ATHLET®

Product description:
The ATHLET® is a vertebral body replacement implant for use in the cervical spine. It 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 stabilisation. 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 visualisation. Implantation is facilitated by use of the 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.

Indications:
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:
- 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

Material:
The implants are made from the following materials:

- ATHLET®: Polyether ether ketone (PEEK-OPTIMA) as per ASTM F2026
- X-ray markers ATHLET®: titanium alloy (TiAl6V4) as per ASTM F 136 / ISO 5832-3

Composition:
PEEK as per ASTM F 2026: 100 %

Titanium alloy (TiAl6V4) as per ASTM F 136 / ISO 5832-3.

For all products made of titanium alloy TiAl6V4:
Nickel-free as per ASTM F 136 / ISO 5832-3
Nitrogen 0.05% max, carbon 0.08% max,
hydrogen 0.012% max, iron 0.25% max, oxygen 0.13% max,
aluminium 5.5–6.5%, vanadium 3.5–4.5%, rest titanium.

The materials are established materials for use as an implant. They are biocompatible, corrosion-resistant and non-toxic in the biological environment and enable interference-free X-ray imaging for PEEK implants.

Sterility:
Sterile implants are supplied in double sterile packaging and are gamma sterilised in accordance with DIN EN ISO 11137. They are intended for single use only and are not reusable.
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. Products with opened primary sterile packaging will not be accepted by SIGNUS and must be disposed of properly.
Instruments supplied non-sterile must be processed before use in accordance with hospital guidelines. The instruments are shipped in instrument trays provided by SIGNUS or in a suitable protective packaging for re-orders.
Instruments must be stored in their original packaging or in the instrument tray.

Reprocessing:
Follow the validated reprocessing procedure in the instructions included with the tray (for valid version see: eifu.signus.com).

Brief instructions:
- Maximum permissible temperature during reprocessing: 137° C
- Reprocessing authorised by manufacturer
- All non-sterile products must be reprocessed in the SIGNUS trays
- Preparation before cleaning, ultrasonic bath if necessary
- Recommended cleaning: mechanical, washer-disinfector, validated according to EN ISO 15883, mild alkaline detergent
- Recommended disinfection: thermal, > 90° C, > 5 min. or A0 value ≥ 3000
- Drying: up to 120° C, 20 min.
- Packaging: according to EN ISO 11607 and EN 868.
- Recommended sterilisation: moist heat, 132° C - 137 °C, 4 min. holding time, EN ISO 17665
- Items to be sterilised must be dry

The instrument tray must undergo a validated cleaning process before being returned. This must be documented on the delivery note provided, which must be enclosed with the return shipment.

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Labelling:
Explanation of the symbols that may be used on the packaging of SIGNUS products:

CE 0483	CE marking	NON STERILE	Non-sterile
	Do not re-use		Double sterile barrier system
REF	Article number	MD	Medical device
	Use by	UDI	Product identification number
	Do not resterilise	LOT	Batch code
0°C 35°C	Temperature limit	eIFU	Consult the electronic Instructions for Use (eifu.signus.com)
	Manufacturer and date of manufacture		Do not use if packaging is damaged
STERILE R	Sterilised using irradiation		Caution

Storage and transport conditions:
Store the products between 0°C and 35°C. During transport, temperatures of up to 40°C can be tolerated for short periods.

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 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.

USA: Federal Law restricts the sale of this product by or on the order of a physician.

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.

Application:
- If there are any preoperative uncertainties relating to the implant system, information must be obtained from SIGNUS.
- Before the surgical intervention, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself and with use of the implant.
- The implant used must be documented in the patient record, indicating the article number, designation and batch number. All necessary data are indicated on the labels in the original packaging or are printed on the implants and must be pasted into the patient record to ensure lot traceability.

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Special requirements for ATHLET® application:
- The implants can be filled with bone and/or bone graft material prior to use. When inserting the implant, ensure that no filler particles fall out of the implant and remain loose in the corpectomy space.
- The trials correspond to the implant height not including the teeth.

Risks:
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.

MRI notes:
An expert report recommends labelling ATHLET® as 'MRI conditional'. A patient with this implant can be safely scanned in an MRI system in accordance with the justification and the test methods in ASTM F2502. Testing of the effects due to forces (ASTM F2052), torque (ASTM F2213), heating (ASTM F2182) or artefact formation (ASTM F2119) was not carried out for the following reasons:
1. Length of metallic objects less than 20 mm
2. Non-metallic PEEK as base material
3. Metal content less than 16% proportional weight
4. Medical devices made of titanium and tantalum are labelled as 'MRI conditional' with < 25 T/m
5. The counterforces of the body hold the implant in position.

Safety report:
The SSCP (Summary of Safety and Clinical Performance) safety report is uploaded here once a year:
https://signus.com/intl/patients/sscp-safety-report.html

Product warranty:
SIGNUS Medizintechnik GmbH warrants that each spinal implant has been manufactured, packaged and tested with the greatest possible care from select materials and under continuous surveillance of the processes involved. Since SIGNUS Medizintechnik GmbH has no influence on the conditions under which a spinal implant is applied and used, nor on the diagnosis of the patient, the method of application or the handling of the spinal implant after it has left the factory, SIGNUS Medizintechnik GmbH gives no warranty either for the success of the procedure or for the non-occurrence of complications. Please inform SIGNUS immediately of any (potential) malfunction of which the user is aware, including the article number(s) and the lot number(s).
All serious incidents that occur in relation to the product must also be reported to the competent authorities of the Member State where the user and/or patient resides. If you have any questions regarding the severity of an incident, please contact SIGNUS.

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