suspected or documented allergy or intolerance to composite materials
• Any case not needing a fusion
• Any patient unwilling to cooperate with postoperative materials
• Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
• These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
• Spondylolisthesis unable to be reduced to Grade 1
• Any case where the implant components selected for use would be too large or too small to achieve a successful result
• Prior fusion to the level to be treated
• Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
• Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance

3.4.2. Contraindications for ACIF cages

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 in 3.3.1.
- Congenital abnormalities
- Presence of spinal tumors
- 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
- Pediatric patients, where the patient has limited to no skeletal growth

3.4.3. Contraindications for lumbar interbody fusion spacers

The following contraindications have been identified for the lumbar spine cages.

- The Orthobion posterior lumbar cages/transforaminal lumbar cage/ posterior-transforaminal lumbar cage is contra-indicated for cervical spine surgery
- Any case not described in the above indications for the Lumbar spine cages under 3.3.2.
- Infection, local to the operative site
- Signs of local inflammation, Fever or leukocytosis, Morbid Obesity, Pregnancy, mental illness, cancer, Smoking, Alcoholism or drug addiction

Any other condition which could preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
Suspected or documented allergy or intolerance to composite materials
Any case not needing a fusion
Any patient unwilling to cooperate with postoperative materials
Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
Spondylolisthesis unable to be reduced to Grade 1
Any case where the implant components selected for use would be too large or too small to achieve a successful result
Prior fusion to level to be treated
Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance

3.5. Device Describtion

The named devices in Chapter 3 are made of PEEK Optima LT1 (Invibio) with Titan or Tantal X-Ray MArker. It is available
a) un-coted trade name prefix reCreo,
b) with TSC coating from Orthobion GmbH trade name prefix TSC.

The Cages are milled out of Invibio PEEK Optima LT1 rods. It is gamma ray sterilized and packed in Blisters. The spinal Cages are used to treat spinal instabilities. The devices are delivered clean and sterile.

3.5.1. Previous Generations

N/A

3.5.2. Accessories

ACIF	PLIF / PTLIF / TLIF	TLIF Banana
Direct Connection: 99.009 Inserter ACIF 99.026 ACIF Inserter Thread	Direct Connection: 99.004 Lumbar Inserter 99.025 Lumbar Inserter Thread	Direct Connection: 99.006 TLIF Banana Inserter
Trial Instruments: 99.011 Trial Cage Inserter 99.170- 99.185 Trial Cages	99.121. Trial Cage Inserter 99.151 – 99.164 Trial Cages	99.005 T-Handle 99.230 - -99.248 Trial Cages

3.5.3. Combination with other devices

N/A

3.6. Residual Risks and side effects

The Product Risk Management process for Orthobion Spacer Group has been performed based on the PRM Plan [FO Riskplan 2021 001]. All planned activities have been performed accordingly and are documented in the PRM File. Objective evidence of risk control measures and verification activities is included in the PRM file and the completeness of the risk management file for conformity assessment/market authorization has been reviewed as part of the Technical File compilation.
The overall residual risk is acceptable.

3.7. Warning and preauctions

PRECAUTIONS
SURGICAL TECHNIQUE: Before Use, please consult the Orthobion Surgical Technique
INSTRUMENTS: To implant a Orthobion Cage, special Instruments are needed.
IMPLANT SELECTION: The Orthobion posterior lumbar cage is available in a wide variety of sizes to insure appropriate sizing of the implanted components. The potential for success of the fusion is increased by way of selecting the correct size of implant. Under sizing, or over sizing the implant can lead to apremature failure of the component.
DELAYED UNION OR NON-UNION: The Orthobion cage is designed to assist in providing an adequate biomechanical environment for fusion. If a delayed union or non-union occurs, the implant may fail due to component fatigue. Patients should 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 the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRA-INDICATIONS section of this document should be considered for interbody fusion surgery using the Orthobion posterior lumbar cage. The benefit of spinal fusions has not been adequately established in patients with stable spines. In addition, 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 components should be handled and stored appropriately to protect them from un-intentional damage. The surgeon should avoid introducing notches or scratches into the cage surface, as these may induce premature failure of the component. Care must be taken when placing the posterior lumbar cage to avoid damage.
PATIENT EDUCATION: Pre-operative instructions to the patient are essential. The patient should be made aware of the limitations and potential adverse effects of the surgery. The patient should be instructed to limit the post-operative activity as this will reduce the risk of bent, broken and/ or loose implant components. The patient must be made aware that implant components may bend, break and/ or loosen, even though restrictions in activity are followed.
MRI SAFETY INFORMATION: Non-clinical testing and MRI simulations demonstrated that every implant from the Interbody Fusion Device Family is MR Conditional. A patient with an implant from the Interbody Fusion Device Family may be safely scanned under the following conditions:
• Static magnetic field of 1.5-Tesla or 3-Tesla, only
• Maximum spatial gradient magnetic field of 10,000-Gauss/cm (100-T/m)
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode
Under the scan conditions defined, the Interbody Fusion Device is expected to produce a maximum temperature rise of 1.3°C after 15-minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the Interbody Fusion Device extends approximately 5-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

3.8. Other relevant aspects of safety

Affected product(s)	FSCA ref. Number	Problem description	Action taken / to be taken	Risk asssesment
TSC PLIF	02317/20	Product labeled with PLIF but was packed with a TSC ACIF Cage	Recall of both LOT PLIF and ACIF. Check all Products at packaging company Barcode to check on box label and blister label	Risk acceptable
TSC domed ACIF	23243/21	Missing x-Ray marker	Recall of LOT 0CK. Update inprocess Control at milling and assembly as well as packiging	Risk acceptable

4. Summary of the Clinical Evaluation

4.1. Summary of clinical data related to equivalence devices

N/A

4.2. Summary of clinical data before CE-Marking

N/A

4.3. Summary of clinical data from other sources

4.3.1. Clinical Data from Registries of Devices or Clinical Trials

Cervical Spacer

Clinicaltrials.gov database was searched for relevant studies in timeframe 2017-2021 with the same indications as for DUE. Only completed studies with results have been chosen. 11 studies were observed (see literature search protocol [6]), 2 of which were duplicates. Remaining studies were excluded after analysis. The reasons for this were either different treatment methods or use of non-equivalent or similar cages than those set out.

Lumbar Spacer

The search in the clinical trial registries revealed 22 entries for the similar lumbar interbody fusion devices since last clinical evaluation.

The reporting of the results is limited. Therefore, the information of 2 Studies can partly be used to demonstrate the performance and safety of the products, but it does give a tendency that the products are performing within their intended use and the listed indication (chapter 6.3.2). The results of the clinical trial are important and partly reply to the claims mentioned in the section 3.10 Claims and 3.11 Benefits.

4.3.2. Clinical Data From Literature Review

Cervical Spacer

In view of the search period for clinical data from scientific literature (01. 01.2017– 28. 10.2021) the number and quality of the papers have been assessed as relevant and are deemed to be adequate to evaluate the performance of the evaluated medical device and are listed below.

In all these studies have been seen positive clinical outcomes such as bone union, bone fusion (radiologic measures), improvements in JOA-, NDI-, VAS scores arm and neck pain, improvements in cervical lordosis and increase of height. Despite the identified and observed side/ adverse effects a longer survey period with radiological follow up is needed to identify all possible side effects ad find out the cause of failed fusion.

All risks revealed in these studies were analyzed and evaluated. Risk minimization measures were defined and taken.

Lumbar Spacer

Clinical data from literature review have been not observed with following reasons:

- clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated have been not observed, because the currently CER does not refer to an equivalent device.
- reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated have been not observed, because DUE PMCF study has been published in other time frame than the current literature update cycle.

4.4. Overall summary of clinical performance and safety

4.4.1. Cervical Spacer

PRE CLINICAL TESTING:

The required technical tests were performed and assessed as compliant with the standard. These results are part of the technical documentation of the Orthobion Cervical interbody fusion spacer group.

The medical device Orthobion Cervical interbody fusion spacer group therefore meets all of the essential requirements to Appendix I of the MDD.

From Orthobion clinical data on DUE:

- The clinical data of 2 years PMCF after surgery was evaluated in surveillance period March 2017-March 2018. In this period 63 patients have been operated. Indication for operation were radiculopathy (n=56) and myelopathy (n=7). Patients were all treated with a nano-titanium layer coated PEEK cage (TSC cage, Orthobion)

- Safety: None of the patients required post-operative 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.

From clinical data on equivalent devices:

For evaluation of the safety of the Orthobion ACIF Spacer group clinical studies for equivalence devices were analyzed and evaluated. Most studies had no adverse events. There have been studies where known side effects have occurred. These side effects have been treated as risks in RA.

Only in one literature study (study with device PEEK cage MC+®/ LDR medical), five patients died during hospitalisation due to respiratory failure or bedsore complications

PMS:
The search in the safety databases revealed 2 events for the Orthobion Cervical and Lumbar interbody spacer group in timeframe of 2016-2021. Based on the number of devices sold in this timeframe (30288 devices), it confirms the security of the Orthobion cages. No serious incident and no Serious Adverse Event (SAE) for Orthobion Cervical interbody fusion spacer group were reported in safety databases in timeframe 2016-2021.

STATE OF THE ART:
In summary, the systematic reviews and meta-analyses identified in SOTA demonstrated that contemporary fusion techniques are effective and safe. They differ in some outcome parameters and complications but usually differences are within clinically acceptable ranges.

RISK RELATED TO MEDICAL DEVICE:
After implementation of the risk control measures for risks listed the residual risk was assessed again. Remaining individual risks and overall residual risks are assessed in the risk management system. The overall residual risk is acceptable.

CLINICAL DATA ON SAFETY
Evaluation of clinical data on safety showed that all claims that have been established have been confirmed.

4.4.2. Lumbar Spacer

PRE CLINICAL TESTING:
The required technical tests were performed and assessed as compliant with the standard. These results are part of the technical documentation of the Orthobion Lumbar interbody fusion spacer group.
The medical device Orthobion Lumbar interbody fusion spacer group therefore meets all of the essential requirements to Appendix I of the MDD and applicable parts of the MDR.
PMS:
Based on the analysis of the collected data, it is concluded that the benefit risk profile of the mentioned devices has not been adversely impacted and remains unchanged.
The search in the safety databases revealed no one event for the Orthobion Lumbar interbody spacer group. The search in the safety databases revealed many incidents related to the similar benchmark devices. This data confirms the safety of the Orthobion Lumbar interbody spacer group.
STATE OF THE ART:
In summary, the systematic reviews and meta-analyses identified in SOTA demonstrated that contemporary fusion techniques are effective and safe. They differ in some outcome parameters and complications but usually differences are within clinically acceptable ranges.
RISK RELATED TO MEDICAL DEVICE:
After implementation of the risk control measures for risks listed the residual risk was assessed again. Remaining individual risks and overall residual risks are assessed in the risk management system. The overall residual risk is acceptable.
CLINICAL DATA ON SAFETY
No new risks were discovered. The risk is on a very low level.
No incidents impacting the safety and performance for the Orthobion's Lumbar Cages in clinical use have been found in this timeframe.

4.5. Ongoing or planned post marked clinical follow up

A continuous Post Market Surveillance is going on to evaluate a potential PMCF Study.

5. Possible diagnostic and therapeutic alternatives

The literature search has been conducted in order to find reviews, meta-analyses, and guidelines to show the technical and medical background to Lumbar Spacer. Especially, publications with focus on other Lumbar Spacer are included in these sections on the current state of the art (SOTA).

The SOTA was performed on in-depth assessment of alternative treatment methods to the target population for the same indications, the medical condition(s) and epidemiology of the condition.
Evaluation of epidemiological data has shown that males older than 65 years are the most affected population by DDD.
The investigation of relationship between DDD and genetic markers based on systematic review/meta-analysis showed that association of LDDD and genetic markers is weak and require further investigation.
Evaluation of radiological and other findings in LDDD gave following conclusions:

- synovial cyst herniation might be a manifestation of an unstable spinal level.
- a reliable diagnostic tool that could help a clinician to determine if a disc is the source of the pain in patients with chronic lower back pain is still not available
- Huang et al. revealed in his meta-analyse that Modic* changes 1 and 2 were more common in the lowest two levels, especially in L5/S1. Shiri at al meta-analyzed degeneration and pain among fighter pilots. There were no differences in the prevalences of low back pain and lumbar disc degeneration between fighter pilots and helicopter or transport/cargo pilots

Analysis of general trend and outcomes revealed that Lumbar fusion surgery rates increased, and posterior and transforaminal interbody fusion (PLIF and TLIF) had significantly higher fusion rates compared to instrumented posterolateral fusion (PLF).
Clinical success rate was statistically higher with minimally invasive surgery (MIS) versus non-MIS fusion
*Modic is a simple descriptive system for radiologists to describe radiological findings in MRI images. In Modic type 1 there is vascular development in the vertebral body, with findings of inflammation and edema, but no trabecular damage or marrow changes. In Modic type 2 there are changes in bone marrow, with fatty replacement of formerly red, cellular marrow normally seen there. With Modic type 2 changes the marrow is substituted by visceral fat. Modic Changes type 3 are less common, with fractures of the trabecular bone, along with trabecular shortening and widening.

6. Suggested profile and training for users

The Orthobion Medical devices are suggested for a licensed practitioner / surgeon or persons lawfully engaged in the manufacture of distribution of the product because of any potentiality for harmful effect, or the supervision of the method of its use, or the collateral measures necessary to its use is not safe for other person groups.

It is necessary to train the surgeon about the connection between the Cage and instrument. Also instruments which are necessary for the surgery. A special training for a spinal surgery is required, this is part of the vocational training.

7. Reference to any harmonized Standards

7.1. Standards

See 4-2 TDF 00A Relevante Regelwerke

8. Change History SSCP

Revision	Change	Editor	released	Language	Validated by NB
02	Insert chapter 3.3.1, 3.4.1 Edit Chapter 3.6, 3.7, 3.8, 7	WKL	28.06.2022	EN	
03	Update Chapter 7	WKL	23.05.2023	EN	
04	Update according to new CER	WKL	27.11.2023	EN	