RESUME DES CARACTERISTIQUES DE SECURITE ET DES PERFORMANCES CLINIQUES

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

C DISC

Table of Contents

INTRODUCTION

This Summary of Safety and Clinical Performance (SSCP) is produced in alignment with the requirements of COUSIN BIOTECH's Clinical Evaluation Plan (TF17(A)_CER_ISSUE-1) and REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, referencing the MDCG 2019 – 9 - Summary of safety and clinical performance: A guide for manufacturers and notified bodies.

This 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 SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

This SSCP is an important source of information for intended users – both healthcare professionals and if relevant for patients. It is one of several means intended to fulfil the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information. The SSCP for Sterile Cervical Disc Device composed of C DISC includes both information intended for healthcare professionals (Section A) as well as for the patient (Section B).
The SSCP for C DISC is based on the following documentation pertaining to the C DISC*:*

- Clinical Evaluation Report (CER)
- Post-Marketing Surveillance (PMS) plan and regular reports
- Post-Marketing Clinical Follow-up (PMCF) plan and regular reports
- Design verification/validation reports
- If appropriate, the IFU

The SSCP shall be reviewed on an annual basis and updated if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete after implementation of the PMCF reports and of the Periodic Safety Update Report (PSUR). Any pertinent modification in the documentation pertaining to C DISC shall be implemented in all sections of the SSCP if needed.

The SSCP of C DISC must contain all the information detailed in this template. However, the manufacturer may add further information from the Technical Documentation (TD) of the device to enhance the comprehension of the mandatory information if it does not affect the readability of the SSCP and if it excludes any element of a promotional nature.
For the sake of objectivity and impartiality to the patients, information in the SSCP shall adequately summarize both favorable and unfavorable data.
The IFU shall provide all relevant information needed to directly access SSCP in Eudamed. The IFU shall be updated regularly on this database. The following applies to the IFU:

- It shall state that the SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI.
- It should provide the URL to the Eudamed public website: https://ec.europa.eu/tools/eudamed
- It should state the value of the Basic UDI-DI. Alternatively, another metadata can be stated provided it can be used to unambiguously search and find the intended SSCP in Eudamed.

The MDR requires that the SSCP shall be written in a way that is clear to the intended user and, if relevant, to the patient. The SSCP should therefore be translated into the languages accepted in the Member States where the device is sold/envisaged to be sold. By analogy, this is also a requirement for an IFU.

Manufacturer's references number for SSCP: TF(X)_SSCP_YYYY
*X= Number of the technical file and Y=Name of the device

SECTION 1: SSCP FOR USERS/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 device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals. A summary intended for patients can be found in Section 2.

1. DEVICE IDENTIFICATION AND GENERAL INFORMATION

1.1. DEVICE TRADE NAME(S)

The family identified and concerned by the SCCP is Sterile Cervical Disc Device, included: C DISC

1.2. MANUFACTURER'S NAME AND ADDRESS

COUSIN BIOTECH
Allée des Roses
59117 Wervicq-Sud
FRANCE

1.3. MANUFACTURER'S SINGLE REGISTRATION NUMBER (SRN)

The Single Registration Number (SRN) of the manufacturer is FR-MF-000001179.

1.4. BASIC UDI-DI

The Basic UDI-DI for the C DISC is 376018557DISCCERVIMP32

1.5. MEDICAL DEVICE NOMENCLATURE DESCRIPTION / TEXT

The EMDN code of the Sterile Cervical Disc Device is: P09070201 "Disc Prostheses"

The GMDN code of the Sterile Cervical Disc Device is: 48164 ''Cervical total disc replacement prosthesis''

1.6. CLASS OF DEVICE

All the *Sterile Cervical Disc Device* included in this EC technical file are in Class III according to the Annex VIII, Chapter III, Rule 8, Dash 9 of the classification criteria of the Regulation (EU) No 2017/745.

1.7. YEAR WHEN THE FIRST CERTIFICATE (CE) WAS ISSUED COVERING THE DEVICE

The products concerned by this CE marking file have been initially developed, CE marked and then commercialized under the name ''CERADISC'' by the company CERAVER – Les laboratoires Ostéal Médical. Since 2017, about 658 CERADISC have been sold in France and in Portugal. Then, in November 2025, COUSIN BIOTECH has purchased the implant and will act as its distributor until 31 December 2027. During

this period, COUSIN BIOTECH will prepare the submission according to the Regulation (UE) 2017/745. After the approval of the Notified Body (SGS), COUSIN BIOTECH will become the legal manufacturer of the implant, which will then be marketed under the name ‘‘C DISC’’.

1.8. AUTHORISED REPRESENTATIVE IF APPLICABLE, NAME AND SRN

Not applicable.

1.9. NOTIFIED BODY’S NAME AND SINGLE IDENTIFICATION NUMBER

SGS Belgium NV
SGS House - Noorderlaan 87 (RPR Antwerpen BTW BE 0404.882.750)
Anvers, 2030
Belgique

The Single identification number of SGS is CE 1639.

2. INTENDED USE OF THE DEVICE

2.1. INTENDED PURPOSE

The intended purpose of the Sterile Cervical Disc Device is cervical disc arthroplasty that involves replacing one or more degenerative intervertebral discs via an anterior approach. Its purpose is to restore disc height at the level in question, while providing a degree of functional mobility compatible with the physiological kinematics of the spinal segment, helping to maintain reduced or absent pain following satisfactory decompression.

2.2. INDICATIONS AND TARGET POPULATION(S)

The intended patient population of the SCDD is only fully grown adults.

The indications for the C DISC cervical disc prosthesis are symptomatic cervical degenerative disc disease of the cervical spine from C3 to T1 in adults, which may be accompanied by radiculopathy, moderate myelopathy, functional/neurological deficit in the arm and/or neck, at one or more levels (maximum 3 levels), with at least one of the following pathologies:

- Disc herniation,
- Disc protrusion with canal stenosis,
- Mild or moderate spondylarthrosis.

The mobility of the level to be operated on must be assessed beforehand.

The insertion of a cervical disc prosthesis is considered when all non-surgical alternatives have been exhausted and deemed less appropriate and/or less effective.

2.3. CONTRAINDICATIONS AND/OR LIMITATIONS

The **contraindications** of the Sterile Cervical Disc Device are:

Contraindications related to the pathology:

- Severe cervi-osteoarthritis or ossification myelopathy (OPLL),

- Severe facet osteoarthritis,
- Predominant posterior compression spinal canal stenosis,
- Spondylolisthesis, retrolisthesis,
- Significant segmental instability,
- Posture of the cervical spine in segmental kyphosis,
- Fracture,
- Surgical history of laminectomy and/or fusion by posterior approach of the segment concerned.

Patient-related contraindications:

- Osteoporosis or severe osteopenia,
- Metabolic Bone Diseases,
- Systemic Inflammatory Osteoarticular Diseases,
- Rheumatoid arthritis,
- Bone tumour in the affected area,
- Any acute, chronic or local infection,
- Severe alcoholism,
- Pregnancy,
- Morbid (class III) obesity,
- Lack of patient cooperation,
- Senility,

Implant-related contraindications:

- Allergy to at least one of the implant materials,

3. DEVICE DESCRIPTION

3.1. DESCRIPTION OF THE DEVICE

3.1.1. GENERAL DESCRIPTION

The prosthesis consists of three components and is designed for cementless implantation:
- A superior endplate made of CoCrMo unalloyed titanium-coated, Ti;
- An inferior endplate made of CoCrMo unalloyed titanium-coated, Ti;
- A mobile nucleus made of UHMWPE placed between the two endplates.

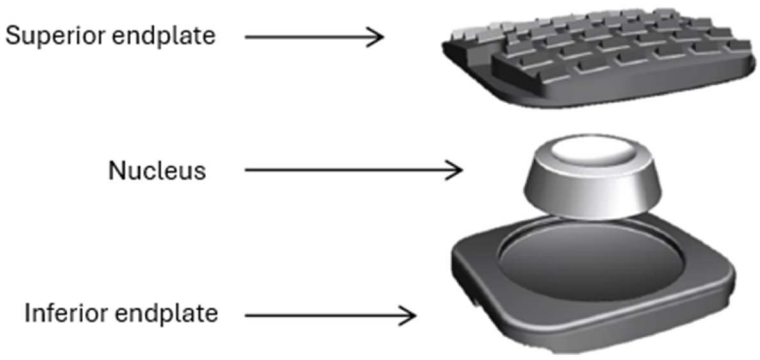

Figure 1: View of the C DISC prothesis

The teeth on the outer sides of the two plates enable cement-free implantation. With a height of 0.5 mm, they penetrate the bone locally, ensuring primary anterior-posterior stability.

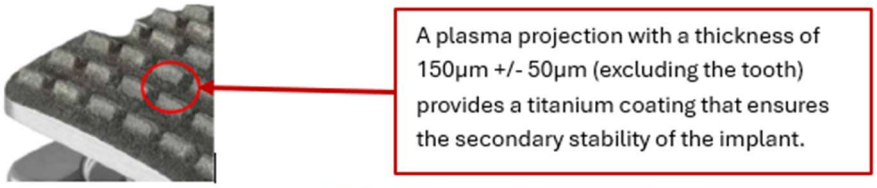

Figure 2: C DISC endplate surface

Cervical disc arthroplasty involves replacing one or more degenerative intervertebral discs via an anterior approach. Its purpose is to restore disc height at the level in question, while providing a degree of functional mobility compatible with the physiological kinematics of the spinal segment, contributing to the maintenance of reduced or absent pain following satisfactory decompression.

The placement of a cervical disc prosthesis is considered when all non-surgical alternatives have been exhausted and deemed less appropriate and/or less effective.

The indications for the C DISC cervical disc prosthesis are symptomatic cervical degenerative disc disease of the cervical spine from C3 to T1 in adults, which may be accompanied by radiculopathy, moderate myelopathy, functional/neurological deficit in the arm and/or neck, at one or more levels (maximum 3 levels), with at least one of the following pathologies:

- Disc herniation,
- Disc protrusion with canal stenosis,
- Mild or moderate spondylarthrosis.

The mobility of the level to be operated on must be assessed beforehand.

Thanks to its double radius and double articulated surfaces, the core allows for an instantaneous centre of rotation that can be located either on the upper or lower plate. Stability is ensured by self-centring.

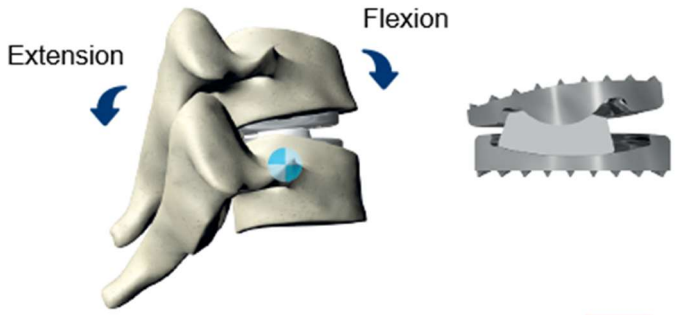

Figure 3: Lower centre of rotation

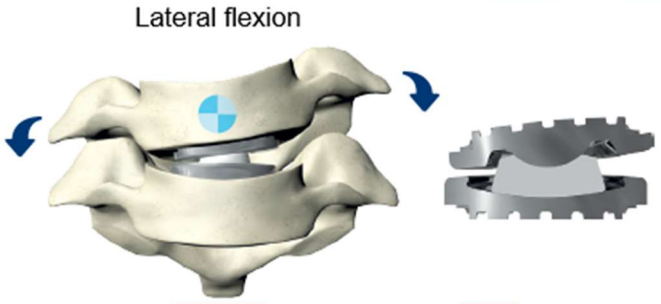

Figure 4: Upper centre of rotation

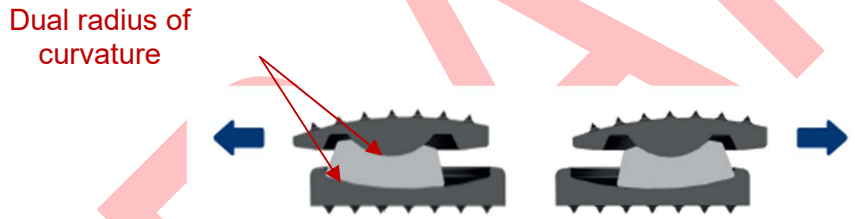

Figure 5: Pure translation

3.1.2. LIST OF REFERENCES

PRODUCT CODE	PRODUCT SHAPE	DESCRIPTION
19000		Small (13x15) – H5
19005		Small (15x15) – H5
19010		Small (13x15) – H6
19015		Small (15x15) – H6
19020		Small (13x15) – H7
19025		Small (15x15) – H7
19100		Medium (15x17) – H5
19105		Medium (17x17) – H5
19110		Medium (15x17) – H6
19115		Medium (17x17) – H6
19120		Medium (15x17) – H7
19125		Medium (17x17) – H7
19130		Medium (15x17) – H8

19135		Medium (17x17) – H8
19260		Large (17x19) – H5
19265		Large (19x19) – H5
19270		Large (17x19) – H6
19275		Large (19x19) – H6
19280		Large (17x19) – H7
19285		Large (19x19) – H7
19290		Large (17x19) – H8
19295		Large (19x19) – H8

Table 1: References of Sterile Cervical Disc Device

3.1.3. PRINCIPLES OF OPERATION

The C DISC device is a medical device which is used with a clamp and intended for cervical disc arthroplasty. The device is made of:

- A superior endplate made of CoCrMo unalloyed titanium-coated, Ti;
- An inferior endplate made of CoCrMo unalloyed titanium-coated, Ti;
- A mobile nucleus made of UHMWPE placed between the two endplates.

The C DISC device is packaged and sterilised, mounted on a gripping clamp. It is this forceps that attaches to the gripping rod, which is part of the ancillary equipment. This gripping clamp is made of alloy of titanium $TiAl_6V_4$. The two devices together are considered a system.

3.1.4. KEY FUNCTIONAL ELEMENTS

The functions of the device under these normal conditions of use - that is, when implanted in the lower cervical intervertebral space - are as follows:

- Maintenance of intervertebral height,
- Stability within the intervertebral space through secure seating, ensured by its anatomical contouring and fixation at the device–vertebra interface,
- Device mobility based on a dual spherical articulation, whose respective radii and spatial arrangement provide a resulting kinematic behavior that adapts to the physiological motion of a functional unit of the lower cervical spine,
- Stability within the intervertebral space due to the device's non-constrained, self-stabilizing, and adaptive kinematic design.

The upper endplates feature a curvature that varies depending on the size:

- S 23,3mm,
- M 33,1mm,
- L 46,1mm.

In addition, a 3° angle is incorporated into all upper endplates, thereby providing a theoretical 3° of lordosis when the prosthesis is in the neutral position.

For the inferior endplate, it is flat and free of angulation. This configuration provides an anatomical profile that helps preserve the vertebral endplate bone stock and ensures natural stability. This stability is further enhanced by the presence of 0.5mm-high teeth, which, by locally penetrating the bone provide primary anteroposterior stability of the implant.

A pure titanium coating, applied by plasma-spray deposition, is added to the entire bone-facing surface of the endplates, with a thickness of 150µm ± 50µm. This coating optimizes contact between the vertebral endplates and the prosthetic endplates, helps distribute and reduce stresses at the interface, and promotes secondary stability at the prosthesis–bone interface.

3.1.5. MATERIALS AND CONTAINED SUBSTANCES

Duration of use or contact with the body
Long term (permanent)

Materials or substances in contact with the patient tissues
The body part on which the device acts or with which it interacts

BRAND NAME	PART OF THE DEVICE	RAW MATERIALS (Commercial name)
C DISC	**Superior endplate**	CoCrMo unalloyed titanium-coated, Ti
	Inferior endplate	CoCrMo unalloyed titanium-coated, Ti
	Mobile Nucleus	UHMWPE
	Grasping forceps	Alloy of titanium $TiAl_6V_4$

Table 2: Materials or substances in contact with the patient tissues for Sterile Cervical Disc Device

Other substances

A medicinal substance (including a human blood or plasma derivative)	**NO**
Tissue(s) or cells of human or animal origin, or their derivatives	**NO**
Substances or combinations of substances that are absorbed by or locally dispersed in the human body	**NO**
Materials incorporated into the device that contain or consist of CMR (carcinogenic, mutagenic or toxic to reproduction) substances or endocrine-disrupting substances	**YES**
Materials that could result in sensitisation or an allergic reaction by the patient or user	**NO**

3.2. A REFERENCE TO PREVIOUS GENERATION(S) OR VARIANTS IF SUCH EXIST, AND A DESCRIPTION OF THE DIFFERENCES

Several changes have been implanted through the years, the table below summarises them:

Change identifiant	Effective date	Summary
DCR 2018-009	2013	Oil change at GSELL VASCO 1000 -> 5000
DCR 2018-012	2013	Oil change at Plailly HYSOL XB -> SWISSCOOL
DCR 2018-013	2015	Oil change at Plailly SWISSCOOL -> HYSOL XB
PCR 2018-010	2015	Oil change at Westlake subcontractor
DCR 2018-009	2018	Oil change at GSELL: VASCO 1000 → 5000

Change identifiant	Effective date	Summary
DCR 2018-012	2018	Oil change in Plailly: HYSOL XB → SWISSCOOL
DCR 2018-013	2018	Oil change in Plailly: SWISSCOOL → HYSOL XB
PCR 2018-010	2018	Oil change by Westlake subcontractor
DCR 2018-014	Abandoned	Validation of the CODESOFT software used for printing labels. New logos
PCR 2018-016	2024	Standardisation of the Dow Corning anti-blocking agent formulation (DC 365) on CARTOLUX blister packs
DCR 2018-052	10/2021	Qualification of a new TRUMPF laser marking machine
PCR 2017-045	2018	A change of washing powder at Westlake
DCR 2018-006	2020	A New Lease of Life for the Springs, 29 January 2018, CEA
/	Mars 2021	CEA's New Revitalisation Programme
DCR 2020-104	2020	Approval of a second gamma sterilisation subcontractor (IONISOS)
PCR 2020-109	2020	Replacement of the M52 decontaminant with the Hexanios G + R decontaminant
DCR 2021-025	2021	Expansion of the product range
DCR 2022-003	2022	Update to the plans to include microblasting
PCR 2022-005	2022	Extension and refurbishment of the premises housing SIMAGEC's medical packaging operations
PCR 2022-006	2025	Rachat de BEMIS par Nelipack
PCR 2022-017	2022	TRUMPF machine validation
PCR 2023-004	2023	Validation of MT-03 plate on MULTIVAC T250 machine_142470
PCR 2023-009	In progress	Addition of a third-party supplier for the conversion of PETG pellets into PETG sheets at Cartolux
PCR 2021-040 et PCR 2021-042	2023	Validation of a new cleaning process in accordance with ISO 19227 and a change in additives.
PCR 2023-010	In progress	Switch from ECOCOOL CS+ machining fluid to VASCO 5000 at the subcontractor SFERIC
PCR 2024-015	In progress	Approval of a new gamma irradiation service provider: STERIS France
PCR 2024-031	2025	Outsourcing of the manufacture of 65x40 adhesive Tyvek grip tabs to an external supplier, CME, at SIMAGEC
PCR 2024-037	Under review	Addition of subcontractor XNMT for the machining of PE components

Change identifiant	Effective date	Summary
PCR 2025-002 :	Under review	Addition of CERAMED as a subcontractor for titanium plasma spray coating
PCR2025-007	In progress	Reduction to a single Vdmax25 family and reduction of bioload families for monitoring
DDM 8551	In progress	Reducing & optimisation of the floor area of the cleanroom
PCR 2025-011	2025	Reduce the number of labels inside the boxes from 4 to 3.
PCR 2025-003	2025	Change of oven at GSELL /
CR26020	On going	Implementation of C DISC elements in Cousin Biotech's quality system Submission of the technical file for the CE certification according to Regulation (UE) 2017/745

Table 3: Changes that have taken place

3.3. DESCRIPTION OF ANY ACCESSORIES WHICH ARE INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

Accessories included: Grasping forceps is included. It exists in three sizes:
- Small (S),
- Medium (M),
- Large (L).

Accessories not included but necessary for use:

Under MDD, the instruments were classified as Class I. Note that the instruments are currently being submitted by the legal manufacturer in MDR with the new classification according to MDR 2017/45, Ire.

The reusable instruments used to implant this device are the following:

INSTRUMENTS REFERENCE	USE	Manufacturer
RCBCDDISTU	Distraction Pliers	COUSIN BIOTECH (the technical file has not been submitted yet)
19608	Distraction Pliers	CERAVER
RCBCDPEBOU	Small Disc Space Opener (13x15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMOBOU	Medium Disc Space Opener (15x17)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGRBOU	Large Disc Space Opener (17x19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPECAU	Square Small Disc Space Opener (15x15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMOCAU	Square Medium Disc Space Opener (17x17)	COUSIN BIOTECH (the technical file has not been submitted yet)

RCBCDGRCAU	Square Large Disc Space Opener (19x19)	COUSIN BIOTECH (the technical file has not been submitted yet)
19616	Pin for Caspar Distractor 16mm	CERAVER
19605	Pin for Caspar Distractor 12mm	CERAVER
19602	Pin for Caspar Distractor 14mm	CERAVER
19610	Screwdriver for Caspar Pins	CERAVER
19601	Nut for Caspar	CERAVER
19600	Right Caspar Distractor	CERAVER
19545	Medium H5-height template	CERAVER
19609	DISTRACTEUR TYPE CASPAR GAUCHE	CERAVER
19609	Left Caspar Distractor	CERAVER
19548	Medium H8-height template	CERAVER
19607	GABARIT AP	CERAVER
19607	AP Measurement Device	CERAVER
19603	GABARIT DE LARGEUR « SMALL »	CERAVER
19604	GABARIT DE LARGEUR « MEDIUM »	CERAVER
19603	Footprint Trial Device Small	CERAVER
19604	Footprint Trial Device Medium	CERAVER
19605	Footprint Trial Device Large	CERAVER
19535	Small Trial Device H5	CERAVER
19536	Small Trial Device H6	CERAVER
19537	Small Trial Device H7	CERAVER
19545	Medium Trial Device H5	CERAVER
19546	Medium Trial Device H6	CERAVER
19547	Medium Trial Device H7	CERAVER
19548	Medium Trial Device H8	CERAVER
19555	Large Trial Device H5	COUSIN BIOTECH (the technical file has not been submitted yet)
19556	Large Trial Device H6	COUSIN BIOTECH (the technical file has not been submitted yet)
19557	Large Trial Device H7	COUSIN BIOTECH (the technical file has not been submitted yet)
19558	Large Trial Device H8	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPG56U	Small Trial Device H5-H6 (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPG67U	Small Trial Device H6-H7 (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMG56U	Medium Trial Device H5-H6 (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMG78U	Medium Trial Device H7-H8 (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGG56U	Large Trial Device H5-H6 (17 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)

RCBCDGG78U	Large Trial Device H6-H7 (17 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPC56U	Square Small Trial Device H5-H6 (15 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPC67U	Square Small Trial Device H6-H7 (15 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMC56U	Square Medium Trial Device H5-H6 (17 x 17)	CERAVER
RCBCDMC78U	Square Medium Trial Device H7-H8 (17 x 17)	CERAVER
RCBCDGC56U	Square Large Trial Device H5-H6 (19 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGC78U	Square Large Trial Device H6-H7 (19 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
19240	Implant Holder - Body	COUSIN BIOTECH (the technical file has not been submitted yet)
19240_06	Implant Holder - Rod	CERAVER
RCBDPORTU	Implant Holder	CERAVER
RCBDINPOU	Inner Rod for Implant Holder	CERAVER
RCBDEMPLU	Implant Holder	CERAVER
RCBCDBUTEU	Adjustable Stop for Implant Holder	CERAVER
19421	Revision Instrument Small Cranial	CERAVER
19422	Revision Instrument Small Caudal	CERAVER
19423	Revision Instrument Medium Cranial	COUSIN BIOTECH (the technical file has not been submitted yet)
19424	Revision Instrument Medium Caudal	COUSIN BIOTECH (the technical file has not been submitted yet)
19425	Revision Instrument Large Cranial	COUSIN BIOTECH (the technical file has not been submitted yet)
19426	Revision Instrument Large Caudal	COUSIN BIOTECH (the technical file has not been submitted yet)
19419	Clamp for Releasing Revision Instruments	COUSIN BIOTECH (the technical file has not been submitted yet)
19420	Clamp for Opening Revision Instruments	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDREPOU	Implant Repositioner	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPEABU	Small Implant Removal Clamp (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMOABU	Medium Implant Removal Clamp (15 x 17)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGRABU	Large Revision Clamp (17 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDABLAU	Revision Instrument	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMARTU	Slap Hammer	COUSIN BIOTECH (the technical file has not been submitted yet)

RCBDMEASU	AP Measuring Device	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBDCONTU	Container	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBDCOUVU	Lid	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCONOU	Optional Container	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCOUOU	Lid for Optional Container	COUSIN BIOTECH (the technical file has not been submitted yet)

Table 4: Instruments references

3.4. DESCRIPTION OF ANY OTHER DEVICES AND PRODUCTS WHICH ARE INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

No other devices are intended to be used in combination with C DISC implants in addition to generic surgical instruments.

4. RISKS AND WARNINGS

4.1. RESIDUAL RISKS AND UNDESIRABLE EFFECTS

The undesirable side effects of the Sterile Cervical Disc Device are:
The list of side effects listed below is not exhaustive.

Potential or actual adverse effects of cervical disc prostheses are:
- Migration of one of the components or implant,
- Insertion of prosthetic plates into the vertebral bodies,
- Loss of mobility,
- Failure of the medical device (wear, breakage, disassembly, etc.),
- Inflammation, Tissue reaction to prosthesis materials,
- Fracture of bone structures near the medical device,
- Allergies to the materials of the implant,

Potential or actual adverse effects related to the surgical procedure are:
- Dysphagia, hoarseness/dysfunction of the vocal cords,
- Visceral wound (esophagus, airway, etc.),
- Airway obstruction,
- Pneumonia, Atelecticasis,
- Phlebitis, Thrombotic accidents,
- Cerebrovascular accident (CVA),
- Myocardial infarction,
- Haemorrhage requiring a blood transfusion,
- Hematoma and/or poor healing,
- Infection, Sepsis,
- Death,
- Dysesthesia, numbness, Paresthesia,
- Damage to neurovascular structures,
- Soft tissue injury, spinal cord injury, nerve root injury,

- Dural tear, cerebrospinal-fluid leak, compressive anterior meningocele,
- Change in spinal alignment, sagging, spinal instability,
- Implant loosening and migration leading to instability,
- Increase of operating time, Delayed surgery,
- Ectopic ossification,

Other potential or actual adverse reactions:

- Adjacent level degeneration/disease,
- Heterotopic ossification of the cervical spine,
- Persistence or postoperative recurrence of pain or functional/neurological deficit,
- Re-intervention due to one of the set of effects listed above.

4.2. WARNINGS AND PRECAUTIONS

The warnings of the Sterile Cervical Disc Device, including warning concerning surgical technique, are described below:

- Preoperative Precautions

The following factors may significantly influence clinical outcomes:

- Effective mobility of the spinal segment considered for arthroplasty.
- Patient activity level or occupation: if the patient's profession or activities require lifting heavy loads and/or performing significant muscular exertion, the resulting forces may lead to failure of biological fixation and/or of the implantable device.
- Senility, mental illness, or substance abuse disorders (e.g., alcoholism): such conditions may cause the patient to disregard necessary precautions and limitations associated with the use of the implantable device, potentially compromising implant integrity or leading to other complications.
- Certain degenerative bone conditions: in some cases, the progression of degenerative diseases at the time of implantation may significantly shorten the implantable device's service life (e.g., severe osteoporosis and/or osteomalacia).

- Intraoperative Precautions

- Reusable instruments intended for implantation of the C DISC cervical disc prosthesis must be cleaned and sterilized before use. Refer to the instructions for use detailing the recommended cleaning and sterilization procedures supplied with the instruments.
- The C DISC cervical disc prosthesis is delivered pre-assembled and sterile on a specially designed grasping clamp. Specific instructions for handling and using this assembly are provided in the surgical technique.
- The environment and handling of both the implantable device and the instruments must maintain sterility throughout the entire surgical procedure. Careful handling of the implant is essential. Do not subject the implant to shocks or impacts. Do not allow the implantable device to come into contact with metallic or other surfaces that may damage its surfaces. Do not use the implantable device if it shows scratches or other alterations that could compromise its performance.
- Do not allow the titanium powder–based coating to come into contact with cloth or other materials that may contaminate it.
- Medical devices must not undergo any treatment or modification.
- During disc space preparation, template insertion, and final insertion of the implantable device into the intervertebral space, any force, vibration, shock, or impaction applied to the operated cervical

segment must be minimized. Adequate access to the disc space must be achieved using the provided distraction instruments.
- Before releasing the implant from the holder, an intraoperative radiograph must be taken to confirm correct positioning of the implant.

- Postoperative Precautions

  - The patient should be informed of the limitations associated with the C DISC cervical disc prosthesis and advise them on the permissible level of activity.
  - High-energy sports and activities involving head impacts—such as combat sports and acrobatics—are discouraged, as they may cause abnormal wear, dislocation, or migration of the implant.
  - Carefully structure early postoperative care to maintain joint mobility and prevent any dislocation.
  - Every patient with a C DISC cervical disc prosthesis must undergo postoperative follow-up by an orthopaedic surgeon or neurosurgeon. This follow-up is necessary to detect signs of wear, dislocation, or migration before functional symptoms appear.
  - Radiographic examinations should be performed regularly and compared with immediate postoperative images to detect any medium- or long-term changes or progressive shifts in implant position, component fracture and/or disassembly, or bone remodelling.
  - The implants are compatible with MRI examinations using a static magnetic field of 3 Tesla or less. However, they may generate artifacts that must be considered for proper image interpretation. A 48-hour delay between implantation and MRI is recommended. Safety, compatibility, heating, and migration of the CERADISC implant have not been directly tested in MRI; evaluation was based on comparison with equivalent medical devices available on the market.
  - The patient should be encouraged to immediately inform their physician of any unusual changes in the operated joint.
  - MRI compatibility: COUSIN BIOTECH bipolar head components are non-ferromagnetic. Their geometry does not promote induced currents, and they are secured to the bone or implant, reducing the risk of displacement. Their safety—particularly regarding heating and migration—was assessed using published data and comparison with devices of similar composition, shape, and intended use. This evaluation concluded that MRI examinations up to 3 Tesla pose no danger and that the devices are conditionally compatible.
  - As a precaution, MRI examinations should be avoided within 48 hours of implantation, and the imaging specialist should be informed of any recent implant placement if an MRI is deemed necessary.
  - Note that any device with high contrast relative to surrounding biological tissues may generate artifacts that must be considered for proper imaging and interpretation. Patients with implants should be advised to inform all relevant healthcare professionals (radiologists and radiologic technologists) of the presence of an implant prior to imaging examinations.

4.3. OTHER ASPECTS OF SAFETY, INCLUDING A SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION (FSCA INCLUDING FSN) IF APPLICABLE

No FSCA has been issued since 2018.

5. SUMMARY OF CLINICAL EVALUATION AND INFORMATION ON POST-MARKET CLINICAL FOLLOW-UP

5.1. SUMMARY OF CLINICAL DATA RELATED TO EQUIVALENT DEVICE, IF APPLICABLE

Not applicable.

5.2. SUMMARY OF CLINICAL DATA FROM INVESTIGATIONS OF THE DEVICE BEFORE CE-MARKING, IF APPLICABLE

Not applicable.

5.3. SUMMARY OF CLINICAL DATA FROM OTHER SOURCES, IF APPLICABLE

According to the Clinical Evaluation Report:

A systematic review of literature was conducted on Medline, Google scholar, Elsivier, Cochrane Library, Clinical Trial and FDA TPLC. The following articles were identified and included in the clinical evaluation of C DISC.

The following clinical situations are represented:
- Arthropathic facet-syndrome,
- Foraminal stenosis,
- Degenerative discopathy,
- Intervertebral ligament insufficiency / segmental instability.

Table 5 - Synthetic table of performances and link to benefits

Performance	Linked Benefit	clinical studies in support	Other relevant data	Ranking of data	Limitation of data / uncertainties	Missing data
Cervical disc degenerative disease 1 level						
Improves/ maintain motion >threshold	Improved QoL (indirect)	CERADISC PMCF study interim report 2026 (Charles et al. 2020)	PMCF general methods Preclinical	Rank 3 Rank 7 Rank 11-12	Preliminary descriptive results on first 44/107 patients (/145) Short follow-up Partial duplication	No
Improves function >threshold		CERADISC PMCF study interim report 2026 (Charles et al. 2020)	PMCF general methods	Rank 3 Rank 7		No
Decreases Pain >threshold		CERADISC PMCF study interim report 2026 (Charles et al. 2020)	PMCF general methods	Rank 3 Rank 7		No
Improves quality of life significant	Improved QoL (direct measurement)	CERADISC PMCF study interim report 2026 (Charles et al. 2020)	PMCF general methods	Rank 3 Rank 7		No
Cervical disc degenerative disease >1 level (2-3 levels)						
Improves/ maintain motion >threshold	Improved QoL (indirect)	CERADISC PMCF study interim report 2026 (Charles et al. 2020)	PMCF general methods Preclinical	Rank 3 Rank 7 Rank 11-12	Preliminary descriptive results on first 59/107	No

Performance	Linked Benefit	clinical studies in support	Other relevant data	Ranking of data	Limitation of data / uncertainties	Missing data
Improves function >threshold		CERADISC PMCF study interim report 2026 (Charles et al. 2020)	PMCF general methods	Rank 3 Rank 7	patients (/145) Short follow-up Partial duplication	No
Decreases Pain >threshold		CERADISC PMCF study interim report 2026 (Charles et al. 2020)	PMCF general methods	Rank 3 Rank 7		No
Improves quality of life significant	Improved QoL (direct measurement)	CERADISC PMCF study interim report 2026 (Charles et al. 2020)	PMCF general methods	Rank 3 Rank 7		No

Table 6 - Studies performed on the device (according to CEP)

Type of study	Citation/ Study reference	N Patients	N DEVICE
PMCF study	CERADISC Observational PMCF Study 2026 (interim report)	107 patients included at the time of report. (/145 planned inclusions)	160 described (196 calculated from levels treated)
Literature	(Charles et al. 2020)	29	ND

Only one version of the device exists
The adaptation of size was made only to conform to the patient anatomy
- The size was chosen to provide the best possible coverage of the vertebral bodies.
- The selected height had to be compatible with the height of the adjacent healthy discs

For the documented sizes (160 implants) the distribution covers all footprints and all thicknesses except the highest one (expected)

Size	N implants	% documented implants
Small (13×15)	39	24.4%
Medium (15×17)	71	44.4%
Large (17×19)	50	31.3%
Total	**160**	**100%**

Height	N implants	%
H5	106	66.3%
H6	50	31.3%
H7	4	2.5%
H8	0	0%
Total	**160**	**100%**

- The most commonly used size is Medium 15×17 H5 with 49 implants.
- Implants with a height of 5 mm account for around two-thirds of those used

The total number of patients included in the studies is 107, which is sufficient to cover most use and situations

Note: the inclusions of the PMCF study have been completed, and 145 patients are now included with a 2-3 y follow-up

According to the PMS Data:
Since 2018, 658 devices have been launched on the market. 2 complaints have been reported, in 2023 – REC2023-02 - and in 2024 – REC2024-01 -. Both are materiovigilances:

Table 7 - Materiovigilances reported since 2018

N° complaint	Reference	Description	Incident typology
REC2023-02	19110	On 09/05/2023, in a spinal surgery operating room, during the placement of a cervical prosthesis, it was found that the prosthesis holder surrounding the implant had failed during the procedure, at the time the surgeon impacted the prosthesis, making the device unusable. A device of the same reference and identical batch was used. No clinical consequences were observed in the 57-year-old patient.	Unintentional ejection (A050302) / No device problem found (C19) / No health consequences or impact (F26)
REC2024-01	19270	Patient with C6-C7 distal hernia, C6-C7 prosthesis placement with left dislocation. No neurological impact	Migration (A010402) / No device problem found (C19) / Additional Surgery (F1901)

The total number of customer complaints concerning C DISC is low compared to the number of products sold (0.3%).

Based on the low frequency of complaints, the safety profile of the implants is confirmed.

5.4. AN OVERALL SUMMARY OF THE CLINICAL PERFORMANCE AND SAFETY

In accordance with MDR 2017/745 UE, and with the PMS procedure, a post-marketing surveillance plan has been established. This plan describes the activities implemented by COUSIN BIOTECH to continually update the data presented in this Clinical Evaluation Report and in particular:

- The acceptability of the risk benefit ratio compared to the state of the art and current clinical knowledge, and therapeutic alternatives.
- The adequacy of the information provided with the device compared to expectations in terms of instructions and risk management measures.
- The suitability of the device (including the information of the IFU) in relation to the clinical needs of the target users and the usability of the products.
- Consistency of performances and benefits claimed by the COUSIN BIOTECH for the device based on available clinical data

5.5. ONGOING OR PLANNED POST MARKET CLINICAL FOLLOW-UP

For the Sterile Cervical Disc Device, a PMCF Study is ongoing:

- CERADISC Observational PMCF Study 2026 (ID-RCB: 2023-A01046-39)

Follow up (current interim analysis):

- Pre-operative visit: 107/107 patients,
- Intervention: 107/107 patients,
- 1-3 months follow up: 107/107 patients,
- 6 months visit follow-up: 92/107 patients,
- 1 year follow-up: 87/107 patients,
- 2 years follow-up: 65/107 patients,
- 5 years follow-up 23/107 patients,
- 7 years follow-up: none.

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Patients suffering from symptomatic cervical degenerative disc disease (SCDD) may be managed using different diagnostic and therapeutic approaches depending on the severity of symptoms, neurological status, and response to conservative treatment.

In the initial stages, non-surgical management is generally recommended. Conservative treatment options include analgesic medication, non-steroidal anti-inflammatory drugs (NSAIDs), physiotherapy, activity modification, cervical immobilization, and epidural steroid injections. These approaches aim to reduce pain and improve functional status. However, in some patients, conservative treatments may fail to provide adequate symptom relief.

When conservative treatment is unsuccessful or when neurological impairment persists, surgical treatment may be considered. The traditional surgical approach for symptomatic cervical DDD is anterior cervical discectomy and fusion (ACDF). This procedure involves removal of the degenerated intervertebral disc followed by stabilization of the segment using bone grafts and/or interbody cages, with or without anterior plate fixation. ACDF has been widely used for several decades and is considered an established treatment option.

An alternative surgical treatment is cervical disc arthroplasty (CDA), which consists of replacing the degenerated intervertebral disc with an artificial disc prosthesis intended to preserve motion at the treated spinal level. Motion preservation may help maintain more physiological biomechanics of the cervical spine compared to fusion procedures.

Both ACDF and cervical disc arthroplasty are recognized treatment options for appropriately selected patients with cervical degenerative disc disease. The choice of treatment depends on several factors, including the patient's clinical condition, anatomical considerations, surgeon preference, and the presence of contraindications such as significant facet joint degeneration, instability, or osteoporosis.

7. SUGGESTED PROFILE AND TRAINING FOR USERS

The C DISC STERILE CERVICAL DISC DEVICE is intended exclusively for use by a surgeon (orthopaedic surgeon or neurosurgeon).

8. REFERENCE TO ANY HARMONISED STANDARDS AND COMMON SPECIFICATIONS APPLIED

Harmonised standards title	Date
EN ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes	September 2021 + A11
NF EN ISO 9001 Quality Management systems - Requirements	October 2015 +A1:2024
NF EN ISO 14630 – Non-active surgical implants – General requirements	December 2024
NF EN ISO 21534 – Non-active surgical implants – Joint replacement implants – Particular requirements	August 2009
ISO 18192-1 – Implants for surgery – Wear of total intervertebral spinal disc prostheses – Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions	December 2018 + A1:2018
ASTM F2346 – Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs	February 2026
NF EN ISO 5832-12 – Implants for surgery – Metallic materials – Part 12: Wrought cobalt-chromium-molybdenum alloy	July 2019
NF EN ISO 5832-3 – Implants for surgery – Metallic materials – Part 3: Wrought titanium-6 aluminium-4 vanadium alloy	December 2021
ASTM F136 – Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications	February 2026
NF ISO 5834-1 – Implants for surgery – Ultra-high-molecular-weight polyethylene – Part 1: Powder form	July 2025
NF ISO 5834-2 – Implants for surgery – Ultra-high-molecular-weight polyethylene – Part 2: Moulded forms	September 2025
ASTM F648 – Standard Specification for UHMWPE Powder and Fabricated Form for Surgical Implants	April 2021
ASTM F1580 – Standard Specification for Titanium and Titanium-6Aluminum-4Vanadium Alloy Powders for Coatings of Surgical Implants	July 2026
NF ISO 13179-1 – Implants for surgery – Plasma-sprayed unalloyed titanium coatings on metallic surgical implants – Part 1: General requirements	December 2021
NF EN 556-1 – Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices	July 2024
NF EN ISO 11137-1 – Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	January 2016 + A2:2019
NF EN ISO 11137-2 – Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose	December 2015 + A1:2023
NF EN ISO 11137-3 – Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects	July 2017
NF EN ISO 11737-1 – Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	January 2018 + A1:2021
NF EN ISO 11737-2 – Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	May 2020
European Pharmacopoeia – Sterility	Ph. Eur. 2.6.1 (current edition)
European Pharmacopoeia – Bacterial endotoxins	Ph. Eur. 2.6.14 (current edition)
NF EN ISO 14971 – Medical devices – Application of risk management to medical devices	December 2019 + A11 (December 2021)
EN IEC 62366-1 – Medical devices – Application of usability engineering to medical devices	2015 + A1:2020

NF S94-091 – Surgical implants – Cleaning validation of orthopaedic implants prior to final packaging	August 2013
NF ISO 19227 – Implants for surgery – Cleanliness of orthopaedic implants – General requirements	August 2018
NF EN ISO 9377-2 – Water quality – Determination of hydrocarbon oil index – Part 2: Solvent extraction and gas chromatography method	December 2000
NF EN 1484 – Water analysis – Guidelines for the determination of total organic carbon (TOC) and dissolved organic carbon (DOC)	July 1997
NF EN ISO 10993-1 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	December 2025
NF EN ISO 10993-3 – Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	December 2014
NF EN ISO 10993-5 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	July 2010 +A11:2025
NF EN ISO 10993-10 – Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	February 2023
NF EN ISO 10993-23 – Biological evaluation of medical devices – Part 23: Tests for irritation	March 2021 +A1:2025
NF EN ISO 10993-11 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	May 2018
NF EN ISO 10993-12 – Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	July 2021 + A1:2025
NF EN ISO 10993-15 – Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys	July 2023
NF EN ISO 10993-17 – Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substance	July 2023 + A1:2025
NF EN ISO 10993-18 – Biological evaluation of medical devices – Part 18: Chemical characterization of materials	May 2020 + A1:2023
NF EN ISO 14644-1 – Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	February 2016
NF EN ISO 14644-2 – Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance	February 2016
NF EN ISO 14644-3 – Cleanrooms and associated controlled environments – Part 3: Test methods	October 2019
NF EN ISO 14644-4 – Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up	December 2022
NF EN ISO 14644-5 – Cleanrooms and associated controlled environments – Part 5: Operations	June 2025
NF EN 17141 – Cleanrooms and associated controlled environments – Biocontamination control	August 2020
NF EN ISO 11607-1 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	January 2020 +A1:2023
NF EN ISO 11607-2 – Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	January 2020 +A11:2023
ASTM F88 – Standard Test Method for Seal Strength of Flexible Barrier Materials	May 2023
ASTM F1929 – Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	November 2023
ASTM F1980 – Standard Guide for Accelerated Aging of Sterile Barrier Systems	December 2021
ASTM F1886 – Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	October 2025
ASTM F1140 – Internal Pressurization Failure Resistance of Unrestrained Packages	October 2025
ISO 2859-1 – Sampling procedures for inspection by attributes	January 2026
ASTM D4169 – Performance Testing of Shipping Containers and Systems	December 2023

ASTM F2503 – Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	April 2026
DIN 1041 – Information supplied by the manufacturer of medical devices	December 2009
NF EN ISO 20417 – Medical devices – Information to be supplied by the manufacturer	April 2026
NF EN ISO 15223-1 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied	September 2021 + A1:2025
NF EN ISO 14155 – Clinical investigation of medical devices for human subjects – Good clinical practice	August 2020 + A11:2024

SECTION 2: SSCP FOR PATIENTS

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 people. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

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 condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1. DEVICE IDENTIFICATION AND GENERAL INFORMATION

1.1. DEVICE TRADE NAME(S)

The family identified and concerned by the SCCP is Sterile Cervical Disc Device, included: C DISC

1.2. MANUFACTURER'S NAME AND ADDRESS

COUSIN BIOTECH
Allé des Roses,
59117 Wervicq-Sud
FRANCE

1.3. BASIC UDI-DI

The Basic UDI-DI for the C DISC is 376018557DISCCERVIMP32

1.4. YEAR WHEN THE FIRST CERTIFICATE WAS ISSUED COVERING THE DEVICE

The products concerned by this document file have been initially developed, CE marked and then commercialized under the name ''CERADISC'' by the company CERAVER – Les laboratoires Ostéal Médical. Since 2017, about 658 CERADISC have been sold in France and in Portugal. Then, in November 2025, COUSIN BIOTECH has purchased the implant and will act as its distributor until 31 December 2027. During this period, COUSIN BIOTECH will prepare the submission according to the Regulation (UE) 2017/745. After the approval of the Notified Body (SGS), COUSIN BIOTECH will become the legal manufacturer of the implant, which will then be marketed under the name ''C DISC''.

2. INTENDED USE OF THE DEVICE

2.1. INTENDED PURPOSE

The intended purpose of the Sterile Cervical Disc Device is cervical disc arthroplasty the surgical replacement of one or more degenerative intervertebral discs via an anterior approach. Its purpose is to restore disc height at the level in question, while providing a degree of functional mobility compatible with the physiological motion of the spinal segment, help spinal decompression, and relieve or at least reduce pain.

2.2. INDICATIONS AND INTENDED GROUPS

The intended patient population of the SCDD is only fully grown adults.

The indications of the Sterile Cervical Disc Device are symptomatic cervical degenerative disc disease of the cervical spine from C3 to T1 in adults, which may be accompanied by radiculopathy (nerve roots damage), moderate spinal cord injury, functional/neurological deficit in the arm and/or neck, at one or more levels (maximum 3 levels), with at least one of the following pathologies:

- Disc herniation,
- Disc protrusion with root canal stenosis,
- Mild or moderate spondylarthrosis (or spondylosis, a degeneration of the spine joints)

The mobility of the level to be operated on must be assessed beforehand.

The insertion of a cervical disc prosthesis is considered when all non-surgical alternatives have been exhausted and deemed less appropriate and/or less effective.

2.3. CONTRAINDICATIONS

The **contraindications** of the Sterile Cervical Disc Device are:

Contraindications related to the pathology

- Severe cervi-osteoarthritis or ossification myelopathy (OPLL),
- Severe facet osteoarthritis,
- Predominant posterior compression spinal canal stenosis,
- Spondylolisthesis, retrolisthesis (displaced or unstable vertebrae),
- Significant segmental instability,
- Posture of the cervical spine in segmental kyphosis (inversion of the neck curve),
- Fracture,
- Surgery such as laminectomy and/or fusion by posterior approach of the segment concerned.

Patient-related contraindications

- Osteoporosis or severe osteopenia (insufficient bone density),
- Metabolic Bone Diseases,
- Systemic Inflammatory Osteoarticular Diseases,
- Rheumatoid arthritis,
- Bone tumour in the affected area,
- Any acute, chronic or local infection,
- Severe alcoholism,
- Pregnancy,
- Morbid (class III) obesity,
- Lack of patient cooperation,
- Senility,

Implant-related contraindications

- Allergy to at least one of the implant materials.

3. DEVICE DESCRIPTION

3.1. DEVICE DESCRIPTION AND MATERIALS/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

3.1.1. GENERAL DESCRIPTION

The prosthesis consists of three components and is designed for cementless implantation:

- A superior endplate made of Cobalt-Chrome alloy, with pure titanium coating;
- An inferior endplate made of Cobalt-Chrome alloy, with pure titanium coating;
- A mobile nucleus made of UHMWPE (dense Polyethylene) placed between the two endplates.

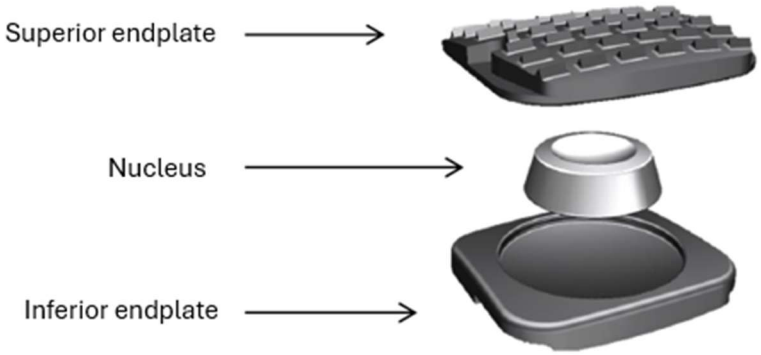

Figure 6: View of the C DISC prothesis

The teeth on the outer sides of the two plates enable cement-free implantation. With a height of 0.5 mm, they penetrate the bone locally, ensuring primary anterior-posterior stability.

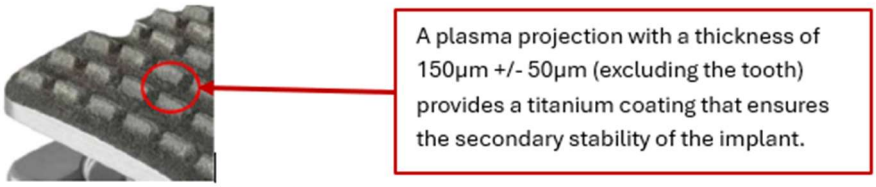

Figure 7: C DISC endplate surface

The intended purpose of the Sterile Cervical Disc Device is cervical disc arthroplasty, the surgical replacement of one or more degenerative intervertebral discs via an anterior approach. Its purpose is to restore disc height at the level in question, while providing a degree of functional mobility compatible with the physiological motion of the spinal segment, help spinal decompression, and relieve or at least reduce pain.

The placement of a cervical disc prosthesis is considered when all non-surgical alternatives have been exhausted and deemed less appropriate and/or less effective.

The indications of the Sterile Cervical Disc Device are symptomatic cervical degenerative disc disease of the cervical spine from C3 to T1 in adults, which may be accompanied by radiculopathy (nerve roots damage), moderate spinal cord injury, functional/neurological deficit in the arm and/or neck, at one or more levels (maximum 3 levels), with at least one of the following pathologies:

- Disc herniation
- Disc protrusion with canal stenosis
- Mild or moderate spondylarthrosis (or spondylosis, a degeneration of the spine joints)

3.1.2. LIST OF REFERENCES

PRODUCT CODE	PRODUCT SHAPE	DESCRIPTION
19000		Small (13x15) – H5
19005		Small (15x15) – H5
19010		Small (13x15) – H6
19015		Small (15x15) – H6
19020		Small (13x15) – H7
19025		Small (15x15) – H7
19100		Medium (15x17) – H5
19105		Medium (17x17) – H5
19110		Medium (15x17) – H6
19115		Medium (17x17) – H6
19120		Medium (15x17) – H7
19125		Medium (17x17) – H7
19130		Medium (15x17) – H8
19135		Medium (17x17) – H8
19260		Large (17x19) – H5
19265		Large (19x19) – H5
19270		Large (17x19) – H6
19275		Large (19x19) – H6
19280		Large (17x19) – H7
19285		Large (19x19) – H7
19290		Large (17x19) – H8
19295		Large (19x19) – H8

Table 8: References of Sterile Cervical Disc Device

3.1.3. MATERIALS AND CONTAINED SUBSTANCES

Duration of use or contact with the body
Long term (permanent)

Materials or substances in contact with the patient tissues
The body part on which the device acts or with which it interacts

BRAND NAME	PART OF THE DEVICE	RAW MATERIALS (Commercial name)
C DISC	**Superior endplate**	Cobalt-Chrome alloy, with pure titanium coating
	Inferior endplate	Cobalt-Chrome alloy, with pure titanium coating
	Mobile Nucleus	UHMWPE (dense Polyethylene)
	Grasping forceps	Alloy of titanium $TiAl_6V_4$

Table 9: Materials or substances in contact with the patient tissues for Sterile Cervical Disc Device

Other substances

A medicinal substance (including a human blood or plasma derivative)	**NO**
Tissue(s) or cells of human or animal origin, or their derivatives	**NO**
Substances or combinations of substances that are absorbed by or locally dispersed in the human body	**NO**
Materials incorporated into the device that contain or consist of CMR (carcinogenic, mutagenic or toxic to reproduction) substances or endocrine-disrupting substances	**YES**
Materials that could result in sensitisation or an allergic reaction by the patient or user	**NO**

3.2. INFORMATION ABOUT MEDICINAL SUBSTANCES IN THE DEVICE, IF ANY

Not applicable

3.3. DESCRIPTION OF HOW THE DEVICE ACHIEVING ITS INTENDED MODE OF ACTION

The C DISC device is a medical device which is used with a clamp and intended for cervical disc arthroplasty (replacement of the disc by an artificial disc).
The device is made of:

- A superior endplate made of Cobalt-Chrome alloy, with pure titanium coating;
- An inferior endplate made of Cobalt-Chrome alloy, with pure titanium coating;
- A mobile nucleus made of UHMWPE (dense Polyethylene) placed between the two endplates.

The C DISC is provided sterile in a protective package. It is preassembled with a grasping forceps that allows the surgeon to position the C DISC to replace the natural disc.

Functions of the device under these normal conditions of use, i.e. when implanted in the lower cervical intervertebral space, are as follows:

- Maintenance of intervertebral height.
- Stability within the intervertebral space through proper seating: anatomical conformation and fixation at the device/vertebra interface.
- Device mobility, based on a double spherical articulation whose respective radii and positioning provide a resultant range of motion similar to a functional lower cervical spine.
- Stability within the intervertebral space, ensured by the non-constrained, self-stabilising, and adaptive nature of the device's kinematics.

3.4. DESCRIPTION OF ACESSORIES, IF ANY

Accessories included: Grasping forceps is included. It exists in three sizes:
- Small (S)
- Medium (M)
- Large (L)

Accessories not included but necessary for use:
The reusable instruments used to implant this device are the following:

INSTRUMENTS REFERENCE	USE	Manufacturer
RCBCDDISTU	Distraction Pliers	COUSIN BIOTECH (the technical file has not been submitted yet)
19608	PINCE DE DISTRACTION	CERAVER
RCBCDPEBOU	Small Disc Space Opener (13x15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMOBOU	Medium Disc Space Opener (15x17)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGRBOU	Large Disc Space Opener (17x19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPECAU	Square Small Disc Space Opener (15x15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMOCAU	Square Medium Disc Space Opener (17x17)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGRCAU	Square Large Disc Space Opener (19x19)	COUSIN BIOTECH (the technical file has not been submitted yet)
19616	BROCHE 16mm	CERAVER
19602	BROCHE 14mm	CERAVER
19610	PORTE-BROCHE	CERAVER
19601	ECROU DE VERROUILLAGE	CERAVER
19600	DISTRACTEUR TYPE CASPAR DROIT	CERAVER
19537	Small H7-height template	CERAVER
19545	Medium H5-height template	CERAVER
19609	DISTRACTEUR TYPE CASPAR GAUCHE	CERAVER
19547	Medium H7-height template	CERAVER
19548	Medium H8-height template	CERAVER
19607	GABARIT AP	CERAVER
19556	Large H6-height template	CERAVER
19557	Large H7-height template	CERAVER
19603	GABARIT DE LARGEUR « SMALL »	CERAVER
19604	GABARIT DE LARGEUR « MEDIUM »	CERAVER
19605	GABARIT DE LARGEUR « LARGE »	CERAVER
19535	GABARIT DE HAUTEUR SMALL H5	CERAVER
19536	GABARIT DE HAUTEUR SMALL H6	CERAVER
19537	GABARIT DE HAUTEUR SMALL H7	CERAVER
19545	GABARIT DE HAUTEUR MEDIUM H5	CERAVER
19546	GABARIT DE HAUTEUR MEDIUM H6	CERAVER
19547	GABARIT DE HAUTEUR MEDIUM H7	CERAVER
19548	GABARIT DE HAUTEUR MEDIUM H8	CERAVER
19555	GABARIT DE HAUTEUR LARGE H5	CERAVER
19556	GABARIT DE HAUTEUR LARGE H6	CERAVER
19557	GABARIT DE HAUTEUR LARGE H7	CERAVER
19558	GABARIT DE HAUTEUR LARGE H8	CERAVER
RCBCDPG56U	Small Trial Device H5-H6 (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)

RCBCDPG67U	Small Trial Device H6-H7 (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMG56U	Medium Trial Device H5-H6 (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMG78U	Medium Trial Device H7-H8 (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGG56U	Large Trial Device H5-H6 (17 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGG78U	Large Trial Device H6-H7 (17 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPC56U	Square Small Trial Device H5-H6 (15 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDPC67U	Square Small Trial Device H6-H7 (15 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMC56U	Square Medium Trial Device H5-H6 (17 x 17)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMC78U	Square Medium Trial Device H7-H8 (17 x 17)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGC56U	Square Large Trial Device H5-H6 (19 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGC78U	Square Large Trial Device H6-H7 (19 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
19240	PREHENSEUR – CORPS	CERAVER
19240_06	PREHENSEUR – TIRANT	CERAVER
RCBDPORTU	Implant Holder	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBDINPOU	Inner Rod for Implant Holder	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBDEMPLU	Implant Holder	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDBUTEU	Adjustable Stop for Implant Holder	COUSIN BIOTECH (the technical file has not been submitted yet)
19421	INSTRUMENT DE REVISION – CORPS SUPERIEUR SMALL	CERAVER
19422	INSTRUMENT DE REVISION – CORPS INFERIEUR SMALL	CERAVER
19423	INSTRUMENT DE REVISION – CORPS SUPERIEUR MEDIUM	CERAVER
19424	INSTRUMENT DE REVISION – CORPS INFERIEUR MEDIUM	CERAVER
19425	INSTRUMENT DE REVISION – CORPS SUPERIEUR LARGE	CERAVER
19426	INSTRUMENT DE REVISION – CORPS INFERIEUR LARGE	CERAVER
19419	INSTRUMENT DE REVISION – CAPOT DE DEVERROUILLAGE	CERAVER
19420	INSTRUMENT DE REVISION – CAPOT DE VERROUILLAGE	CERAVER
RCBCDREPOU	Implant Repositioner	COUSIN BIOTECH (the technical file has not been submitted yet)

RCBCDPEABU	Small Implant Removal Clamp (13 x 15)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMOABU	Medium Implant Removal Clamp (15 x 17)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDGRABU	Large Revision Clamp (17 x 19)	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDABLAU	Revision Instrument	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCDMARTU	Slap Hammer	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBDMEASU	AP Measuring Device	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBDCONTU	Container	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBDCOUVU	Lid	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCONOU	Optional Container	COUSIN BIOTECH (the technical file has not been submitted yet)
RCBCOUOU	Lid for Optional Container	COUSIN BIOTECH (the technical file has not been submitted yet)

Table 10: Instruments references

4. 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.

4.1. HOW POTENTIAL RISK HAVE BEEN CONTROLLED OR MANAGED

To control and manage potential risks, the manufacturer complies with applicable regulations, standards and directives. The manufacturer applies risk management, continuous evaluation of clinical evidence, post-market surveillance and vigilance processes. This includes continuous review of clinical data and feedback on device use.

4.2. REMAINING RISKS AND UNDESIRABLE EFFECTS

The undesirable side effects of the Sterile Cervical Disc Device are:
The list of side effects listed below is not exhaustive.

Potential or actual adverse effects of cervical disc prostheses are:

- Migration of one of the components or implant,
- Insertion of prosthetic plates into the vertebral bodies,
- Loss of mobility,
- Failure of the medical device (wear, breakage, disassembly, etc.),
- Inflammation, Tissue reaction to prosthesis materials
- Fracture of bone structures near the medical device
- Allergies to the materials of the implant, in particular Cobalt, chrome, molybdenum, polyethylene, titanium

Potential or actual adverse effects related to the surgical procedure are:

- Dysphagia, hoarseness/dysfunction of the vocal cords,
- Visceral wound (esophagus, airway, etc.),
- Airway obstruction,
- Pneumonia, Atelecticasis,
- Phlebitis, Thrombotic accidents,
- Cerebrovascular accident (CVA),
- Myocardial infarction,
- Haemorrhage requiring a blood transfusion,
- Hematoma and/or poor healing,
- Infection, Sepsis,
- Death,
- Dysesthesia, numbness, Paresthesia,
- Damage to neurovascular structures,
- Soft tissue injury, spinal cord injury, nerve root injury,
- Dural tear, cerebrospinal-fluid leak, compressive anterior meningocele,
- Change in spinal alignment, sagging, spinal instability,
- Implant loosening and migration leading to instability,
- Increase of operating time, Delayed surgery,
- Ectopic ossification (abnormal bone growth near the disc that may prevent its motion),

Other potential or actual adverse reactions:

- Adjacent level degeneration/disease,
- Heterotopic ossification of the cervical spine,
- Persistence or postoperative recurrence of pain or functional/neurological deficit,
- Re-intervention due to one of the set of effects listed above.

4.3. WARNINGS AND PRECAUTIONS

The warnings of the Sterile Cervical Disc Device, including warning concerning surgical technique, are described below:

- Preoperative Precautions

The following factors may significantly influence clinical outcomes:

- Effective mobility of the spinal segment considered for arthroplasty.
- Patient activity level or occupation: if the patient's profession or activities require lifting heavy loads and/or performing significant muscular exertion, the resulting forces may lead to failure of biological fixation and/or of the implantable device.
- Senility, mental illness, or substance abuse disorders (e.g., alcoholism): such conditions may cause the patient to disregard necessary precautions and limitations associated with the use of the implantable device, potentially compromising implant integrity or leading to other complications.
- Certain degenerative bone conditions: in some cases, the progression of degenerative diseases at the time of implantation may significantly shorten the implantable device's service life (e.g., severe osteoporosis and/or osteomalacia).

- Postoperative Precautions

- The patient should be informed of the limitations associated with the C DISC cervical disc prosthesis and advise them on the permissible level of activity.
- High-energy sports and activities involving head impacts—such as combat sports and acrobatics—are discouraged, as they may cause abnormal wear, dislocation, or migration of the implant.
- Carefully structure early postoperative care to maintain joint mobility and prevent any dislocation.
- Every patient with a C DISC cervical disc prosthesis must undergo postoperative follow-up by an orthopedic surgeon or neurosurgeon. This follow-up is necessary to detect signs of wear, dislocation, or migration before functional symptoms appear.
- Radiographic examinations should be performed regularly and compared with immediate postoperative images to detect any medium- or long-term changes or progressive shifts in implant position, component fracture and/or disassembly, or bone remodeling.
- The implants are compatible with MRI examinations using a static magnetic field of 3 Tesla or less. However, they may generate artifacts that must be considered for proper image interpretation. A 48-hour delay between implantation and MRI is recommended. Safety, compatibility, heating, and migration of the C DISC implant have not been directly tested in MRI; evaluation was based on comparison with equivalent medical devices available on the market.
- The patient should be encouraged to immediately inform their physician of any unusual changes in the operated joint.
- Note that any device with high contrast relative to surrounding biological tissues may generate artifacts that must be considered for proper imaging and interpretation. Patients with implants should be advised to inform all relevant healthcare professionals (radiologists and radiologic technologists) of the presence of an implant prior to imaging examinations.

4.4. SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION (FSCA INCLUDING FSN), IF APPLICABLE

No FSCA has been issued since 2018.

5. SUMMARY OF CLINICAL EVALUATION AND ON POST-MARKET CLINICAL FOLLOW-UP

5.1. CLINICAL BACKGROUND OF THE DEVICE

Sterile Cervical Disc Device was already CE-marked and available on the French market since 2017 (Directive 93/42/CEE). The technical file for the CE certificate in accordance with European Regulation 2017/745, will be submitted on the 30th July 2026 for the 19XXX references.

As part of the decision made by Cousin Biotech following its acquisition of “CERADISC” from Ceraver, no change has been implemented for this MDR application. Ceraver becomes a subcontractor in the medical device manufacturing chain. The specifications of the final product remain unchanged. No change regarding the clinical performances and the safety of the product.

5.2. CLINICAL EVIDENCE FOR THE CE MARKING

- As one device is implanted, the number of patients exposed to the device for all countries during the reporting period is 503.
- In clinical studies: 145 patients (as of today in the PMCF study, 107 described in the available interim report with 160 devices described.
- In literature: 29 patients.

Table 11 - Studies performed on the device

Type of study	Citation/ Study reference	N Patients	N DEVICE
PMCF study	CERADISC Observational PMCF Study 2026 (interim report)	107 patients included at the time of report. (/145 planned inclusions)	160 described (196 calculated from levels treated)
Literature	(Charles et al. 2020)	29	ND

5.3. SAFETY

Clinical risks are within the rates expected with this type of surgery. This confirms acceptability of the device benefit/risk profile according to current knowledge in this medical field and available medical alternatives.

Incident typology	Source	Acceptability threshold (similar devices) %	Observed
Migration of one of the components of the implant, (extrusion, expulsion, dislocation, anterior/posterior migration, malposition or unintended movement)	Human factors (choice of implant, surgical technique) Patients factors	≤5.5%	<1% - 1 vigilance - 1 case in study
Insertion of prosthetic plates into the vertebral bodies, subsidence, collapse or loss of implant support.	Patients factors	≤ 3.3%	none
Loss of mobility, spontaneous fusion with/without Heterotopic ossification	Patients factors	<25% at 5y	2.8% at 2y
Heterotopic ossification, asymptomatic	Patients factors	Frequent, up to 98% radiographic	ND
Failure of the MD (wear, breakage, disassembly, etc.),	Quality problem	isolated cases	None
Inflammation, Tissue reaction to prosthesis materials (biological response), Osteolysis	Patients factors Surgical technique	4.2% symptomatic Osteolysis	None
Bone / radiographic changes, asymptomatic	Patients factors	60.5% to 63.7%	None
Fracture of bone structures near the DM	Patients factors	isolated cases	None
Dysphagia (swallowing) hoarseness/dysfunction of the vocal cords (Dysphonia, hoarseness, recurrent laryngeal nerve injury)	Surgical trauma	≤2.0%. Conservative rounded threshold	None
Visceral wound (esophagal perforation, Airway obstruction, etc)	Surgical trauma	isolated cases	None
Serious neurological deterioration, neurological injury, neuropathy, spinal cord compression/injury or paralysis/paresis	Surgical trauma	≤5.6%	none

Incident typology	Source	Acceptability threshold (similar devices) %	Observed
Dysesthesia, Paresthesia numbness	Surgical trauma	isolated cases	none
Dural tear, cerebrospinal-fluid leak, compressive anterior meningocele after CDA.	Surgical trauma	≤3.0%.	none
Other complications of surgery Pneumonia/atelectasia, thrombophlebitis/ pulmonary embolism; major cardiovascular event / myocardial infarction; Death	General complications of surgery Patient factors	Isolated cases	None
Haemorrhage requiring a blood transfusion	Patient factors Surgical trauma	≤1.0%. Conservative rounded threshold	None
Hematoma and/or poor healing	General complications of surgery Patient factors	isolated cases	1 case requiring intervention
Infection, Sepsis	General complications of surgery	≤3.6% for confirmed SSI/periprosthetic infection in routine follow-up	None
Dysesthesia, numbness, Paresthesia	Surgical trauma		None
Damage to neurovascular structures, Horner syndrome (autonomic lesion) Vascular trauma	Surgical trauma	isolated cases <1.1%	None
Soft tissue injury, spinal cord injury, nerve root injury	Surgical trauma		None
Change in spinal alignment, sagging, spinal instability	Surgical trauma	isolated cases	None
Adjacent level degeneration/disease radiographic	Patient factors	NA variable, frequent	None
Adjacent level degeneration requiring reintervention	Patient factors	NA variable, frequent, up to 45% long term	None
Heterotopic ossification of the cervical spine	Patient factors	<25% at 5y	2.8% with complete fusion No myelopathy
Persistence or postoperative recurrence of pain or functional/neurological deficit,	Patient factors	Worsened pain ≤15 % recurrent pain ≤21%	Not described
Implant removal due to one of the set of effects listed above.	/	≤2.4%. Conservative threshold.	None
All index level reinterventions	Patient factors	1–3 years: ≥95% free from index-level SSI/revision 5–7 years: ≥90% free from index-level SSI/revision >7 years: ≥85% free from index-level	None

The manufacturer continuously collects clinical data and ensures yearly updates of this summary of safety and clinical performance. The next yearly update will include the results of

- The CERADISC Observational PMCF Study next interim report in Q2 2027,
- The scientific literature review,
- The post market surveillance of the device.

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

REVISION HISTORY

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
01	27/07/2026	Creation of the document	☐ Yes Validation language: English
			☐ Yes Validation language: ☐ No