

Summary of safety and clinical performance (SSCP)

ATHLET

Vertebral Body Replacement

Manufacturer's reference number: SSCP 001 ATHLET

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Purpose

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 ATHLET vertebral body replacement (VBR) device by SIGNUS Medizintechnik GmbH.

The SSCP is not intended to

- give general advice on the diagnosis or treatment of particular medical conditions, nor
- replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of a particular device, nor
- replace the mandatory information on implant cards or in any other mandatory documents.

This SSCP contains information for users/healthcare professionals and patients. Therefore, the SSCP has four parts:

1. General Information for Users/Healthcare Professionals and Patients
2. Summary of Safety and performance data for Users/Healthcare Professionals
3. Summary of Safety and performance data for patients
4. References

Change history

Version	Author	Date	History Description
3	Dr. Fatemeh Shekoohishooli	30.06.2025	Update of the validated SSCP for 2024/2025
2	Dr. Stefan Schumacher	02.12.2024	Update of the validated SSCP for 2022/2023.
1	Dr. Georg Lambert	02.06.2022	Update of the draft according to deviation report from mdc. This revision 1 in English language has been validated by the Notified Body.
0	Dr. Stefan Kling	30.09.2020	First draft version

Terms, definitions and abbreviations

Term / Abbreviation	Definition
ACCF	'ACCF' is the short form of Anterior Cervical Corpectomy and Fusion. ACCF is the removal of one or more vertebral bodies in the cervical spine with subsequent insertion of a vertebral body replacement implant (VBR) with the aim of bone fusion.
ACDF	'ACDF' is the short form of Anterior Cervical Discectomy and Fusion. In ACDF, the intervertebral disc is removed and the adjacent vertebrae are fused to ensure stability.
Benchmark Device	A benchmark device is a similar product whose data is used for comparison with the device to be evaluated.
Benefit-risk-determination	'benefit-risk determination' means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions]
CER	Clinical Evaluation Report
Clinical benefit	'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health; [Regulation (EU) 2017/745; Article 2 Definitions]
Clinical data	'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following: clinical investigation(s) of the device concerned, clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated, 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, clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up; [Regulation (EU) 2017/745; Article 2 Definitions]
Clinical evaluation	'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyze and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions]
Clinical evidence	'clinical evidence' means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions]

Term / Abbreviation	Definition
Clinical investigation	'clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device [Regulation (EU) 2017/745; Article 2 Definitions] Systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device. Note: 'clinical trial' or 'clinical study' are synonymous with 'clinical investigation'. [EN ISO 14155:2011]
Clinical performance	'clinical performance' means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions] Behavior of a medical device or response of the subject(s) to that medical device in relation to its intended use, when correctly applied to appropriate subject(s). [EN ISO 14155:2011]
FDA	The 'Food and Drug Administration' is the health authority responsible for U.S. market approval and monitoring of medical devices in the USA.
Hazard	Potential source of harm. [EN ISO 14971:2012]
Hazard due to substances and technologies	For the purpose of this MEDDEV document, a hazard that is seen with products that share specific characteristics. Note: This includes products that contain the same materials and substances, material combinations, use the same technologies, produce similar abrasion, are used with the same type of surgical approach, share the same manufacturing procedures or impurities, or share other characteristics. [MEDDEV 2.7/1 rev.4]
Incident	'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect; [Regulation (EU) 2017/745; Article 2 Definitions]
Intended purpose	'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation; [Regulation (EU) 2017/745; Article 2 Definitions]
Instruction for use (IFU)	'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken; [Regulation (EU) 2017/745; Article 2 Definitions]
JOA	Japanese Orthopedic Association (JOA) Scoring System (17-2) for cervical myelopathy
MDCG	Medical Device Coordination Group

Term / Abbreviation	Definition
MDR	Medical device regulation
Myelopathy	Myelopathy is caused by degeneration of the intervertebral disc and/or vertebral bones, resulting in narrowing of the spinal canal (spinal stenosis) ultimately causing compression of the spinal cord. Myelopathy can result in pain, weakness, altered sensation or difficulty controlling specific muscles.
Performance	'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions]
PMCF	Post-market clinical follow-up
PMCF plan	the documented, proactive, organised methods and procedures set up by the manufacturer to collect clinical data based on the use of a CE-marked device corresponding to a particular design dossier or on the use of a group of medical devices belonging to the same subcategory or generic device group as defined in Directive 93/42/EEC. The objective is to confirm clinical performance and safety throughout the expected lifetime of the medical device, the acceptability of identified risks and to detect emerging risks on the basis of factual evidence. [MEDDEV 2.12/2 rev.2]
PMCF study	A study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a device when used in accordance with its approved labelling. [MEDDEV 2.12/2 rev.2]
Post-market surveillance (PMS)	'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
Risk	'risk' means the combination of the probability of occurrence of harm and the severity of that harm; [Regulation (EU) 2017/745; Article 2 Definitions] Combination of the probability of occurrence of harm and the severity of that harm. [EN ISO 14971:2012]
Risk management	Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk. [EN ISO 14971: 2012]
Serious Incident	'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; [Regulation (EU) 2017/745; Article 2 Definitions]
UDI	Unique Device Identification

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1 General Information for Users / Healthcare Professionals and Patients

The first chapter of this part contains regulatory information about the device, the manufacturer and the notified body. The second chapter provides information about the intended use as well as indications and contraindications. The device and its application are described in the third sub-chapter.

1.1 Device identification and general regulatory information

Aspect	Description
Device trade name:	ATHLET
Manufacturer's name:	SIGNUS Medizintechnik GmbH Industriestr. 2 63755 Alzenau
Manufacturer's single registration number (SRN)	DE-MF-000006200
Basic UDI-DI	4047844010100230521XP
Medical device nomenclature description / text (EMDN codes)	P09070199 SPINAL FUSION SYSTEMS - OTHERS
Applicable code(s) per Commission implementing Regulation (EU) 2017/2185	MDN1102 Bones and skeletal implants
Class of Device:	Class III according to Annex VIII, rule 8 indent 9 (Regulation (EU) 2017/745)
Year when the first certificate (CE) was issued covering the device	2007
Authorized representative if applicable; name and the SRN	SIGNUS distributes and sales the device by itself
Notified body:	mdc medical device certification GmbH No. 0483

1.2 Intended use of the device

Aspect	Description
Intended purpose:	ATHLET is a vertebral body replacement implant for use in the cervical spine.
Indications and target population	ATHLET can be used with the following diseases: • Instabilities and constrictions of the cervical spine (C3 – C7) with various underlying causes. It is used following cervical corpectomy with anterior access. The indications refer to a patient target group with mature skeleton.
Contraindications and/or limitations	• Anomalous bone density, osteoporosis or osteomalacia that prevents stable anchorage of the implant • Allergy or intolerance to the implant material • Surgical conditions that rule out any potential benefit from spinal surgery (such as severe damage to bone structures at the implantation site, badly distorted anatomy due to anomalies) • Medical conditions that could prevent successful implantation (e.g. obesity, mental disorders, pregnancy, paediatric cases, patients in poor general health, systemic or metabolic diseases, lack of patient compliance) • Cases that are not mentioned under Indications

1.3 Device description

1.3.1 Function of the device

The ATHLET® serves as a temporary placeholder to restore the spine until firm bony fusion has taken place. It is not explanted again but remains in the patient. The implant is available in various footprints, heights and angles to enable adaptation to different patient anatomies. The upper and lower sides have small serrations. The ATHLET® implant features cavities that can be filled with autologous bone and / or bone graft material to encourage bone ingrowth. With ATHLET®, bone material is placed around the implant. ATHLET® must be secured with additional stabilization. This is achieved with a ventral plate (ASCOT® or TOSCA®). ATHLET® consists of polyether ether ketone (PEEK-OPTIMA®). The radiolucent PEEK-OPTIMA implants feature superior and posterior X-ray markers to enable intraoperative and postoperative visualization. Implantation is facilitated by the use specially developed accessories for insertion and positioning of the implant. Only these accessories ensure safe use. The corresponding product information provides further system-related information on the surgical method.

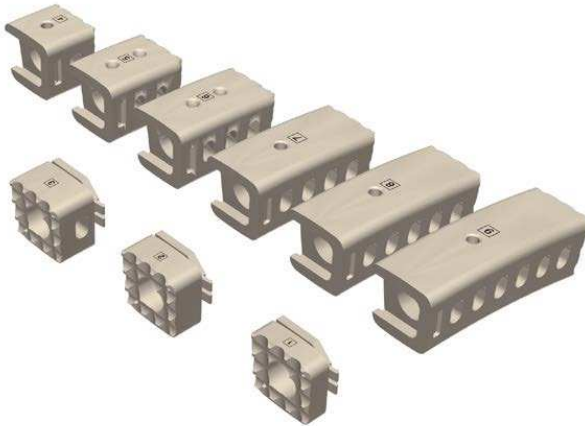


Fig. 1: ATHLET implant components

The ATHLET implants have a three-dimensional, rectangular form and are hollow. A trapezoidal footprint of ATHLET was chosen because that the surface of the vertebral body can be well covered. The trapezoidal footprint of ATHLET is 14mm in length. The width of ATHLET trapezoidal footprint at its widest point (anterior) is 15 mm and at its narrowest point (posterior) 13 mm.

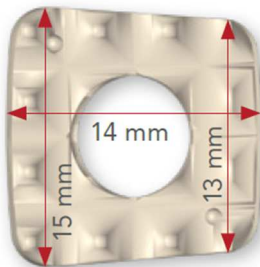


Fig. 2: Trapezoidal footprint of ATHLET

The upper and lower surfaces have 1 mm spikes which assist in the positive anchorage of the implants between the superior and inferior vertebral bodies.

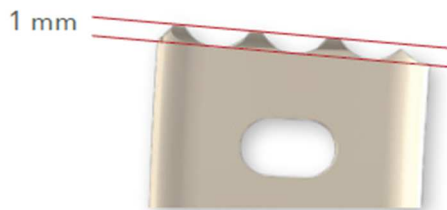


Fig. 3: Upper and lower surfaces with toothed design

ATHLET is a modular system. The implants are made of PEEK. To allow an adaption to individual patients, 14 implant components are available. There are 9 implant components as standards. These include 6 basic bodies and 3 end bodies. Due to the range and combination of base and end bodies, height increments of 16 - 50 mm are possible.

To enable a height gradation between 12 - 68 mm, 2 one-piece implants and 3 basic bodies can be provided additionally.

Depending on the implant size, a predefined lordosis angle is available. The smallest lordosis angle of 3.4° is available for an implant height of 12 mm and the largest lordosis angle of 19.5° is available for an implant height of 68 mm. The selection of the components for a defined size can be assisted via a table on the ATHLET template. Assembly of the modular components of ATHLET is done via a click mechanism. The dovetail guidance aims to prevent potential slippage of the components until the hooks audibly click into place (see Fig. 4:).

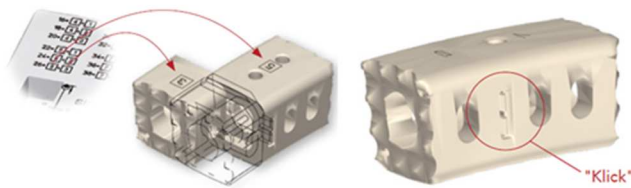


Fig. 4: Assembly of ATHLET

The disconnecter can be used to release assembled components while the trials are used for determination of the correct implant size. And with the inserter and the associated length plates, the implants can be placed in the desired position. The implants are not "stand-alone" products and must always be applied with additional fixation (ASCOT or TOSCA plate). The two SIGNUS plate systems (TOSCA or ASCOT) are pre-lordosed and coordinate with the lordotic angle of ATHLET. They can be connected to ATHLET with the connector screw (article number: ATM309). After the preformed plates have been attached to the corresponding vertebral bodies with screws, the second step to connect the plate with the "ATHLET" as a SIGNUS's vertebral body replacement device can be performed. For this the screw (article number: ATM309) is attached to the screwdriver and fixed by pressing the screwdriver sleeve downwards. The screw is then screwed into ATHLET through the slotted hole in the plate. For final tightening of the screw, the sleeve of the screwdriver must be pulled back again.



Fig. 5: ATHLET used together with TOSCA cervical stabilization plate

1.3.2 Information about medicinal substances in the device, if any

ATHLET does not contain any medicinal substances.

1.3.3 Implantation of the device

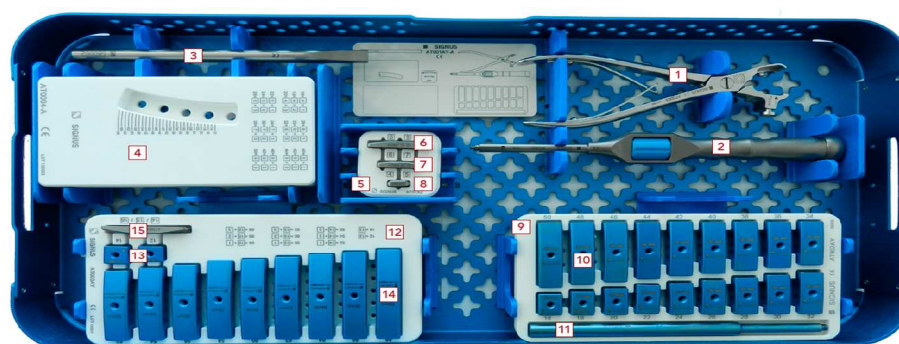
ATHLET is inserted by the anterior approach in the cervical spinal region, first described by Smith & Robinson in 1958. Preparation of muscles, nerves, vessels, trachea and esophagus must be performed meticulously as injuries lead to severe complications and long-term consequences for the patient. In the next step, corpectomy is performed, including the adjacent intervertebral discs. The inferior and superior endplates of the vertebral body are cleaned from cartilage and carefully flattened. Residual intervertebral disc material is removed to maximize the contact area and to ensure that the implant sits securely. Doing so it must be avoided that too much or all of the cortical base and cover plates are removed. The posterior longitudinal ligament should only be removed as part of any necessary decompression. The height of the VBR devices has to be determined by means of trials. Once adequate height and lordosis have been determined, the appropriate implant is removed from the sterile packaging. The correctly adjusted device is then inserted filled and surrounded by bone fragments to improve the fusion outcome. In addition, the segment must be stabilized with a ventral fixation system (such as TOSCA or ASCOT).

1.3.4 A reference to previous generation(s) or variants if such exist, and a description of the differences

Since the market launch of ATHLET in 2007 there was only one design change after market launch at the ATHLET device, improving its locking mechanism. No variants of ATHLET other than the different product sizes are available.

1.3.5 Description of any accessories which are intended to be used in combination with the device

Instruments are available from SIGNUS for the discrimination of the correct size and the insertion and if necessary the removal procedure.



Nr.	Art. Nr.	Beschreibung	Description	Nr.	Art. Nr.	Beschreibung	Description
1	AT0003	Löseinstrument	Disconnecter	9	AT002AY	Tray für Probeinstrumente	Tray for trials
2	AT0001	Setzinstrument	Inserter	10	AT1016 – AT1050	Probeinstrumente 16–50mm	Trials 16–50mm
3	GB0002	Positionierer	Positioner	11	AT1100	Setzinstrument für Probeinstrumente	Inserter for trials
4	AT0004-A	Vergleichsplatte	Template	12	AT003AY	Tray für Probeinstrumente	Tray for trials
5	AT01AZ	Tray für Längsplatten	Tray for inserter plates	13	AT1012 – AT1014	Probeinstrumente 12–14mm	Trials 12–14mm
6	AT0007	Längsplatte groß 8/9	Inserter plate large 8/9	14	AT1052 – AT 1068	Probeinstrumente 52–68mm	Trials 52–68mm
7	AT0006	Längsplatte mittel 6/7	Inserter plate medium 6/7	15	AT0008	Längsplatte XL 14/15/16	Inserter plate XL 14/15/16
8	AT0005	Längsplatte klein 4/5	Inserter plate small 4/5				

Fig. 6: Instrument tray

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1.3.6 Description of any other devices and products which are intended to be used in combination with the device

See 1.3.1.

1.4 Risks and warnings

1.4.1 Residual risks and undesirable effects

These instructions for use do not list the general risks associated with surgery or the complications that can arise from spinal surgery. The following are potential risks and complications related to the implant and which may necessitate repeat surgery:

- Loss of anchorage / fixation, subsidence or dislocation of the implant
- Pseudoarthrosis / absence of fusion
- Sensitivity to foreign bodies, allergic reactions or other local / systemic adverse reactions to the implant materials used
- Incorrect placement
- Vascular lesion
- Neural lesions with reversible or permanent neurological deficits or paralysis
- Infection
- Wear or breakage of implant components
- Pain or recurrent pain

These risks can potentially lead to injuries of all degrees of severity to the surrounding tissue, the nerves and blood vessels, which can in extreme cases even lead to death.

1.4.2 Warnings and precautions

1.4.2.1 Warnings

- The spinal implants are intended for single use only and must not be re-used. Reprocessing and / or reuse can result in infection and / or loss of function and in extreme cases may lead to the death of the patient.
- SIGNUS implants must be used only with the specified instruments.
- Correct implantation cannot be guaranteed if implants are placed with other instruments.
- The attending physician, who must be trained and experienced in carrying out spinal interventions, is responsible for determining the indication, selecting the implant and performing the implantation.
- Unless otherwise specified, SIGNUS products must not be combined directly with the materials / components from other systems.
- Check the implant for scratches and other obvious damage. A damaged implant must not be used.
- Since the implant may have been damaged, do not reinsert the implant after it has been removed from the site.
- When inserting the implant, particular attention must be paid to protecting the nerve structures and blood vessels, and increased force must also be avoided.
- It is important to avoid overdistraction of the segment.
- Aftercare and follow-up examinations must be tailored to the individual patient's requirements and must be determined by the treating physician. After the intervention, the patient should be allowed only very limited physical activity for an appropriate postoperative period. This applies in

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particular to the lifting of loads, rotating movements and any type of sport. Falls and sudden, jerky movements of the operated region must be avoided.

- ATHLET® is connected to the SIGNUS plate systems ASCOT® or TOSCA® using the ATM309 connecting screw. The connecting screw must only be used in this combination.

1.4.2.2 Precautions

- Sterile implants must be considered potentially infectious after use. They must therefore be disposed of properly (hazardous medical waste) according to the relevant hygiene and waste disposal guidelines. At the end of their service life, instruments must be similarly disposed of or prepared correctly before disposal. Ensure that sharp or pointed implants as well as instruments are handled carefully to prevent injuries.
- Store sterile products in their original packaging.
- Do not remove products from their protective packaging until immediately before use.
- Check expiry date and integrity of the sterile packaging before use. The product must not be used if the sterile packaging is damaged or if the expiry date has been exceeded.
- All information about the surgical technique, the range of implants, the instruments and their use, as well as assembly and disassembly, is provided in detail in the SIGNUS product information. This information must be available on site and must be known to the surgical team.
- Before performing the surgery, ensure that all necessary implants and instruments are to hand and fit for purpose.
- The size indicated on the implant must be compared with the size determined using the trial implant / height indicator.
- After preparation, carefully inspect the corpectomy cavity for bone fragments.
- The surgery must be carried out under fluoroscopic guidance. The correct position of the implant must be verified using radiography.
- The implant must be firmly connected to the inserter intended for the implant to prevent damage to the implant and potential injury to the patient.
- Avoid removing too much or all of the cortical inferior and superior plates. This may weaken the endplates and thus lead to subsidence of the implant into the adjacent vertebral body. To avoid displacing the nucleus and the inner annulus in the spinal canal during the implantation and to prevent interference with the bony ingrowth, ensure that the disc material is carefully removed.
- Ensure that the implant makes the greatest possible contact with the adjacent vertebrae in order to avoid point stresses and to encourage fusion of the segment.
- The implants are not stand-alone prostheses but must always be inserted with additional fixation.
- In the postoperative phase, special care must be taken to ensure that the patient is given all the necessary information by the treating physician according to the patient's individual requirements.
- Ensure that the implant is correctly aligned while disconnecting. The implant may otherwise be damaged.
- The implant must always be fixed using a longitudinal plate attached to the inserter to prevent damage to the implant during insertion.

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1.4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

During the lifetime of ATHLET, there were no serious incidents or recalls being reported to the authorities by SIGNUS. In one case, SIGNUS had to respond to an entry in the FDA database MAUDE. Report number 9615021-2019-00001: ATHLET. This was due to the negative publications by Koenig et al. (6, 7) about ATHLET that reported incidents of secondary subsidence and secondary dislocation classified as serious injury (see chapter 2.2.2.2). The data delivered by the named literature is included in the clinical evaluation process for ATHLET. Subsidence and dislocation are known risks addressed in the IFU.

1.5 Suggested profile and training for users

Only surgeons experienced in spine surgery and orthopedic implants must use the ATHLET system. SIGNUS offers teaching and training for surgeons and their teams at its webpage (www.SIGNUS.com).

2 Summary of Safety and Performance data for Users/Healthcare Professionals

The following text includes medical terminology that is not considered for patients. If you are patient, please go to chapter 3.

2.1 Residual risks and undesirable effects

According to the analysis of market feedback, clinical studies, and scientific literature, no systematic failures or complications related to ATHLET were observed. Thus, the safety of ATHLET is confirmed. Nevertheless, as described in the instruction for use and chapter 1.4.1 of this SSCP residual risks from both the surgical procedure and the medical device remain.

The surgical approach to the spine, the removal of the original intervertebral disc and the insertion of the device was briefly described in chapter 1.3.3 of this SSCP. From the understanding of this surgical procedure, it is obvious that potential intraoperative complications are related to surgery and not the device itself. Device-unrelated complications include lesions of vessels and nerves next to the operating field, incorrect placement, and infection, as listed in chapter 1.4.1. These complications depend on factors that cannot be controlled by the manufacturer, but rather on situation-specific factors (e.g. surgical application, patient-specific factors).

In accordance with the "Summary of Safety and Clinical Performance MDCG 2019-9 v1 Quantitative data", we present the complications associated with clinical data that were gathered through a retrospective, noninterventional, uncontrolled customer survey study of our device in 2023 (see chapter 2.2.2.1) as well as through literature research for the subject device (see chapter 2.2.2.2) as well as a state-of-the-art (SOTA) analysis of literature performed in the clinical evaluation process.

Tab. 1: Assessment of residual risks as mentioned in the IFU. See 2.2.2.1 and 2.2.2.2 for an analysis of the referenced scientific papers/studies.

Residual risks	Likelihood
Loss of anchorage / fixation, subsidence or dislocation of the implant	The SOTA literature reports values between 1.4% and 11.1% for subsidence, graft dislodgement or implant dislocation. The severity of these events is not reported. Not all of these events will result in revision. Within the subject device data rates between 8.2% and 32% are reported for this group of events: König 2015 (6) reports on six cases (32%) of subsidence. However, no information is given on the amount of subsidence. The cases were not symptomatic. König 2014 (7) reports on four cases (20%) of subsidence. Again, there is no information on the amount of subsidence and the cases were not symptomatic. Schulz 2017 (9, 10) reports 8.2% subsidence, and in the customer survey study values for symptomatic subsidence of 6.58% and for symptomatic dislocation of 2.35% were reported.
Pseudoarthrosis / absence of fusion	The reviews for the SOTA found average values between 1.32% and 7.22% (with the highest underlying study reporting 21%). Fusion levels of over 80% were found in the literature on the subject device. König 2015 (6) reports that all cages without subsidence or revision fused. Schulz 2017 (9, 10) reported a fusion rate of 81.6% (Grade 1&2). In the expert report a fusion rate of 80% is given, and the customer survey study revealed a value of 76.5% fusion. Without being able to present hard scientific proof one can assume that most non-fusions are due to the general biological status of the patient and not the poor

	engraftment of implants.
Infection	The likelihood of infection after ACCF found in the SOTA is higher compared to the likelihood in the risk analysis. However, it can be assumed that many sources for infection are independent of the implant. No information in the SOTA or in the analysis of the subject device papers was found in implant specific risk factors for infection. A likelihood level of <0.01% in the risk analysis is therefore an estimation as no reports on the respective events are available.
Pain or recurrent pain	The risk analysis rates the likelihood levels up to $\geq 10\%$. This is based on the Koenig publications reporting high levels of revision due to subsidence.
incorrect placement	Neither the SOTA nor the data on the subject device provide specific information. The likelihood is estimated as 0.01-<0.1%.
vascular lesion / neural lesions with reversible or permanent neurological deficits or paralysis	Neither the SOTA nor the data on the subject device provide specific information. The likelihoods are estimated as <0.01% to 0.01-<0.1% in case of wrong handling of the devices.
Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse reactions to the implant materials used	Neither the SOTA nor the data on the subject device provide specific information. The likelihood is estimated as 0.01-<0.1% (allergies).
Wear or breakage of implant components	Both wear and mechanical failure of the implant are rated with a likelihood of 0.01-<0.1%. There are no reports within the SOTA or subject device literature on such events. Within the PMS such events were reported, however, the number is within the expected range.

Revision rates due to implant failure are reported as 0% - 19% in the underlying studies. A revision rate of 19% is regarded as high by SIGNUS. A value of 5% should not be exceeded. The customer survey study (0.5% implant related and 4.9% overall revisions), the papers by Schulz 2017 (3%) (9, 10) and the paper by König 2015 (5%) (6) report according revision rates. Revision rates are dependent on the underlying pathology. A subgroup of tumor patients might well show higher rates than 5%.

From another side, biocompatibility was successfully tested in the pre-clinical phase, and neither in scientific literature nor in databases of health authorities there were hints that the materials used led to any undesired body reactions such as allergies or local reactions. However, theoretically the occurrence of such adverse reactions is possible.

SIGNUS tested the mechanical stability, biocompatibility, and sterility of the subject device extensively in the laboratory. Clinical studies and experience from market surveillance since the market launch in 2007 support safety and effectiveness of the device.

SIGNUS conducts continuous market monitoring in order to identify risks and to react immediately if necessary. Consequences of this effort are described in chapter 3.1.2. Furthermore, information material and training for surgeons, as well as patients following the instructions of their surgeons also reduces risks.

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NOTE: It is the user's responsibility to ensure that the surgical procedure is performed correctly. Appropriate clinical training as well as a theoretical and practical proficiency of all the required operating techniques, including the use of this product, are prerequisites for the successful use of this product. SIGNUS offers teaching and training for clinicians and their teams at its webpage (www.SIGNUS.com).

NOTE: SIGNUS is not responsible for complications caused by failure to follow the warnings and precautions listed in chapter 1.4.2.

NOTE: The user is obligated to report all severe events in connection with the product to the manufacturer and the responsible authorities of the state in which the user is located.

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

2.2.1 Summary of clinical data related to equivalent device, if applicable

Not applicable

2.2.2 Summary of clinical data from investigations of the device after the CE-marking

2.2.2.1 Studies initiated by SIGNUS

In 2023 SIGNUS conducted a customer survey study involving twenty-nine surgeons using ATHLET and covering about 1276 cases.

The surgeons reported on average that subsidence occurred in 16% of the cases (answers between 0% and 100%). The users obviously did not use a uniform definition of subsidence; the surgeon who reported 100% subsidence reported 0% symptomatic subsidence. When multiplying the percentage of symptomatic cases reported with the number of cases reported in total this results in 84 cases of symptomatic subsidence or 6.58%. Symptoms of subsidence were neck pain (between 5 and 10%) and general pain. Eight surgeons reported symptomatic subsidence in 2.35% of the cases resulting in neck pain and difficulties to swallow and were treated by revision or additional fixation.

For dislocation an average value of 3.3% was reported.

Within the state-of-the-art (SOTA) assessment in the clinical evaluation report (CER) a rate of below 10% for subsidence and dislocation of the implant was defined. The customer survey showed 6.58% subsidence and 2.35% dislocation which indicates that the implant is working as intended.

When adjusting for the number of surgeries per surgeon and the percentage of revision reported there were 62 revisions in total or 4.9%. Four surgeons reported implant related revisions, of which one surgeon commented that the revisions were due to dislocations in osteoporotic patients suffering from falls. Proportion of implant related revisions is 0.51%.

A rate of below 5% for revision of the implant was defined in SOTA assessment in the CER. Within the survey 0.5% implant-related revisions and 4.9% overall revisions were seen, which is within the expected values.

The fusion rate reported by surgeons that always checked fusion after 12 months was 76.5%, and the non-Fusion rate reported by surgeons that always checked fusion after 12 months was 17.4%. Therefore, the fusion rate fell slightly below the target value of 80% set in the CER. Upon reviewing the raw data, fusion status was consistently assessed after 12 months by eight surgeons, with four of them reporting fusion rates at or above the target. Conversely, the other four surgeons reported

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average fusion rates below the target of 80%. The data highlights several methodological limitations that should be considered: E.g. two of the four surgeons mentioned reporting lower rates noted that 40% of their cases involved tumor surgeries, which naturally tend to have lower fusion rates. One customer specifically commented that fusion is not always the primary goal in such cases, further complicating direct comparisons. The other two of the four mentioned surgeons, on the other hand, primarily performed degenerative procedures, where higher fusion rates would typically be expected. Despite this, both surgeons reported no complications and expressed 100% satisfaction with the product. One of these two surgeons, while reporting a lower fusion rate of 74%, noted an acceptable non-fusion rate of 14% which suggests that 12% of the cases were classified as “unclear fusion” but did not exhibit signs of non-fusion. It is reasonable to assume that some of these “unclear” cases may achieve fusion with longer follow-up. The second surgeon reported data on 10 cases, with a fusion rate of 70%, a non-fusion rate of 30%, and a revision rate of 3 %. While the fusion and non-fusion rates appear consistent, the revision rate of 3% in such a small sample is evidently not feasible and likely reflects reporting errors or inconsistencies in the survey responses.

Given the limited dataset, we do not see a need for immediate corrective action for the following reasons:

- The non-fusion rates reported are considered acceptable, considering that the fusion rate could improve with extended follow-up.
- A case sample of 10 cases is small, and even one additional fused case would elevate the fusion rate to 80%, aligning with the target threshold.
- The survey requested estimates, which introduces inherent variability in the reported figures. This applies to both lower and higher fusion rates. Therefore, qualitative assessments provided by the surgeons hold greater significance in this context, and both surgeons rated the product’s performance as excellent.
- Both surgeons reporting low fusion rates confirmed that they had not encountered any complications or reportable events associated with the use of the ATHLET. Furthermore, they see no discernible differences in terms of safety and performance when compared to similar products from other manufacturers. They expressed satisfaction with its performance and did not attribute any failure to achieve fusion to the design of the implant. This suggests that the reported lower fusion rates may be attributed to the design of the survey (e.g., imprecise fusion values estimated via a slider, which do not necessarily reflect the actual values), or to general tendencies at the surgeons’ respective clinics, which might have lower fusion rates with VBRs, rather than being implant related. Both scenarios indicate that the reported low fusion rates are not a reflection of implant performance.

The surgeons generally expressed satisfaction with the performance of the implant. The observed outcomes for fusion rate, subsidence and revision were compared to benchmark data against the data presented in the CER. We consider the observed average fusion rate of 76.5%, which is close to target value, acceptable and do not recommend further action currently. No new risks associated with the device were identified, and no additional measures were deemed necessary.

2.2.2.2 Other studies

Özkan et al. 2015 (5) report in their paper on the treatment of traumatic spinal injuries in children. The one case reported on the ATHLET is a revision case of a 19-year-old male receiving ATHLET in combination with anterior and posterior fixation. No information on the outcome of this case is given.

König and Spetzger 2015 (6) used the SIGNUS ATHLET VBR and TOSCA (titanium plate) for the treatment of patients with cervical spondylotic myelopathy. The retrospective case series with 20 patients, with a range of age from 44 to 76 years, shows in 4 cases of the single and multilevel procedures subsidence of the implant and in 2 cases secondary severe dislocation. According to Odom criteria 10 patients (50%) had excellent, 6 (30%) good, 2 (10%) satisfactory and 2 (10%) poor outcomes after an average follow-up time of 20 months. In the 2 cases which were addressed as a result with complications, there was 1 with osteoporotic bone. This patient suffered from a fracture of the adjacent vertebral bodies and a dislocation of the implant 2 months after surgery. Therefore, they performed a 4-level corpectomy in the second operation including ATHLET and TOSCA Expansion from C3 to T1 as well as posterior fusion from C3 to T1.

The authors conclude that due to the high rate of secondary subsidence (20%) and secondary dislocation (10%) in combination with a poor to satisfactory outcome according to Odom criteria in 20%, it is not recommending the use of this PEEK implant for cervical VBR.

We do not agree with the conclusion of the paper. The authors report that a 20% rate (six cases) of complicated outcome is not acceptable and thus the use of the technique was discontinued. This is not comprehensible since the authors themselves give reasons for the complications.

There were seven two-level cases with 2 dislocations. One in a woman with poor bone quality due to renal failure with a fracture of the adjacent vertebra and one kick-out dislocation 4 months after surgery. Thus, one dislocation was due to low bone quality and the authors state that primary circumferential fusion would have been indicated. Additionally low bone quality not allowing safe implantation is a contraindication in the IFU.

We also have problems understanding the exact numbering of the complications. The authors state: "In contrast to those advantages the authors observed 2 cases (10%) of implant kick-out dislocation and 4 cases (20%) of cage subsidence. In **one** of these **6** complicated cases there was evidence of low bone quality. Thus, primary circumferential surgery would have been a better option in this case. **Two** other patients from this group were suspicious to have **osteoporosis**, and one of them had 2-level corpectomy plus 1-level discectomy (Fig. 6). The latter conformed to criteria for primary circumferential fusion. In **4** of the **6** complicated cases there were no risk factors for subsidence...."

These cases remain with no obvious reason for subsidence. The authors state that these cases were among the first cases operated and the results could be compromised by the learning curve. It is also noted that none of these cases had clinical consequences in terms of JOA.

The explanation that PEEK cages might be inferior due to the mismatch of elasticity between PEEK and bone is not comprehensible for us. The alternative (titanium cages) has an even higher mismatch.

We do not want to say that the information is irrelevant. Dr. König and Dr. Spetzger are respected and knowledgeable spine surgeons and they certainly had a reason for their decision. There also has been a case of dislocation (figure 4 of the paper) without obvious reason. Within the PMCF process we focus on instability of the cage possibly leading to dislocation and subsidence. Our first expert opinion comes to similar conclusions. The author also points out that the subsidence seen in the König paper is not associated with any clinical symptoms.

König and Spetzger 2014 (7) report on decompression of the spinal canal or a vertebral body replacement on 32 patients. 3 different VBRs (distractable titanium cage ADD plus was used in six cases; 19 operations with ATHLET and seven cases with iliac crest autograft) were used for the restoration of the vertebral bodies. In all 3 groups one dislocation was observed after 15 months of follow-up. In addition, 6 subsidence cases were determined with the ATHLET implant. The mean JOA score improved from 12.0 to 14.5 points in the titanium group, from 13.5 to 15.5 in the PEEK group, and from 11.9 to 12.6 in the autograft group. The mean JOA score between titanium and autograft group in the postoperative JOA score was 1.9 points and between PEEK and autograft group in the postoperative JOA score was 2.9 points. The recovery rates were 0.50 (titanium group), 0.57 (PEEK group), and 0.14 (bone graft group). It turned out that the JOA and the recovery rate were the best in the ATHLET group.

Similar to König (2015) the authors recommend not to use the ATHLET due to the high subsidence rate.

We do not agree with the conclusion of the paper.

- The authors report that each group had one case of dislocation. However, the size of the groups was not the same. The percentage of dislocation was:
 - o ADD plus: 16.7% (1/6)
 - o Iliac crest: 14.3% (1/7)
 - o ATHLET: 5.3% (1/19)
- No quantitative data on subsidence is given (for example subsidence >3mm). The cases are all asymptomatic, the authors state that there was no worsening of the JOA score.
- JOA score increased more in the ATHLET group compared to the other groups.

The author of the 1st expert report comes to similar conclusions as he states that due to no negative consequences the subsidence reported in this paper are not pathologic.

König et al. 2015 (8) describe 6 cases in which a VBR had to be implanted. The mean age at the time of surgery was 68 years (range, 53-76 years). The underlying pathologies included spontaneous fractures due to poor bone quality in one patient with chronic renal failure and multilevel spondylotic myelopathy in another patient. All patients had neck pain, and four showed signs of myelopathy. Five patients complained of radicular symptoms, and the patient with tuberculosis had dysphagia. ATHLET was implanted in 4 of the 6 cases.

- Case 1: ATHLET and TOSCA, Tuberculosis – Generally successful
- Case 4: ATHLET, history of renal failure with low bone quality. Fair outcome. No anterior stabilization was performed. This case should be excluded since the treatment was not done according to the IFU (insufficient bone quality is a contraindication and no fixation was added).
- Case 5: ATHLET and TOSCA. Outcome good after infection
- Case 6: ATHLET and TOSCA, additionally fusion cage. Plate from C3 – C7. Screw subsidence at C3. Good result

The paper is a collection of difficult cases. The authors do not draw conclusions on safety and performance of implants.

In a retrospective study of Schultz et al. 2016 (9) 101 patients after PEEK cage-ACCF with a minimum follow-up of 6 months have been described. For the determination of the efficiency and safety of the implant, the hardware and implant-related surgical failures were analyzed, and the sagittal parameters and the CT fusion rate were determined. The neck disability index (NDI) and the European myelopathy score (EMS) were assessed. Screw complications were detected in 8/101 cases and 3 cases of cage

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dislocation occurred, resulting in an overall implant related revision rate of 3% (all revision cases showed cage dislocation). The rate of cage subsidence >3 mm was 12% and solid fusion was achieved in 82% of the patients. NDI, EMS and lordotic alignment improved significantly. In the discussion of the publication, it is further mentioned that in a longer follow-up a 2-year collective (n=72) carries out an implant-related revision (revision rates of 1.4%) and in the 5-year collective (n = 38) no additional revisions occurred (revision rates of 0 %). The result of this study is that ATHLET is a safe and effective alternative to titanium cages or autogenous bone graft for ACCF.

The second publication by [Schultz et al. 2017 \(10\)](#) reports on the same patient group: The results of 101 patients with a median age of 65 years (36–89) treated with ATHLET are compared retrospectively with 25 patients treated with Ulrich's implant ADD. The comparison revealed that there were more complications in the ADD group than in the ATHLET group. The authors described that this increased complication (such as screw complications and overdistraction) correlates in part with the higher age and the multi-level restoration of the patients in the ADD group. In the longer time course, both groups showed a higher degree of fusion and thus no case of unstable pseudoarthrosis in the entire group. The fusion rate was 82% in ATHLET and 54% in ADD. According to the authors of the publication and the inclusion of the inhomogeneity of the two groups, there is no significant difference between the groups with respect to the fusion rate. This publication shows that ATHLET is a safe and effective alternative vertebral body replacement compared to other titanium VBRs.

2.2.3 Summary of clinical data from other sources, if applicable

2.2.3.1 Clinical evidence from market surveillance activities

Since its introduction into the market, a total of 8 product complaints in 15 parts related to ATHLET have been recorded, which resulted in an overall calculated occurrence rate of 0.095% and a justified complaint rate of 0-013%. Two complaints (from 2013 and 2014) have been rated as actually related to a malfunction of the implant and triggered a design change. Since then, a total of 3 complaints were noted, of which none has been classified as implant related.

2.2.3.2 Evaluation of surgery accompanying sheets

Surgeries performed between July 2018 and May 2025

The table below gives an overview on the data on ATHLET surgeries performed between 07/2018 and 5/2025 and accompanied by SIGNUS' sales personnel. The surgeries were mainly primary surgeries (92); 4 were follow-up surgeries, mainly due to previously implanted devices (cages or prosthesis), and 16 revisions.

Tab. 2: Overview on ATHLET data from accompanied surgeries.

	Average	Min / Max	%
Duration of surgery	3.66	0.75 – 10 h	
Patient age	63.44	18 – 94	
Total number of cases	110		
Male	57		53
Female	51		47
	Numbers		% Positive outcome
Successful vs. unsuccessful surgeries (surgeons answer)	109/0		100
Surgeon satisfied with surgery	108/0		100
Implant related complications (yes/no)	0/51		100
Instrument related complications (yes/no)	0/51		100
Procedure related complications (yes/no)	1/50		98.0
Instrument handling (good/bad)	106/1		99.1
Implant handling (good/bad)	107/0		100
Surgeon satisfied with instruments (yes/no)	62/0		100
Comparison to previous generation (better/worse)	10/1		90.9
Healing according to expectation (yes/no)	3/0		100

16 out of 110 operations were revision operations. Most revisions (9) were due to other implants, and ATHLET was implanted during the revision surgery. In one of these cases there is a comment that paraplegia occurred after fracture. However, the fracture was the cause of implantation of the ATHLET and not the result of the implantation.

The surgeons rated the operation as successful and were satisfied with the handling of the instruments and the implants. There were no complications with the implants and instruments. The surgeons were 100% satisfied with both implants and instruments, and 99% rated instrument handling as good. They were also 100% satisfied with the surgery.

2.2.3.3 Expert reports

Two expert options on ATHLET have been gathered within the PMCF process:

1. University Hospital Ulm 2021: The implant is used by the author in 2 hospitals. 73 patients were treated since 2013. The authors report a success rate of roughly 85%. The reasons for not successful implantations are not associated with the implant. The author assesses the safety and performance of the implant as good. The author also comments on the studies published on the ATHLET, specifically the critical publications by König et al (6, 7). In the view of the author the results obtained by König do not justify König's conclusion that the ATHLET should not be used.

2. University Hospital Bonn 2022: The author reports on 158 patients treated with ATHLET. The indications treated are within the indications in the IFU. Similar to the 1st expert report the success rate is between 80% and 90%; the non-successful treatments are not due to malfunction of the ATHLET. The fusion rate is estimated to 80%. No implant related complications were noted. The author specifically states that there are no hints that ATHLET might lead to increased complications such as a higher subsidence or lower stability.

2.2.4 An overall summary of the clinical performance and safety

The experiences made so far with ATHLET have been presented and discussed in previous chapters. These data demonstrate that ATHLET performs well and safe and does not behave differently from the benchmark. Nevertheless, there are some residual risks of the procedure and the device that SIGNUS is aware of even when they were rarely or not described in the data sources reviewed. These residual risks are listed in chapter 1.4.1 of this SSCP document.

The ATHLET implant has been on the market since 2007 with ~16.000 implants distributed. The number of complaints on the implants are low and increasing sales suggest surgeons satisfaction with the implant.

The available data does not indicate performance and safety differences of the ATHLET to other devices used. The papers including the most data from the group of Schulz et al. suggest a trend towards better performance of the ATHLET compared to other devices, however, not being statistically significant. The papers by König conclude that the ATHLET is inferior due to high subsidence rates which is also not significant and, in our view, also not supported by the presented data in the papers. Thus, from the published literature data we do not see any indications which would suggest inferior performance of the ATHLET.

Therefore, it can be concluded that ATHLET is achieving the performance intended by the manufacturer.

2.3 Ongoing or planned post-market clinical follow-up

After completion of the customer survey study, there is currently no study going on or planned. PMCF concentrates on regular measures (literature research etc.).

2.4 Possible therapeutic alternatives

Corpectomy is a highly invasive treatment and other treatments should be considered before performing corpectomy. The risk that surgeons would perform corpectomy without considering other methods was assessed in the risk analysis and regarded as low. In the case of degenerative disease conservative therapy should always be performed before surgery. Indications for surgery are described in textbooks (e.g. (1)).

In case surgery is indicated, different surgical procedures are available. In the cervical spine the most prominent are anterior cervical discectomy and fusion (ACDF) or posterior approaches. Again, the decision processes of which treatment is adequate for the individual indication is described in textbooks (9) and not given here. Briefly, corpectomy (ACCF) provides better decompression since the access to the canal is larger. However, ACCF is more invasive and associated with more complications compared to ACDF, which is underlined by two current papers (3, 4).

The situation in treatment of instabilities (fractures, deformities, tumors) is similar. Many spinal fractures (for example A0 fractures) can (and should) be treated conservatively while type C fractures mostly require surgery. The AO surgery reference guide gives suggestions for treatment options. However, also here the choice of surgical technique has to depend on the individual fracture (2). A description of the decision process on when corpectomy will be performed goes beyond the scope of this SSCP.

2.5 Suggested profile and training for users

See chapter 1.5.

2.6 Reference to any harmonized standards and common specifications (CS) applied

During the preparation of the report, the homepage of the EU Commission was searched for applicable Common Specifications. No applicable Common Specifications could be found which had to be taken into account in the preparation of this report.

The following table shows the harmonized standards which were applied to our product.

Table 2: Harmonized standards applied

Standard	Title	Edition
EN ISO 10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	2021
EN ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2021
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	2015/ A2:2019
EN ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2015/A1:2023
EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020/A1:2023
EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020/A1:2023
EN ISO 11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	2018 / A1:2021
EN ISO 11737-2	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2020
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016/AC:2018/A11:2021
EN ISO 14971	Medical devices - Application of risk management to medical devices	2019/A11:2021
MDR: EN ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	2021

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3 Summary of Safety and Performance data for patients

NOTE: 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.

The general information about the device including product description and intended use are given in chapter 1.

The information presented in this chapter is intended for patients and laypersons.

3.1 Risks

NOTE: This document is not a substitute for consulting your doctor if you are concerned about side effects. The following points are an indication of when you should see your doctor. It may but does not have to be related to the device:

3.1.1 Residual risks and undesirable effects

Contact your healthcare professional if you think that you are experiencing symptoms that may be related to the use of the ATHLET. As described in the instructions for use, some residual risks from both the surgical procedure and the medical device remain that cannot be completely excluded. In the following, we explain these potential causes for the symptoms and describe how frequently they have occurred with ATHLET and comparable products. General risks associated with surgery such as vessel and organ injuries or infection are assumed known. They are therefore not described here and need to be discussed with your surgeon. Remaining risks from the medical device are:

- Foreign body reaction and allergies are potentially given but not observed for ATHLET so far. SIGNUS estimates a likelihood of 0.01-<0.1%.
- Loss of anchorage/fixation, subsidence or dislocation are reported in the literature with a probability of up to 11.1% for other VBR implants. For ATHLET there is one group that reports rates of 32% and 20% subsidence, but no information is given on the actual amount of subsidence, and the cases were not symptomatic. Others reported 8.2% subsidence for ATHLET, and in a customer survey study 6.58% for symptomatic subsidence and 2.35% for symptomatic dislocation were found.
- Estimation for pain or recurrent pain is up to $\geq 10\%$. This is based on single publications reporting high levels of revision due to subsidence, although this is not necessarily related to pain.
- It is not in all cases possible to achieve fusion the vertebral bodies. Literature gives average values for non-fusion between 1.32% and 7.22%, with the highest underlying study reporting 21%). For ATHLET, fusion levels of over 80% were found in the literature, and a customer survey study revealed a value of 76.5% fusion.
- Wear or breakage of implant components are further potential complications, but there are no specific reports in the literature on such problems. Estimated occurrence rate is 0.01 - <0.1%.

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3.1.2 How potential risks have been controlled or managed

SIGNUS tested the mechanical stability, biocompatibility, and sterility of ATHLET extensively in the laboratory. A customer survey study and experience from market surveillance since the market launch in 2007 support safety and effectiveness of the device. SIGNUS conducts continuous market monitoring in order to identify risks and reacts immediately if necessary.

Furthermore, information material and training for surgeons, as well as patients following the instructions of their surgeons also reduces risks.

3.1.3 Summary of any field safety corrective action, (FSCA including FSN) if applicable

Since market launch in 2007, no risks or complications were identified that would have required action by SIGNUS. In one case, SIGNUS responded to an entry in the FDA database MAUDE, see chapter 1.4.3.

3.2 Summary of clinical evaluation and post-market clinical follow-up

3.2.1 Clinical background of the device

ATHLET is indicated for instabilities and constrictions of nerves due to a narrowing of the spinal canal (stenosis) with different underlying causes in the cervical spine. Instability of the spine may derive from trauma, inflammation or tumors. In mild cases the necessary fixation may be an external collar for the cervical spine, or treatment requires a removal of vertebral bodies (corpectomy) with additional fixation. In the cervical spine, corpectomy is also a treatment option for degenerative changes, trauma or tumors which may also lead to severe stenosis and require surgery.

3.2.2 The clinical evidence for the CE marking

ATHLET was initially CE marketed and launched to the market in 2007. Clinical evidence for CE marking is based on laboratory testing, scientific literature, market feedback, and clinical data with ATHLET from clinical trials.

3.2.2.1 Clinical data from ATHLET studies

SIGNUS did a customer survey study involving twenty-nine surgeons and 1276 cases with ATHLET. The surgeons generally expressed satisfaction with the performance of the implant. Subsidence, dislocation, and revision rates were within the ranges found in the literature, see also 3.1.1. The fusion rate fell slightly below the target value derived from literature, which we consider acceptable and do not recommend further action at this time. No new risks associated with the device were identified, and no additional measures were deemed necessary.

3.2.2.2 Clinical data from other sources, e.g. market feedback

In the period 2019 – 2025 (June) there was 1 complaint on 2 parts due to unsuccessful assembly of the implant. The root cause could not be determined, but the most likely reason was assumed to be a single handling error that caused bent hooks and PEEK particles. As the user followed the instructions for use by not implanting the device, there were no additional risks for the patient, user or third parties.

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3.2.3 Safety

The data of preclinical and clinical testing demonstrate that ATHLET performs well and safe and does not behave differently from the benchmark. Nevertheless, there are some residual risks of the procedure and the device that SIGNUS is aware of even when they were rarely or not described in the data sources reviewed. These residual risks are listed in chapter 1.4.1 of this SSCP document.

The mechanical properties of ATHLET were tested in the laboratory and successfully compared with other state of the art devices.

According to the current knowledge based on the state of the art as well as the product-specific data sets provided by tests, clinical data and scientific literature, the benefits outweigh the risks of the application of ATHLET. The analysis and assessment of potential risks has shown that there are no increased residual risks for patients in the context of the intended use of ATHLET, which can be confirmed by the product-related clinical data. Risk reduction measures also were adequate.

In conclusion, the presented and evaluated data confirms the safety and clinical performance of ATHLET. Clinical data is similar to benchmark devices, and from a clinical point of view, the risk-to-benefit ratio is regarded as positive.

3.3 Ongoing or planned post-market clinical follow-up

After completion of the customer survey study, there is currently no study going on or planned. PMCF concentrates on regular measures (literature research etc.).

3.4 Possible therapeutic alternatives

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

Corpectomy is an invasive treatment and other treatments should be considered before performing corpectomy. In the case of degenerative disease conservative therapy should always be performed before surgery. In general, when conservative treatment fails, surgery is usually done to prevent damage to the spinal cord or nerves, which can lead to paralysis.

If surgery is indicated, different surgical procedures are available. E. g. there are anterior or posterior approaches to the cervical spine, and very briefly, corpectomy (anterior cervical corpectomy and fusion = ACCF) provides better decompression of the nerves because the access to the spinal canal is larger, but therefore it is also more invasive and associated with more complications compared to anterior cervical discectomy and fusion (ACDF).

The decision processes of which treatment is adequate for the individual indication cannot be given here but needs to be made with your healthcare professional.

3.5 Suggested training for users

See chapter 1.5.

4 References

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